MIPLC Studies 1

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Patents in the Food Sector

A Retrospective with Special Emphasis on the TRIPs Agreement

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MIPLC Munich Intellectual Property Law Center
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PREFACE

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Heidelberg, June 18, 2008

Eva Willnegger

Contents

Zusammenfassung in deutscher Sprache

Abbreviations

ABl	Amtsblatt
AIPPI	Association Internationale pour la Protection de Propriété Intellectuelle
Art.	Article
ASSINSEL	The International Association of Plant Breeders for the Protection of Plant Varieties
BGH	Bundesgerichtshof
Bl. f. PMZ	Blatt für Patent-, Muster- und Zeichenwesen
BPatG	Bundespatentgereicht
CIAA	Confederation of the Food and Drink Industries in the EU
CPVO	Community Plant Variety Protection Office
CPVR	Regulation (EC) No. 2100/94 on Community Plant Variety Rights of July 17, 1994
Doc.	Document
ECJ	European Court of Justice
EG	Europäische Gemeinschaften
EIPR	European Intellectual Property Review
EPC	European Patent Convention
EPO	European Patent Office
et al.	Et alii
etc.	Et cetera
Exemption	Exemption to patentability of food-related substances
EU	European Union
FAO	Food and Agricultural Organization of the United Nations
FDA	Food and Drug Administration
Food	Food-related substances
FUFOSE	Functional Food Science in Europe
GATT	General Agreement on Tariffs and Trade
GRUR	Gewerblicher Rechtsschutz und Urheberrecht
GRUR Int.	Gewerblicher Rechtsschutz und Urheberrecht, Internationaler Teil
IFIC	International Food Information Council
IIC	International Review of Industrial Property and Copyright Law
ILSI	International Life Sciences Institute
IPC	International Patent Classification
ISAAA	International Service for the Acquisition of Agri-Biotech Applications
ISF	International Seed Federation
Mitt.	Mitteilungen der deutschen Patentanwälte
NACE	Nomenclature des Activités dans la Communauté Européenne
No.	Number
Nr.	Nummer
OJ EC	Official Journal of the European Communities
PatG	Patentgesetz

PCT	Patent Cooperation Treaty
s.	And the subsequent page
SaatG	Saatgutverkehrsgesetz
Sec.	Section
SIPO	State Intellectual Property Office of the People's Republic of China
SortG	Sortenschutzgesetz
SPC	Supplementary Protection Certificate
ss.	And the susbsequent pages
Strasbourg vention	Convention on the Unification of Certain Points of Substantive Law Con- on Patents for Invention of November 27, 1963
TRIPs	Agreement on Trade Related Aspects of Intellectual Property Rights
U.S.	United States of America
U.S.C.	United States Code
UK	United Kingdom
UKHL	United Kingdom House of Lords
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
UPOV	International Union for the Protection of New Varieties of Plants
USDA	United States Department of Agriculture
USPTO	United States Patent and Trademark Office
USTR	United States Trade Representative
VDI	Verein deutscher Ingenieure
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

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Introduction

During the last few centuries a highly industrialized food sector has been evolving. The food sector is now one of the most important industrial sectors. This dissertation reflects on the role of the food sector and its particular role in patent law. Interestingly enough, food, being central to every human being, has been excluded from patentability in many patent laws, e.g. in the very first German Patent Act of 1877. 90 years later, this exemption to patentability has been abolished in Germany. Thus the first chapter is dedicated to the question of why food-related substances, which in the following will be abbreviated with food, were excluded from patentability in Germany and why this exemption was abolished in 1967. It furthermore investigates the consequences of the exemption to patentability of food in Germany, which will in the following be abbreviated with exemption.

History repeats itself. This is also true for the exemption. As Germany excluded food in its first Patent Act, so did many developing or emerging countries - and are still doing so today. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) now forces all Members of the World Trade Organization to abolish the exemption. Thus the TRIPs Agreement substantially affected the food sector when it was adopted. *Straus*[1] has described the impact of the TRIPs Agreement on genomic inventions in a way that generally applies to all food-related inventions and therefore to the food sector as a whole:

> "Bearing in mind all the specific phases of the food production process it seems clear that under the TRIPs Agreement, WTO Members have to provide patent protection and/or plant variety protection respectively, for all genomic inventions involved in that process at its different stages and their resulting end products including final foods."

For this reason, this study looks at the Patent Acts of Germany, Brazil, China, and India in a comparative law approach with respect to the exemption and the effects of its abolition.

The second part of this dissertation is dedicated to the description of the food sector of today and particularly its technological developments. Here, first and foremost the influence of biotechnology on the food sector is described. The production of agricultural raw materials has been largely influenced by biotechnology. First, the production of plant-derived agricultural raw materials is shown. Next, the production of animal-derived agricultural raw materials is analyzed in this respect. Finally, the influence of biotechnology on the production of processed food is discussed.

1 *Straus*, Genomics and the Food Industry: Outlook from an Intellectual Property Perspective, in: *Vaver&Bently* (eds.), Intellectual Property in the New Millennium – Essays in Honour of William R. Cornish, Cambridge 2004, 124, 134.

The third and last part of this dissertation is dedicated to the intellectual property situation of the food sector of today. The protection of food-related inventions under European law is examined. The patentability of inventions related to the production of agricultural raw materials and of processed food is analyzed. It shows that though the exemption has been abolished, protection in this sector is still different from that in other fields of technology.

Part I. Patentability of food from 1877 to 2005 in Germany compared to Brazil, China and India

The following review compares retrospectively the patent acts of Germany and of the emerging countries Brazil, China, and India with regard to patentability of food-related inventions, which will in the following be abbreviated with the patentability of food.

The food sector is of enormous economic importance, as it is one of the biggest industrial sectors. Moreover, the food sector has an outstanding position compared to other industrial sectors, as it affects health and nutrition. The food sector covers the basic needs of every human being and has guaranteed the survival of many generations of mankind. This unique position is reflected first and foremost in the patent system, where food has always had an exceptional position.

Nevertheless, the food sector has not yet been the focus of patent law and literature. Apart from *Straus*,[2] who investigated the patentability of genomic inventions in the food sector, there have indeed been few studies on the exemption to patentability of food. Therefore it is the aim of this thesis to identify and analyze the patentability of food in Germany, Brazil, China, and India in a comparative manner in the time period from 1877 to 2005.

Many patent systems have one phenomenon in common: the exemption. The very first German patent law, the Patent Act of 1877, excluded food from patentability. This exemption was abolished 90 years later. Until 1995, many developing or emerging countries had also excluded food from patentability. The TRIPs Agreement changed this situation sustainably. Art. 27 of the TRIPs Agreement declares inventions in all fields of technology patentable subject matter.

By 2005, thanks to the TRIPs Agreement, most countries of the world had provided intellectual property protection for food by patents or *sui generis* rights. This development is exemplified by Germany on the one hand and the developing or emerging countries Brazil, China, and India on the other hand. The exemption in the German Patent Act of 1877 proved to be rather formal in nature. In fact, case law has guaranteed the protection of formally excluded subject matter and by doing so circumvented the legislature's intention. In 1967 food became patentable as such. Germany's food sector has been thriving since then. This prospering period is reflected in an increasing number of food-related patents as will be demonstrated in the following analysis.

2 *Straus*, Genomics and the Food Industry: Outlook from an Intellectual Property Perspective, in: *Vaver&Bently* (eds.), Intellectual Property in the New Millennium – Essays in Honour of William R. Cornish, Cambridge 2004, 124.

The TRIPs Agreement has led to the patentability of food, most notably in Brazil, China and India. The economic effects of this change are mirrored in numbers of patent applications, which have almost doubled in Brazil and China since food became patentable. Prospering food sectors, increasing foreign direct investments and declining food prices indicate that patentability of food does not restrict food availability nor negatively influence the food sector. From the following analysis it can thus be concluded that the patentability of food has positive effects on economic welfare.

A. Patentability of food in Germany

Germany's approach to the patentability of food is one of the eldest in modern societies. The first German Patent Act of 1877 already excluded food from patentability, but allowed the patentability of food-related processes. The German approach is representative for many developed countries and its development will be later in history repeated by many developing or emerging countries. The path for the exemption in the German Patent Act of 1877, its perpetuation in the Amending Act of 1891, and its abolition in 1967 are the main focus of this section.

I. The exemption in the German Patent Act of 1877

1. German Patent Act of 1877

Germany was at the time of the genesis of the first German Patent Act of 1877 a divided country with many sovereign nations under the umbrella of supranational agreements. Only at the birth of the first German Empire under the emperor Friedrich could a common Patent Act be adopted.

The uniform German Patent Act was primarily based on the results of the enquete commission "Enquete über die reichsgesetzliche Regelung des Patentwesens." The enquete commission was an expert group launched by the Federal Council in 1876 to work out a draft of a uniform German Patent Act.[3] This commission broadly discussed a potential exemption to patentability of food.[4] Its members were split with respect to the patentability of food. *Von Steinbeis,*[5] the representative of the state Wuerttemberg,

3 *Lenz*, Entwurf eines Patentgesetzes, Berlin 1877.

4 Ergebnis der Enquete über die reichsgesetzliche Regelung des Patentwesens, No. 70 der Drucksachen, Bundesrat, Session von 1978, 12.

pleaded against the exemption. According to him, every invention capable of serving public welfare should be patentable.

The well-known legal scholar and author of the first commentary on the German Patent Act *Klostermann* was in favor of excluding food from patentability.[6] He pointed out that patents on food could be potentially abused as a means of unfair marketing. This danger of abuse has led to an exemption of food in many other countries. Other experts did not share this opinion because the patent system did not aim at the protection of the public from misleading advertisement with patents that were abused as a certificate of quality.[7] The German industrialist and founder of the formerly Berlin and nowadays Munich based corporation Siemens Aktiengesellschaft which mainly produces electronic equipment *von Siemens* stressed that the German patent system would not be a mere registry system, but a thorough examination of the respective patent application. This examination could prevent the abuse of patents for marketing reasons.[8] Finally, only one of the 20 experts voted for the exemption.[9]

Nevertheless the first draft of a uniform German Patent Act excluded food from patentability. Astonishingly, this first draft did not follow the suggestion of the enquete commission to allow the patentability of food. It was brought forward by chancellor *von Bismarck* on February 24, 1877. This first draft stated with regard to patentable subject matter and exemptions to patentability:

> "Patents shall be granted for any new invention which is susceptible of industrial application except: (...) inventions of food and drugs, as far as the inventions do not regard methods of production thereof."[10]

After a first reading in parliament, the draft was handed over to a special commission appointed by parliament to discuss the draft.[11] A minority of the commission pleaded against an exemption of food. These opponents of the exemption to patentability of food argued with the common welfare guaranteed by the patent system. Moreover, they criti-

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5 Ergebnis der Enquete über die reichsgesetzliche Regelung des Patentwesens, No. 70 der Drucksachen, Bundesrath, Session von 1978, 12. *Möhler*, Entwicklung des gewerblichen Rechtsschutzes in Württemberg, Stuttgart 1927, 87.

6 Klostermann, Das Patentgesetz für das deutsche Reich vom 25. Mai 1877: Nebst Einl. u. Comm. und mit vergleichender Uebersicht der ausländischen Patentgesetze, Berlin 1877.

7 *Von Steinbeis*, Ergebnis der Enquete über die reichsgesetzliche Regelung des Patentwesens, No. 70 der Drucksachen, Bundesrath, Session von 1978, 12.

8 Ergebnis der Enquete über die reichsgesetzliche Regelung des Patentwesens, No. 70 der Drucksachen, Bundesrath, Session von 1978, 12.

9 Ergebnis der Enquete über die reichsgesetzliche Regelung des Patentwesens, No. 70 der Drucksachen, Bundesrath, Session von 1978, 13.

10 Entwurf eines Patentgesetzes nebst Motiven zur Vorlage an den Reichstag, Nr. 8 der Drucksachen, 3. Legislatur-Periode, 1. Sitzung 1877. “Ausgenommen sind: 1. Erfindungen, deren Verwerthung den Gesetzen oder guten Sitten zuwiderlaufen würde; 2. Erfindungen von Mustern oder Modellen, welche lediglich die Verschönerung oder die Ausschmückung eines Gegenstandes bezwecken; 3. Erfindungeen von Genuß- oder Arzneimitteln, soweit die Erfindungen nicht das Verfahren zur Herstellung der Gegenstände betreffen.”

11 Bericht der VII. Kommission betreffend den derselben zu Vorberathung überwiesenen Entwurf eines Patentgesetzes, No. 144 der Drucksachen, Deutscher Reichstag, 3. Legislatur-Periode, 1. Session 1877.

cized the lack of convincing arguments. Nevertheless, the majority of the commission endorsed the exemption. This endorsement was based on the arguments of the first draft.

The commission approved the first draft and clarified the wording of the exemption. The term "Nahrungsmittel" was substituted by the term "Nahrungs- und Genussmittel." This new wording was only intended to clarify what food was and had no effect on the scope of the exemption.[12]

This draft was ratified by the German legislative body, the so called "Reichstag", on May 25, 1877. The German Patent Act became effective on July 1, 1877 and codified the first uniform German patent system. Sec. 1 of the German Patent Act of 1877 excluded food, pharmaceuticals and chemical substances from patentability:

> "Patents shall be granted for any new inventions which are susceptible of industrial application except: 1. Inventions the exploitation of which would be contrary to law or morality. 2. Inventions of food and foodstuffs or drugs and substances which are chemically manufactured as far as the inventions do not regard methods of productions thereof."[13]

2. The scope of the exemption

The scope of the exemption is defined by the interpretation of the term "Nahrungs- und Genussmittel" in the German Patent Act of 1877.

"Nahrungsmittel" was defined as "was bestimmt ist, durch Eintritt in den Stoffwechsel zur Erhaltung und Entfaltung des menschlichen Organismus zu dienen."[14] A substance or a composition must have the purpose of being metabolized in the human organism in order to be qualified as a "Nahrungsmittel".[15] Substances intended for use of food and for non-food use were only excluded from patentability when their main purpose was to be metabolized in the organism.[16]

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12 Bericht der VII. Kommission betreffen den derselben zu Vorberathung überwiesenen Entwurf eines Patentgesetzes, No. 144 der Drucksachen, Deutscher Reichstag, 3. Legislatur-Periode, 1. Session 1877, 6.

13 Sec. 1 of the German Patent Act of May 25, 1877, Reichsgesetzblatt 1877, 501. "Patente werden erteilt für neue Erfindungen, welche eine gewerbliche Verwerthung gestatten. Ausgenommen sind: 1. Erfindungen, deren Verwerthung den Gesetzen oder guten Sitten zuwiderlaufen würde; 2. Erfindungen von Nahrungs-, Genuß- und Arzneimitteln, sowie von Stoffen, welche auf chemischen Wegen hergestellt werden, soweit die Erfindugnen nicht ein bestimmtes Verfahren zur Herstellung der Gegenstände betreffen."

14 *Kohler*, Handbuch des deutschen Patentrechts in rechtsvergleichender Darstellung, Mannheim 1900, 173, *Nastelski,* in: *Reimer* (ed.), Patentgesetz und Gebrauchsmustergesetz, 3rd ed., Köln 1968, 115.

15 Another definition of the term "Nahrungsmittel" is "Mittel (…), die zur Ernährung des Menschen dienen, von ihm genossen werden, um in den Stoffwechsel des menschlicheen Organismus zum Zweck der Ernährung einzutreten." *Nastelski,* in: *Reimer* (ed.), Patentgesetz und Gebrauchsmustergesetz, 3rd ed., Köln 1968, 115.

16 *Kohler*, Handbuch des deutschen Patentrechts in rechtsvergleichender Darstellung, Mannheim 1900, 175, *Pietzcker*, Patentgesetz und Gebrauchsmusterschutzgesetz, Berlin&Leipzig 1929, 147.

"Genussmittel ist, wass zu dem Zwecke in uns aufgenommen wird, um Gefühls-, Geschmacks- oder Geruchssinn in wohlthuender Weise zu beeinflussen."[17] Inventions were only classified as "Genusssmittel" if they were intended for consumption in the human organism.[18] Odorous substances, tobacco, cigars and cigarettes as well as cosmetics, were not qualified as "Genussmittel", as they were not consumed in the human organism.[19]

The exemption referred only to food, e.g. substances or compositions. The exemption did not cover patents on food-related processes. The wording "as far as the inventions do not regard methods of production thereof" of Sec. 1 of the German Patent Act of 1877 did not explicitly refer to food. It referred directly only to chemical substances. The rationale of Sec. 1 of the German Patent Act of 1877 was only to keep food *per se* free from patent protection. Moreover, food was regarded as a chemical substance. Thus, food-related processes were considered patentable.[20]

Feed was in principle patentable, because food did not include feed according to the "allgemeinen Sprachgebrauch und die Ausdrucksweise verschiedener anderer Reichsgesetze."[21] Consequently also patents on feed-related processes were obtainable.

The exemption was not included in the German Utility Model Act, the "Gebrauchsmustergesetz" (GebrMG). Utility models granted the owner similar rights as patents. But the reasons for the exemption applied also to utility models. Thus, the exemption was considered valid for utility models too, and food was consequently not eligible for protection by utility models.[22]

17 *Kohler*, Handbuch des deutschen Patentrechts in rechtsvergleichender Darstellung, Mannheim 1900, 173.

18 *Nastelski,* in: *Reimer* (ed.), Patentgesetz und Gebrauchsmustergesetz, 3rd ed., Köln 1968, 115.

19 *Metzger*, Nahrungsmittel und Erfindungsschutz: Eine Zusammenstellung patent- und erfinderrechtlicher Gesichtspunkte für die Lebensmittelindustrie, Ph.D. Thesis, University of Erlangen 1951, 12.

20 The patentability of processes for the production of chemical substances was directly referred to in Sec. 1 PatG of 1877. *Seligsohn*, Patentgesetz und Gesetz, betreffend den Schutz von Gebrauchsmustern, 7th ed., Berlin&Leipzig 1932, 53.

21 *Nastelski,* in: *Reimer* (ed.), Patentgesetz und Gebrauchsmustergesetz, 3rd ed., Köln 1968, 115. *Kohler*, Handbuch des Deutschen Patentrechts in rechtsvergleichender Darstellung, Mannheim 1900, 173. The "Nahrungsmittelgesetez vom 14. Mai 1879" was also not applicable to animal feed. The rationale of the German Patent Act of 1877 would have also required that feed be excluded from patentability as well, as the constellation of interests with regard to feed is comparable with that to food. *Nastelski,* in: *Reimer* (ed.), Patentgesetz und Gebrauchsmustergesetz, 3rd ed., Köln 1968, 115.

22 *Nastelski,* in: *Reimer* (ed.), Patentgesetz und Gebrauchsmustergesetz, 3rd ed., Köln 1968, 1854.

The reactions to the exemption diverged from agreement to disagreement. The legislature's justification and the different opinions in jurisprudence about the exemption in the German Patent Act of 1877 are explained.

The legislature of the first German Patent Act of 1877 justified the exemption with the danger of diminishing food availability and the danger of unfair competition. Public health and nutrition were considered superior public goods and thus led to the exemption in the German Patent Act of 1877. These superior public goods prohibited any drop in food availability. Patents were regarded as monopolies at that time that entailed the danger of excluding the public from beneficial food. Moreover, patents on food would prohibit competition. Thus, patents on food might lead to a price increase for food.

Another reason for this step was related to unfair competition. The public was to be protected from advertising with patents, as it could associate regulatory approval with a patent on a food. This assumption could lead to blind confidence in patented food. Additionally, the exemption would not cause a gap in protection. Patents on food-related processes would guarantee effective protection. Process patents on food-related inventions were considered politically appropriate because unlimited consumption of food would be possible. Potential misuse of food-related patents would be avoided by disclosure of the patent application. This disclosure would allow the public to assess the benefits of an invention.[23]

Many authors attacked the exemption in the German Patent Act of 1877 because they were not convinced of the legislature's reasons for excluding food from patentability. The author of the most acknowledged commentary on the German Patent Act of 1877, *Kohler,* criticized the German Patent Act of 1877, based on his assertion that not the patent system, but competition law was the proper means to prevent the abuse of patents for advertising purposes. *Kohler* also stated that the option of compulsory licenses would ensure public nutrition and availability of food. There was hardly any necessity for the exemption in view of compulsory licenses.[24] He suggested expropriation as an effective means to make patent-protected food accessible to the public.[25]

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23 Entwurf eines Patentgesetzes nebst Motiven zur Vorlage an den Reichstag, Nr. 8 der Drucksachen, 3. Legislatur-Periode, 1. Sitzung 1877, 17.

24 *Damme&Lutter*, Das deutsche Patentrecht: Ein Handbuch für Praxis und Studium, 3rd ed., Berlin 1925, 202.

25 *Kohler*, Handbuch des deutschen Patentrechts in rechtsvergleichender Darstellung, Mannheim 1900, 172, 173, *Ephraim*, Deutsches Patentrecht für Chemiker, Halle an der Saale. 1907, 103, *Osterrieth*, Lehrbuch des gewerblichen Rechtsschutzes, Leipzig 1908, 77, *Hubmann&Götting*, Gewerblicher Rechtsschutz, 7th ed., München 2002, 177. Dissenting *Seligsohn*, who judges the exemption to patentability of foodstuffs as abolutely important for public welfare ("größte Wichtigkeit für die Volkswohlfahrt"), Patentgesetz und Gesetz, betreffend den Schutz von Gebrauchsmustern, 7th ed., Berlin&Leipzig 1932, 53.

Kohler[26] argued that the exemption did not meet its goal at all because it did not guarantee the availability of beneficial food-related inventions. Market exclusivity due to patent protection constitutes the award for the inventor's hard and costly work. The exemption thus diminishes the incentive for inventors to create new beneficial food.

The author of a well-known commentary on the German Patent Act, *Seligsohn,*[27] discovered an anomaly in the exemption and the patentability of food-related processes. Concerns about substance patents for food apply also to patents on food-related processes. This anomaly is based on the legislature's intention to enable the economic exploitation of more effective processes.

The reasoning behind of Sec. 1 German Patent Act of 1877 should also have required the exemption to patentability of food-related processes because of the economically comparable threat of monopolies.[28] Patents on food-related processes could influence food availability to the same extent as patents on substances. A patent on a breakthrough innovation in the form of a food-related process can endanger food availability in the same way as a patent on food.

Food was regarded as a chemical substance that was excluded from patentability in the German Patent Act of 1877. So patenting food would not have been possible even without the exemption.[29] The exemption to patentability of chemical substances was widely criticized, too.[30] Supporters of the exemption of chemical substances argued that chemical substances as opposed to mechanical products, were discoveries rather than inventions and therefore must be excluded from patentability. Finally, the legal scholar *Gareis* argued that public welfare rather than an inventor's rights justified the exemption leaving no space for patent protection in areas of public interest.[31]

An international survey of the patentability of food in the 19th century delivered a cleaved picture. While there was no exemption in Anglo-American legal systems, many other countries[32] did exclude food from patentability.

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26 Even more convincing the wording of *Kohler*: "(Verhinderung von Monopolen als Argument) enthält ein Moment, das gerade in Gegentheil umschlägt; denn da das Erfinderrecht die Menschheit bereichert, so sollte man gerade das Erfinderrecht auf dieses Gebiet lenken: solches könnte nur dazu führen, dass die Erfindungen vermehrt und dadurch die Lebensgüter der Menschheit gesteigert werden. Sollte die Allgemeinbenützung der Erfindung unumgänglich sein, so wäre nöthigenfalls vom Recht der Enteignung Gebrauch zu machen." In: *Kohler*, Handbuch des deutschen Patentrechts in rechtsvergleichender Darstellung, Mannheim 1900, 173.

27 *Seligsohn,* Patentgesetz und Gesetz, betreffend den Schutz von Gebrauchsmustern, 7th ed., Berlin&Leipzig 1932, 53.

28 *Nastelski,* in: *Reimer* (ed.), Patentgesetz und Gebrauchsmustergesetz, 3rd ed., Köln etc. 1968, No. 87, Sec. 1, 115.

29 *Kent*, Das Patentgesetz vom 7.4.1891, Berlin 1906, No. 348, Sec. 1.

30 *Metzger*, Nahrungsmittel und Erfindungsschutz: Eine Zusammenstellung patent- und erfinderrechtlicher Gesichtspunkte für die Lebensmittelindustrie, Ph.D. Thesis, University of Erlangen 1951, 3.

31 *Gareis*, Das Deutsche Patentgesetz vom 25. Mai 1877 samt den hierzu erschienenen Verordnungen und Bekanntmachungen, Berlin 1877, 39.

32 Luxembourg, Sweden, Norway, Tunis, Austria, Denmark, Hungary, Russia, Finland and Japan, in: *Kohler*, Handbuch des deutschen Patentrechts in rechtsvergleichender Darstellung, Mannheim 1900, 176.

II. The Amending Act of 1891 and the *Kongorot* decision

The exemption refers only to food, but not to food-related processes.[33] So substance claims were excluded from patentability, but process claims were allowable under the German Patent Act of 1877.

Parallel imports of food from countries where food-related processes were not patentable could not be prohibited, as the scope of process patents did not extend to the product directly obtained from the process. Switzerland did not have a patent system until 1888 and chemical substances were not patentable until 1907 in the Swiss patent system.[34] Consequently, there was no patent protection for food and chemical substances in general. The circumvention of patented processes by imports from Switzerland was considered to be an enormous deficit.[35]

The deficits in the scope of protection of the German Patent Act of 1877 led to the Amending Act of 1891, which increased the scope of protection of patents on food-related processes as described below, but did not yet abolish the exemption. An expert commission, the "Enquete in Betreff der Revision des Patentgesetzes vom 25. Mai 1877," was appointed to draft the Amending Act. The task was to improve and internationalize the German Patent Act of 1877. The enquete commission focused on an extension of the scope of process patents to include the product that was directly obtained from a patented process.[36] The discussion was concentrated on processes for chemical substances in general. The abolition of the exemption to patentability of food, pharmaceuticals and chemical substances was not discussed. The reasons for this omission have not been traceable. The exemption was only negotiated in the context of improvement of process patents.[37]

33 *Kohler*, Handbuch des Deutschen Patentrechts in rechtsvergleichender Darstellung, Mannheim 1900, 176.

34 *Stolz*, Der Aufbruch der Schweiz ins Industriezeitalter, 7, in: *Stolz*, Industrialisierung und Innovation in Großbritannien und der Schweiz, Basel 2004, available at www.wwz.unibas.ch/wige/-lehre/skripten_stolz/Stolz_Vorl2_Schweiz_im_Industriezeitalter.pdf.

35 Swiss exports of dye used for colouring and printing to Germany, one of the main producers of coal based dye, amounted to 1.75 million *Reichsmark* in 1884. Bericht der Enquete-Kommisssion zur Revision des Patentgesetzes, Berlin 1887, 16.

36 Stenographische Bereichte über die Verhandlungen der Enquete in Betreff der Revision des Patentgesetzes vom 25. Mai 1877, Berlin 1887, questions 7-9, 89.

37 The representatives of the chemical industry opposed patents for chemical substances in the first place during the negotiations of the German Patent Act of 1877. These representatives persisted during the negotiations of the Amending Act of 1891 that product claims would prevent improvements of the production process and therefore could not be allowed. Bericht der Enquete-Kommisssion zur Revision des Patentgesetzes, Berlin 1887, 19.

The Amending Act of 1891 extended the scope of process patents to the products directly obtained by such a process.[38] Imports from countries that did allow process patents on chemical substances, the so-called illoyal imports,[39] could finally be prohibited. Hence, the scope of protection of patents on food-related processes was extended substantially. Furthermore, the Amending Act of 1891[40] codified a shift of the burden of proof regarding the infringement of patents on food-related processes. Infringements of process patents are generally hard to prove. This is especially the case for processes that result in identical products. Until then, the burden of proof lay with the owner of a patent; it was now shifted to the potential infringer. Thus the potential infringer of a patent on a food-related process had to prove that the food product in question had not been produced by the patented process.[41] This was an improvement with respect to patent enforcement for the patent owner.

Additionally, the *Kongorot*[42] decision of the Supreme Court of the German Empire, the *Reichsgericht*, in 1889 closed gaps in protection by allowing patents on analogous chemical processes. The *Kongorot* decision formed the basis for the patentability of the so-called chemical-analogous processes. Food-related processes were patentable, when they were new and based on an inventive step. Patents on processes that were known in the art but led to new and valuable food were therefore not allowable. This gap in protection due to the exemption to patentability of food, pharmaceuticals and chemical substances caused the *Reichsgericht* to allow patents on chemical-analogous processes. Patents were thus allowable for processes known in the art as long as they lead to valuable and non-obvious products.[43] *Von Kreisler* pointed out that the *Kongorot* decision was based rather on economic needs than on juridical logic.[44]

After 1891, patents on food were *de facto* obtainable. The exemption in the German Patent Act of 1877 thus was a formal exemption due to the Amending Act of 1891 and the *Kongorot* decision that bypassed the exemption and paved the way for the patentability

38 Sec. 4: Ist der Patentschutz für ein Verfahren erteilt, so erstreckt sich die Wirkung auch auf die durch das Verfahren unmittelbar hergestellten Erzeugnisse. Patentgesetz, 7.4.1891, Reichsgesetzblatt 1891, 501. [Translation: If the subject matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such a process.]

39 *Klöppel*, Patentrecht und Gebrauchsmusterrecht, Berlin 1908, 43.

40 Sec. 35 PatG of the German Patent Act of 1877 amended in 1891: Wer wissentlich oder aus grober Fahrlässigkeit den Bestimmungen der §§ 4 und 5 zuwider eine Erfindung in Benutzung nimmt, ist dem Verletzten zur Entschädigung verpflichtet. Handelt es sich um eine Erfindung, welche ein Verfahren zur Herstellung eines neuen Stoffes zum Gegenstande hat, so gilt bis zum Beweise des Gegenteils jeder Stoff von gleicher Beschaffenheit als nach dem patentierten Verfahren hergestellt. Patentgesetz vom 7. April 1891, Reichsgesetzblatt 1891, 501 [Translation: Whoever uses an invention disregarding Secs. 4 and 5 in a conscious or grossly negligent way, is committed to compensation. If the invention concerns the process of a new substance, every substance is considered to be manufactures by the same process unless the opposite is proven].

41 *Klöppel*, Patentrecht und Gebrauchsmusterrecht, Berlin 1908, 44.

42 Reichsgericht vom 20.03.1889 = 7 Gareissche Sammlung 47.

43 *Kreisler*, Für und wider den Schutz von chemischen Stoffen, Arznei-, Nahrungs- und Genussmitteln, GRUR 1951, 534, 537.

44 *Kreisler*, Für und wider den Schutz von chemischen Stoffen, Arznei-, Nahrungs- und Genussmitteln, GRUR 1951, 534, 537.

of food. Process patents for the production of substances that were excluded from patentability provided a similar scope of protection as substance patents.[45] Such process patents were consequently also referred to as "conditional" substance patents. Additionally, patents on chemical-analogous processes were granted even if they were not new. The Amending Act of 1891 and the *Kongorot* decision balanced the interests of both inventors and those who feared the negative effects of an absolute protection of food.[46]

III. The patentability of food in the Amending Act of 1967

Reasons of public nutrition and health led to the exemption in the German Patent Act of 1877. Ninety years later, the exemption was removed in the German Patent Act of 1967, as none of the prejudices against patents on food could be verified in practice. Consequently, the exemption was no longer politically necessary, having become obsolete.

The abuse of patents on food for marketing purposes could not be prevented by the exemption. In 1967, there was still unfair competition in food advertising even without patents on food.[47] The exemption to patentability of chemical substances could not justify the exemption because countries granting patents on chemical substances, like UK or the U.S., were in good economic positions.[48]

All in all, there was no justification for the exemption.[49] The food sector was deprived of substance patents as the most important tool to protect its inventions. Therefore the food sector was discriminated against without substantial reasons.[50] As a consequence, the exemption was abolished by the Act of 1967 amending the German Patent Act.

The implementation of the European Patent Convention (EPC) caused a reform of the German Patent Act in 1967. The draft of the EPC did not exclude food, pharmaceuticals and chemical substances from patent protection.[51] Its implementation into the German

45 *Hubmann&Götting*, Gewerblicher Rechtsschutz, 7th ed., München 2002, 117. *Kreisler*, Für und wider den Schutz von chemischen Stoffen, Arznei-, Nahrungs- und Genussmitteln, GRUR 1951, 534, 537, e.g. German patent DE 745312.

46 *Klöppel*, Patentrecht und Gebrauchsmusterrecht, Berlin 1908, 44.

47 *Metzger*, Nahrungsmittel und Erfindungsschutz: Eine Zusammenstellung patent- und erfinderrechtlicher Gesichtspunkte für die Lebensmittelindustrie, Ph.D. Thesis, University of Erlangen 1951, 2.

48 *Metzger*, Nahrungsmittel und Erfindungsschutz: Eine Zusammenstellung patent- und erfinderrechtlicher Gesichtspunkte für die Lebensmittelindustrie, Ph.D. Thesis, University of Erlangen 1951, 5.

49 *Metzger*, Nahrungsmittel und Erfindungsschutz: Eine Zusammenstellung patent- und erfinderrechtlicher Gesichtspunkte für die Lebensmittelindustrie, Ph.D. Thesis, University of Erlangen 1951, 2, 6.

50 *Rheinfelder,* Die Bedeutung des im Vorentwurf für ein europäisches Patentrecht vorgesehenen Patentschutzes für chemische Stoffe, GRUR 1964, 354, 358, Die Lissabonner Konferenz, Bericht von Mitgliedern der deutschen Delegataion, GRUR Int. 1959, 58, 67. The U.S. allowed substance patents for chemical inventions before 1877. England has removed substance protection for chemical inventions in 1919 and reestablished substance claims for chemical inventions in 1949. *Zutrauen*, Über den Schutz chemischer Erfindungen in Frankreich, GRUR Int. 1958, 331.

51 *Nastelski,* in: *Reimer* (ed.), Patentgesetz und Gebrauchsmustergesetz, 3rd ed., Köln 1968, 127.

Patent Act would thus have required a change of the substantive patent law and especially the abolition of the exemption to patentability of food, pharmaceuticals and chemical substances.[52] The draft of the EPC was available but not yet agreed upon. Consequently, the German government only proposed a reform of the procedural law of the PatG, leaving the exemption to patentability of food untouched. Thus the draft of the Amending Act of 1967, the "Regierungsentwurf zum Gesetz vom 4.9.1967"[53] did not propose the patentability of food, pharmaceuticals or chemical substances. The patentability of food in the German Patent Act of 1967 was proposed in a later stage of the legislation process by the "Rechtsausschuss (12. Ausschuss) des Deutschen Bundestages," a commission of the Lower House of the German Parliament, which will in the following be called *Rechtsausschuss*.

The *Rechtsausschuss* criticized the fact that the exemption to patentability of food, pharmaceuticals and chemical substances caused inventors to apply for patents on every imaginable process for the production of the excluded substance.[54] The result of this practice was comparable to substance patents *per se*. Moreover, the *Rechtsausschuss* criticized as a consequence of this practice, the German Patent Office (DPA) had been overloaded with patent applications. Substance claims could therefore alleviate the workload of the DPA to a large extent.[55]

The *Rechtsausschuss* also argued that there was no justification for an exemption to patentability of food, pharmaceuticals and chemical substances.[56] Substance patents were allowable in many developed countries, and it was good practice in those countries to allow patents on food, pharmaceuticals and chemical substances without detrimental economical effects. Moreover, the Federal Republic of Germany had obliged itself to allow substance patents in the Convention on the Unification of Certain Points of Substantive Law on Patents for Invention, also called Strasbourg Convention of November 27, 1963. The ratification of this agreement made substance patents unavoidable.[57]

52 Regierungsbegründung, Durcksache Deutscher Bundestag 4. Wahlperiode, Drucksache V/714, 11

53 Deutscher Bundestag, 5. Wahlperiode, Drucksache V/714, Anlage 1, 2.

54 "(...) die Anmelder von Stofferfindungen versuchen, sich möglichst alle denkbaren Verfahren zur Herstellung dieser Stoffe schützen zu lassen, um auf diese Weise im praktischen Ergebnis doch das zu erreichen, was durch das Verbot des Stoffschutzes ausgeschlossen werden soll." *Nastelski,* in: *Reimer* (ed.), Patentgesetz und Gebrauchsmustergesetz, 3rd ed., Köln 1968, 127.

55 "(...) das Patentamt (wird) mit Verfahrensanmeldungen belastet..., die möglichereweise nicht oder jedenfalls nicht in diesem Ausmaß eingereicht werden würden, wenn die Möglichkeit bestünde, für den Stoff selbst Patentschutz zu erlangen.", and "Der Ausschuß ist aber der Auffassung, daß bei Einführung des Stoffschutzes die Wahrscheinlichkeit oder jedenfalls die Möglichkeit einer nicht unerheblichen Entlastung des Patentamts gegeben ist.", *Nastelski,* in: *Reimer* (ed.), Patentgesetz und Gebrauchsmustergesetz, 3rd ed., Köln 1968, 127.

56 "Das Verbot des Stoffschutzes in der gegenwärtigen Situation unserer Wirtschaft auch sachlich nicht mehr (...) gerechtfertigt (ist)." *Nastelski,* in: *Reimer* (ed.), Patentgesetz und Gebrauchsmustergesetz, 3rd ed., Köln 1968, 127.

57 *Nastelski,* in: *Reimer* (ed.), Patentgesetz und Gebrauchsmustergesetz, 3rd ed., Köln 1968, 127.

Moreover, the *Rechtsausschuss* pointed out that Sec. 8 of the German Patent Act empowers the "Bundesregierung" to allow the use of an invention that is in the public interest. Consequently, there was no need to expand the possibility of compulsory licenses in order to compensate for the disadvantages of the patentability of food.[58]

Finally, the exemption was abolished in 1967. This was mainly because the fears and arguments concerning food, pharmaceuticals and chemical substances proved to be unjustified. Food was henceforth treated like any other area of technology. Utility models for food were now also admissible as a consequence of the patentability of food in the German Patent Act of 1967.[59]

IV. Consequences of the patentability of food in Germany

This section explains the consequences of the patentability of food in Germany measured by the number of patent applications regarding food-related inventions. Food biotechnology-related inventions constitute a particularly new field of technology and are therefore of special interest to this thesis. Therefore, food biotechnology-related inventions are also shown as a separate segment of food-related inventions. First, fields of inventions related to food and food biotechnology are defined in a technological and an economic sense. Technological classes that constitute food-related inventions in an economic sense are identified. Then the rise in food-related German patent applications as a consequence of the patentability of food is shown.

58 *Nastelski,* in: *Reimer* (ed.), Patentgesetz und Gebrauchsmustergesetz, 3rd ed., Köln 1968, 128.
59 *Nastelski,* in: *Reimer* (ed.), Patentgesetz und Gebrauchsmustergesetz, 3rd ed., Köln 1968, 1854.

Food in a technological and an economic sense is assessed by a linkage between the technology of food-related patent applications to the food sector in an economic sense. The International Patent Classification (IPC)[60] classifies all fields of technology. The Statistical Classification of Economic Activities in the European Community classifies the economic activities in all industrial sectors of the European Union. A concordance between these classifications is used to determine food-related patent applications.

Inventions belong to certain fields of technology. These fields are classified in the IPC system. The IPC is the basis for classifying patent applications worldwide and constitutes the internationally acknowledged standard classification for patent applications. Every patent application is classed in one or more classes of the IPC. One class of the IPC is designated the main class of the respective patent application. Additional classes are designated as secondary classes. Food-related patent applications are those patent applications with a food-related main and/or secondary class.

The IPC system has eight different sections.[61] Section A covers human necessities. Subsections of section A are agriculture, foodstuffs and tobacco, personal or domestic articles and health and amusement. Section A and its subsections are subdivided into 15 classes, which are again subdivided into subclasses.

Patent applications referring to agriculture matter most in the food sector. For this reason, the IPC subclasses of agriculture (A01), baking (A21), meat treatment (A22) and foods or foodstuffs and their treatment[62] (A23), are examined with respect to the amount of annual patent applications in each subclass. Furthermore, the relevant subclasses of biochemistry (C12) and the sugar industry (C13) are assessed.

60 The IPC is based on the Strasbourg Agreement Concerning the International Patent Classification, which was concluded in 1971 and became effective in 1975. The IPC system is open to the parties to the Paris Convention for the Protection of Industrial Property and was joined by 55 states in 2005, WIPO, 2005,
available at www.wipo.int/treaties/en/ShowResults. jsp?lang=en&treaty_id=11.
However, the industrial property offices of more than 100 states, four regional offices and the International Bureau of the WIPO under the Patent Cooperation Treaty (PCT) actually use the IPC, WIPO, 2004, available at www.wipo.int/classifications/-ipc/en/preface.htm. Few countries like the U.S., also use their own classification systems in addition to the IPC.

61 Section A: Human necessities; Section B: Performing operations, transporting; Section C: Chemistry, metallurgy; Section D: Textiles, paper; Section E: Fixed constructions; Section F: Mechanical engineering, lighting, heating, weapons, blasting; Section G: Physics; Section H: Electricity. According to IPC, 7th ed., available at www.wipo.int/classifications/fulltext/new_ipc/.

62 Patent applications which are covered by other classes are excepted by A23.

Patent applications relating to mechanical engineering are not considered in this statistical survey. Mechanical engineering plays an important role in the food sector, but it is not specific to the food sector because its inventions are usually applied in different sectors. Furthermore, the exemption, which is of special interest in this context, was limited to food-related substances.

The subclasses of IPC concerning food-related patents are chosen according to the Statistical Classification of Economic Activities in the European Community, the so-called NACE.[63] NACE uses criteria like technical specificities of the production process or the organization of the production process through chained industries. NACE aims at establishing a common statistical classification of economic activities within the EU in order to ensure comparability between the national and European classifications and hence national and European statistics. Technological and economic indicators are linked by a concordance between technology and industry classifications.[64] *Schmoch et al.* performed an empirical study to develop a concordance between the codes of the IPC and the industrial sectors defined by NACE codes based on data of 3,000 companies.[65]

Table 1 shows food-related technological IPC subclasses that have been identified using this concordance of IPC with the economic classification NACE.[66] The IPC title and examples according for the respective IPC subclass are listed in column 2 of table 1.[67] Moreover, the denomination[68] of the respective IPC subclass used in the following statistical survey is given in column 3 of table 1.[69]

The IPC subclasses listed in table 1 cover all technological areas relevant to the food sector in the economic sense, comprising baking, preserving and pasteurization, dairy, oil and fats, coffee, cocoa and confectionery, proteins, brewing, vinegar and alcoholic beverages, and sugar processing. The IPC subclass feed (A23K) is also examined, as

63 *Nomenclature des Activités dans la Communauté Européenne (*NACE) Rev.1. NACE is a derived classification in the family of International Classifications NACE Rev.1 - Statistical Classification of Economic Activities in the European Community, ISBN 92-826-8767-8, available at www.europa.eu.int/comm/eurostat/. This classification is very similar to the English SIC and the U.S. Standard Industrial Classification Manual, in: *Schmoch et al.,* Linking Technology Areas to Industrial Sectors, Final Report to the European Commission, DG Research, Karlsruhe etc. 2003, available at www.isi.fraunhofer.de/p/Downloads/Microsoft%20Word%20-%20Report%20Technology%20Industry%20.pdf.

64 *Schmoch et al.,* Linking Technology Areas to Industrial Sectors, Final Report to the European Commission, DG Research, Karlsruhe etc. 2003, 16, available at www.isi.fraunhofer.de/p/-Downloads/Microsoft%20Word%20-%20Report%20Technology%20Industry%20.pdf.

65 *Schmoch et al.,* Linking Technology Areas to Industrial Sectors, Final Report to the European Commission, DG Research, Karlsruhe etc. 2003.

66 *Schmoch et al.,* Linking Technology Areas to Industrial Sectors, Final Report to the European Commission, DG Research, Karlsruhe etc. 2003, 67.

67 IPC, 7th ed., available at www.wipo.int/classifications/fulltext/new_ipc/.

68 This denomination is used because the official title is often long and rather complex.

69 Field Definitions by IPC, 7th ed., in: *Schmoch et al.,* Linking Technology Areas to Industrial Sectors, Final Report to the European Commission, DG Research, Karlsruhe etc. 2003, 67, available at www.isi.fraunhofer.de/p/Downloads/Microsoft%20Word%20-%20Report%20Technology%20 Industry%20.pdf.

feed-related processes and substances are a pre-stage of food production and thus are similar to those in human nutrition. Furthermore, there is the catch-all subclass A23L, which is labelled miscellaneous food because it contains those food-related patent applications which are not covered by A23B to A23J.

Food biotechnology-related patent applications are defined as patent applications whose main or secondary classes are both in the food-related IPC subclasses of table 1 and in the biotechnology-related IPC subclasses of table 2. Biotechnology-related IPC subclasses were defined via a concordance between technological and economic classifications according to *Schmoch et al.*[70] Biotechnology-related IPC subclasses are determined using pharmaceutically related subclasses as a basis and leaving out subclasses related to organic or inorganic chemistry. Table 2 shows the IPC title of the respective biotechnology-related IPC subclass in column 2.[71] Moreover, the denomination of a respective IPC subclass used in the following statistical survey is given in column 3 of table 2.

70 *Schmoch et al.,* Linking Technology Areas to Industrial Sectors, Final Report to the European Commission, DG Research, Karlsruhe etc. 2003, 67.

71 IPC 7th ed., available at www.wipo.int/classifications/fulltext/new_ipc/.

Table 1:
Food-related technological subclasses of IPC according to NACE.[72]

IPC sub-class	Title and examples of the respective IPC subclass	Denotation
A01H	New plants and processes for obtaining them; plant reproduction	Plants
A21D	Treatment, e.g. preservation of flour or dough, e.g. by addition of materials; baking; bakery products; preservation thereof	Bakery
A23B	Preserving, e.g. by canning, meat, fish, eggs, fruit, vegetables, edible seeds; chemical ripening of fruit or vegetables; the preserved, ripened, or canned products	Preserving
A23C	Dairy products, e.g. milk, butter, cheese; milk or cheese substitutes; making thereof	Dairy
A23D	Edible oils or fats, e.g. margarines, shortenings, cooking oils	Oils and fats
A23F	Coffee; tea; their substitutes; manufacture, preparation, or infusion thereof	Coffee and tea
A23G	Cocoa; chocolate; confectionery; ice cream	Confectionery
A23J	Protein compositions for foodstuffs; working up proteins for foodstuffs; phosphatide compositions for foodstuffs	Proteins
A23K	Fodder	Feed
A23L	Foods, foodstuffs, or non-alcoholic beverages not covered by subclasses A23B to A23J; their preparation or treatment, e.g. cooking, modification of nutritive qualities, physical treatment; preservation of foods or foodstuffs, in general	Miscellaneous food
A23P	Shaping or working of foodstuffs	Shaping
C12C	Brewing of beer	Brewing
C12F	Distillation or rectification of fermented solutions; recovery of by-products; denaturing of, or denatured, alcohol	Distillation

72 Field Definitions by IPC, 7th ed., in: *Schmoch et al.,* Linking Technology Areas to Industrial Sectors, Final Report to the European Commission, DG Research, Karlsruhe etc. 2003, 67.

Table 1 - continuation:
Food-related technological subclasses of IPC according to NACE.[73]

IPC sub-class	Title and examples of the respective IPC subclass	Denotation
C12G	Wine; other alcoholic beverages; preparation thereof	Alcoholic beverages
C12H	Pasteurization; sterilization; preservation; purification; clarification; ageing	Pasteurization
C12J	Vinegar; its preparation	Vinegar
C13F	Preparation or processing of raw sugar, sugar or syrup	Sugar
C13J	Extraction of sugar from molasses	Sugar
C13K	Glucose, invert sugar, lactose, maltose, synthesis of sugars by hydrolysis of di- or polysaccharides	Sugar

73 Field Definitions by IPC, 7th ed., in: *Schmoch et al.,* Linking Technology Areas to Industrial Sectors, Final Report to the European Commission, DG Research, Karlsruhe etc. 2003, 67.

Table 2:
Biotechnology-related technological subclasses of IPC according to NACE.[74]

IPC sub-class	Title and examples of the respective IPC subclass	Denotation
C07H	Sugars, derivatives thereof; nucleosides, nucleotides, nucleic acids (DNA or RNA concerning genetic engineering, vectors, isolation and preparation)	Nucleic acids
C12N	Microorganisms or enzymes, compositions thereof, propagating, preserving or maintaining microorganisms, mutation or genetic engineering, culture media	Microorganisms
C12P	Fermentation or enzyme-using processes to synthesize a desired chemical compound or composition or to separate optical isomers from a racemic mixture	Fermentation

2. Rise in food-related German patent applications

The rise of food-related German patent applications indicates that the food sector has made frequent use of the possibility to patent food since the abolition of the exemption in 1967. Food-related German patent applications rose from 97 in 1970 to 535 in 2001 and thus have more than quintupled which is shown in table 3.[75] The maximum was 726 food-related patent applications in 1997. The decrease in the following years might be due to a database defect occurring when data from the respective patent offices have not yet been delivered. The most important technological developments in the food sector, first and foremost biotechnological developments are explained in part II.

a. Overview

Altogether there were 13,206 food-related German patent applications from 1970 to 2001. Miscellaneous food (A23L) ranked 1st, with a total of 4,054 applications, confectionery ranked 2nd, with 1,479 applications, and feed (A23K) 3rd, with 1,325 applications. Bakery (A21D), with a total of 866, preserving (A23B), with 865, and dairy

74 Field Definitions by IPC, 7th ed., in: *Schmoch et al.,* Linking Technology Areas to Industrial Sectors, Final Report to the European Commission, DG Research, Karlsruhe etc. 2003, 67.

75 The overview given in table 3 refers to national German patent applications. European patent applications with designation Germany are not included.

(A23C), with 837 applications had a similar amount of food-related German patent applications during the period from 1970 to 2001. This indicates comparable levels of R&D expenditures in these three segments. These highest ranking IPC subclasses have high degrees of processing in common and show that the food sector mainly concentrates on higher forms of processing and diversification.[76]

The most frequent subclasses in 1999 were miscellaneous food (A23L), with 235 applications, confectionery (A23G), with 83 applications, and feed (A23K), with 48 applications. Plants (A01H) rank 4th, with 41, shaping (A23P) ranks 5th, with 40 applications, and dairy (A23C), 6th with 36 applications in 1999, followed by bakery (A21D), with 34 applications, and preserving (A23B), with 31 German food-related patent applications in 1999.[77]

b. Dairy and confectionery

The food sector tends towards higher forms of processing illustrated by the increase of German patent applications in these subclasses. Dairy and confectionery have applied more and more sophisticated forms of processing. German patent applications in confectionery (A23G) have risen by 1,600%, and in dairy (A23C) by 500% from 1970 to 1999.[78]

The steadily increasing German patent applications in the dairy and in the confectionery segment reflect their economic importance within the food sector. The share of the dairy segment in the total turnover of the German food sector was 16% in 2005 ranking second, whereas the share of the confectionery segment in the total turnover of the German food sector amounted to 9% ranking 4.[79]

76 This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit. For an overview see table 3. For the technological background see part II.

77 This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit. For an overview see table 3.

78 This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit. For an overview see table 3. For an overview of the technology see Table 11 and the explanations thereto.

79 Bundesvereinigung der deutschen Ernährungsindustrie, 2006, available at www.bve-online.de/.

c. Feed

Feed was the highest ranking subclass in 1970 apart from the catch-all IPC subclass miscellaneous food (A23L). Feed has never been excluded from patentability. Thus the feed segment of the food sector was already familiar with the patent system. German patent applications in feed (A23K) only rose by 280%, from 17 to 48 from 1970 to 1999.[80]

This increase in German patent applications indicates, that the feed segment has increased its R&D expenditures, but not as much as other segments of the food sector that involve higher forms of processing.

d. Plants

Though plant varieties have been excluded from patentability since 1967 according to sec. 2 para. 2 of the German Patent Act, patents on higher taxonomic groupings than a plant variety are obtainable.[81] Plants (A01H) rank 4th in the scale of overall patent applications with 41 German patent applications in 1999, reflecting the huge development of plant research.[82] Plants (A01H) did not have any applications in 1970 at all. Intense R&D activity has taken place since then, indicated by annually over 35 applications filed since 1999. Plants (A01H) is the only food-related IPC subclass that mainly represents the production of agricultural raw materials, while the other food-related subclasses are primarily involved in the production of processed food.[83]

80 This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit. For an overview see table 3.

81 BGH, Usambaraveilchen, BlfPMZ 1974, 203. A detailed legal explanation follows in Part III section A subsection I.

82 For the technological background see part II, section A, subsection I.

83 This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit. For an overview see table 3.

Table 3:
Food-related national German patent applications with priority from 1970 to 2001.[84]

Year	A01H	A21D	A23B	A23C	A23D	A23F	A23G	A23J	A23K	A23L	A23P	C12C	C12F	C12G	C12H	C12J	C13F	C13J	C13K	Sum
70	0	11	4	7	2	6	5	1	17	25	2	8	1	3	1	0	2	0	2	**97**
71	0	9	15	11	1	11	21	7	18	29	1	26	2	6	4	2	4	1	2	**170**
72	2	13	18	11	4	8	26	1	27	44	0	19	5	10	5	1	3	2	8	**207**
73	14	15	23	26	0	10	35	6	22	70	7	22	4	10	9	0	2	2	5	**282**
74	4	17	23	15	3	8	32	4	30	65	3	17	6	16	5	0	1	1	4	**254**
75	0	16	30	24	5	6	39	11	35	70	2	27	1	9	6	1	2	2	7	**293**
76	0	27	25	19	1	7	19	6	32	59	1	22	3	4	8	0	2	0	4	**239**
77	4	25	30	20	2	11	31	8	39	47	0	16	1	6	2	1	6	1	7	**257**
78	15	25	21	27	2	18	49	5	27	92	23	22	5	29	5	1	8	0	3	**377**
79	3	18	27	22	4	4	44	8	41	80	4	30	1	17	6	0	9	1	7	**326**
80	1	19	21	28	6	11	33	18	60	88	11	30	3	18	5	0	2	0	5	**359**
81	3	25	21	29	1	17	36	4	50	101	11	30	7	20	4	0	10	0	15	**384**
82	2	25	26	21	2	15	47	10	55	113	11	21	3	9	5	0	12	0	7	**384**
83	2	23	26	34	2	9	42	8	40	101	11	27	2	16	7	2	8	0	7	**367**
84	8	25	32	27	2	14	47	9	43	117	13	19	2	19	7	0	13	0	1	**398**
85	6	25	27	19	0	7	47	7	55	106	16	32	2	38	5	0	7	0	5	**404**
86	10	34	47	32	5	18	56	4	66	137	31	25	10	24	16	0	18	1	2	**536**
87	16	24	24	31	3	17	65	2	53	128	27	15	5	19	9	1	2	0	4	**445**
88	15	25	21	27	2	18	49	5	27	92	23	22	5	29	5	1	8	0	3	**377**
89	8	27	18	21	3	9	54	4	22	115	19	21	1	15	6	0	3	0	1	**347**

84 Food-related patent applications are the IPC subclasses of table 1. It is referred to the first priority date that is claimed by the respective German patent application. This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit. PlusPat is the world's largest international patent database. It merges the EPO's worldwide collection with the USPTO, WIPO and Japanese patent information. It covers more than 50 million patent documents from 75 patenting authorities. Available at www.questel-orbit.com/EN/Prodsandservices/ PlusPat.htm.

Table 3 - continuation:
Food-related national German patent applications with priority from 1970 to 2001.[85]

Year	A01H	A21D	A23B	A23C	A23D	A23F	A23G	A23J	A23K	A23L	A23P	C12C	C12F	C12G	C12H	C12J	C13F	C13J	C13K	Sum
90	22	28	23	25	5	14	28	5	32	115	19	11	0	15	8	0	4	0	2	**356**
91	12	28	18	29	7	4	38	8	34	93	19	11	2	15	5	2	3	0	1	**329**
92	19	35	26	21	5	7	44	10	43	134	24	28	1	18	6	2	8	2	2	**435**
93	15	31	45	40	4	8	53	7	30	176	30	26	2	16	11	0	4	0	1	**499**
94	18	39	41	39	6	18	56	15	51	194	29	30	1	22	14	0	5	0	2	**580**
95	17	33	37	31	5	16	53	13	35	206	29	37	0	26	16	0	7	0	0	**561**
96	32	47	26	41	5	20	95	11	52	239	36	40	0	27	11	0	6	1	3	**692**
97	23	50	37	38	5	9	82	21	46	265	58	44	2	27	11	0	7	0	1	**726**
98	27	53	38	40	6	18	68	16	62	261	44	28	1	19	12	1	9	0	1	**704**
99	41	34	31	36	3	18	83	16	48	235	40	19	0	17	7	1	5	0	1	**635**
00	38	44	36	27	1	10	50	8	70	265	37	20	2	26	13	0	3	0	1	**651**
01	37	16	28	19	2	8	52	7	63	192	34	32	1	31	8	0	5	0	0	**535**
Total	**414**	**866**	**865**	**837**	**104**	**374**	**1479**	**265**	**1325**	**4054**	**615**	**777**	**81**	**576**	**242**	**16**	**188**	**14**	**114**	**13206**

85 Food-related patent applications are the IPC subclasses of table 1. It is referred to the first priority date that is claimed by the respective German patent application. This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit. PlusPat is the world's largest international patent database. It merges the EPO's worldwide collection with the USPTO, WIPO and Japanese patent information. It covers more than 50 million patent documents from 75 patenting authorities. Available at www.questel-orbit.com/EN/Prodsandservices/ PlusPat.htm.

3. Rise in food biotechnology-related German patent applications

a. Overview

Biotechnology plays an important role in the food sector with 1,078 patent applications out of a total of 13,206 food-related patent applications over the period from 1970 to 2001 as shown in table 4.[86] The share of food biotechnology-related German patent applications in food-related German patent applications was 8.2% during the period from 1970 to 2001. This share has rather constantly risen and generally followed the development of food-related German patent applications. For the period since 1978, the low points of food-related German patent applications with 326 in 1979 and 329 in 1991, correspond to the low points of food biotechnology-related German patent applications with 8 in 1979 and 18 in 1991.[87]

Food biotechnology-related German patent applications rose from 0 in 1970 to 73 in 1999. Until 1977, there was only an annual maximum of 8 food biotechnology-related German patent applications, while in 1978 a significant amount of 55 food biotechnology-related German patent applications were filed. The number of food biotechnology-related German patent applications fluctuated until 1990, with a minimum of 9 in 1979 and a maximum of 56 in 1986. From 1991 on there was a rather constant rise in food biotechnology-related German patent applications, from 18 to its maximum of 76 in 2000 and fluctuating only to a minimum of 56 in 1997.[88]

This rise is due to the increasing influence of biotechnology in the food sector. Biotechnology has become an important tool in the food sector,[89] with molecular breeding and genetically modified plants in the production of agricultural raw materials, and genetically modified microorganisms for fermentation or synthesis of food additives in the production of processed food. An overview of the technological developments is given in part II.

86 The overview given in table 4 refers to national German patent applications. European patent applications with designation Germany are not included.

87 This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit. For an overview see table 4.

88 This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit. For an overview see table 4.

89 Other relevant applications areas of biotechnology are the "Red Biotechnology" in the pharmaceuticals sector and the "White Biotechnology" for industrial applications.

"Green Biotechnology" as plant biotechnology is called, has increased remarkably, from 0 German patent applications in 1970 to 35 in 2000 (IPC subclass plants (A01H). The first 10 plant biotechnology-related German patent applications were filed in 1978. This amount decreased substantially in the following years. Plant biotechnology-related German patent applications have been rising rather constantly since 1984, from 1 to over 30 from 1999 on. This corresponds to the pioneering research in plant biotechnology that took place around 1983.[90] The constant level of plant biotechnology-related German patent applications indicates a steady R&D level in plant biotechnology. This reflects the steady implementation of plant biotechnology and the future potential of plant biotechnology.[91]

Meanwhile, plant biotechnology makes up for the lion's share of food biotechnology-related German patent applications. Since 1999, plant biotechnology-related German patent applications have accounted for over 45% of all food biotechnology-related German patent applications. The proportion of plant biotechnology-related German patent applications in food-related German patent applications is remarkably high and is the highest compared to other segments of the food sector. This ratio rose rather constantly from 12% in 1984 to 100% in 1993, and has levelled off at around 90% since 1994. The vast development and the important role of plant biotechnology in the food sector is indicated by the rise of German patent applications in plants (A01H).[92]

90 *Zambryski et al.*, Ti Plasmid Vector for the Introduction of DNA to Plant Cells without Alteration of their Normal Regeneration Capacity, 2 European Molecular Biology Organization Journal 2143 (1983).

91 This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit. For an overview see table 4.

92 This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit. For an overview see table 4. For the technological development see part II, section A, subsection I.

c. Feed biotechnology

Feed biotechnology is an emerging technology of the feed segment. Feed biotechnology-related German patent applications appeared first in 1975 with 1 application and increased since then to a maximum of 24 applications in 2001, accounting for 38% of feed-related German patent applications. This share has been rather constant since 1993, at about 10%. Feed biotechnology has the second-highest share of food biotechnology-related German patent applications among food-related German patent applications after plant biotechnology. This corresponds to the strong presence in the industry of feed additives like the enzyme phytase and the essential amino acid lysine that are produced by genetically modified microorganisms in the feed segment.[93]

d. Biotechnology in other segments of the food sector

Further IPC subclasses with significant food biotechnology-related German patent applications are miscellaneous food (A23L), with 17, and bakery (A21D), dairy (A23C), confectionery (A23G), proteins (A23J), brewing (C12C), distillation (C12F) and alcoholic beverages (C12G) with fewer than 5 in 1999. Oils and fats (A23D), vinegar (C12J), and the sugar subclasses (C13F, C13J, C13K) have not had any food biotechnology-related German patent applications from 1999 to 2001.[94]

The share of food biotechnology-related German patent applications apart from plants and feed among food-related patent applications ranges between 25% in vinegar (C12J) as well as 20% in sugar (C13K) and 1% in coffee and tea (A23F) and in confectionery (A23G) during the period from 1970 to 2001. Proteins (A23J), with 11%, and brewing (C12F), with 17% also showed high shares.[95]

93 This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit. For an overview see table 4. For an overview of the technology see table 9, part II, section A, subsection I and part II, section B, subsection I.

94 This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit. For an overview see table 4.

95 This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit. For an overview see table 4.

The proportion of food-biotechnology related German patent applications in other segments of the food sector than plants and feed has been rather small. The proportion of food biotechnology-related German patent applications among the confectionery subclass (A23G) has been minimal. There have been only 11 food biotechnology-related patent applications in confectionery during the period from 1970 to 2001. So biotechnology plays only an inferior role in the confectionery segment, where microorganisms are used only to a limited extent.[96]

Segments of the food sector which employ fermentation by microorganisms show a high degree of food biotechnology-related German patent applications, with 25% in vinegar (C13J), 20% in sugar (C13K), 17% in distillation of fermented solutions (C12C), 13% in feed (A23K), and 11% in proteins (A23J) from 1970 to 2001.[97]

The increasing number of German patent applications in these IPC subclasses reflects the notable influence of biotechnology on the improvement of fermentation processes and on the synthesis of food additives. Moreover, biotechnology has led to a range of new food additives and new processes in the production of processed food, such as in the processing of the sweetener aspartame.[98]

96 This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit. For an overview see table 4.

97 This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit. For an overview see table 4.

98 For an overview of the technology see table 11 showing uses of enzymes in the production of processed food, part II, section B, subsection I.

Table 4:
Food biotechnology-related national German patent applications with a priority from 1970 to 2001.[99]

Year	A01H	A21D	A23B	A23C	A23D	A23F	A23G	A23J	A23K	A23L	A23P	C12C	C12F	C12G	C12H	C12J	C13F	C13J	C13K	Sum
70	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
71	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	**1**
72	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
73	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	**1**
74	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	**1**
75	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	**2**
76	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	**1**
77	0	0	0	0	0	0	0	0	4	2	0	2	0	0	0	0	0	0	0	**8**
78	10	3	2	7	0	0	0	0	8	11	2	1	2	3	0	1	2	0	3	**55**
79	1	0	1	1	0	0	0	1	1	1	0	2	0	0	0	0	0	0	1	**9**
80	0	1	0	3	0	1	0	2	9	5	0	4	1	1	3	0	0	0	0	**30**
81	0	0	0	1	0	0	0	1	6	2	0	2	1	1	2	0	0	0	4	**20**
82	1	1	0	1	0	0	0	0	2	5	0	0	0	1	0	0	0	0	0	**11**
83	0	4	1	8	0	0	0	4	7	8	0	0	0	0	1	0	0	0	1	**34**
84	1	1	0	0	0	0	0	1	6	8	0	0	0	2	0	0	0	0	0	**19**
85	3	2	2	3	0	0	0	4	6	8	0	2	1	4	0	0	0	0	2	**37**
86	8	1	0	5	0	0	1	1	13	9	0	5	5	5	1	0	0	1	1	**56**
87	13	2	2	2	0	0	1	1	5	8	0	1	2	2	1	0	0	0	1	**41**
88	10	3	2	7	0	0	0	0	8	11	2	1	2	3	0	1	2	0	3	**55**
89	7	0	0	0	0	0	0	1	2	3	1	0	0	2	0	0	0	0	0	**16**

99 Food biotechnology-related patent applications are IPC subclasses of table 1 linked with IPC subclasses of table 2. It is referred to the first priority date that is claimed by the respective German patent application. This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit.

Table 4 - continuation:
Food biotechnology-related national German patent applications with a priority from 1970 to 2001.[100]

Year	A01H	A21D	A23B	A23C	A23D	A23F	A23G	A23J	A23K	A23L	A23P	C12C	C12F	C12G	C12H	C12J	C13F	C13J	C13K	Sum
90	19	1	2	2	0	0	0	1	3	4	0	0	0	0	0	0	0	0	0	**32**
91	7	0	1	1	0	0	0	0	3	3	0	1	0	0	1	0	0	0	1	**18**
92	18	7	2	1	0	0	0	0	1	10	0	6	0	1	0	2	0	0	0	**48**
93	15	1	0	2	0	0	1	0	3	19	0	5	0	0	1	0	2	0	1	**50**
94	17	4	2	6	1	0	2	1	7	15	1	3	0	2	0	0	1	0	0	**62**
95	16	4	2	2	0	0	2	2	5	21	1	0	0	1	1	0	2	0	0	**59**
96	29	5	0	1	0	1	0	1	8	24	0	2	0	1	1	0	0	0	2	**75**
97	21	3	0	2	1	0	1	0	6	16	1	1	0	1	1	0	1	0	1	**56**
98	22	4	1	1	1	0	1	2	9	17	0	4	0	1	0	0	0	0	1	**64**
99	33	1	1	2	0	1	2	5	9	15	1	1	0	2	0	0	0	0	0	**73**
00	35	2	1	0	0	0	0	1	14	17	1	3	0	0	2	0	0	0	0	**76**
01	32	0	0	0	0	0	0	0	24	10	0	1	0	1	0	0	0	0	0	**68**
Total	**318**	**50**	**22**	**58**	**3**	**3**	**11**	**29**	**171**	**253**	**10**	**48**	**14**	**34**	**15**	**4**	**11**	**1**	**23**	**1078**

100 Food biotechnology-related patent applications are IPC subclasses of table 1 linked with IPC subclasses of table 2. It is referred to the first priority date that is claimed by the respective German patent application. This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit.

The German food sector has performed well since the introduction of food patentability in 1967, corresponding to its increasing patenting activity since 1970, as shown in tables 3 and 4. Meanwhile, it has become one of the most important industrial sectors. The German food sector comprised 5,970 companies with over half a million employees in 2004. The sector's turnover increased from €116.9 billion in 1998 to €133.6 billion in 2005.[101] The domestic sales rose from €96.6 billion in 1998 to €104,2 billion in 2005 by 8%, whereas the exports rose from €20.3 billion in 1998 to €29.4 billion in 2005 by 45%.[102] The tremendous increase of the exports might be due to the influence of the common market within the European Union. The share of exports in the sector's turnover steadily rose from 17.3% in 1998 to 22% in 2005.[103] This indicates that the patentability of food introduced by the Amending Act of 1967 had a promoting effect on the food sector.

Falling prices for food and reduced shares of food in consumer spending indicate that patents on food have not limited food availability. Food prices have not increased since the patentability of food in 1967, as the share of food prices in consumer spending has been constantly declining from 16.7% in 1980 to 12.2% in 2004.[104] Falling food prices render the fears of the legislature of 1877 about negative effects of patents on food availability unjustified.

Moreover, the share of costs of agricultural raw materials in consumer food spending constantly dropped from 50% in the early 1970s to 26% in 2004 while margins of food trade and the production of processed food have steadily increased.[105] The declining share of agricultural products in consumer food spending is caused by the division of labor and an increased demand for processed food combined with complementary services. This again indicates that the patentability of food had a rather positive effect on food production and availability in Germany.

101 Bundesvereinigung der deutschen Ernährungsindustrie, 2006, available at www.bve-online.de/.
102 Bundesvereinigung der deutschen Ernährungsindustrie, 2006, available at www.bve-online.de/.
103 Bundesvereinigung der deutschen Ernährungsindustrie, 2006, available at www.bve-online.de/.
104 A representative basket of commodities with 24 food articles costs least in Germany compared to the European Nations amounting only to 80% of the European average in 2004. Landesbauernverband Niedersachsen, Nahrungsmittel in Deutschland besonders preiswert, press release of March 9, 2005, available at www.landvolk.net/3747.htm.
105 Informationsdienst Wissenschaft, Anteile der landwirtschaftlichen Erzeugererlöse an den Verbraucherausgaben für Nahrungsmittel in Deutschland leicht gestiegen, 2005, available at www.idw-online.de/pages/de/news97492.

V. Assessment of the exemption in Germany from 1877 to 1967

The exemption in the German Patent Act of 1877 has been a rather formal exemption. The economic need to protect the inventions of certain industrial sectors has generated case law to bypass the exemption. The exemption in the German Patent Act of 1877 was made a formal exemption by the Amending Act of 1891 and the *Kongorot* decision, which acknowledged the patentability of analogous chemical processes.

Special fields of technology should not be discriminated against by an exemption to patentability, because the patent system *per se* is neutral.[106] It aims at giving the inventor an incentive to disclose his invention and rewards him for doing so.[107]

106 The first economic study performed on the patent system in 1958 by the American economist *Machlup* for the U.S. congress concluded as follows: "No economist on the basis of present knowledge, could possibly state with certainty that the patent system, as it now operates, confers a net benefit or a net loss upon society. The best he can do is state assumptions and make guesses about the extent to which reality corresponds to these assumptions." *Machlup*, An Economic Review of the Patent System – Study of the Subcommittee on Patents, Trademarks and Copyrights of the Committee on the Judiciary United States Senate Eighty-fifth Congress, second session, Study No. 15, Washington, D.C., 1958, 79. In spite of this difficult economic evaluation *Machlup* summoned the four theories underlying the patent system as following, *Machlup*, *supra*, 19 ss. The "natural law" thesis according to which the inventor has a natural property right in his own ideas. The "reward-by-monopoly" thesis considers the patent grant as an equitable remuneration of the inventor for his intellectual property work performed for the benefit of the community. The "monopoly-profit-incentive" thesis considers patent protection as an instrument for the promotion of technical and economic progress. Finally, the "exchange-for-secrets" thesis justifies patent protection with the obligation of the inventor to disclose his inventive idea to the public as early as possible. All four theories have in common that they do not distinguish between certain fields of technology. Thus it can be concluded that the patent system should be neutral for all fields of technologies. *Beier* confirmed in 1970, that the reward-by-monopoly, the monopoly-profit-incentive and the exchange-for-secrets thesis theories still apply to the policy aims of patent protection in most parts of the world, *Beier*, Traditional and Socialist Concepts of Protecting Inventions, 1 IIC 328 (1970), *Beier&Straus*, The Patent System and Its Informational Function – Yesterday and Today, 5 IIC 387, 392 (1977). *Adrian* points out, that neutrality of the patent system is limited by immanent borders by constitutional law, ordre public and morality, *Adrian*, Patentrecht im Spannungsfeld von Innovationsschutz und Allgemeininteresse, Berlin 1996, 16. Again, there is no distinction between different fields of technology.

107 Motives for patent protection are technical, economic and social promotion by protection of intellectual property of the inventor, awarding of the inventor himself, stimulation of the economy and encouraging the disclosure of technical knowledge. For an oveview see *Beier*, Die herkömmlichen Patentrechtstheorien und die sozialistsche Konzeption des Erfinderrechts, GRUR 1970, 1, *Oddi*, TRIPS – Natural Rights and a "Polite Form of Economic Imperialism", 29 Vanderbilt Journal of Transnational Law 415, 417 (1996).

Socio-political battles should not to be fought at the expense of patent law. A patent grants an absolute right, so in this area legal certainty seems to be crucial. The potential infringer as well as the public should be certain about the scope of a patent in order to determine whether they are infringing this patent. Changing political circumstances therefore should not be relevant to the patentability of an invention.[108]

The exemption severely complicated the application procedure by introducing the possibility of an unclear definition of the scope of the exemption, because there are always border cases.[109] With *Straus*[110] it can only be concluded with regard to exemptions to patentability: „Controversies and differences of opinion are pre-programmed in this context." Furthermore, as *Straus*[111] put it with respect to the exemption to patentability of plant varieties according to Art. 53(b) EPC and Art. 27(3)(b) TRIPs exemptions to patentability bear the danger of "petrification ... in patent law in a field that urgently requires a dynamic legal response to developments in science and technology."

108 The relatively low flexibility of the patent sysem is mirrored by following quotation: „The patent community clings religiously to the one-size-fits-all credo, preserving the inertia of the system against the business concerns of particular industries, and preserving it against scrutiny that might lead to an empirical understanding of costs and benefits - and winners and losers. Designed for an industrial economy and resistant to change, the system has become complex and opaque in its application to a diverse, networked economy based on information and services. *Kahin,* "The Expansion of the Patent System: Politics and Political Economy, First Monday, volume 6, number 1 (2001), available at http://firstmonday.org/issues/issue6_1/kahin/index.html.

109 In context with the exemption to patentability in Art. 27(3)(b) TRIPs. *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, in: *Beier&Schricker* (eds.), From GATT to TRIPs – The Agreement on Trade-Related Aspects of Intellectual Property Rights, Weinheim 1996, 160, 185.

110 In context with the exemption to patentability in Art. 27(3)(b) TRIPs. *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, in: *Beier&Schricker* (eds.), From GATT to TRIPs – The Agreement on Trade-Related Aspects of Intellectual Property Rights, Weinheim 1996, 160, 185.

111 *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, in: *Beier&Schricker* (eds.), From GATT to TRIPs – The Agreement on Trade-Related Aspects of Intellectual Property Rights, Weinheim 1996, 160, 185.

Consequently exemptions to patentability complicate the patent system, which intends to reward the inventor, and finally they hinder economic growth. Furthermore, an exemption imposes commercial disadvantages on a country in global competition, whenever other countries do not exclude the respective subject matter from patentability. The dramatically declining field trials of genetically modified plants in Europe in comparision to the U.S. mirror the exemption to patentability of plant varieties under the EPC whereas the U.S. allows patents for plant varieties.[112] Moreover there is almost no significant cultivation of genetically modified plants in Europe[113], whereas the share of transgenic corn in the U.S. was 38% of the complete U.S. maize acreage.[114]

All in all the exceptional position of the food sector is mirrored in the exemption and in a need to keep food-related inventions free from patent protection. Basically it was this need that caused the exemption in the German Patent Act of 1877.

112 For the exemption to patentability of plant varieties see Part III, section II, subsection 1. Since June 1996 the field trials performed in the EU has been declining by two thirds, *Menrad et al*., Review of GMOs under Research and Development and in the Pipeline in Europe, 69, Figure F1, European Science and Technology Observatory of the European Commission 2003, available at www.jrc.es, 69, Figure F1. See also *Straus*, Measures Necessary for the Balanced Co-Existence of Patents and Plant Breeder's Rights – A Predominantly European View, Doc. WIPO-UPOV/SYM/02/07 (2002), 2.

113 In 2005, only 0,1 million hectares of transgenic plants were cultivated in Spain, which constituted the biggest area of transgenic plants in Europe. Other European countries that commercialized transgenic plants were Germany, Portugal, France and the Czech Republic *James*, Executive Summary of Global Status of Commercialized Biotech/GM Crops: 2005, ISAAA Briefs No. 34, Ithaca, NY 2005, 4 s. A future use of plant biotechnology in Europe could lead to enormous harvest increases, lower production costs and less need for crop protection. It was estimated that the harvest of maize, sugar beet and potatoes would increase by 7.8 million tons and the net farmers' income would increase by €1 billion with 9.8 million kg less agrochemicals. *Gianessi et al.*, Pflanzenbiotechnologie: Potenzial zur Verbesserung des Pflanzenschutzes in der europäischen Landwirtschaft – Eine Zusammenfassung von drei Fallstudien, National Center for Food and Agricultural Policy, Washington 2003, 3.

114 In 2005, 49,8 million hectares of transgenic plants were cultivated in the U.S., *James*, Executive Summary of Global Status of Commercialized Biotech/GM Crops: 2005, ISAAA Briefs No. 34, Ithaca, NY 2005, 4 s. The positive impacts of transgenic plants in U.S. agriculture has been recently described by *Sankula et al.*, Biotechnology Derived Crops Planted in 2004 – Impacts on US Agriculture, National Center for Food and Agricultural Policy (2006), 100, available at www.ncfap.org.

B. Patentability of food under the TRIPs Agreement

As Germany excluded food from patentability from 1877 to 1967, so have many emerging or developing countries excluded food from patentability until recently. At the start of the TRIPs negotiations, 35 countries of the 92 Paris Convention Members excluded food from patentability.[115] Furthermore, 9 countries excluded food-related processes[116] and microorganisms[117] from patentability.

115 Australia (where the Commissioner can refuse to grant a patent therefor where the product is a mere mixture of known ingredients), Bolivia, Brazil, Bulgaria, Canada (unless produced by processes also claimed or their equivalents), China, Czechoslovakia, Colombia, Cuba, Denmark, Ecuador, Egypt (as regards chemical inventions), Finland, German Democratic Republic, Hungary, Iceland, India, Libya (as regards chemical inventions), Malawi, Mexico, Mongolia, New Zealand (where the Commissioner can refuse a patent therefor), Norway, Peru, Poland, Portugal, Republic of Korea, Romania, Thailand, Tunisia, Venezuela, Viet Nam, Yugoslavia, Zambia (where the Registrar can refuse a patent therefor where the product is a mere mixture of known ingredients), Zimbabwe (where the Registrar can refuse a patent therefor where the product is a mere mixture of known ingredients), WTO, Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property, Negotiating Group on TRIPs, Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property, Doc. MTN.GNG/NG11/W/24 (1988), p. 31.

116 Australia (where the Commissioner can refuse a patent therefor where the process produces a mere mixture of known ingredients by mere admixture), Brazil, Colombia (unless if exploited in Colombia), Denmark, Malawi, Mexico, New Zealand (where the Commissioner can refuse a patent therefor where the process produces a mere mixture of known ingredients by mere admixture), Zambia (where the Registrar can refuse a patent therefor where the process produces a mere mixture of known ingredients by mere admixture), Zimbabwe (where the Registrar can refuse a patent therefor where the process produces a mere mixture of known ingredients by mere admixture), Negotiating Group on TRIPs, Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property, Doc. MTN.GNG/NG11/W/24 (1988), p. 32.

117 Brazil, Cuba, Czechoslovakia (if used in industrial manufacture), German Democratic Republic, Hungary, Malaysia (except for man-made living micro-organisms), Spain, Romania, Yugoslavia, WTO, Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property, Negotiating Group on TRIPs, Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property, Doc. MTN.GNG/NG11/W/24 (1988), p. 32.

Plant varieties were excluded from patentability in 44 countries[118], and biological processes for breeding plant varieties or animal species in 42 countries.[119] The TRIPs Agreement substantially changed this situation. *Straus*[120] summarizes the impact of the TRIPs Agreement on the food sector as follows:

> "Bearing in mind all the specific phases of the food production process it seems clear that under the TRIPs Agreement, WTO Members have to provide patent protection and/or plant variety protection respectively, for all genomic inventions involved in that process at its different stages and their resulting end products including final foods."

The TRIPs Agreement was the result of linking the patent system with international trade. Astonishingly, it was not the doctrine of the positive effects of the patent system on national economies that led to it.[121]

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118 Algeria, Austria, Bahamas, Barbados, Belgium, Brazil, Bulgaria, Canada, China (except for relevant processes), Colombia, Cuba, Cyprus, Denmark, Ecuador, EPC, Finland, France, German Democratic Republic, Germany (Federal Republic of), Ghana, Israel, Kenya, Luxembourg, Malaysia, Mexico, Netherlands, Nigeria, Norway, OAPI1, Peru, Poland, Portugal, Romania, South Africa, Soviet Union, Spain, Sri Lanka, Sweden, Switzerland2, Thailand, Uganda, United Kingdom, United Republic of Tanzania, Yugoslavia, WTO, Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property, Negotiating Group on TRIPs, Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property, Doc. MTN.GNG/NG11/W/24 (1988), p. 31.

119 Algeria, Austria, Bahamas, Barbados, Belgium, Brazil, Canada, Colombia, Cuba, Cyprus, Denmark, Ecuador, EPC, Finland, France, German Democratic Republic, Germany (Federal Republic of), Ghana, Israel, Italy3, Kenya, Luxembourg, Malaysia, Mexico, Mongolia, Netherlands, Nigeria, Norway, OAPI1, Peru, Poland, Portugal, South Africa, Spain, Sri Lanka, Sweden, Switzerland2, Thailand, Uganda, United Kingdom, United Republic of Tanzania, Yugoslavia;WIPO, Existence, Scope and Form of Generally Accepted and Applied Standards/Norms for the Protecting of Intellectual Property, WIPO Doc. DOK/WO/INF/29 (1988), Annex II, 96.

120 *Straus*, Genomics and the Food Industry: Outlook from an Intellectual Property Perspective, in: *Vaver&Bently* (eds.), Intellectual Property in the New Millennium – Essays in Honour of William R. Cornish, Cambridge 2004, 124, 134.

121 "Dass mit (dem) TRIPs Abkommen hohe Schutzstandards (...) der Rechte des geistigen Eigentums international verpflichtend statuiert werden konnten, war keineswegs das Ergebnis der allgemeinen internationalen Überzeugung von den positiven Wirkungen dieser Rechte auf Innovationspotentiale der nationalen Wirtschaften. Vielmehr stellt TRIPS das Ergebnis der Verknüpfung des Schutzes der Rechte des geistigen Eigentums mit dem internationalen Handel dar." *Straus*, Der Beitrag Deutschlands zur Entwicklung des internationalen gewerblichen Rechtsschutzes, GRUR Int. 2003, 805, 811.

I. Negotiations with respect to food[122]

The mutual dependence of developing countries and developed countries paved the way for negotiations. Export markets for agricultural products or textiles were traded against a minimum standard of patent protection.[123] The negotiations for the TRIPs Agreement[124] based on the GATT Agreement were a reaction to the changing technological structure of the world economy.[125]

The developing countries opposed an inclusion of the TRIPs Agreement in GATT negotiations, but finally negotiated over the patent system, because of economic pressure exerted on them by the developed countries.[126] Reciprocal concessions by developed countries included a commitment to reduce agricultural export subsidies and textile quotas and an import license for agricultural products. These concessions were linked with threats that the U.S. would pursue sanctions and abandon the GATT altogether if its negotiating agenda was not accepted.[127]

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122 *Goebel*, Pflanzenpatente und Sortenschutzrechte im Weltmarkt – Zugleich ein Beitrag zur Revision von Art. 27 Abs. 3 b) TRIPS-Übereinkommen, Berlin 2001, 137, *Rott*, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen, Baden-Baden 2002, 67, *Arup*, The Prospective GATT Agreement for Intellectual Property Protection, Australian Intellectual Property Law Journal 1993, 181, 182, *Chason et al.,* Trade-Related Aspects of Intellectual Property Rights, Deventer Bosten 1994, 15, *Cottier*, The Prospect of Intellectual Property in GATT, Common Market Law Review 1991, 383, *Drahos*, Global Property Rights in Information: The Story of TRIPS and the GATT, Prometheus 1995, 6, *Drexl*, Entwicklungsmöglichkeiten des Urheberrechts im Rahmen des GATT, 293, *Evans*, The Making of the Agreement on Trade-Related Aspects of Intellectual Property Rights, World Competition 1994 No. 2, 136, 142, *Faupel*, GATT und geistiges Eigentum, GRUR Int. 1990, 255, *Croome*, Reshaping the World Trading System, Geneva 1995.

123 *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, in: *Beier&Schricker* (eds.), From GATT to TRIPs – The Agreement on Trade-Related Aspects of Intellectual Property Rights, Weinheim 1996, 160, 168.

124 *Abbott,* Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework, 22 Vanderbilt J. Transnat'l L. 689 (1989).

125 *Barton,* The Economics of TRIPS: International Trade in Information Intensive Products, 33 George Washington International Law Review 473 (2001), *Correa*, Integrating Public Health in Patent Legislation in Developing Countries, South Centre 2000, *Maskus,* Intellectual Property Rights in the Global Economy, Institute for International Economics 2000.

126 *Abbott*, Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework, 22 Vanderbilt Journal of Transnational Law 689, 719 (1989).

127 *Abbott,* The TRIPS-Legality of Measures Taken to Address Public Health Crises: Responding to USTR-State-Industry Positions that Undermine the WTO, in: *Kennedy et al.* (eds.), The Political Economy of International Trade Law: Essays in Honor of Robert E. Hudec, Cambridge 2002, 311, 314.

At the beginning of the Uruguay Round in 1987 some participants of the Negotiating Group on TRIPs referred in particular to the exclusion in some countries of chemical, pharmaceutical and food products:

> "The protection of processes of manufacture only, where it exists, is not regarded by these participants as an adequate substitute, because of difficulties of enforcement and the scope for inventing around the patent."[128]

Some other participants expressed the view that intellectual property rights are monopoly rights which are

> "created by society in order to promote certain goals, but which in themselves create economic distortions, both generally and to trade in particular. It was therefore justifiable and necessary for countries to frame these rights in such a way as to limit these distortions and to serve the particular national objectives justifying their creation, such as the promotion of national technological, creative and industrial resources, consumer protection, health, food supply etc."[129]

Up to the end of 1989 the views on patentability of food in the Negotiating Group of the TRIPs Agreement were divided.[130] There was a heated controversy on what should count as patentable subject matter. Health and pharmaceuticals dominated the negotiations of the TRIPs Agreement while, surprisingly, the food sector was left out with the exemption of plants and animals.[131] India wanted to leave the exemption to patentability to the WTO Members, which would have made the exemption to patentability of pharmaceuticals, agrochemicals and food possible. The U.S., Japan and Australia voted for the patentability of inventions in all fields of technology. The European countries agreed, but proposed an optional exemption to patentability of plant varieties and animal species similar to Art. 53(b) EPC. Brazil argued for the patentability of inventions in all fields of technology under the condition of wide exemptions for public benefits.[132] Canada and some emerging countries proposed the exemption to patentability of plants and animals, and not only of plant varieties, as in the European approach.[133] The different approaches of India, Brazil, the U.S. and Europe are shown in the following.

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128 Negotiating Group on TRIPs, Compilation of Written Submission and Oral Statements, Doc. MTN.GNG/NG11/W/12 (1987), No. 37. Argumented repeated in: Negotiating Group on TRIPs, Compilation of Written Submission and Oral Statements,
WTO Doc. MTN.GNG/NG11/W/12/Rev.1 (1988), No. 41.

129 Negotiating Group on TRIPs, Compilation of Written Submission and Oral Statements,
Doc. MTN.GNG/NG11/W/12 (1987), No. 50.

130 Negotiating Group on TRIPs, Synoptic Tables Setting Out Existing Standards and Proposed Standards and Principles, Doc. MTN.GNG/NG11/W/32/Rev.2 (1990).

131 *Straus*, Genomics and the Food Industry: Outlook from an Intellectual Property Perspective, in: *Vaver&Bently*, Intellectual Property in the New Millennium – Essays in Honour of William R. Cornish, Cambridge 2004, 124.

132 "Patents should be granted to those inventions which satisfy the criteria of patentability, with the exception of inventions that are contrary to morality, religion, public order, public health and bearing in mind public interest and technological and economic development conside-rations."Negotiating Group on TRIPS, Doc. MTN.GNG/NG11/W32/Rev.2, 85.

133 WTO Committee on Trade and the Environment, Doc. WT/CTE/W/8, Environment and TRIPs, 24.

India entered TRIPs negotiations regarding patentable subject matter with the following statement:

> "Every country should be free to determine both the general categories as well as the specific products or sectors that it wishes to exclude from patentability under its national law taking into consideration its own socio-economic, developmental, technological and public interest needs. It would not be rational to stipulate any uniform criteria for non-patentable inventions applicable alike both to industrialised and developing countries or to restrict the freedom of developing countries to exclude any specific sector or product from patentability.
>
> Developing countries should be free to provide for process patents only in sectors of critical importance to them such as food, pharmaceutical and chemical sectors."[134]

India shared the view of many developing countries and countries in transition, claiming with respect to the duration of a patent on food that

> "developing countries should also be free to set a shorter duration of patents in sectors of critical importance to them, such as the food, pharmaceutical and chemical sectors, or even to exclude such sectors from patentability."[135]

Furthermore, India claimed with respect to compulsory licenses and patents on food:

> "Apart from compulsory licences, developing countries should be free to provide for the automatic grant of non-voluntary licences in sectors of critical importance to them, such as food, pharmaceuticals and chemicals. The grant of such "licences of right" will not be subject to any administrative scrutiny or judicial review as the patents themselves will be deemed to be endorsed with the words "licence of right". The patent owner will be entitled to compensation in accordance with the host country's law.
>
> Where the public interest, and in particular national security, food production, poverty alleviation, nutrition, health care or the development of other vital sectors of the national economy so requires it, the host country government or any third person designated by it should be free to work and use the patented invention in the country, including the importation of the patented product if necessary, without the consent of the patent owner on such terms and conditions as the host country government may decide."[136]

All in all, India regarded the food sector as of critical importance to developing countries. India therefore claimed that the food sector should be kept free of patents. Moreover, patents on food-related inventions should have a short duration. Finally, if food-related inventions should be patented, they should nevertheless remain available due to an automatic grant of non-voluntary licenses. Summarizing India's view at the beginning of TRIPs negotiations, India was interested in keeping the food sector as free as possible from patents.

134 Negotiating Group on TRIPs, Synoptic Tables Setting Out Existing Standards and Proposed Standards and Principles, Doc. MTN.GNG/NG11/W/32/Rev.2 (1990), 87.

135 Negotiating Group on TRIPs, Synoptic Tables Setting Out Existing Standards and Proposed Standards and Principles, Doc. MTN.GNG/NG11/W/32/Rev.2 (1990), 93.

136 Negotiating Group on TRIPs, Synoptic Tables Setting Out Existing Standards and Proposed Standards and Principles, Doc. MTN.GNG/NG11/W/32/Rev.2 (1990), 101.

2. The approach of Brazil

Brazil entered negotiations with the following statement:

> "Patents should be granted to those inventions which satisfy the criteria of patentability, exception made to inventions that are contrary to morality, religion, public order, public health and bearing in mind public interest and technological and economic development consideration."[137]

With respect to the duration of a patent, Brazil was of the view that:

> "Countries have the right to establish a term of protection in accordance with their national interests, provided that the following criteria of the Paris Convention are met; priority, independence of patents and national treatment."[138]

Summarizing Brazil's statement, this country shared the view of India to leave developing countries as much freedom as possible in adapting their patent systems to their needs, e.g. in keeping patent protection rather weak by the possibility of excluding subject matter and adjusting the duration of a patent to their needs.

3. The approach of the U.S.

The U.S. view was contrary to the views of India and Brazil, hardly allowing exemptions to patentability:

> "Patents shall be granted for all products and processes which satisfy the criteria or conditions for patentability."[139]

137 Negotiating Group on TRIPs, Synoptic Tables Setting Out Existing Standards and Proposed Standards and Principles, Doc. MTN.GNG/NG11/W/32/Rev.2 (1990), 87.

138 Negotiating Group on TRIPs, Synoptic Tables Setting Out Existing Standards and Proposed Standards and Principles, Doc. MTN.GNG/NG11/W/32/Rev.2 (1990), 93.

139 The U.S. proposal on patentable subject matter further explained: "Examples of items which do not meet these criteria are: materials consisting solely of printed matter, scientific principles, methods of doing business, and algorithms and mathematical formulas per se, including those incorporated in computer programs. A patent application or a patent, however, may be withheld from publication if disclosure of the information contained therein would be detrimental to the national security." Negotiating Group on TRIPs, Synoptic Tables Setting Out Existing Standards and Proposed Standards and Principles, Doc. MTN.GNG/NG11/W/32/Rev.2 (1990), 92.

4. The approach of the European Communities

The proposal of the European Communities seemed to be in between the U.S. view, rendering all fields of technology including food patentable subject matter, and the view of the developing countries excluding food, pharmaceuticals and chemicals from patent protection.

> "Patents shall be available for inventions in all fields of technology, except for:
> - inventions the publication or exploitation of which would be contrary to "ordre public" or morality;
> - plant or animal varieties or essentially biological processes for the production of plants or animals; this does not apply to microbiological processes or the products thereof."[140]

This proposal was made though Art. 53(b) EPC seemed "somewhat outdated"[141] already at the time of proposing it to the Negotiating Group on TRIPs. The question was raised whether plant varieties and animal species would not have undergone any regulation at all had it not been for Art. 53 (b) EPC.[142]

5. Further negotiations

The Trade Negotiations Committee of the Uruguay Round of Multilateral Trade did not particularly discuss the patentability of food.[143] In its Mid-Term Meeting of 3-9 December 1988 in Montreal and 3-8 April 1989 in Geneva the Trade Negotiations Committee adopted only that "participants' concerns such as food security" should be taken into account during GATT negotiations and invited its members to propose "ways to take account of the possible negative effects of the reform process on net food-importing developing countries."[144]

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140 Negotiating Group on TRIPs, Synoptic Tables Setting Out Existing Standards and Proposed Standards and Principles, Doc. MTN.GNG/NG11/W/32/Rev.2 (1990), 87.

141 *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, in: *Beier&Schricker* (eds.), From GATT to TRIPs – The Agreement on Trade-Related Aspects of Intellectual Property Rights, Weinheim 1996, 160, 185. See also *Armitage*, Updating the European Patent Convention, GRUR Int. 1990, 662, 664 s., *Cottier*, The Prospects for Intellectual Property in GATT, Common Market Law Review 1991, 383, 400, *Reichmann*, 1993 Fordham Intellectual Property Media & Entertainment Law Journal 193.

142 *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, in: *Beier&Schricker* (eds.), From GATT to TRIPs – The Agreement on Trade-Related Aspects of Intellectual Property Rights, Weinheim 1996, 160, 185.

143 Negotiating Group on TRIPs, Meeting of Negotiating Group of 14-15 November 1988, Doc. MTN.TNC/11 (1989).

144 Negotiating Group on TRIPs, Meeting of Negotiating Group of 14-15 November 1988, Doc. MTN.TNC/11 (1989), 11.

During the following discussions the understanding of the developing countries underlying the TRIPs Agreement with respect to food was defined as follows:

> "property systems served as an instrument, in conjunction with others such as policies relating to transfer of technology and foreign direct investment, of national economic policy to further the process of economic and technological development and the public interest more generally. Therefore, in evolving standards of trade-related intellectual property rights, developmental and public interest concerns such as poverty alleviation, provision of health care, nutrition and food production, and technological considerations such as the promotion of scientific and technological capability, generation and diffusion of technical knowledge and its incorporation into the production process, and improvement of access to technology on fair and reasonable terms, had to be taken into account in order to balance the protection provided to the creators or owners of intellectual property."[145]

Transition periods were claimed to compensate for the introduction of product protection for food on behalf of the developing countries such that

> "if an agreement was reached at the end of the negotiations to introduce product protection for pharmaceuticals, chemicals and foodstuffs, it would involve a change from the present situation prevailing in many countries, (...), of mainly granting process patents (and) (...) that such a transfer to a new regime could not be effected quickly and therefore required that the Group should work out meaningful transitional arrangements that would enable concerned industries to adjust to the new situation while allowing the legitimate rights of patent holders to be respected."[146]

During negotiations India's representative persisted

> "that the approach in most of the proposals of allowing certain general exclusions from patentability but not allowing the exclusion of specific sectors or products would not be acceptable to his delegation because of the critical importance of some sectors such as pharmaceuticals, chemicals and foodstuffs for his country. Developing countries should have the option of either excluding certain sectors altogether from patentability or of granting process protection alone. Any restrictions in this respect would have serious repercussions for their future social, economic and technological development. It would not be appropriate to prescribe uniform criteria on the subject of exclusions from patentability applicable to developed and developing countries alike."[147]

Furthermore, India insisted on the necessity of their "license of right" approach, because "the granting of licences of right was necessary to remedy the extreme forms of abuses that might arise, especially in certain critical sectors like pharmaceuticals, agro-chemicals and foodstuffs."[148]

145 Negotiating Group on TRIPs, Meeting of Negotiating Group of 11-12 May 1989, Doc. MTN.GNG/NG11/12 (1989), 1.
146 Negotiating Group on TRIPs, Meeting of Negotiating Group of 12-14 July 1989, Doc. MTN.GNG/NG11/14 (1989), No. 74.
147 Negotiating Group on TRIPs, Meeting of Negotiating Group of 12-14 July 1989, Doc. MTN.GNG/NG11/14 (1989), No. 79.1.
148 Negotiating Group on TRIPs, Meeting of Negotiating Group of 12-14 July 1989, Doc. MTN.GNG/NG11/14 (1989), No. 83.3.

The following argument was raised in response to India's proposal:

> "By providing patent protection governments would be in a better position to monitor and control the use of inventions in industry. Rather than making exceptions for areas such as pharmaceuticals, agricultural chemicals and foodstuffs, the public interest was best served by granting protection and thereby providing incentives for research and development."[149]

Some developing countries referred to the historical development of the patent system in Germany as shown in part I, section A, subsection I, expressly claiming the same right to develop their patent system according to their status of industrial development:

> "What (the developing countries) were seeking was to be able to enjoy the same degree of freedom in this matter as had been enjoyed by the present industrialized countries when they had been at a comparable level of development. In this regard they recalled that some of the present industrialized countries had only recently introduced full patent protection in certain sectors, notably in the chemical, pharmaceutical and foodstuff sectors, and some were not intending to make such changes until later this decade. These policies had presumably been followed because they were considered to be likely to assist in the development of the industrial and technological capabilities in these sectors. It was only when sufficient industrial and technological strength had been attained that these countries had come to the view that tightening levels of patent protection would be in their interest. It thus had to be recognized that the patent system was, and historically had been, an important instrument of national economic development policy. There were, for example, good reasons sometimes for excluding products from patent protection and only providing process protection; research and development activity in the invention of new and more efficient and economical processes of production could be hamstrung by product protection."[150]

Furthermore, the developing countries stressed "the need in developing countries for essential articles, such as medicine and food, to be available at reasonable prices to the public. The monopoly right granted by the patent system inhibited competition and led to artificial prices being maintained in these sectors."[151]

6. Intermediate result

As an intermediate result, a draft text which was intended to provide a profile of the current state of work in the Negotiating Group in July 1990 and of the options for the possible results of the negotiations defined the patentable subject matter as follows:

> "Patents shall be [available] [granted] for [any inventions, whether products or processes, in all fields of technology,] [all products and processes] which are new, which are unobvious or involve an inventive step and which are useful or industrially applicable."[152]

149 Negotiating Group on TRIPs, Meeting of Negotiating Group of 30 October – 2 November 1989, Doc. MTN.GNG/NG11/16 (1989), No. 28.

150 Negotiating Group on TRIPs, Meeting of Negotiating Group of 2, 4, and 5 April 1990, Doc. MTN.GNG/NG11/20 (1990), No. 31.

151 Negotiating Group on TRIPs, Meeting of Negotiating Group of 2, 4, and 5 April 1990, Doc. MTN.GNG/NG11/20 (1990), No. 33.

152 Negotiating Group on TRIPs, Status of Work in the Negotiating Group, Doc. MTN.GNG/NG11/W/76 (1990), 17.

With regard to exemptions to patentability not food *per se* but plants were proposed to be excluded:

> "[Any] plant or animal [including micro-organisms] [varieties] or [essentially biological] processes for the production of plants or animals; [this does not apply to microbiological processes or the products thereof]. [As regards biotechnological inventions, further limitations should be allowed under national law]."[153]

The subsequent negotiations led to specification of this proposal. The European countries suggested an obligation to protect plant varieties by a *sui generis* system or by plant patents in addition to the optional exemption to patentability of plant varieties.[154] The supporters of an exemption to patentability of plant varieties specified their proposal to an exemption to patentability of parts of plants as well as processes for the production thereof.

> "PARTIES shall provide for the protection of plant varieties by patents and/or by an effective sui generis system."[155]

A rather wide clause giving the parties the possibility to "exclude from patentability certain kinds of products, or processes for the manufacture of those products on grounds of public interest, national security, public health or nutrition"[156] would have allowed the parties to exclude food from patentability.

Moreover,

> "Nothing in this Agreement shall be construed to prevent any PARTY from taking any action necessary: (...) (ii) where a patent has been granted for an invention capable of being used for the preparation or production of food or medicine, for granting to any person applying for the same a licence limited to the use of the invention for the purposes of the preparation or production and distribution of food and medicines."[157]

The decisive negotiations in December 1991 resulted in a compromise that combined the European proposal with a revision no later than 4 years after the TRIPs Agreement becomes effective. The exemption was adopted as formulated in the draft by GATT Director-General *Dunkel*:

> "Members may also exclude from patentability plants and animals other than microorganisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."[158]

153 Negotiating Group on TRIPs, Status of Work in the Negotiating Group, Doc. MTN.GNG/NG11/W/76 (1990), 17.
154 Negotiating Group on TRIPs, Doc. 2341, October 1, 1990, 23.
155 Negotiating Group on TRIPs, Status of Work in the Negotiating Group, Doc. MTN.GNG/NG11/W/76 (1990), 18.
156 Negotiating Group on TRIPs, Status of Work in the Negotiating Group, Doc. MTN.GNG/NG11/W/76 (1990), 17.
157 Negotiating Group on TRIPs, Status of Work in the Negotiating Group, Doc. MTN.GNG/NG11/W/76 (1990), 21.
158 WTO, Doc. NTN. TNCW/FA.

This final codified version represented an extension of the European approach from plant varieties and animal species to plants and animals. According to *Straus*, "there is not the slightest doubt that the possibility of excluding "plants and animals" from patentability goes beyond the EPC exclusion of "plant and animal varieties."[159] This clause set minimum standards for the protection of inventions in the food sector. Food- and food biotechnology-related inventions were patentable subject matter. Animal-related inventions could be excluded from patentability without any compensation by other protection mechanisms. Members could further exclude plant varieties from patentability but they had to establish an effective protection mechanism for plant varieties. Thus, plant-related inventions were protectable at least by a *sui generis* system.

7. Summary

All in all, the draft of the TRIPs Agreement was determined by the demands of the developed countries, especially of the U.S., the EU, and Japan. However, the developing countries were successful in incorporating provisions on compulsory licensing.[160] The main concessions to the developing countries were transition periods and a temporary moratorium on non-violation causes of action in the TRIPs Agreement.[161] Organizations outside GATT contributed little to the TRIPs Agreement. Although the TRIPs Agreement deeply affects the food sector of the developing countries, the WHO and the FAO were largely absent from the negotiations.[162]

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159 *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, in: *Beier&Schricker* (eds.), From GATT to TRIPs – The Agreement on Trade-Related Aspects of Intellectual Property Rights, Weinheim 1996, 160, 184. Under EPC case law, plant variety is defined as: "any plant grouping within a single botanical taxon of the lowest known rank which is characterized by at least one single transmissible characteristic distinguishing it from other plant grouping and which is sufficiently homogeneous and stable in its relevant characteristics, EPO, Plant Cells/Plant Genetic Systems, 1996 OJ EPO 545, headnote 11.

160 Further harmonization of the international patent system is object the current negotiations for a Substantive Patent Law Treaty (SPLT), see *Straus&Klunker*, Harmonisierung des internationalen Patentrechts, GRUR Int. 2007, 91, 100 s.

161 *Abbott,* The TRIPS-Legality of Measures Taken to Address Public Health Crises: Responding to USTR-State-Industry Positions that Undermine the WTO, in: *Kennedy et al.* (eds.), The Political Economy of International Trade Law: Essays in Honor of Robert E. Hudec, Cambridge 2002, 311, 314.

162 A main reason that the TRIPs Agreement negotiations took place at the GATT negotiations was the perception among developed countries that WIPO was not up to the job of policing intellectual property rights. However, WIPO did prepare a few background papers for the TRIPs Agreement negotiating group. *Abbott,* The TRIPS-Legality of Measures Taken to Address Public Health Crises: Responding to USTR-State-Industry Positions that Undermine the WTO, in: *Kennedy et al.* (eds.), The Political Economy of International Trade Law: Essays in Honor of Robert E. Hudec, Cambridge 2002, 311, 315.

Food-related inventions were discussed to some extent in the context of pharmaceuticals, biotechnology, and plant varieties.[163] Of 87 derestricted official documents from the 1986–94 Uruguay Round trade talks only nine documents of the Negotiating Group on TRIPs are concerned with the patentability of food.[164]

Patents related to drugs and plant varieties drew the most attention at the time, because of feared price increases and limited distribution of new technologies in developing countries. In retrospect, the food sector was of rather little importance compared to the pharmaceutical sector, which played a key role in the negotiations of the TRIPs Agreement. The food sector more or less subscribed to the view of the pharmaceutical sector, as their interests are nearly identical.[165] In the end, the food sector was well represented in that way.[166]

The pharmaceutical sector supported the abolition of the exemption to patentability of pharmaceuticals and chemical substances.[167] Its lobbying finally led to the patentability of chemical substances, food, and pharmaceuticals codified in Art. 27 of the TRIPs Agreement. This article paved the way for the patentability of food in those WTO Members that until then had excluded food from patentability.

163 *Maskus,* Intellectual Property Rights in the Global Economy, Institute for International Economics 2000, 52.

164 Available at http://www.wto.org/english/tratop_e/trips_e/trips_e.htm#NegHist. These documents comprise Doc. MTN.GNG/NG11/W/12, MTN.GNG/NG11/W/12/Rev.1, MTN.GNG/NG11/-W/24, MTN.TNC/11 MTN.GNG/NG11/12, MTN.GNG/NG11/14, MTN.GNG/NG11/16, MTN.GNG/NG11/20, MTN.GNG/NG11/W/76, and MTN.GNG/NG11/W/32/Rev.2.

165 According to an interview with former interim head of the patent division of Nestlé, NESTEC S.A., Vevey, Switzerland, *Wavre,* November 21, 2003. Estimates suggest the costs of launching successful food products and genetic plant improvements are perhaps even higher than the costs of developing a biotechnological medicine or other pharmaceuticals. In: *Maskus*, Intellectual Property Rights in the Global Economy, Institute for International Economics 2000, 54.

166 On the other hand, this rather weak position of the food sector compared to the pharmaceutical sector seemed to hinder the food sector when in 1999 the pharmaceutical industry blocked the European utility patent negotiations. According to an interview with former interim head of the patent division of Nestlé, NESTEC S.A., Vevey, Switzerland, *Wavre,* November 21, 2003; *Boppart,* Harmonisierung des Erfindungsschutzes durch Gebrauchsmuster in Europa - das Interesse der Lebensmittelindustrie, Master Thesis, Swiss Federal Institute of Technology, Zurich 2000, available at www.bepress.com/ndsip/.

167 The strong position of the pharmaceutical sector is best demonstrated by the intermediary protection mechanisms for pharmaceuticals in the TRIPs Agreement during the transition periods.

II. Contents with respect to food

Art. 27 of the TRIPs Agreement states that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application" and are sufficiently disclosed in the patent application.[168] Thus, patent protection must be extended to food.

An invention may be excluded from patentability if its commercial exploitation is against the public order or morality concerning human, animal, and plant life and health, or to avoid serious harm to the environment.[169] The exemptions to patentability must not be based only on national prohibition laws. Thus inventions in the field of plants and animals are discriminated against, in comparison to other fields of technology, by Art. 27 (3)(b) of the TRIPs Agreement. This provision allows the exemption to patentability of plants and animals and essentially biological processes for their production, codifying a contra-exemption for non-biological and microbiological processes.

Developing countries were obliged to implement the TRIPs Agreement within 10 years and to provide patent protection for pharmaceuticals, chemicals, microorganisms and food. A mailbox facility and exclusive marketing rights were a partial compensation for these long transition periods.[170] Under the mailbox provision, patent applications during the transition period must be accepted by the respective Member and stored until the introduction of the patent system. These patent applicants can claim the date of the "mailbox" application as a priority date in the later examination process. The mailbox facility of Art. 70(8) of the TRIPs Agreement is limited to pharmaceuticals and agrochemicals and does not apply to food.[171] Article 70(9) of the TRIPs Agreement provides for exclusive marketing rights, but again only to pharmaceuticals and agrochemicals, as these are of utmost importance. It provides temporary protection until the respective patents are examined.

168 Art. 29(1) of the TRIPs Agreement. This provision ensures that patents are granted on a more rational basis. "Der vollständige Ausschluss der Patentierbarkeit kommt gerade bei nützlichen Erfindeungen, deren freie Verfügbarkeit gesichert werden soll, nicht mehr in Betracht." *Rott*, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen, Baden-Baden 2002, 335.

169 Art. 27(2) of the TRIPs Agreement.

170 Art. 70(8) and 70(8) of the TRIPs Agreement.

171 *Maskus,* Intellectual Property Rights in the Global Economy, Institute for International Economics 2000, 25. However, Art. 70 (8) TRIPs does not constitute the obligation not to reject the patent application on a pharmaceutical or an agrochemical as of 2005; *Hohmann*, Die WTO-Streitbeilegung in den Jahren 1998-1999, EuZW 20000, 421, 426. For the economic implications of Art. 70(8) TRIPs see *Bronckers*, The Impact of TRIPS: Intellectual Property Protection in Developing Countries, Common Market Law Review 31 (1994), 1245, 1253.

The U.S. requested consultations on India's compliance with the mailbox facility provision and the provision on exclusive marketing rights for pharmaceuticals and agrochemicals on July 2, 1996 before the Dispute Settlement Body (DSB) of the WTO.[172] Violations of the Art. 27, 65 and 70 TRIPs were claimed. The DSB established a panel which found that India has not complied with its obligations under Art. 70(8)(a) or Art. 63(1) and (2) TRIPS by failing to establish a mechanism that adequately preserves novelty and priority in respect of applications for product patents for pharmaceutical and agricultural chemical inventions, and was also not in compliance with Article 70(9) of the TRIPS Agreement by failing to establish a system for the grant of exclusive marketing rights. On 15 October 1997, India notified its intention to appeal certain issues of law and legal interpretations developed by the Panel. The Appellate Body upheld, with modifications, the Panel's findings on Art. 70(8) and 70(9).[173] At the DSB meeting of 22 April 1998, the parties announced that they had agreed on an implementation period of 15 months from the date of the adoption of the reports i.e. it expired on 16 April 1999. India undertook to comply with the recommendations of the DSB within the implementation period. On 14 January 1999, the US requested consultations with India in accordance with Art. 21(5) of the DSU regarding the Patents Amendment Ordinance of 1999 promulgated by India to implement the rulings and recommendations of the DSB. At the DSB meeting on 28 April 1999, India presented its final status report on implementation of this matter which disclosed the enactment of the relevant legislation to implement the recommendations and rulings of the DSB.[174] Food was not particularly addressed in the judgement. The exemption of food in the Indian Patent Act occurred only in the context of pharmaceuticals and agrochemicals. Thus, the Indian Minster for Industry was asked by the panel whether applications for product patents in the pharmaceutical, food, and agricultural chemical areas had been received in anticipation of changes in the Indian Patents Act 1970 in accordance with the requirements of the World Trade Organization. The Minister responded by stating that the patent offices had received 893 patent applications in the field of drugs or medicine from Indian as well as foreign companies or institutions as of July 15, 1996.[175]

As developing countries have to provide neither a "mailbox" facility nor exclusive marketing rights with respect to food, food remains *de facto* excluded from patentability until the expiration of the transition period.

172 India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, September 5, 1997, World Trade Doc. WT/DS50/R.

173 India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, December 19, 1997, World Trade Doc. WT/DS50/AB/R.

174 Available at www.wto.org/english/tratop_e/dispu_e/cases_e/ds50_e.htm.

175 India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, September 5, 1997, World Trade Doc. WT/DS50/R, No. 2.6.

Developed countries were required to fully implement the TRIPs Agreement as of January 1, 1996,[176] while developing countries and emerging countries were given a transition period until January 1, 2000.[177] Longer transition periods were provided for least-developed countries until January 1, 2004 and, according to a recent decision of the WTO's TRIPs Council, until July 1, 2013.[178] This decision does not affect the transition period for patents for pharmaceutical products, which was agreed in 2002.[179] Consequently, least-developed countries will not have to protect these patents until January 1, 2016.[180]

Developing countries having to introduce patent systems on inventions that were excluded from patentability were given a transition period until January 1, 2005.[181] Least-developed countries have to provide patent protection for pharmaceuticals as of according to the WTO ministerial conference in Doha in 2001.[182] During this transition period, Members were only allowed to change their patent systems if these changes were in accordance with the TRIPs Agreement.[183]

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176 Developed countries could often not comply with this rather short one year transition period. *Doermer*, Dispute Settlement and New Developments Within the Framework of TRIPS – an Interim Review, 31 IIC 1 (2000).

177 Art. 3, 4 and 5 TRIPs codifying national treatment and most favored nation principle were exempted of the transition periods. It was furthermore acknowledged in India - Patent Protection for Pharmaceutical and Agricultural Chemical Products, Report of the Appellate Body, adopted 16 January 1998, Doc. WTO/DS50/AB/R, 7.46 that the transition periods were not applicable to the procedural provisions of Art. 63 and 64 TRIPs, *Doermer*, Dispute Settlement and New Developments Within the Framework of TRIPS – an Interim Review, 31 IIC 1 (2000), *Macdonald-Brown/Ferera*, First WTO Decision on TRIPs, EIPR 1998, 69, 72 s, *Rott*, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen, Baden-Baden 2002, 134 ss. Some authors seem to be of the opinion, that the transition periods were the only concession made to the developing countries: *Cottier*, The Prospects for Intellectual Property in GATT, Common Market Law Review 1991, 383, 400, *Primo Braga*, Trade-related Intellectual Property Issues: The Uruguay Round Agreement and its Economic Implications, in: *Martin&Winters* (eds.), The Uruguay Round and the Developing Countries, Cambridge 1996, 341, 355, *Faupel*, GATT und Geistiges Eigentum, GRUR Int. 1990, 255, 266.

178 World Intellectual Property Report 01/06, 14, 15. The criteria for classing as least developed countries is explained in *Rott*, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen, Baden-Baden 2002,146 ss.

179 WTO, Intellectual Property: Poorest Countries Given More Time to Apply Intellectual Property Rules, WTO:2005 Press releases Press/424 of November 29, 2005.

180 WTO, Intellectual Property: TRIPS and Public Health – Council Approves LDC decision with Additional Waiver, WTO 2002 Press release Press/301 of June 28, 2002.

181 Art. 65-66 of the TRIPs Agreement. *Lehman*, Intellectual Property under the Clinton Administration, 27 George Washington Journal of International Law and Economics 204, 409 s. (1993-1994), *Pechman*, Seeking Multilateral Protection for Intellectual Property: The United States "TRIPs" over Special 301, 7 Minnesota Journal of Global Trade 179, 191, *Gupta*, The Uruguay Round of Multilateral Negotiations of GATT, in: *Gupta* (ed.), GATT Accord and India, New Delhi 1995, 113, 121.

182 World Intellectual Property Report 01/06, 14, 15.

183 Art. 65(5) of the TRIPs Agreement. Government agencies like the USPTO, the EPO, the WIPO and the WTO provide the technical assistance for the implementation of the TRIPs Agreement. This involves review of and drafting assistance on laws concerning intellectual property rights and their enforcement. Training programs usually cover the substantive provisions of the TRIPs Agreement, Office of the U.S Trade Representative (USTR), 2003 Special 301 Report, 4, available at www.ustr.gov/reports/2003/special301.htm.

There is only one provision in the TRIPs Agreement mentioning food in the sense of nutrition. Art. 8 of the TRIPs Agreement states that WTO Members may introduce measures necessary to protect public health and nutrition. Furthermore, the public interest in sectors of vital importance to their socio-economic and technological development can be promoted. These measures are only allowable if they are in conformity with the TRIPs Agreement.

III. Consequences

Straus[184] thinks of the TRIPs Agreement as a revolution in patent law and states:

> "The TRIPs Agreement constitutes an immensely important milestone in patent law (...) reducing the deficits in protection that were inherent in the Paris Convention for over 100 years (...)."

The TRIPs Agreement led to a more rational understanding of the patent system.[185] Food was not in the focus of the negotiations for the TRIPs Agreement, as it was disucssed only in context with pharmaceuticals and agrochemicals, but not on its own. In contrast, pharmaceuticals were widely debated in the ministerial conferences of the WTO. Its Members' governments agreed on August 30, 2003, on legal changes facilitating the import of cheaper drugs into developing countries under compulsory licensing if these countries cannot manufacture the medicines themselves.[186] There have been no such initiatives for food-related inventions. The patentability of food has not yet been particularly discussed at any of the Ministerial Conferences.

184 *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, in: *Beier&Schricker* (eds.), From GATT to TRIPs – The Agreement on Trade-Related Aspects of Intellectual Property Rights, Weinheim 1996, 160, 214.

185 Rott, Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen, Baden-Baden 2002, 336.

186 WTO, Decision Removes Final patent Obstacle to Cheap Drug Imports, press release 350/Rev.1 of August 30, 2003.

C. Patentability of food in Brazil, China, and India

The historical development regarding the patentability of food under the TRIPs Agreement in Brazil, China and India is shown in a comparative manner taking into account the historical development in Germany.[187] The question, why there was an exemption to patentability of food and the question, which consequences had its abolition will be answered. First, the implementation of the TRIPs Agreement in Brazil, China and India is shown retrospectively. Next the increase in food-related patent applications as a consequence of the abolition of the exemption to patentability is demonstrated. As Director General of WIPO *Idris* puts it "one of the most reliable indicators of innovation in a particular country or region is patenting activity."[188] Finally the economic situation of the food sector in Brazil, China and India is used as an indicator of the economic influence of the patentability of food-related inventions.

I. Implementation of the TRIPs Agreement in Brazil

The first Brazilian Patent Act of 1809 excluded food from patentability.[189] Since then food has not been patentable. Brazil ratified the TRIPs Agreement by decree No. 1.355 on December 30, 1994, which entered into force on January 1, 1995. Brazil is considered a developing country, and thus enjoyed a transition period of 4 years under Art. 65 (2) of the TRIPs Agreement for implementing the TRIPs Agreement. Brazil enjoyed another transition period of 5 more years under Art. 65(4) of the TRIPs Agreement with respect to substances initially excluded from patentability, namely food. Brazil amended its patent system in 1996 by the Industrial Property Law of May 14, 1996, which entered into force on May 15, 1997.[190] Sec. 8 of this law states that "any invention complying with the requirements of novelty, inventive activity and industrial application shall be patentable."

187 A recent study by *Imam* discusses the benefeits through stronger patent protection in Brazil, China and India and claims that reforming the domestic patent protection systems of developing countries is the first step towards meaningful economic growth, *Imam*, How Does Patent Protection Help Developing Countries?, IIC 2006, 245.

188 *Idris&Arai*, The Intellectual Property-Conscious Nation: Mapping the Path From Developing to Developed, WIPO Publication No. 988(E) (2006), 13.

189 *Graca Aranha*, The Challenge for the Medium Sized Office, WIPO Conference on the International Patent System, Geneva, March 25-March 27, 2002, available at www.wipo.int/patent/-agenda/ en/meetings/2002/presentations/gracaaranha.pdf.

190 Law No. 9,279; English version available at wwww.e-moeller.com/Ingles/htm/Legislation-Brazil-01.htm.

Thus food was patentable under the new Brazilian Patent Act of 1996 as of 1997. Pipeline applications could be filed during the transitional period between May 16, 1996 and May 15, 1997. According to Art. 229 of the Brazilian Industrial Property Law, the provisions of this law would be applied to all pending patent applications. The patentability of food and processes for the production of food would be conditioned by the provisions of subsequent Articles 230 and 231, the so called pipeline provisions. According to the pipeline provisions a patent application had to have been filed abroad, the date of the first foreign filing being acknowledged. Furthermore the subject-matter should not have been placed on any market on the direct initiative of the proprietor or by third parties with his consent. Finally third parties should not have carried out in Brazil serious and effective preparations for exploiting the subject matter of the application or patent. If the subject matter of interest had already been claimed in a pending Brazilian patent application, a new application could be filed under the pipeline provisions, provided that the applicant abandoned the pending application.[191]

The pipeline provision entered into force on May 15, 1996 and expired on May 15, 1997. Pipeline patent applications on food must have been filed no later than May 15, 1997. They can claim the earliest priority provided that they have not been marketed and enjoy the term of protection from their earliest priority date. Brazil amended this provision by Provisional Measure No. 2006 of December 12, 1999.[192] Patent applications on food that have not been filed in accordance to pipeline protection are considered rejected. Moreover, the Brazilian Patent and Trademark Office is obliged to publish the referred rejections. This indicates Brazil's intention to reduce protection for food-related inventions to the absolute minimum under Art. 70(8)(9) of the TRIPs Agreement.[193]

"The whole or part of any living creature" is excluded from patentability in Brazil.[194] Transgenic microorganisms, however, are patentable.[195] Transgenic microorganisms are defined as "organisms, except the whole or part of plants or animals, expressing, through a direct human intervention in their genetic composition, a characteristic not normally attained by the species under normal conditions."[196] Thus, Brazil has used the option provided by Art. 27(3)(b) of the TRIPs Agreement to exclude plants and animals from patentability. The protection of plant varieties according to Art. 27(3)(b) of the TRIPs Agreement is provided for by Brazil's plant variety protection system. The Cultivar Protection Bill was adopted in 1991 and amended in 1995 and 1996.[197]

191 Art. 230 (5) of the Brazilian Industrial Property Law.
192 Law No. 10.196 of February 14, 2001.
193 *Franz*, Die unmittelbare Anwendbarkeit von TRIPS in Argentinien und Brasilien, GRUR Int. 2002, 1001, 1009.
194 Sec. 18(3) of the Brazilian Industrial Property Law.
195 Sec. 18(3) of the Brazilian Industrial Property Law.
196 Sec. 18(3) of the Brazilian Industrial Property Law.
197 Cultivar Protection Bill, which was established in 1991 and now incorporates aspects of Bills No. 1325 of 1995 and No. 1457 of 1996.

Brazil became a Member of UPOV on May 23, 1999. But it has adopted only the UPOV Convention of 1978 with considerably lower protection standards compared to the UPOV Convention of 1991.[198] Meanwhile, Brazil's plant variety protection system has adopted certain provisions even of the UPOV Convention of 1991, e.g. the provision on essentially derived plant varieties. Thus, Brazil is in compliance with Art. 27(3)(b) of the TRIPs Agreement.

In addition, Secs. 68 ss. of the Brazilian Industrial Property Law codify compulsory licenses. Compulsory licenses in the pharmaceutical sector are widely discussed in Brazil with respect to public health.

Brazil's patent system is now largely compliant with the TRIPs Agreement. But Brazil suffers from a significant backlog of pending patent applications in recent years. Moreover, the patent enforcement is considered rather weak in Brazil.[199]

II. Implementation of the TRIPs Agreement in China

China's patent system began with China's entry into WIPO in 1980. Since then, China has ratified the Paris Convention and established the State Intellectual Property Office (SIPO) with responsibility for granting patents in China. The regulatory framework was modeled after the EPC.[200] Article 25(1) of the first Chinese Patent Act of 1984 set forth that food, beverages and flavourings, pharmaceuticals, and substances obtained by means of a chemical process are not patentable subject matter. Furthermore, animal species and plant varieties were excluded from patentability. Patents on processes for the production of these excluded subject matters were obtainable, however.[201] As Germany had excluded food from patentability because of concerns about nutrition and food availability, so did China exclude food and animal and plant varieties from patentability.[202]

198 *Straus&von Pechmann*, Die Diplomatische Konferenz zur Revision des Internationalen Übereinkommens zum Schutz von Pflanzenzüchtungen, GRUR Int. 1991, 507.

199 USTR, 2005 Special 301 Report, available at www.ustr.gov/assets/Document_Library/Reports_ Publications/2005/2005_Special_301/asset_upload_file195_7636.pdf.

200 *Parry*, Intellectual Property and the Challenge of China, The Scientist, May 23, 2995, 41.

201 *Yu*, The Second Amendment of the Chinese Patent Law and the Comparison between the New Patent Law and TRIPS, 4 The Journal of World Intellectual Property 137, 145 (2001).

202 "Pharmazeutische Erzeugnisse, Nahrungsmittel, chemische Stoffe und andere Substanzen sowie neue Tierarten und Pflanzensorten stehen in einem engen Zusammenhang mit Leben und Gesundheit der Menschen (...)." *Guo*, Entstehung und Grundzüge des chinesischen Patentgesetzes, GRUR Int. 1985, 1.

The Chinese Patent Act of 1992 removed the exemption to patentability of food.[203] The initial concerns that patents on food would deteriorate food availability have been regarded as unfounded, so that the exemption to patentability of food could not be justified further.[204] Animal species and plant varieties were still excluded from patentability, but the scope of process patents was extended to the product directly obtained from the process.[205]

China acceded the WTO on December 11, 2001 in order to acquire advanced technology from developed countries and to protect its own indigenous technology. Moreover, the U.S. played an active role in advocating the need for intellectual property rights in China. Although China was not a Member of the WTO at the time, it participated in the negotiations of the TRIPs Agreement.[206] The Second Amendment to the Chinese Patent Law was adopted on August 25, 2000 and entered into force on July 1, 2001, bringing China's patent system to further TRIPs compliance.[207] Animal and plant varieties are still excluded from patentability, making restricted use of Art. 27(3)(b) of the TRIPs Agreement, as only varieties are excluded, but not higher taxonomical groupings. Plant varieties are protected by plant variety protection under the Regulations on the Protection of New Varieties of Plants of October 1, 1997. China became a Member of UPOV on April 23, 1999, of the UPOV Convention of 1978.[208] Thus, China has chosen a *sui generis* system for the protection of plant varieties under Art. 27(3)(b) of the TRIPs Agreement. Patents are obtainable for processes used in producing products concerning animal and plant varieties. In the mean time, China is considered to have a "pro-active and visionary strategy" regarding intellectual property.[209]

203 *Yu*, The Second Amendment of the Chinese Patent Law and the Comparison between the New Patent Law and TRIPS, 4 The Journal of World Intellectual Property, 137, 145 (2001).

204 *Ganea*, Die Neuregelung des chinesischen Patentrechts, GRUR Int. 2002, 686, 706.

205 *Ganea*, Die Neuregelung des chinesischen Patentrechts, GRUR Int. 2002, 686, 689.

206 *Yang*, The Development of Intellectual Property in China, 25 World Patent Information 131, 136 (2003), *Chengsi*, TRIPS and Intellectual Property in China, 19 European Intellectual Property Review 243, 244 (1997).

207 *Yu*, The Second Amendment of the Chinese Patent Law and the Comparison between the New Patent Law and TRIPS, 4 The Journal of World Intellectual Property 137 (2001).

208 Available at www.upov.int.

209 *Idris&Arai*, The Intellectual Property-Conscious Nation: Mapping the Path From Developing to Developed, WIPO Publication No. 988(E) (2006), 33.

III. Implementation of the TRIPs Agreement in India

The establishment of the patent system in India commenced in 1856 with the Act of Protection of Inventions based on the British patent law of 1852.[210] The Patent Act of India of 1911 allowed patenting of food, pharmaceuticals and chemicals. After India gained independence in 1947, a new Patent Bill was tabled in Parliament in 1965 and was reintroduced in 1967, resulting in the Patents Act of 1970 becoming effective on April 20, 1972. It excluded food from patentability:

> "In the case of inventions claiming substances intended for use, or capable of being used, as food or as medicine or drug (...) no patents shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable."[211]

Food was defined as "any article of nourishment (including) any substance intended for the use of babies, invalids or convalescents as an article of food or drink."[212] Food-related substances had been excluded from patentability. The term of protection of food-related processes was restricted to 7 years from the filing date of the complete specification. The existing patents on food were transformed to "licenses of right":

> "Every patent in force at the commencement of this Act in respect of inventions relating to substances used or capable of being used as food or as medicine or drug shall be deemed to be endorsed with the words "Licenses of right"(...)."[213]

Licenses of right had the effect that "any person who is interested in working the patented invention in India may require the patentee to grant him a license for the purpose on such terms as may be mutually agreed upon (...)."[214] The remuneration however, was limited to a maximum of 4% of the net ex-factory sale price of the patented article.[215] Finally, methods of agriculture and horticulture were not considered an invention and therefore were not patentable.[216]

210 *Mukherjee*, The Journey of Indian Patent Law towards TRIPS Compliance, IIC 2004, 125.
211 Sec. 5(1)(a) of the Indian Patent Act of 1970.
212 Sec. 2(1)(g) of the Indian Patent Act of 1970.
213 Sec. 87(1)(a)(i) of the Indian Patent Act of 1970.
214 Sec. 88(1) of the Indian Patent Act of 1970.
215 Sec. 88(5) of the Indian Patent Act of 1970.
216 Sec. 3(h) of the Indian Patent Act of 1970.

India for years strictly refused to negotiate about patent protection, but finally embraced the "macro-economic marriage of convenience"[217] provided by the TRIPs Agreement. Many Indians have acknowledged the beneficial effects of the TRIPs Agreement:

> "There is only one aspect as regards property rights. We have to change the patent laws and patent laws will now cover food, pharmaceuticals and chemicals. (...) In ten years both the tariff on textiles and the quota system are envisaged to be abolished. All I am trying to convey is that this Agreement, on the whole, will be beneficial for our country (...)."[218]

The TRIPs Agreement has generated a controversy in India. Although most people are aware of the TRIPs Agreement, its full implications with respect to patents on food are not understood by many, as demonstrated by the following quotation showing the prevailing fears in India today.

> "Intellectual property rights will deprive us of our basic right to exchange seeds amongst each other, which has for decades served as major catalyst for stimulating agricultural growth. It has been the source of indigenous innovation for centuries in India. The government is selling our indigenous knowledge and information networks to foreign companies, as can be seen in the case of the neem tree. In India, the neem tree has been used for centuries in the fields as a pesticide and at home as a herb to cure common colds. But today, it has become the property of U.S. company, who has patented its properties to use as a pesticide. We see this as a modern form of colonization by the West."[219]

India is obliged to meet all the provisions of the TRIPs Agreement from January 1, 1995. India has been classed as a developing country in WTO terms, and thus enjoys the complete term of the transition period of ten years to introduce the patentability of food January 1, 2005. India is required to implement exclusive marketing rights according to Art. 70(8) and (9) of the TRIPs Agreement with respect to pharmaceuticals and agrochemicals during the transition period.

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217 *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, in: *Beier&Schricker* (eds.), From GATT to TRIPs – The Agreement on Trade-Related Aspects of Intellectual Property Rights, Weinheim 1996, pp. 160, 168 citing *Primo Braga*, The North-South debate on Intellectual Property Rights, in: *Smith* (ed.), Global Rivalry and Intellectual Property – Developing Canadian Strategies, Halifax 1991, 173, 177.

218 *Barooha*, Prolegomena, in: *Bhorali* (ed.), GATT Agreement or Dunkel Draft Treaty – Its Impact on Agriculture Industry – TRIPs and TRIMs and Drug Industry, New Delhi 1994, 1, 3, *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, in: *Beier&Schricker* (eds.), From GATT to TRIPs – The Agreement on Trade-Related Aspects of Intellectual Property Rights, Weinheim 1996, 160, 169, No. 37.

219 Spokesman for the Andhra Pradesh Agricultural Labourers Federation, in: *Gallagher,* Guide to the WTO and Developing Countries, London etc. 2000, 248.

The first amendment to the Indian Patent Act of 1970 was enacted in 1999 entering into force retroactively from January 1, 1995.[220] The U.S. requested consultations on India's compliance with the mailbox facility provision and the provision on exclusive marketing rights for pharmaceuticals and agrochemicals on July 2, 1996 before the Dispute Settlement Body (DSB) of the WTO.[221] The DSB established a panel which found that India has not complied with its obligations under Art. 70(8)(a) or Art. 63(1) and (2) TRIPS by failing to establish a mechanism that adequately preserves novelty and priority in respect of applications for product patents for pharmaceutical and agricultural chemical inventions, and was also not in compliance with Article 70(9) of the TRIPS Agreement by failing to establish a system for the grant of exclusive marketing rights. India appealed certain issues of law and legal interpretations developed by the Panel. The Appellate Body upheld, with modifications, the Panel's findings on Art. 70(8) and 70(9).[222] India undertook to comply with the recommendations of the DSB within the implementation period that expired on 16 April 1999. At the DSB meeting on 28 April 1999, India presented its final status report on implementation of this matter which disclosed the enactment of the relevant legislation to implement the recommendations and rulings of the DSB.[223] Food was not particularly addressed in the judgement. The exemption of food in the Indian Patent Act occurred only in the context of pharmaceuticals and agrochemicals. Thus, the Indian Minster for Industry was asked by the panel whether applications for product patents in the pharmaceutical, food, and agricultural chemical areas had been received in anticipation of changes in the Indian Patents Act 1970 in accordance with the requirements of the World Trade Organization. The Minister responded by stating that the patent offices had received 893 patent applications in the field of drugs or medicine from Indian as well as foreign companies or institutions as of July 15, 1996.[224] Exclusive marketing rights were introduced only with respect to pharmaceuticals, but not for food.[225]

220 *Ganguli,* Towards TRIPs Compliance in India: The Patents Amendment Act 1999 and Implications, 21 World Patent Information 279 (1999).

221 India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, September 5, 1997, World Trade Doc. WT/DS50/R.

222 India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, December 19, 1997, World Trade Doc. WT/DS50/AB/R.

223 Available at www.wto.org/english/tratop_e/dispu_e/cases_e/ds50_e.htm.

224 India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, September 5, 1997, World Trade Doc. WT/DS50/R, No. 2.6.

225 WTO, India- Patent Protection for Pharmaceutical and Agricultural Chemical Products, Report of the Appellate Body, adopted 16 January 1998, Doc. WTO/DS50/AB/R.

The second amendment[226] in continuation of the first amendment of 1999 harmonized the patent term to 20 years irrespective of the field of technology. Moreover, it introduced the publication of the patent application 18 months after filing and a reversal of the burden of proof for patents pending in court. Plants and animals were excluded from patentability, including "plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals."[227]

Protection for plants is provided under the Protection of Plant Varieties and Farmers Rights Act of 2001.[228] India has made full use of the options of Art. 27(3)(b) of the TRIPs Agreement. It established a *sui generis* system for the protection of plant varieties. In contrast to Brazil and China, India's *sui generis* system is not in compliance with UPOV.[229] Though India is not yet a Member of UPOV, the reason for India's solo attempt might be "the necessity of protecting the rights of farmers in respect of their contribution to conserving, improving and making available plant genetic resources for the development of new plant varieties."[230] Any plant variety "which involves any technology which is injurious to the life or health of human beings, animals or plants"[231] is excluded from plant variety protection, including genetic use restriction technologies and the terminator technology. The third amendment to the Indian Patent Act of 1970 was enacted on April 5, 2005, entering into force retroactively from January 1, 1995. It led to an abolition of the exemption to patentability of food.[232] Henceforward, food is patentable as mandated in Art. 27(1) of the TRIPs Agreement. India's patent system is now largely compliant with the TRIPs Agreement.

226 *Ganguli*, Intellectual Property Rights - Unleashing the Knowledge Economy, New Delhi 2001, *Bhattacharjee et al.*, Basmati Rice: A Review, 37 International Journal of Food Science and Technology 1 (2002).

227 Sec. 4(e) of the Indian Patent Act of 2002. The Patents (Amendment) Act, 2002, No. 38 of 2002, of June 25, 2002, available at www.patentoffice.nic.in/.

228 Act 53 of 2001, available at www.genecampaign.org/india-pvp-2001-en.pdf.

229 Especially the famers' rights provisions and the strong public interest clauses seem to be contrary to UPOV, *Sahai*, India's Plant Variety Protection and Farmers' Rights Act, 2001, 84 Current Science 407, 411 (2003).

230 *Sahai*, India's Plant Variety Protection and Farmers' Rights Act, 2001, 84 Current Science 407, 411 (2003).

231 Sec. 29(3) of the Plant Varieties and Farmers Rights Act of 2001.

232 Sec. 5 of the Indian Patent Act of 1970 was deleted. The Patents (Amendment) Act, 2005, No. 15 of 2005, of April 5, 2005, available at www.patentoffice.nic.in/.

IV. Consequences of the patentability of food

The effects of the patentability of food are reflected in the use of the national patent systems in Brazil, China and India.[233] Food-related patent applications act as an indicator of the technological and economical performance in the food sector. According to Director General of WIPO *Idris* "patents are a key measure of the extent and success of an innovation culture. They can be used to measure the level of R&D activities, and ultimateley, how effective those are, what structure they are taking, and which industries appear to be successful, and which not."[234]

1. Rise of food-related patent applications

Table 5 shows the development of food-related Brazilian, Chinese and Indian patent applications. Table 5 shows the sum of national and foreign applications.

233 On the general benefits of the implementation of the TRIPs Agreement in India and China see *Straus&Klunker*, Harmonisierung des internationalen Patentrechts, GRUR Int. 2007, 91, 100 s.

234 *Idris&Arai*, The Intellectual Property-Conscious Nation: Mapping the Path From Developing to Developed, WIPO Publication No. 988(E) (2006), 13. For further information on the economic influences of patents, see *Straus&Klunker*, Harmonisierung des internationalen Patentrechts, GRUR Int. 2007, 91, 100.

Table 5:
Food-related Brazilian, Chinese and Indian patent applications with priority from 1990 to 2001.[235]

Year	Brazil	China	India
90	35	471	22
91	39	605	44
92	46	981	35
93	54	1751	49
94	46	1569	53
95	52	1467	76
96	50	1537	43
97	118	1527	55
98	119	1561	41
99	119	1579	23
00	128	1945	3
01	96	2210	0

Food-related Brazilian patent applications amounted to 35 patent applications in 1990 and increased steadily to a maximum of 128 in 2000. The decline in 2001 to 96 might be due to a database effect. This occurs typically in the latest years of a database, because the data from the national offices have not yet been integrated into the database. Brazilian patent applications jumped from 50 in 1996 to 118 in 1997. This doubling is due to the abolition of the exemption to patentability of food, which became effective in 1997. Thus, the patentability of food due to Art. 27 of the TRIPs Agreement has led to a substantial increase of food-related patent applications. German food-related patent applications, by comparison, did not increase significantly from 1996 to 1997 but stayed rather constant. This indicates that the patentability of food led to the doubling of Brazilian food-related patent applications in 1997. Food-related Brazilian patent applications are rather few compared to German patent applications which amounted to 726 in 1997. The number of food-related Brazilian patent applications averaged less than 20% of those in Germany from 1990 to 2001.

235 Food-related patent applications are the IPC subclasses of table 1. It is referred to the first priority date that is claimed by the respective national patent application. This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit.

Chinese food-related patent applications rose tremendously from 471 in 1990 to 2,210 in 2001. Chinese food-related patent applications rose by nearly 80% from 1992 to 1993. This increase corresponds to the abolition of the exemption in the Chinese Patent Act of 1992. German patent applications rose only by 15%, from 435 in 1992 to 499 in 1993. Chinese food-related patent applications were nearly four times as high as food-related patent applications in Germany in 2001 due to high foreign direct investments made in China. Foreign patent flows into China have been dominated by the U.S., Japan and the EU, accounting for 86% of foreign patent applications until 1995.[236] Domestic Chinese firms file for more and more patent applications to enhance their strategic competitive value. This phenomenon is called the Great Wall of patents in China.[237] Many foreign companies are now confronted with numerous domestic Chinese patent applications and the danger of costly and lengthy patent disputes.

Food-related Indian patent applications have risen from 22 in 1990 to a maximum of 76 in 1995. The following decline in 2000 and 2001 might be due to a database effect. The abolition of the exemption cannot be measured yet because the respective changes of the Indian Patent Act have only gone into force retroactively on January 1, 2005. Nevertheless, there have been comparatively few food-related Indian patent applications in recent years. India had a similar amount of food-related patent applications as Brazil during the period from 1990 to 1996. However, food-related Indian patent applications decreased from 1997 on, whereas food-related Brazilian patent applications doubled from 1996 to 1997. Food-related Indian patent applications amounted to a maximum of 14% of the corresponding number of applications in Germany in 1995 and averaged 8% of that number during 1990 and 1999. This indicates that there have been rather little R&D activities in the food sector by domestic or foreign companies.

2. Rise of food-biotechnology-related patent applications

The share of food-biotechnology-related Brazilian, Chinese and Indian patent applications has been relatively small, averaging less than 5% of all food-related patent applications in those countries during the period from 1990 to 2001.

236 *Yang*, The Development of Intellectual Property in China, 25 World Patent Information 131, 140 (2003).

237 *Hu&Jefferson*, China: A Great Wall of patents, New Economist, October 20, 2005.

Table 6:
Food biotechnology-related Brazilian, Chinese and Indian patent applications with priority from 1990 to 2001.[238]

Year	Brazil	China	India
90	0	10	0
91	1	19	0
92	1	19	1
93	6	25	0
94	1	21	0
95	2	34	0
96	1	57	1
97	19	47	3
98	5	41	1
99	8	49	0
00	5	45	0
01	3	105	0

Food biotechnology-related Brazilian patent applications have been fluctuating from 0 in 1990 to a maximum of 19 in 1997, which is shown in table 6. The rise from 1 in 1996 to 19 in 1997 corresponds to the abolition of the exemption in 1997. Whereas food-related Brazilian patent applications were constant from 1997 on, food biotechnology-related Brazilian patent applications decreased steadily. The share of food biotechnology-related patent applications of the total food-related Brazilian patent applications amounted to 16% in 1997 and decreased to 4% in 2000. The food biotechnology-related Brazilian patent applications amounted to one-third of the number of food biotechnology-related German patent applications, which numbered 56 in 1997.

238 Food biotechnology-related patent applications are IPC subclasses of table 1 linked with IPC subclasses of table 2. It is referred to the first priority date that is claimed by the respective national patent application. This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit.

Food biotechnology-related Chinese patent applications rose rather constantly from 10 in 1990 to 57 in 1996 and levelled off around 50 between 1997 and 2000, doubling to 105 in 2001. The abolition of the exemption in 1992 led to a slight increase from 19 to 25 in 1993. This does not reflect the 80% increase of food-related Chinese patent applications from 1992 to 1993 following the abolition of the exemption. The food biotechnology-related Chinese patent applications made up an average of 3% of all food-related Chinese patent applications during the period from 1990 to 2001. This share is considerably lower than the Chinese-to-German ratio of food biotechnology-related German patent applications, which averaged 10% during the period from 1990 to 2001. Food biotechnology-related Indian patent applications have been minimal, with a maximum of 3 in 1997.

3. Development of the food sector and food prices in Brazil

The turnover of the Brazilian food sector totaled U.S.$101.2 billion in 2000, accounting for 17% of Brazil's GDP and representing a decline from 18% or U.S.$99.3 billion, in 1994.[239] Brazil's agricultural production amounts to 7.8% of Brazil's GDP, with U.S.$46.4 billion in 2000, declining from 8.4% or U.S.$46.0 billion, in 1994.[240] Nevertheless, it faces a prosperous future. Brazil holds a strong position in international production of agricultural raw materials and is becoming a serious competitor in world production of agricultural raw materials. It has increased its production of agricultural raw materials and gained global market shares for major raw materials like soybean. The soybean production doubled from 18.5 million tons in 1991 to 41.5 million tons in 2001. Brazil has developed from a net importer of wheat, corn, cotton and rice to the world's third-leading corn producer with net exports of 2.7 million tons of corn in 2000-2001.[241]

Substantial undeveloped, but viable land remains available for the production of agricultural raw materials. A strong domestic demand from an increasingly urbanized population is backed by a growing per capita income. Last but not least, Brazil has established an extensive agricultural research network for the development of new plant varieties and the adaptation of existing plant varieties to tropical conditions.

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239 Including Tobacco processing and transportation costs incurred by manufacturing firms, In: *Azevedo et al.*, The Food Industry in Brazil and the United States: The Effects of the FTAA on Trade and Investment, Buenos Aires 2004, 4, Table 2, using data from the Central Bank of Brazil, available at www.iadb.org/intal/Publicaciones/Azevedo-Chaddad-Farina_WP-SITI-07.pdf.

240 *Azevedo et al.*, The Food Industry in Brazil and the United States: The Effects of the FTAA on Trade and Investment, Buenos Aires 2004, 4, Table 2, using data from the Central Bank of Brazil, available at www.iadb.org/intal/Publicaciones/Azevedo-Chaddad-Farina_WP-SITI-07.pdf.

241 *Schnepf et al.*, Agriculture in Brazil and Argentina: Developments and Prospects for Major Field Crops, Agriculture and Trade Report No. (WRS013) 85, December 2001, 1, 2, available at www.ers.usda.gov/publications/wrs013/.

However, the commercial planting of genetically modified plants is currently prohibited. The lower costs of genetically modified plants contributes to a "significant illicit flow from Argentina into Brazil's South."[242] The share of illegal genetically modified soybean in Brazil has been estimated at between 20% and 40%.

The share of the production of processed food in Brazil's GDP was 9.2%, amounting to U.S.$54 billion, in 2000, declining from 9.8%, with U.S.$53 billion, in 1994.[243] The Brazilian food sector faces a fast increase in food consumption and in market opening to foreign investments. The entry of foreign companies has forced the domestic food companies to invest more and to modernize their manufacturing facilities. The Brazilian food sector is now one of the most competitive food sectors in South America and has emerged as one of the leading suppliers of the world food market.[244] Employment in the food sector rose from 902,542 employees or 18.3% of Brazil's manufacturing sector in 1996 to 976,783 employees, being 18.7% of Brazil's manufacturing sector in 2000. The sector relies mainly on natural resources and labor, and has implemented labor-saving technologies only to a rather small extent. This situation is also caused by the low availability of technology. Substantial structural changes have recently taken place in the Brazilian food sector. The dairy segment was deregulated, consolidated and internationalized. In 1991, the three leading dairy companies had concentrated 52% of the Brazilian dairy market, while in 1996 they already controlled 61% of this market.[245] The Brazilian food sector is highly concentrated. In 2001, the top ten food companies in Brazil had a combined market share of 26%, a slight decline from 28% in 1994.[246]

The Brazilian food sector is largely influenced by multinational companies.[247] Their value share of food shipments increased from 19% in 1996 to 27% in 2000. The share of employment of multinational food companies amounted to 17% in 2000, rising from 10.9% in 1996. These companies are more technology-intensive than domestic ones, which is indicated by the significantly lower share of employment compared to the value of their shipments.

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242 *Schnepf et al.*, Agriculture in Brazil and Argentina: Developments and Prospects for Major Field Crops, Agriculture and Trade Report No. (WRS013) 85, December 2001, 61, 63, available at www.ers.usda.gov/publications/wrs013/.

243 *Azevedo et al.*, The Food Industry in Brazil and the United States: The Effects of the FTAA on Trade and Investment, Buenos Aires 2004, 4, Table 2, using data from the Central Bank of Brazil, available at www.iadb.org/intal/Publicaciones/Azevedo-Chaddad-Farina_WP-SITI-07.pdf.

244 MarketResearch.com, Country Industry Forecast – The Brazilian Food and Beverages Industry, November 3, 2004, available at www.marketresearch.com/map/prod/1060463.html.

245 *Azevedo et al.*, The Food Industry in Brazil and the United States: The Effects of the FTAA on Trade and Investment, Buenos Aires 2004, 7, Table 5, 8, 30, Table 20, using data from the Annual Industrial Research, Brazilian Institute of Geography and Statistics, available at www.iadb.org/intal/Publicaciones/Azevedo-Chaddad-Farina_WP-SITI-07.pdf.

246 *Farina&Viegas*, Foreign Direct Investment and the Brazilian Food Industry in the 90s, 5 International Food and Agribusiness Management Review 2003, Issue 2, Table 6, available at www.ifama.org/nonmember/OpenIFAMR/Articles/v5i2/efarina.pdf.

247 *Cabral&Traill,* Determinants of a Firm's Likelihood to Innovate and Intensity of Innovation in the Brazilian Food Industry, 1 Chain and Network Science 33 (2001).

The 8 largest multinational food companies, originating in the U.S., Argentina, France, Italy and Switzerland, controlled about 20% of the Brazilian food market in 2001. That share was only 13% in 1994.[248]

Thirty percent of all food expenditures in Brazil are held by agricultural products. The share of processed foods amounts to 35% of the Brazilian food expenditures. Since 1997, food prices for important agricultural raw materials like soybean, coffee and sugar have been rather depressed. In addition to these low prices, consumer food prices fell by almost 30% between 1994 and 2001.[249] The most important price reductions occurred in processed food, in which multinational companies have intensely invested. Launches of new food products increased substantially in the same period.[250]

Declining food prices and increasing industrialization of the food sector, combined with an increasing number of patent applications for food-related inventions indicate that the patentability of food had a positive rather than a negative effect on the food sector in Brazil.

4. Development of the food sector and food prices in China[251]

In the last several years, China has seen an economic growth rate of 7-9%.[252] This has lifted many parts of the population out of subsistence economy. It is foremost the middle class that is demanding more processed food. A large share of the agricultural raw materials is directly consumed by the rural population, which amounts to 60% of China's population. The reliance on self-produced food has fallen since 1990 as rural households purchased an increasing share of their food.[253] The fast-growing retail and catering sectors are sustaining this process. China's land resources are under pressure due to the needs for further industrialization, modern housing and infrastructure. A handicap is also the water and energy shortage, as well as environmental degradation. Therefore,

248 *Azevedo et al.*, The Food Industry in Brazil and the United States: The Effects of the FTAA on Trade and Investment, Buenos Aires 2004, 52, Table 34 using data from the Annual Industrial Research from Brazilian Institute of Geography and Statistics,
available at www.iadb.org/intal/Publicaciones/Azevedo-Chaddad-Farina_WP-SITI-07.pdf.

249 *Azevedo et al.*, The Food Industry in Brazil and the United States: The Effects of the FTAA on Trade and Investment, Buenos Aires 2004, 5, 10,
available at www.iadb.org/intal/Publicaciones/ Azevedo-Chaddad-Farina_WP-SITI-07.pdf.

250 *Farina&Viegas*, Foreign Direct Investment and the Brazilian Food Industry in the 90s, 5 International Food and Agribusiness Management Review 2003, Issue 2, graph 1,
available at www.ifama.org/nonmember/OpenIFAMR/Articles/v5i2/efarina.pdf.

251 *Gale et al.*, China's Food and Agriculture: Issues for the 21st Century, USDA, Economic Research Service, 2002, available at www.ers.usda.gov/publications/aib775/.

252 *Shane&Gale*, China: A Study of Dynamic Growth, USDA Economic Research Service Doc. WRS-04-08, 2004.

253 *Gale et al.*, Commercialization of Food Consumption in Rural China, USDA, Economic Research Report No. 8, 2005, available at www.ers.usda.gov/publications/ERR8/.

China will rely on net imports of food in the coming years.[254] China's trade surplus in agricultural products[255] results from exported vegetables, fruits, poultry, corn, and rice. In 2003, China became a net importer of agricultural raw materials with a trade deficit of U.S.$2 billion due to price increases in soybean and cotton imports. In 2003, the urban per capita income was more than three times higher than the rural figure. Structural imbalance has arisen from a concentration in few coastal areas whereas rural, western areas have shown less growth.[256]

Initially, China's food sector was dominated by the agricultural production, whereas the production of processed food was less important. The reason was that consumers prepared their own meals of rice, noodles, raw vegetables and meat. The food processing sector grew simultaneously with consumer demand for higher quality and convenience food.[257] China accounts for 51% of the global pork and 31% of the global rice consumption.[258] Lately, organic food is more in demand generating a green food sector in "full-swing" development. This new tendency is due to the rapid growth of China's national economy and per capita income. The output of organic food has increased by nearly 30% annually, and exports have grown by 50%. By 2003, 2,047 companies were involved in "green food" production, with domestic sales reaching 72.3 billion yuan and exports surpassing U.S.$1 billion.[259]

The Chinese food sector feared China's WTO entry. Headlines like "Food sector to face fierce competition after WTO entry"[260] showed the concerns of many food companies. Many companies feared going bankrupt after China joined the WTO, because of "intensive competition from overseas food giants that will flock into the domestic market after China joins the WTO." Food from China was believed uncompetitive as a result of poor quality, packaging and marketing in comparison to foreign food. China's WTO entry led to a restructuring of its food sector, eliminating small companies without specialized products.[261]

254 Ministry of Foreign Affairs of Denmark, May 30. 2005, Food sector in China, available at www.ambbeijing.um.dk/da/menu/Eksportraadgivning/Markedsmuligheder/Sektoranalyser/FoedevarerLandbrugOgFiskeri/FoodBeijing/.

255 *Gale&Hansen*, China's Exports Outpaced Imports during WTO Year One, USDA, Economic Research Service, FAU-79-02, 2003.

256 *Shane&Gale*, China: A Study of dynamic growth, USDA, Economic Research Service Doc. WRS-04-08, 2004, 9, 14.

257 *Gale et al.*, China's Food and Agriculture: Issues for the 21st Century, USDA, Economic Research Service, 2002, available at www.ers.usda.gov/publications/aib775/.

258 FoodNavigator Europe of June 27, 2005, China: massive opportunities for food makers and ingredients firms,
available at www.foodnavigator.com/news/news-ng.asp?id=60899-china-mas-sive-opportunities.

259 Chinadaily of October 8, 2004,
available at www.chinadaily.com.cn/english/doc/2004-10/08/content_380415.htm.

260 China.org, December 31, 2000, available at www.china.org.cn/ english/2000/Oct/3360.htm.

261 China.org, December 31, 2000, available at www.china.org.cn/ english/2000/Oct/3360.htm.

In 1999, China's food sector had a turnover of U.S.$80 billion, while in the first 7 months of 2004 it generated U.S.$104.8 billion. This contributes to nearly 10% to the country's total and represents an increase of 20%. Exports of food reached U.S.$10.69 billion from January 2004 to July 2004, which was 7.7% more than last year. Imports of food soared by 50.6% or U.S.$11.47 billion, producing a deficit of U.S.$780 million during that period.[262]

China may likely become the first country feeding its population mainly with genetically modified rice. It has already authorized the cultivation of genetically modified cotton since 1997 and intends to permit the commercialization of genetically modified rice by 2007. This unprecedentedly rapid development is due to the Chinese government's decision to make the cultivation of genetically modified rice the principal topic of its agricultural policy. The fact that Chinese consumers have hardly any other choice than to accept the decision of their government facilitates the implementation of this policy. In contrast to the Western world, in China, research in genetically modified rice is exclusively financed by the public sector. China has invested the equivalent of more than €155 million in research in agricultural biotechnology, of which 20% are for rice only.[263]

The increasing industrialization of the food sector, as well as enormous investments in new technologies, combined with a constantly rising number of patent applications for food-related inventions, indicate that the patentability of food had rather a positive than a negative effect on the food sector in China.

5. Development of the food sector and food prices in India

India's economy and its food sector have made remarkable progress since 1947. Nevertheless, India is often characterized as a "lumbering elephant compared with the tigers such as Malaysia and Thailand and the dragon China of Southeast and East Asia."[264] India's food sector is characterized by governmental protectionism and is currently considered non-competitive. The annual costs of India's subsidies for food production totaled U.S.$14.5 billion in 2003-2004 and were about U.S.$12.3 billion over the last 5 years. This is at least 12% of the GDP of Indian's food sector and amounts to 15% of all governmental expenditures.[265]

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262 *Wang Wenzhe*, cited in: People's Daily Online, September 12, 2004, available at www.english. people.com.cn/200409/12/eng20040912_156 701.html.

263 *Huang*, Center for Chinese Agricultural Policy, Chinese Academy of Sciences, Beijing, cited in: *Cuchet&Masingue*, OGM - Le coup de tonnerre chinois, Science&Vie N° 1054, July 2005, 126, 133.

264 *Landes*, The Elephant is Jogging: New Pressures for Agricultural Reform in India, USDA, Economic Research Service 2004, available at www.ers.usda.gov/amberwaves/February04/Features/ ElephantJogs.htm.

265 Including outlays of food grain procurement, storage and distribution, electrical power, fertilizer, and irrigation water. Indirect subsidies such as subsidized credit are not included. *Lands&Govindan,* USDA, Foreign Agricultural Services, Global Agricultural Information Network Report Number IN-4089, India Agricultural Situation – Indian Agriculture: Status and Reform Potential, 2004, 6, 11, available at www.fas.usda.gov/gainfiles/ 200408/146107265.pdf.

Though the food sector has recently been liberalized, there has been only little investment in this sector. There are two reasons for this: the lack of infrastructure and government disincentives:

> "The cost of getting goods to market is very high because of the large number of middlemen, prohibitions on land consolidation, and lack of investment in transportation and refrigerated delivery networks."[266]

Though the per capita calorie consumption increased by 20% during the period from 1980 to 2000 in India, a remarkable share of India's population still has not enough food. A third of the population is still living below the poverty line. In the 1990s, the prices for staple food increased, being a principal constraint to access to food.[267] The average Indian household spends about 55% of its income on food.[268]

Also, the Indian food sector has witnessed fast growth in most segments, with a turnover of the total food market of U.S.$69.4 billion in 2000. Processed food amounted to U.S.$22.2 billion. Export of processed food brought in U.S.$3.2 billion in 1998-99. Rice accounted for 46% of these exports, whereas marine products accounted for over 34%. India is the world's second-largest producer of fruits and vegetables, but only 2% thereof is processed. India produces many spice varieties worth over U.S.$900 million, amounting to 25-30% of the world's production, which are processed for value-addition and export. It grows 22 million tons of oilseeds. Additionally, other important plantation products are tea, coffee, cocoa and cashew. India's livestock population is the largest in the world with 50% of the world's buffaloes and 20% of cattle. In contrast to this, only 1% of meat production is converted to value-added products. India is also the largest milk producer in the world. The semi-processed and ready-to-eat packaged food industry is valued at U.S.$1 billion and grew by 20% in 2000.[269]

A prospering food sector combined with a constantly increasing number of patent applications for food-related inventions indicate that the patentability of food will have rather a positive than a negative effect on the food sector in India.

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266 *Lands&Govindan*, USDA, Foreign Agricultural Services, Global Agricultural Information Network Report Number IN4089, India Agricultural Situation – Indian Agriculture: Status and Reform Potential, 2004, 6, available at www.fas.usda.gov/gainfiles/200408/ 146107265.pdf.

267 *Persaud&Rosen*, Price Policies: India's Consumer and Producer Price Policies: Implications for Food Security, USDA, Economic Research Service, 2003, 1, available at www.ers.usda.gov/publications/gfa14/GFA14-i.pdf.

268 *Landes*, The Elephant is Jogging: New pressures for Agricultural Reform in India, USDA, Economic Research Service 2004, available at www.ers.usda.gov/amberwaves/February04/Features/ ElephantJogs.htm.

269 Indian Ministry of food production Industries 2000, using data from Source - APEDA Export Statistics and Annual Report 1999-2000 of the Indian Ministry of food production Industries, available at www.mofpi.nic.in/industryspecificinformation/index.htm.

D. Nestlé and patentability of food

The impacts of the patentability of food due to the TRIPs Agreement are exemplified by the largest international food company, Nestlé. Nestlé is a conservative food company. It focuses on classical food products, especially convenience products. Nestlé has just started investing in R&D of functional food. It is active in Germany, in China, and in Brazil to a large extent and only to a smaller extent in India.

The philosophy of Nestlé regarding developing countries can be summarized by the statement of its Chief Executive Officer *Brabeck-Letmathe*:

> "When we talk about long-term responsibility and development, we do it with nearly 100 years of experience in manufacturing in the developing world and an even longer history of the company overall. Our basic business principle is to favor long-term development over short-term profit. We aim to build companies over decades, which we expect to last for centuries, industrializing the developing world in the process."[270]

Nestlé's greatest social impact is not in funding projects, but in poverty reduction by means of its basic business development. A recent survey in 16 countries asked the public to name a socially responsible company and then to mention a company that they assume to be socially irresponsible. Nestlé is one of the companies that ranked top of the list of responsible companies. Eight nationals of developing countries spontaneously mentioned Nestlé as a socially responsible company for every 1 who listed Nestlé as irresponsible.[271] This would seem to reflect the fact that Nestlé firmly supports the principles of the United Nations Global Compact and is committed to reflecting these in its business principles and practices. In January 1999, former United Nations Secretary-General *Annan* announced the Global Compact initiative under the mission statement:

> "Let us choose to unite the power of markets with the authority of universal ideals. Let us choose to reconcile the creative forces of private entrepreneurship with the needs of the disadvantaged and the requirements of future generations."[272]

The patenting activity of Nestlé is rather low compared to its trademark activities. Currently Nestlé holds 340 strategic brands protected by 75,000 trademark registrations. Additionally Nestlé holds 6,000 local brands protected by 28,000 trademark registrations.[273] Nestlé owns 9,018 granted national patents as well as 6,127 pending patents.[274] This clearly shows that the main intellectual property focus of Nestlé lies within the field of trademarks.

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270 The UN Global Compact and Nestlé's Experience in Corporate Responsibility for Development, United Nations Global Compact Symposium, Geneva, October 29, 2003, available at www.r0.un-ctad.org/gcandswissbusiness/presentations/Brabeck.pdf.

271 *Brabeck-Letmathe,* The UN Global Compact and Nestlé's Experience in Corporate Responsibility for Development, United Nations Global Compact Symposium, Geneva, October 29, 2003, 9.

272 Available at www.unglobalcompact.org/Portal/Default.asp.

273 WIPO, Nestlé: Streamlining IP to stay on top, WIPO Magazine/Nov.-Dec. 2005, 19.

274 WIPO, Nestlé: Streamlining IP to stay on top, WIPO Magazine/Nov.-Dec. 2005, 19.

Straus[275] points out that "The relative inactivity and low propensity towards patenting on the part of large multinational food companies, which instead rely on their market power, may (...) present an opportunity for innovative biotech companies and research institutions outside the industry."

Nestlé's food-related patent applications have been continually increasing since 1990, as shown in table 7. It is worth mentioning that Nestlé has applied for most patent applications in Brazil, where it already has a strong market position. Nestlé applied for 30 food-related German patent applications in 1990. This number rose rather constantly to its maximum in 1996, with 75 German patent applications. The decrease in the recent years, with 1 application in 2001, is due to the database effect described above.

Nestlé's food-related Brazilian patent applications rose rather constantly from 11 in 1990 to a maximum of 58 in 1998. The abolition of the exemption in Brazil in 1997 did not lead to an increase of food-related patent applications, which dropped from 54 in 1996 to 42 in 1997. This is contrary to the 80% rise of all food-related Brazilian patent applications in 1996-97. The constant rise of Nestlé's food-related patent applications in Brazil indicates that Nestlé's patent strategy has been at least in the short term independent of the patentability of food.

Nestlé has applied for more and more food-related patent applications in China with 7 in 1990 and a maximum of 43 in 1998-99. The decrease to 3 patent applications in 2001 is due to a database effect. The abolition of the exemption in 1992 led to an increase in food-related Chinese patent applications, from 9 in 1992 to 15 in 1993. Then there was a constant increase to 39 in 1996. This indicates that the patentability of food had a long-term effect on Nestlé's patent strategy in China. However, the increase might also be due to Nestlé's increased economic interest in China.

Nestlé has increasingly applied for food-related Indian patents, though the absolute number falls short of those in Brazil and China. This corresponds to Nestlé's lower concentration in India, where it holds only a small share of the food sector. Nestlé applied for 2 food-related Indian patent applications in 1990 and 9 in each of the following 2 years. The peak was 19 in 1997, corresponding to nearly half of Nestlé's German and Brazilian patent applications. The decline from 1999 on could again be caused by a database effect.

275 *Straus*, Genomics and the food industry: outlook from an intellectual property perspective, in: *Vaver&Bently* (eds.), Intellectual property in the new millennium – Essays in Honour of William R. Cornish, Cambridge 2004, 124, 136.

Table 7:
Nestlé's food-related national German, Brazilian, Chinese and Indian patent applications with priority in 1990-2001.[276]

Year	Germany	Brazil	China	India
90	30	11	7	2
91	29	16	12	9
92	27	15	9	9
93	31	18	15	5
94	49	33	21	9
95	55	29	36	18
96	75	54	39	11
97	47	42	30	19
98	43	58	43	17
99	26	57	43	6
00	16	43	31	0
01	1	32	3	0

Table 8 shows Nestlé's food biotechnology-related German, Brazilian and Chinese patent applications, which have been rather low. Nestlé has only applied for 5 food biotechnology related German patent applications from 1990 to 2001. Nestlé's food biotechnology-related Brazilian and Chinese patent applications even exceed German applications from 1993 on, with 2 patent applications each and a maximum of 7 in Brazil in 1999-2000 and 6 in China in 1999. The abolition of the exemption in 1997 did not lead to a substantial increase in food biotechnology-related Brazilian patent applications with 1 in 1996 and 3 in 1997. The same applies to China's abolishing the exemption in 1992. Nestlé filed no food biotechnology-related Chinese patent applications in 1992 and only 2 in 1993.

276 Food-related patent applications are the IPC subclasses of table 1. It is referred to the first priority date that is claimed by the respective national patent application. This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit.

Table 8:
Nestlé's food biotechnology-related German, Brazilian, Chinese and Indian patent applications with priority in 1990-2001.[277]

Year	Germany	Brazil	China	India
90	1	0	0	0
91	1	1	1	0
92	5	1	0	0
93	1	2	2	0
94	2	3	3	0
95	3	2	4	0
96	1	1	3	0
97	2	3	2	0
98	0	3	2	0
99	3	7	6	0
00	3	7	2	0
01	0	3	0	0

The effects of the TRIPs Agreement are a harmonized 20-year patent duration and the possibility of patenting food worldwide, especially in the important markets of Brazil and China. Patent litigation is, however, still a problem. In practice, Nestlé does not litigate infringements of its patents in developing countries. Though the national laws have theoretically become more strict due to the minimum standards of the TRIPs Agreement, patent enforcement is often difficult in developing countries. There are mostly insufficient sanctions for patent infringers. Moreover, the national court systems often have a frail infrastructure. Consequently, patents in developing countries do not in reality confer the same protection as in developed countries.[278]

277 Food biotechnology-related patent applications are IPC subclasses of table 1 linked with IPC subclasses of table 2. It is referred to the first priority date that is claimed by the respective national patent application. This data was collected by the author in cooperation with *Schmoch* in 2004 at the Fraunhofer Institute for Systems and Innovations Research in Karlsruhe using PLUSPAT, a database developed by Questel-Orbit.

278 According to an interview with former head of interim of the patent division of Nestlé, NESTEC S.A., Vevey, Switzerland, *Wavre,* November 21, 2003.

E. Assessment

The TRIPs Agreement has had an enormous effect on the food sector with regard to patentability of food. Food-related inventions are now eligible for patent protection in most countries worldwide with the exemption of plant- and animal-related inventions. Plant varieties have to be protected at least by an effective *sui generis* system. The TRIPs Agreement led to an increase of food-related patent applications in developing countries, where food had often been excluded from patentability.

Brazil, China and India, before being Members of WTO and Parties to the TRIPs Agreement, had excluded food from patentability. China introduced the patentability of food in 1992, even before its WTO entry in 2001, Brazil did so in 1997 along with the ratification of the TRIPs Agreement and India in 2005 making use of the full transition period under Art. 65(2)(4) of the TRIPs Agreement. Plants and animals are excluded from patentability in Brazil and India usint the room to maneuver under Art. 27(3)(b) TRIPs Agreement. China has excluded only animal species and plant varieties. Brazil, China and India have each established a plant variety protection system thus, meeting the requirements of Art. 27(3)(b) of the TRIPs Agreement. Brazil and China have adopted the UPOV Convention of 1978, whereas India has established its own plant variety protection system.

The idea that there is the necessity to prevent monopolies in the arae of nutrition has led to the exemption to patentability of food in developing countries as well as in developed countries. The same reasons that led to the exemption in the German Patent Act of 1877 also led to the exemption in Brazil, China and India.

Two paradoxes dominate public opinion about the food sector. *Straus*[279] summarizes the first anomaly with respect to the TRIPs Agreement and the patentability of food as follows:

> "Whenever the impact of intellectual property rights, especially patents, on modern societies, be it developed or developing, is discussed, two topics dominate the debate: health and medicines, and the fact that the adoption of (...) (TRIPs) in 1994 will, eventually, oblige all (...) (WTO) Members to provide for patent protection for pharmaceuticals. Surprisingly, an equally important aspect of health, namely nutrition and food, and the TRIPs general obligation to patent food products, which before TRIPs in many countries had shared the fate of pharmaceuticals, i.e. had not been eligible for patent protection, is not even touched upon."

279 *Straus*, Genomics and the Food Industry: Outlook from an Intellectual Property Perspective, in: *Vaver&Bently*, Intellectual Property in the New Millennium – Essays in Honour of William R. Cornish, Cambridge 2004, 124.

Second, only patents concerning the production of agricultural raw materials, especially plant-related inventions, are discussed publicly. Patents concerning the production of processed food attract almost no public attention. Patents concerning the production of processed food are commonly accepted, like those in any other industrial sector. Genetically modified organisms play a major role in both the production of agricultural raw materials and the production of processed food. However, only genetically modified plants are on the focus of public discussion. Genetically modified microorganisms used in the production of processed food are not questioned at all.

The food sectors of Brazil, China and India are in different stages of the transition from subsistence farming to modern agriculture. At the same time, food prices have not increased as food sectors have generally prospered in all these countries. Patent applications on food-related inventions have almost doubled in Brazil and China since the introduction of patentability of food. This indicates that patents on food at least have no negative effects on the food sector and food availability in general. Along with an improved patent system, foreign direct investments have increased and foreign companies are willing to invest in developing countries. Consequently, developing countries profit indirectly from the minimum standards set by the TRIPs Agreement with regard to patents.

On the other hand, there is a strong deficit in patent enforcement. This deficit is more a practical than a legal one. So far, the TRIPs Agreement has ordered minimum standards for all WTO Members. But patent enforcement is difficult because of the absence of an effective legal system and judicature and weak sanction mechanisms in developing countries.

Part II. Innovation in today's food sector

After the historical retrospective on the exemption to patentability of food in part I, part II describes the present-day food sector with its most important technological developments and its fields of innovation. The impact of biotechnology on the food sector is of special interest in part II.

The food sector is the largest manufacturing sector in the EU. Its annual production amounts to €626 billion, accounting for 13% of the total manufacturing sector. It is larger than the automobile, chemical, machinery and equipment sectors. Four main fields dominate the food sector: beverages, various products including bakery, chocolate, and confectionery products, and finally meat and dairy. Total food exports to developing countries in 2002 amounted to €46 billion. Seven percent of European food production in 2002 was exported to developing countries. The food sector covers a market of 450 million consumers in the enlarged EU. Food remains amongst the most important consumption items. Together, food and non-alcoholic beverages accounted for an average of 12.8% of total household expenditures in 2000. The European food sector processes 70% of all European agricultural products.[280]

The European food sector is experiencing a rapid structural change. This change is mainly caused by the emergence of huge retail companies and the concentration in the food sector. Key consumer trends include a slow population growth and a rising demand for convenience food. Furthermore, better educated consumers have begun to confront the food sector with concerns about health, nutrition, food safety and the environment.[281]

Innovation is the key instrument for the food sector, as consumers favor new food.[282] Saturation in domestic markets of developed countries and growing competition in export markets makes innovation a crucial tool for the food sector. Moreover, added value and convenience are the driving forces for the development of new food.[283]

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280 Confederation of the Food and Drink Industries in the EU (CIAA), Data and Trends of the EU Food and Drink Industry, Brussels 2003, 5.

281 *Hughes,* Building Partnerships and Alliances in the European Food Industry, in: *Galizzi&Venturini* (eds.)*,* Economics of Innovation: the Case of Food Industry, Heidelberg 1996, 101.

282 *Naderi,* Erfolgreiche und erfolglose Produktinnovationen in der Ernährungsindustrie, Lizensiatsarbeit, Universität Bern 1998, available at www.iop.unibe.ch/Forschung/lizarbeiten.htm.

283 „(...) product development in the food industry strives to provide novel or improved food products with high added-value compared to the raw materials that are used to produce them." *Kleerebezem*, Molecular Advances and Novel Directions in Food Biotechnology Innovation, 17 Current Opinion in Biotechnology 179 (2006).

The production of processed food is based on agricultural raw materials, which are mainly seasonally produced. This seasonal production must be converted into a continuous process in order to secure a constant delivery of processed food to the consumer market. The production of processed food typically comprises the steps of processing, conservation, and packaging.

The starting point for the production of processed food are agricultural raw materials. The characteristics of agricultural raw materials impose specific difficulties on the production of processed food. Agricultural raw materials, unlike other raw materials, are characterized by seasonal production, fluctuating quality, and limited shelf life.[284] These specific features of the production of agricultural raw materials influence innovation in the food sector to a great extent. The specificities of consumer demand and of the production of agricultural raw materials are reflected in the innovation process of the food sector. The most recent innovations, first and foremost regarding biotechnology[285], are explained in the following. Innovation in the production of agricultural materials, comprising the production of plant-derived agricultural raw materials and of animal-derived agricultural raw materials, has been remarkably influenced by biotechnology in recent years. Innovation in the processing of agricultural raw materials has also been changed by biotechnology, paving the way for new food creations.

A. Innovation related to the production of agricultural raw materials

Innovation related to the production of agricultural raw materials has been influenced to a large extent by the implementation of biotechnology. Biotechnology applies to plant production as well as to animal production and opens up completely new fields for agricultural production.

284 *Strecker et al.,* Marketing in der Agrar- und Ernährungswirtschaft, 3rd ed., Frankfurt am Main 1996, 23, 24.

285 „The integration of (new) food functionalities into product formulation in many cases requires research-intensive biotechnological innovation strategies." *Kleerebezem*, Molecular Advances and Novel Directions in Food Biotechnology Innovation, 17 Current Opinion in Biotechnology 179 (2006).

I. Innovation related to the production of plant-derived agricultural raw materials

Innovation related to the production of plant-derived agricultural raw materials has been revolutionized by the implementation of biotechnology. Biotechnology related to the production of plant-derived agricultural raw materials generally aims to enhance a range of traits in plants. Table 9 gives an overview of the categories of such traits. Plant biotechnology used in the production of plant-derived agricultural raw materials focuses mainly on agronomical traits, traits related to the production of processed food, and health-related traits.

Table 9:
Applications of biotechnology in the production of plant-derived agricultural raw materials.[286]

Area	Tool
Agronomical traits[287]	Plant breeding - Trait expression - Selective breeding technologies via molecular markers - Fertility control Pest control - Disease resistance - Insect resistance - Herbicide tolerance Yield enhancement - Biomass production - Crop yield - Abiotic stress tolerance, salt, drought - Plant nutrition and water use
Traits related to the production of processed food	Food Composition - Amino acids, carbohydrates and fatty acids - Phytochemicals, e.g. anti-oxidants, isoflavones Production of processed food - Food quality, improved shelf life, reduced allergenicity/mycotoxins - Plants producing food enzymes, e.g. lactase, lipase - Enzymes for improved food production and consistency with reduced waste, e.g. phytase, cellulase
Health-related traits	- Nutrients, e.g. iron, vitamins - Amino acids, carbohydrates and fatty acids - Phytochemicals, e.g. isoflavones, antioxidants - Nutraceuticals - Production of pharmaceuticals, active molecules in plants

286 *McElroy*, Sustaining Agbiotechnology through Lean Times, 21 Nature Biotechnology 996, (2003). See also *Chua&Tingey*, Plant Biotechnology: Looking Forward to the Next Ten Years, 17 Current Opinion in Biotechnology 103 (2006). For an overview over the application of biotechnology to the staple food crop wheat see *Bhalla*, Genetic Engineering of Wheat – Current Challenges and Opportunities, 24 Trends in Biotechnology 305 (2006).

287 For more information see *Castle et al.*, Agricultural Input Traits: Past, Present and Future, 17 Current Opinion in Biotechnology 105 (2006).

The majority of genetically modified crops are modified with respect to agronomically valuable traits. Such traits include genes for yield increase and pest control.[288] The main emphasis in pest control has been laid on the development of two traits. First, a bacterial gene from *Bacillus thuringiensis* encoding a protein resisting corn borer has been identified.[289] This gene has been introduced in plant species like corn. The so-called Bt-corn is resistant to the corn borer. Bt-corn consequently does not require any application of insecticides against corn borer. Secondly, genes encoding for proteins that deactivate herbicides have been introduced to plant species, making them resistant to herbicides, e.g. glyphosate. Glyphosate is effective at low concentrations. Moreover, glyphosate is not toxic to humans or other mammals and is rapidly degraded by soil microorganisms. Tolerance to glyphosate has been introduced into soy, maize, oilseed rape and sugar beet.

These transgenic plants generate direct economic benefits for farmers by lowering the financial and environmental costs of food production. Consumers profit indirectly from cheaper agricultural raw materials reducing the price of processed food. Since their first commercial introduction, genetically modified plants with agronomical traits have been rapidly adopted in a number of important agricultural markets.[290] Moreover the "American experience from almost a decade-long use of biotechnology-derived crops indicate that these crops have revolutionized crop production and provided vast hope to growers by helping to meet one of the key goals of production agriculture: improving yields with the use of minimal inputs."[291]

Agronomical traits also comprise traits for sustainable food production, e.g. sustainable use of water. The pollution of water can be reduced by using herbicide-resistant plants. These plants generally need only one application of the respective herbicide. Insect-resistant plants generally need no plant protection agents against that insect at all. Finally, plant breeding generates plants being more tolerant of drought and salt. Consequently plant biotechnology has the potential to make an important contribution towards sustainable food production.[292] Traits related to the production of processed food aim at the improvement of the composition of food and feed for better food-production applications.[293] The improvement of plant varieties is currently focused on the supply of high-quality raw materials and the improvement of processability.

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288 E.g. RoundupReady® corn for tolerance to glyphosate-containing herbicides or Bollgard *Bacillus thuringiensis* cotton for lepdiopteran insect control by Monsanto, St. Louis, MO.

289 For the environmental impacts see *Romeis* who measured no direct negative influence on control organisms and concludes that Bt-crops contribute to integrated pest management, *Romeis et al.*, Transgenic Crops Expressing Bacillus Thuringiensis Toxins and Biological Control, 24 Nature Biotechnology 63 (2006).

290 *James,* Global Status of Commercialized Transgenic Crops, 2002, ISAAA Briefs No. 27.

291 *Sankula et al.*, Biotechnology Derived Crops Planted in 2004 – Impacts on US Agriculture, National Center for Food and Agricultural Policy (2006), 100, available at www.ncfap.org.

292 *Bennett,* The Foundation of Food Security, 2003 (2) Syngenta Lectures 4.

293 *McElroy,* Sustaining Agbiotechnology Through Lean Times, 21 Nature Biotechnology 996, 998, table 2 (2003).

Traits related to the production of processed food comprise genes for economically valuable oils, proteins and starches. Modified fatty acid composition, e.g. genetically modified soybean plants yielding oil low in polyunsaturated fats, and altered carbon-partitioning for novel starch production in potatoes, are examples of this.[294]

The first generation of genetically modified plants with traits relevant for the production of processed food was commercialized in the 1990s. The FlavrSavr® tomato by Calgene was genetically modified to delay fruit softening for longer maturation and improved flavor. Polygalacturonase breaks down the pectin that holds cell walls together causing the softening of fruits. The introduction of an polygalacturonase antisense gene into the tomato plant neutralized the gene encoding polygalacturonase. Such genetically modified fruits showed a longer shelf-life than the wild type.

Genetically modified plants with improved quality traits for feed are another field of plant biotechnology in the food sector. Such genetically modified plants have a higher content of feed additives like essential amino acids or essential fatty acids. Plants can perform complex synthesis. The carotinoide astaxanthin is a basic feed additive in the breeding of salmon. It is responsible for the characteristic reddish color of salmon. Wild salmon is provided with astaxanthin from crustaceans. Salmon farms must add astaxanthin as a feed additive. The chemical synthesis of astaxanthin requires 13 steps. Genetically modified plants expressing high levels of astaxanthin could be fed to salmon, making the addition of astaxanthin to feed unnecessary.[295]

Improved nutritional quality is another object of plant biotechnology in the food sector. A sweet potato has already been developed with greater protein quality.[296] Soybean and corn plants have been modified to improve their oil, protein, and carbohydrate content.[297] A rice strain has been genetically modified in order to express additional vitamin A, the so-called GoldenRice®.[298] Vitamin A deficiency causes blindness and affects up to 250 million children worldwide. Thus, GoldenRice® has been called a "major advance in global nutrition."

Health-related traits in genetically modified plants relate to the yield and efficacy of neutraceuticals or pharmaceuticals derived from natural plant products. Genetically modified plants are used as biological factories for the production of complex molecules. Therapeutic molecules have been manufactured in genetically modified plants. Plants offer a flexible manufacturing scale at low capital. Hence, genetically modified plants represent alternative manufacturing systems for pharmaceuticals.[299]

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294 *Weck,* The Transgenic Plant Market: Profits from New Products and Novel Drugs, Drug&Market Development Report No. 9070 (2002).

295 Available at www.astaxanthin.org.

296 *Moffat*, Crop Engineering Goes South, 285 Science 370, 371 (1999).

297 *Mazur et al.*, Gene Discovery and Product Development for Grain Quality Traits, 285 Science 372 (1999).

298 *Ye et al.*, Engineering the Provitamin A (B-Carotene) Biosynthetic Pathway into (Carotenoid-Free) Rice Endosperm, 287 Science 303 (2000).

299 *Andersson&Mynahan*, The Protein Production Challenge, 5 In vivo: The Business and Medicine Report 1 (2001).

Research and implementation of biotechnology in the production of plant-derived agricultural raw materials goes along with R&D expenditures. These expenditures can only be compensated with royalties obtained from farmers for their use of seed. Seeds bring high technology in a reproductive form to farmers. Discovering and proving infringements of plant intellectual property rights is difficult, both in developed and in developing countries. Small-scale farmers and subsistence farming prevail in developing countries, making the enforcement of plant intellectual property rights even harder.[300] License agreements with farmers of patented seeds are hardly enforceable in practice.[301]

The amortization of investment costs is difficult. This unsatisfactory law enforcement has led to biological protection mechanisms based on further innovation in the food sector, the so-called GURTs. GURTs comprise hybrids and genetically modified plants with reduced reproducibility.

Hybrid[302] technology could prevent unlicensed reproduction of protected seed. This technology currently dominates in corn, rape, sugar beet and vegetables. Not only breeders take advantage of hybrid varieties, but farmers do as well. The heterosis effect in hybrid plants produces higher and more constant yields, better resistance to biotic and abiotic stress factors, and improved handling. Farmers are usually willing to pay premium prices for hybrid varieties. But hybrid technology gives breeders a *de facto* protection by discouraging farmers from using harvested seed for replanting. It is even more difficult to use hybrid germplasm for further breeding.[303]

The GURTs are another innovation related to the production of plant-derived agricultural raw materials.[304] Inventions relating to GURTs form a class of their own. GURTs do not have agronomically or physiologically useful traits as opposed to the examples of plant biotechnology described above. The idea of GURTs was to create a mechanism for intellectual property protection in the field of plant biotechnology.[305] GURTs include genetically modified plants whose seed is unable to regerminate, using the so-called terminator technology. Delta and Pine Land Corp. invented and patented[306] this technology in cooperation with the U.S. Department of Agriculture (USDA).

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300 *Otieno-Odek*, Public Domain in Patentability after the Uruguay Round: A Developing Country's Perspective with Specific Reference to Kenya, 4 Tulane J. Int'l & Comp. L. 15, 34 (1995).

301 *Ewens*, Seed Wars: Biotechnology, Intellectual Property, and the Quest for High Yield Seeds, 23 Boston College International & Comparative Law Review 285, 306, (2000).

302 A hybrid is a plant obtained by crossing of two genetically different parental plants. Most often parental plants are separately bred representatives of an "inbred line", which are homozygotic by permanent inbreeding. Hybrid varieties are plant varieties, which are based on a defined combination of inbred lines.

303 *Kock, Porzig, Willnegger*, Der Schutz von pflanzenbiotechnologischen Erfindungen und von Pflanzensorten unter Berücksichtigung der Umsetzung der Biopatentrichtlinie, GRUR Int. 2005, 186.

304 *Aoki*, Neocolonialism, Anticommons Property, and Bio-Property in the (Not-So-Brave) New World Order of International Intellectual Property Protection, 6 Indiana. J. Global Legal Studies 11, 54 (1998).

305 In 2002, Bayer CropScience conducted field trials of transgenic rapeseed, whose seed is sterile due to the terminator technology. Greenpeace states that farmers are deprived of the possibility to sow their seed and the environment is endangered by cross-pollination. Available at www.greenpeace.de.

306 US 5,723,765 "Control of Plant Gene Expression," granted on March 3, 1998, filed on June 7, 1995.

The intention was the creation of plants that produce sterile seeds. Moreover, the exploitation of the biological self-replicating mechanisms of plants by farmers was to be restricted. As a consequence, such seeds could only be consumed or processed, but not sowed again. Since then, several comparable mechanisms have been developed. Syngenta, Pioneer Hi-Bred, Monsanto, BASF Plant Science and others have invented and patented diverse sterility mechanisms as well as other GURTs. A different approach regarding GURTs involves plants that show certain valuable traits only if special chemicals are applied. These mechanisms are called Trait-GURTs. Traits, e.g. herbicide tolerance or salt tolerance, are expressed only if specific chemicals are applied to induce the transcription of certain genes.

The global area of genetically modified plants amounted to 90 million hectares in 2005, rising by 11% from 81 million hectares in 2004.[307] This area is grown by approximately 8.5 million farmers in 21 countries. The first transgenic crops were planted in 1996. All in all, 5% of the world's agricultural area has been cultivated with genetically modified plants. The U.S., Argentina, Brazil, Canada, China, Paraguay, and India are leading with regard to the cultivation of genetically modified plants. The share of developing countries, first and foremost China, India, Argentina, Brazil, and South Africa, cultivating genetically modified plants in 2005 was more than one-third of the global acreage, equivalent to 33.9 million hectares.[308]

Most of the genetically modified plants cultivated show agronomical traits, herbicide tolerance and insect resistance. The plant species are mainly soybean, corn, rape and cotton. The global market value of genetically modified plants was estimated at U.S.$5.25 billion in 2005, rising from U.S.$ 4.7 billion in 2004. This represents 15% of the global crop protection market and 18% of the global seed market.[309]

307 *James*, Executive Summary of Global Status of Commercialized Biotech/GM Crops: 2005, ISAAA Briefs No. 34, Ithaca, NY 2005, 3.

308 *James*, Executive Summary of Global Status of Commercialized Biotech/GM Crops: 2005, ISAAA Briefs No. 34, Ithaca, NY 2005, 6.

309 *James*, Executive Summary of Global Status of Commercialized Biotech/GM Crops: 2005, ISAAA Briefs No. 34, Ithaca, NY 2005, 7. For a more detailed economic analysis with further references see *Brookes&Barfoot,* GM Crops: The Global Economic and Environmental Impact - The First Nine Years 1996-2004, AgBioForum, Vol. 8 (2&3) (2005), Article 15.

II. Innovation related to the production of animal-derived agricultural raw materials

Innovation related to the production of animal-derived raw materials has been largely influenced by the application of biotechnology. The traits addressed by animal biotechnology involve nutrition, breeding and health. With respect to animal nutrition, genetically modified bacteria improve animals' health and the efficiency of their feed-to-weight conversion.[310]

Traditional breeding methods supplemented by molecular breeding, e.g. marker assisted selection, have accelerated the breeding process. Reproductive biotechnology, including artificial insemination and embryo transfer, accelerates it further.[311]

Which genes should be genetically modified to improve animal productivity or health is still difficult to predict. This is due to complex interactions of genes with each other and with the environment. Changes such as the introduction of genes that are involved in the expression of growth hormones have been successful.[312]

Animal biotechnology with regard to genetically modified animals has not yet been implemented to the same extent as plant biotechnology.[313] Genetic modification of animals is still in its infancy. Consequently, genetically modified animals for the production of agricultural raw materials have yet not been marketed in the EU. Rapid advances in molecular biology and developments in reproductive biology provide new tools for further innovation. Table 10 shows fields of biotechnological research related to the production of agricultural raw materials involving animals.

310 *Madden,* Food Biotechnology - An Introduction, ILSI 1995, 23, available at www.ilsi.org/publications/ilsifobi.pdf.

311 FAO, Electronic Forum on Biotechnology in Food and Agriculture, Conference 3: The Appropriateness, Significance and Application of Biotechnology Options in the Animal Agriculture of Developing Countries, June 12–August 25, 2000, available at www.fao.org/biotech/C3doc.htm.

312 *Madden,* Food Biotechnology - An Introduction, ILSI 1995, 24, available at www.ilsi.org/publications/ilsifobi.pdf.

313 "Production of transgenic agricultural mammals is challenging and expensive, especially because of their low reproductive rate and internal fertilization and development." AO/World Health Organisation, Expert Consultation on the Safety Assessment of Foods Derived from Genetically Modified Animals, including Fish, Rom 2003, 5, available at www.who.int/foodsafety/biotech/ meetings/en/gmanimal_reportnov03_en.pdf.

Table 10:
Fields of biotechnological research related to the production of animal-derived agricultural raw materials.[314]

Field of research	Example of biotechnology
Animal nutrition	- Genetically modified probiotics to improve the health and efficiency of feed-to-weight conversion of farm animals
	- Genetically modified rumen bacteria to enable animals to make better use of a wider range of food plants
	- Genetically modified bacteria to enhance the nutritional value of silage
	- Genetically modified bovine growth hormone to enhance milk yield, growth rate and protein-to-fat ratio in meat
Animal breeding and health	- Classical breeding methods supplemented by modern genetic analysis, e.g. marker technology, genetic mapping
	- Reproductive biotechnology including artificial insemination and embryo transfer
	- Genetically modified pigs with growth hormone to enhance growth
	- Cloned sheep to disentangle the role of genes and the environment in an effort to improve the quality of the livestock
	- Genetically modified chickens with genes for viral proteins to give chickens immunity to fatal viruses
	- Transgenic fish with disease resistance and stimulation of growth[315]

314 *Madden,* Food Biotechnology - An Introduction, ILSI 1995, 23, available at www.ilsi.org/publications/ilsifobi.pdf. For a risk assessment of the different technologies used in the production of transgenic animals see FAO/World Health Organisation, Expert Consultation on the Safety Assessment of Foods Derived from Genetically Modified Animals, including Fish, Rom 2003, 6, available at http://www.who.int/foodsafety/biotech/meetings/en/gmanimal_reportnov03_en.pdf. Table 1 of that analysis shows further examples of applications of gene transfer into animals. See also National Research Council, Animal Biotechnology: Science-Based Concerns, Washington, 2002. The website animal biotechnology provided by the Federation of Animal Science Societies provides current topics on the subject animal biotechnology, available at /www.animalbiotechnology.org/.

315 For developmental status and economic impact of transgenic fish see Pew Initiative on Food and Biotechnology, Future fish: issues in science and regulation of transgenic fish, Washington 2003, 1 ss., available at www.pewagbiotech.org.

B. Innovation related to the production of processed food

Innovation related to the production of processed food has also been influenced to a large extent by biotechnology. Biotechnology related to the production of processed food comprises the use of microorganisms, cell cultures and genetic modification. The food sector's ability to develop new processed food products is widened by biotechnology.[316] First, the use of microorganisms in the production of processed food is described. Next, the completely new fields of functional food and nutraceuticals are explained.[317]

I. Use of microorganisms in the production of processed food

The most important field of innovation in the production of processed food with regard to biotechnology is the use of microorganisms.[318] Improved genetically modified microorganisms, especially bacteria and yeasts, are used for conventional fermentation. Genetically modified microorganisms are applied in processing bread, wine, beer, yoghurt and cheese. Additionally, new fermentation products for food or feed additives have been developed using genetically modified organisms. Such fermentation products contain enzymes, vitamins, amino acids and flavoring agents.[319] The evolving concept of functional food, nutraceuticals and dietetic food raises exciting prospects for future implementation of biotechnology in the field of processed food production.[320]

A wide range of food additives, supplements and processing aids are obtained from microorganisms. These include amino acids, citric acid, vitamins, natural colorings and gums, as well as enzymes.

316 *Gardner*, The Development of the Functional Food Business in the United States and Europe, in: *Goldberg* (ed.), Functional Foods, Designer Foods, Pharmafoods, Nutraceuticals, London 1994, 468, 476.

317 For a detailed overview of biotechnology in food production and processing see *Reed&Ngodavithana* (eds.), Biotechnology, 2, ed., volume 9: Enzymes, Biomass, Food and Feed, Weinheim 1995. A recent overview is provided in World Health Organisation, Modern Food Biotechnology, Human Health and Development: An Evidence-Based Study, Geneva 2006, 9 s.

318 For an overview see GMO Compass, Additives, Vitamins, Amino Acids, Enzymes - GM Microorganisms Taking the Place of Chemical Factories (2006), available at http://www.gmo-compass.org/eng/grocery_shopping/ingredients_additives/36.gm_microorganisms_taking_place_chemical_factories.html.

319 FAO, Electronic Forum on Biotechnology in Food and Agriculture, Conference 11: Biotechnology Applications in food production: Can Developing Countries Benefit?, June 14–July 15, 2004, available at www.fao.org/biotech/C11doc.htm.

320 *Hardy*, Nutraceuticals and Functional Foods: Introduction and Meaning, 16 Nutrition 688, 689 (2000).

Amino acids are used to enhance flavors and to act as seasonings, nutritional additives and improvers. Microorganisms overproducing specific amino acids are grown in large fermenters. The acids are secreted into the fermentation medium and harvested. For instance, glutaminic acid produced by microorganisms is used as monosodium glutamate, as a flavor enhancer. The amino acids lysine, cysteine, methionine and phenylalanine are used as supplements in animal feed. Furthermore, citric, acetic, lactic and ascorbic acids are produced in large quantities by microbial fermentation.[321]

Gums are used widely in the food sector as thickeners, emulsifiers and fillers. Gum obtained from seed has been transformed into a gum similar to the expensive locust bean gum using α-galactosidase. The gene encoding the enzyme was inserted into baker's yeast. Bacterial polysaccharides provide novel gums with improved and valuable properties.[322] Important applications of such enzymes produced by genetically modified microorganisms in the food sector are shown in table 11.

321 *Madden,* Food Biotechnology - An Introduction, ILSI 1995, 15, available at www.ilsi.org/publications/ilsifobi.pdf. For an overview see also Biotechnology Industry Organization, Food Biotechnology (2006), available at http://www.bio.org/speeches/pubs/er/food.asp. See also *Kleerebezem*, Molecular Advances and Novel Directions in Food Biotechnology Innovation, 17 Current Opinion in Biotechnology 179 (2006).

322 *Madden,* Food Biotechnology - An Introduction, ILSI 1995, 15, available at www.ilsi.org/publications/ilsifobi.pdf. For an overview see also Biotechnology Industry Organization, Food Biotechnology (2006), available at http://www.bio.org/speeches/pubs/er/food.asp. See also *Kleerebezem*, Molecular Advances and Novel Directions in Food Biotechnology Innovation, 17 Current Opinion in Biotechnology 179 (2006).

Table 11:
Uses of enzymes in the production of processed food.[323]

Enzyme	Product	Use
α-Amylase	Sweeteners	Liquefaction of starch
	Beer	Removal of starch haze
	Bread, cakes and biscuits	Flour supplementation
Amyloglucosidase	Sweeteners	Saccharification
	Low-carbohydrate beer	Saccharification
	Wine and fruit juice	Starch removal
	Bread manufacture	Improved crust color
β- Galactosidase (lactase)	Whey syrup	Greater sweetness
	Lactose-reduced milk and dairy products	Removal of lactose for those who are lactose intolerant
	Ice cream	Prevention of "sandy" texture caused by lactose crystals
Glucose oxidase	Fruit juices	Removal of oxygen
Invertase	Soft-centered sweets	Liquefaction of sucrose
		Sugar syrups
Lipases	Cheese	Flavor development
		Accelerated ripening
	Flavorings	Ester synthesis
Papain	Beer	Removal of protein
Pectinases	Wine and fruit juice	Increased yield, clarification
	Coffee	Extraction of the bean
Proteases[324] (various)	Dairy products	Modification of milk proteins
	Caviar	
	Bread, cakes and cookies	Viscosity reduction of "stickwater"
	Meat	
		Gluten weakening
		Tenderization

323 *Madden,* Food Biotechnology - An Introduction, ILSI 1995, 17, available at www.ilsi.org/publications/ilsifobi.pdf. For an overview see also Biotechnology Industry Organization, Food Biotechnology (2006), available at http://www.bio.org/speeches/pubs/er/food.asp.
See also *Kleerebezem*, Molecular Advances and Novel Directions in Food Biotechnology Innovation, 17 Current Opinion in Biotechnology 179 (2006).

324 A recent review on the application of proteases in food production is provided by *Sumantha et al.*, Microbiology and Industrial Biotechnology of Food-Grade Proteases: A Perspective, 44 Food Technology & Biotechnology 211 (2006).

Biotechnology is applied in milk processing to a large extent.[325] Chymosin and *Lactococcus lactis* are examples of this application of biotechnology.[326] Milk is coagulated by the enzyme chymosin. Originally, this coagulation in cheese production was induced by calf rennet. Chymosin is nowadays produced by genetically modified microorganisms, e.g. *Escherichia coli, Kluyveromyces lactis* or *Aspergillus niger*. Today, at least 50% of cheese is made with chymosin from genetically modified microorganisms. Lipases are added in cheese production to accelerate the ripening process. Whey from cheese processing is treated with the enzyme betagalactosidase in order to form a protein-rich syrup with a range of applications in the confectionery segment.[327] *Lactococcus lactis* is the best studied food microorganism. It is used in the dairy segment for fermentation. Phages pose a significant problem in industrial fermentation.[328] Strains with plasmid-encoded phage-resistance mechanisms successfully counter phage proliferation.[329]

Biotechnology has also improved the production process of fruit juice.[330] Biotechnology helps to overcome the problems posed by the fruit wall constituent pectin in fruit juice processing. The pectin is altered by enzymes during fruit ripening. As a result, the pectin becomes more soluble. Dissolved pectin makes juice more viscous and difficult to press from the fruit. Pectin also helps to retain important compounds of color and flavor within the fruit, so juice pressed from it is of inferior quality. Juice is difficult to purify and to filter because of suspended pectin particles. In the fruit juice segment, pectinases obtained from microorganisms are used to overcome all of these problems. Enzymes extract, clarify and modify juices from such fruits as juice berries, stone and citrus fruits, grapes, apples, pears and even vegetables.[331]

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325 GMO Compass, Processed Foods – Dairy Products and Eggs (2006), available at http://www.gmo-compass.org/eng/grocery_shopping/processed_foods/29.dairy_products_eggs_genetic_engineering.html.

326 For more information on the use of biotechnology for industrial strain development of *lactococcus lactis* see *Vlieg et al.,* Natural Diversity and Adaptive Responses of *Lactococcus lactis*, 17 Current Opinion in Biotechnology 183 (2006).

327 *Madden,* Food Biotechnology - An Introduction, ILSI 1995, 26, available at www.ilsi.org/publications/ilsifobi.pdf.

328 A larger yoghurt factory can process up to 500,000 l of milk, while in the production of cheese, factories may process up to 1,000,000 l daily. Partial phage attacks cause a reduction in the speed of acidification, texture quality, and unpredictable variation in quality.

329 *Garvey et al.,* Molecular Genetics of Bacteriophage and Natural Phage Defence Systems in the Genus *Lactococcus*, 5 International Dairy Journal 905 (1995).

330 GMO Compass, Beverages – Juice, Soft Drinks, Wine, and Beer (2006), available at ww.gmo-compass.org/eng/grocery_shopping/processed_foods/30.beverages_genetic_engineering.html.

331 *Madden,* Food Biotechnology - An Introduction, ILSI 1995, 27, available at www.ilsi.org/publications/ilsifobi.pdf.

Enzymatic treatments are a major way of producing sweeteners.[332] Sweeteners comprise syrups as well as low-caloric sweeteners. Syrups derive from sucrose or starch.[333] High-fructose syrup from corn starch has now eclipsed sucrose as the major sweetener used in the food sector. The production and use of high-fructose syrup in the EU has been limited by quotas intended to protect European sugar beet growers. Nevertheless, more than 8 million tons of high-fructose syrup are processed annually. High-fructose syrup is an alternative to sucrose or invert sugar. It is used in many products, including soft drinks, jam, ice cream, cakes, canned fruit, pickles and sauces. Unlike sucrose, high-fructose syrup remains stable in chilled, frozen and acidic food without forming crystals or undergoing conversion to other sugars.

High-fructose syrup is made from low-cost raw material starch. The starch is converted into syrup by several enzymes. These enzymes are used in distinct stages comprising α-amylase, an enzyme from the bacterium *Bacillus spec.,* to dissolve the starch and to break down the starch into dextrins. Various fungal enzymes are then used to break down the dextrins to glucose. Finally, glucose isomerase converts glucose to fructose, as glucose is about half as sweet as fructose.

332 *Tornare&Kochhar*, Production of Oligosaccharides Using Engineered Bacteria: Engineering of Exopolysaccharides from Lactic Acid Bacteria, in: *Wang&Ichikawa*, Synthesis of Carbohydrates Through Biotechnology, American Chemical Society Symposium Series 873, 139 (2004).

333 GMO Compass, Ingredients and Additives - Corn Syrup, Fructose, and Glucose – All are Products of Starch (2006),
available at http://www.gmo-compass.org/eng/grocery_shopping/ingredients_additives/37.products _ starch_corn_syrup_fructose_glucose.html.

II. Functional food

Another important field of innovation in the production of processed food is functional food.[334] Functional food results from biotechnology as well as from the new developments in traditional food technology like fortification and extraction. "Functional food"[335] describes nutrients or nutrient-enriched food that is designed to prevent diseases. Functional food[336] is "any food or ingredient that has a positive impact on an individual's health, physical performance, or state of mind, in addition to its nutritive value."[337] Functional food is rather a concept than a well-defined food. Functional food addresses various components affecting body functions and belongs to nutrition and not to pharmacology, as it does not comprise pharmaceuticals with therapeutic effects. The borderline between functional food and pharmaceuticals becomes more and more fluent with progress in nutrition science.[338] Table 12 shows areas of human physiology addressed by functional food.[339]

334 Dietetic food is intended for individuals with a specific disease or condition. While functional food improves or maintains health for consumers, dietetic food aims at physicians or health professionals. Dietetic food must fulfill the requirements set out by the EU: "A particular nutritional use must fulfill the particular nutritional requirements: of certain categories of persons whose digestive processes or metabolism are disturbed; or of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs." Art. 2(1), Art. 1(2)(b)(i)(ii) of the EU Directive 89/398/EEC.

335 Functional food is also described by "nutraceuticals" and has to be distinguished from the so called "medical food", which the U.S. Food and Drug Administration (FDA) defines as "formulated to be consumed or administered entirally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, on the basis of recognized scientific principles, are established by medical evaluation.", 21 U.S.C. 360ee(b)(3). For more details see *DellaPenna*, Nutritional Genomics: Manipulating Plant Micronutrients to Improve Human Health, 285 Science 375 (1999), *Mazut, Krebbers&Tingey*, Gene Discovery and Product Development for Grain Quality Traits, 285 Science 372 (1999), *Pridmore et al.*, Genomics, Molecular Genetics and the Food Industry, 78 Journal of Biotechnology 251 (2000).

336 The European Commission's Concerted Action on Functional Food Science in Europe (FUFOSE = Functional Food Science in Europe) involving about 100 European experts in nutrition and medicine developed a parallel definition of the term functional food: "A food can be regarded as functional if it is satisfactorily demonstrated to affect beneficially one or more target functions in the body, beyond adequate nutritional effects, in a way that is relevant to either improved stage of health and well-being and/or reduction of risk of disease. A functional food must remain food and it must demonstrate its effects in amounts that can normally be expected to be consumed in the diet: it is not a pill or a capsule, but part of the normal food pattern." *Diplock et al.* (eds.), Scientific Concepts of Functional Foods in Europe: Consensus Document, 81 British Journal of Nutrition S1 (1999).

337 *Goldberg*, Functional Foods, Designer Foods, Pharmafoods, Nutraceuticals, London 1994, 3.

338 A European Consensus of Scientific Concepts of Functional Foods, 16 Nutrition 689 (2000).

339 For an overview see *Kotilainen et al.*, Health Enhancing Foods – Opportunities for Strengthening the Sector in Developing Countries, World Bank Agriculture and Rural Development Discussion Paper 20, Washington 2006.

Table 12:
Areas of human physiology that are relevant to functional food.[340]

Areas of human physiology	Functional food components to improve the relevant health area
Early development and growth	- Intake of polyunsaturated fatty acids, iron, zinc and iodine (pregnancy) - Oligosaccharides, gangliosides, high-molecular -weight glycoproteins, salt-activated lipases, pre-[341] and probiotics[342] (maturation) - Antioxidant vitamins, trace elements, fatty acids, arginine, nucleotides, probiotics and altered allergenic components (immune system) - Combined effects of calcium and other constituents of growing bone, such as proteins, phosphorus, magnesium and zinc, as well as vitamins D and K, fluorine and boron (osteoporosis)
Regulation of basic metabolic processes	Slower absorption of glucose into the bloodstream, so that insulin requirements are lowered (diabetes mellitus[343])
Defense against oxidative stress	Small-molecular-weight antioxidants, e.g. vitamin E, vitamin C, carotenoids and polyphenols, including flavonoids

340 *Ashwell,* Concepts of Functional Foods, ILSI 2002, 6, available at www.europe.ilsi.org/file/ILSIFuncFoods.pdf. *Goldberg,* Functional Foods, Designer Foods, Pharmafoods, Nutraceuticals, London 1994, 3.

341 A non-digestible food ingredient that beneficially affects the host by selectively stimulating the growth and/or modify the metabolic activity of one or a limited number of bacteria in the colon, that have the potential to improve host health.

342 A live microbial food ingredient that, when ingested in sufficient quantities, exerts health benefits on the consumer. *Mercenier et al,* Genomics of Probiotic Lactic Acid Bacteria : Impacts on Functional Foods, in: *Neeser&German* (eds.), Bioprocesses and Biotechnology for Functional Foods and Nutraceuticals, CRC 2004, 63.

343 Metabolic disorder in which the hormone insulin is ineffective, either because of failure in its secretion by the pancreas or because target tissues are insensitive to its action. In the first one, patients require regular administration of insulin.

Table 12 - continuation:
Areas of human physiology that are relevant to functional food.[344]

Areas of human physiology	Functional food components to improve the relevant health area
Cardiovascular physiology	- Balance of dietary lipids (heart health) - Increase in potassium and reduction in sodium (blood pressure) - Folate, vitamins B6 and B12 (cardiovascular risk) - Soy protein and plant sterol and stanol esters, soluble fiber, antioxidants, including plant flavonoids (LDL[345] cholesterol)
Gastrointestinal physiology	Probiotic bacteria (intestinal microflora)
Cognitive and mental performance, including mood and alertness	- Elevation in blood glucose, caffeine (mental performance, including memory, reaction time) - High-carbohydrate meals, tryptophan (sleepiness and calmness) - Sucrose (distress) - Activation of beta endorphins (pain perception)
Physical performance and fitness	- Oral rehydration products (rapid gastric emptying, fast intestinal absorption, improved water retention, improved thermal regulation, improved physical performance and delayed fatigue)

344 *Ashwell,* Concepts of Functional Foods, ILSI 2002, 6, available at www.europe.ilsi.org/file/ILSIFuncFoods.pdf. *Goldberg,* Functional Foods, Designer Foods, Pharmafoods, Nutraceuticals, London 1994, 3.

345 Low Density Lipoproteins, Plasma lipoproteins containing high concentrations of lipids (low density compared with that of water), including cholesterol, increased concentrations are a risk factor for coronary heart disease.

III. Nutraceuticals

A further important field of innovation in the production of processed food are nutraceuticals. A nutraceutical is defined as "any substance that may be considered a food or part of a food, and provides medical or health benefits, including the prevention and treatment of disease."[346] Nutraceuticals range from isolated nutrients, dietary supplements and diets to genetically modified food, herbal products and processed food such as cereals, soups and beverages. A nutraceutical maintains, supports and normalizes any physiologic or metabolic function. Nutraceuticals can also potentiate or antagonize physiologic or metabolic functions. Drugs are pharmacologically active substances that potentiate, antagonize and modify any physiological or metabolic function. Thus, the differentiation between nutraceuticals and drugs is becoming more difficult.[347] The ongoing research softens the distinction between food and drugs. Public health authorities consider prevention and treatment with nutraceuticals as a vital tool in maintaining health by addressing nutritionally induced acute and chronic diseases.[348]

Nutraceuticals represent the fastest growing segment of the food sector. The market is estimated at U.S.$30 billion, growing 5% yearly.[349] This increase is "a horror vision for one - a fantastic fulfillment, indeed, for others."[350]

One class of nutraceuticals is represented by polyunsaturated fatty acids, the so-called PUFAs. Current interest is devoted to fish oils containing a high share of omega-3 fatty acids, eicosapentaenoic and docosahexaenoic acids. These fatty acids exercise a protective effect on the development of cardiovascular and inflammatory diseases. Fish oils could play a key role in the treatment of dermatitis and psoriasis. Premature infants have limited dietary support of the omega-3 fatty acids required for the normal composition of brain and retinal lipids. Fish oils influence tumor-derived lipolytic and proteolytic factors, receptors and enzymes of cellular signaling.[351]

The essential amino acid tryptophan has often been employed as a drug. The non-essential amino acid arginine has the potential to improve cellular immune response, phygocytosis and maintenance of T-cell function. Arginine retards tumor growth and formation of metastases. Arginine also acts on immunomodulation comprising cellular response, trauma-induced reduction in the T-cell function and phagocytosis.[352]

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346 The Foundation for Innovative Medicine, The Nutraceuticals Initiative: A Proposal for Economic and Regulatory Reform, 46 Food Technology 77 (1992), available at www.fimdefelice.org/archives/arc.revolution.html.

347 *Hardy*, Nutraceuticals and Functional Foods: Introduction and Meaning, 16 Nutrition 688 (2000).

348 *Andlauer&Fürst,* Nutraceuticals: A piece of History, Present Status and Outlook, 35 Food Research International 171 (2002).

349 *Hardy*, Nutraceuticals and Functional Foods: Introduction and Meaning, 16 Nutrition 688, (2000).

350 *Andlauer&Fürst,* Nutraceuticals: A Piece of History, Present Status and Outlook, 35 Food Research International 171, 175 (2002).

351 *Fürst&Kuhn,* Fish Oil Emulsions: What Benefits can they Bring?, 19 Clinical Nutrition 7 (2000).

352 *Andlauer&Fürst,* Nutraceuticals: A Piece of History, Present Status and Outlook, 35 Food Research International 171, 173 (2002).

Glutamine effects catabolic states. Native glutamine is poorly soluble in water. Synthetic glutamine in the form of stable and highly soluble dipeptides enriches food in order to attenuate the expansion of extracellular and total body water. Besides, glutamine influences stress-induced accumulation of extracellular fluid by affecting membrane function, and changes the cellular hydration state. This suggests therapies for extracellular edema. It can also be used to treat insulin resistance, such as diabetes mellitus, sepsis, and trauma. Finally, glutamine (dipeptide) is proposed as a suitable cardioprotective and rescue agent.[353]

Phytochemicals can be used as nutraceuticals. Glucose and insulin regulation is an important feature of phytochemicals. *Agrimonium eupatoia* extract carries on insulin-like activity and stimulates incorporation of glucose into glycogen. New hypoglycemic compounds have been proposed like castanospermine, neomyrtillin (bilberry) and myricetin (tea, berries, fruits). To sum up, more than 1,000 plants have been claimed to offer special benefits in the treatment of diabetes. Lentinan[354] from mushrooms activates the host's immune system and has antitumor and antiviral activity due to an induction of interferon-γ production. It reduces the toxicity of AZT.[355] Prevention of the onset of AIDS symptoms through potentiation of host defense is presently being investigated.[356] Flavonoids and phenolic acids from honey possess antimicrobial activity. Isoflavone phytoestrogens, such as daidzein and genistein, in soy have antidiarrheal, hypolipidemic, anticarcinogenic and antiosteoporotic effects. The consumption of high soy food is associated with lower breast and prostate cancer risks and it improves the bone mineral content.[357]

C. Consumer acceptance of innovation in the food sector

Consumer acceptance is by far the most critical point of the application of biotechnology in the food sector besides the technological feasibility of biotechnological applications. Consumer acceptance of genetically modified food is extremely difficult for several reasons. First of all, the food sector is the subject of great public attention. Negative news from one company can affect the entire food sector. Additionally, the media are interested in sensational negative news about genetically modified food, thus amplifying public controversy about genetically modified food.

353 *Andlauer&Fürst,* Nutraceuticals: A Piece of History, Present Status and Outlook, 35 Food Research International 171, 173 (2002).

354 A polysaccharide characterized as?-1,3-glucan having branching of the 1,6 bonds.

355 A drug commonly used for treating HIV carriers and AIDS patients.

356 *Andlauer&Fürst,* Nutraceuticals: A Piece of History, Present Status and Outlook, 35 Food Research International 171, 174 (2002).

357 *Andlauer&Fürst,* Nutraceuticals: A Piece of History, Present Status and Outlook, 35 Food Research International 171, 174 (2002).

Seed companies, such as Monsanto, Bayer CropScience or Syngenta, have introduced new, innovative genetically modified plant varieties to the market. Most of these varieties are designed for the demands of farmers, like increased resistance and crop efficiency. Only few genetically modified plants with improved quality traits have been marketed. The most important example is Calgene's FlavrSavr tomato. These genetically modified plants have failed to convince consumers. As a consequence, the first generation of genetically modified plants with improved quality traits has been withdrawn from the market. But the acceptance of biotechnology is generally positive as long as biotechnology offers benefits to consumers.[358]

Additionally, public understanding of science is rather poor and unsteady. Only few consumers can assess biotechnology related to the production of agricultural raw materials because there is an insufficient knowledge base. Moreover, food is a particularly sensitive subject matter.[359] Thus biotechnology related to the production of agricultural raw materials affects lives in a more personal way.

Consumer acceptance of biotechnology related to the production of agricultural raw materials is not based on an "objective" technical assessment. Irrational judgements often win out over rational arguments and create distortions of consumer acceptance. The language with regard to biotechnology related to the production of agricultural raw materials has tended to "hijack the debate."[360] Quite often, non-scientific reasons for objection have been expressed as scientific doubts, so that these technologies seem to be simply unacceptable. Consumer acceptance of biotechnology related to the production of agricultural raw materials is reflected by the slogans currently used in advertising food. Attributes such as "natural," "organic," or "additive free" address rather the moral attitude of consumers than scientific assessments of nutritional value.

Moreover, the surveys concerning the acceptance of biotechnology in the food sector show a trend towards increased caution. A reliable information policy about biotechnology related to the production of agricultural raw materials could overcome the prejudices of consumers. There are no data about the long-term effects of genetically modified plants, as biotechnology is a rather new technology. Hence, the discussion concentrates on the potential risks of biotechnology related to the production of agricultural raw materials. This debate seems to make biotechnology unacceptable to many consumers for reasons of future food safety.

Last but not least, liabilities for the outcrossing of genetically modified varieties are not clearly defined between the breeders, distributors, and governmental bodies.[361]

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358 *Gurau&Randhod*, The Atlantic Divide in Food Biotechnology: Differences in Industry, Market and Consumers' Perception between the U.S. and the UK, 5 Int'l J. Biotechnology 141, 153 (2003).

359 *Belton,* Chance, Risk, Uncertainty and Food, 12 Trends in Food Science&Technology 32 (2001).

360 *Belton,* Chance, Risk, Uncertainty and Food, 12 Trends in Food Science&Technology 32, 35 (2001).

361 *Gurau&Ranchhod,* The Atlantic Divide in Food Biotechnology: Differences in Industry, Market and Consumers' Perception between the U.S. and the UK, 5 Int'l J. Biotech. 141, 144 (2003).

Biotechnology in the food sector is more accepted by consumers in the U.S. than in the EU. Most consumers in the U.S. are comfortable with the commercialization of genetically modified plants.[362]

Consumer acceptance of biotechnology related to the production of processed food is harder to assess. The public discussion about biotechnology in the food sector concentrates on the implementation of biotechnology related to the production of agricultural raw materials. Biotechnology related to the production of processed food is considerably less addressed.

There are no public sanctions on cheese processed with chymosin derived of genetically modified microorganisms. The dairy sector has implemented genetically modified microorganisms to a large extent. Nevertheless, there are hardly any reactions from consumers. Also the media hardly address the application of biotechnology related to the production of processed food. Headlines like "GM oilseed rape harms bees and butterflies"[363] reflect the media's focus on biotechnology related to the production of agricultural raw materials.

Non-governmental organizations often protest against genetically modified plants. But genetically modified microorganisms in the production of processed food seem to be ignored by them. The most active opponent of genetically modified organisms, Greenpeace, only addresses issues relating to biotechnology used in the production of agricultural raw materials. Biotechnology related to the production of processed food is completely neglected. The Greenpeace booklet "Food Assistant – Food without genetically modified organisms – special topic dairy products" focuses only on genetically modified plants used as food or feed. The fact that the dairy industry is based on genetically modified organisms is not addressed at all.[364] Greenpeace defends this policy with the disclaimer that such genetically modified microorganisms are cultivated in closed systems of factories and are not intended for release into the environment. Greenpeace concludes that genetically modified microorganisms are not as "dangerous" as genetically modified plants.[365] But there is no denying that protest activity like destroying field trials generates more media attraction than entering a dairy factory.

362 IFIC, Consumer Attitudes towards Food Biotechnology (2000), Washington, DC 2000, *Einsiedel*, Cloning and its Discontents - A Canadian Perspective, 18 Nature Biotechnology, 943 (2000), Eurobarometer, Opinions of Europeans on Biotechnology in 1991, Concertation Unit for Biotechnology in Europe, Brussels 1991, *Gaskell et al.,* Biotechnology and the European Public, 18 Nature Biotechnology 935 (2000), *Priest*, US Public Opinion Divided over Biotechnology, 18 Nature Biotechnology 939 (2000).

363 Translated version, original German title: "Genraps schadet Bienen und Schmetterlingen," Der Spiegel*,* March 22, 2005, available at www.spiegel.de/wissenschaft/mensch/0,1518,347732, 00.html.

364 Translated version, original German title: "Ratgeber-Essen ohne Gentechnik – Schwerpunkt Milchprodukte," Greenpeace, Essen ohne Gentechnik – Ratgeber für gentechnikfreien Genuss, Schwerpunkt Milchprodukte, 8th ed., Hamburg 2005.

365 Greenpeace, Essen ohne Gentechnik – Ratgeber für gentechnikfreien Genuss, Schwerpunkt Milchprodukte, 8th ed., Hamburg 2005, 10.

Biotechnology brings enormous benefits to the production of agricultural raw materials and the production of processed food. Though biotechnology will not address all future food needs, it will be essential to feed a growing world population. To put the impact of biotechnology in a nutshell:

> "Biotechnology is providing a common technical base on which the pharmaceutical, chemical, agricultural, and food production industries can be united (...)."[366]

Applications of biotechnology must be mutually acceptable to consumers, legislatures, farmers and food processors. The success of biotechnology will depend on the attitudes of consumers. Appropriate information policy and public understanding are therefore crucial.[367]

Biotechnology must overcome consumer antagonism. Consumers only pay attention to biotechnology as it relates to the production of agricultural raw materials. Biotechnology related to the production of processed food is hardly perceived by consumers. The controversies surrounding genetically modified food are substantial. The attention paid to process technologies involving genetically modified organisms is minimal and negligible.[368]

Regulations of food biotechnology are an obstacle for the implementation of biotechnology. Biotechnology related to the production of agricultural raw materials as well as in the production of processed food is subject to a complex regulatory framework. Regulations concern the identification of genetically modified food ingredients. Further restrictions apply to the testing of genetically engineered plants and organisms. The implementation of biotechnology in the food sector is limited by restrictive regulatory approval in the EU.

The labelling obligation for food derived of genetically modified plants is supposed to have obvious "ramifications," as consumer acceptance is difficult to gain with respect to clear differentiation and isolation.[369] Food production aids that are derived from genetically modified microorganisms do not have to be labelled. This seems to be inconsistent, as both microorganisms and plants involve genetic modification. The regulatory approval of food made from genetically modified plants is handled rather restrictively in the EU. The *de facto* moratorium on products from genetically modified plants also affects imports of genetically modified plants. Consequently, the EU has refused to allow the sale of 30 U.S. products derived from genetically modified plants since 1998 for precautionary reasons. "This trade barrier harms farmers and consumers around the world by denying them the benefits of productive, nutritious and environmentally friendly biotech products."[370]

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366 *Kenney*, Biotechnology: The University-Industrial Complex, New Haven&London 1986, 218.

367 *Madden,* Food Biotechnology - An Introduction, ILSI 1995, 36, available at www.ilsi.org/publications/ilsifobi.pdf.

368 *Gardner,* The Development of the Functional Food Business in the U.S. and Europe, in: *Goldberg* (ed.), Functional Foods, Designer Foods, Pharmafoods, Nutraceuticals, London 1994, 468, 478.

369 *Gardner,* The Development of the Functional Food Business in the U.S. and Europe, in: *Goldberg* (ed.), Functional Foods, Designer Foods, Pharmafoods, Nutraceuticals, London 1994, 468, 477.

The European Council allows the marketing of genetically modified plants. But it enforces strict labelling and traceability standards.[371] The U.S., Canada, and Argentina are the main exporters of genetically modified agricultural products. These countries have requested that the WTO establish a WTO dispute settlement panel on the European policy with regard to genetically modified agricultural products.[372]

Finally, investments in agricultural biotechnology are declining.[373] *McElroy* summarizes:

"Most life science investors have historically shied away from supporting agricultural biotechnology, but changing consumer acceptance and refinements in infrastructure, intellectual property management and regulations sector may make the sector more attractive in the coming years."[374]

Straus[375] warns of the devastating consequences of discriminating against plant biotechnology through politically motivated regulation. Europe runs a great risk of losing out in this important field of technology - all the more galling given that it was in Europe where much of the pioneering research took place.[376] Consequently, while plant biotechnology is declining in Europe,[377] it continues to grow elsewhere in the world, creating numerous new jobs.

370 *Zoellick,* U.S. Requests Dispute Panel in WTO Challenge to EU Biotech Moratorium, press release by the USTR of August 7, 2003, available at www.ustr.gov/releases/2003/08/03-54.pdf.

371 All products that contain more than 0.9% genetically modified organisms are to be labelled. The traceability requirements are regarded as costly and implement, U.S. Launches Trade War on GM food, 2(2) European Biotech News 5 (2003).

372 If the U.S. succeeds, the EU is to compensate U.S. farmers for their export losses an estimated sum of U.S.$300 million per annum, Transatlantic GM Trade War Escalates, 2(3) European Biotech News 5 (2003).

373 U.S. venture capital investment in biotechnology increased from less than 4% of total VC funding in 2000 to 9% in 2002. However, of those venture capitalists who claim a significant interest in the life sciences, only a handful have invested in agricultural biotechnology.
Available at www.ventureeconomics.com.

374 *McElroy,* Sustaining Agbiotechnology through Lean Times, 21 Nature Biotechnology 996, 2003.

375 The Need to Protect Intellectual Property in Plant Science, Syngenta Lectures Issue 2, 2003, 34, 41.

376 *Zambryski et al.*, Ti Plasmid Vector for the Introduction of DNA to Plant Cells without Alteration of their Normal Regeneration Capacity, 2 European Molecular Biology Organization Journal 2143 (1983).

377 Syngenta decided in 2004 to move its research activities for genetically modified plants entirely from Europe into the "more sympathetic climate of the U.S." Available at www.guardian.co.uk/gmdebate/Story/0,2763,1252345,00.html. Previously, Monsanto has also decided to withdraw from the European seed market.

Part III. Intellectual property situation of today's food sector

Part I examined retrospectively the exemption to patentability of food, its reasons and the consequences of its abolition in Germany in comparison to Brazil, China, and India. Part I showed, that due to the TRIPs Agreement food must now be eligible for patent protection in most countries worldwide. The TRIPs Agreement led to an increase of food-related patent applications in developing countries, where food had often been excluded from patentability. This development is similar to the development in Germany after food-related substances became eligible for patent protection in 1967. Finally, it was shown that the food sector has an exceptional position which has been reflected in patent law by the exemption to patentability of food.

Part II focused on the technological developments in today's food sector. It became clear, that innovation is a key instrument for the food sector. Innovation in the food sector has been influenced to a large extent by the implementation of biotechnology. The use of genetically modified microorganisms in the processing of food seems widely accepted in Europe, whereas the cultivation of genetically modified plants seems to be rejected by consumers. Moreover the labeling requirements could make marketing of products derived of genetically modified plants difficult. Consequently Europe runs a great risk of losing out in this important field of technology.

Finally, the third part of this dissertation analyzes the intellectual property situation of the food sector of today. It shows that though the exemption has been abolished, the food sector's intellectual property situation is nonetheless different from the situation of other industrial sectors. This applies mainly to inventions related to the production of agricultural raw materials and particularly to inventions related to the production of plant-derived agricultural raw materials, whereas inventions related to the production of processed food are treated like inventions in any other industrial sector.

A. Protection of inventions related to the production of plant-derived raw materials

This section discusses the protection of inventions related to the production of plant-derived agricultural raw materials. The example of plant-biotechnological inventions shows that the food sector still has an exceptional position in intellectual property law. This exceptional position is shown by the exemption to patentability of plant varieties and the two exemptions from the scope of a patent and of a plant variety protection right, the breeders' exemption and the farm-saved-seed provision.

Innovations related to the production of plant-derived agricultural raw materials mainly concern plant varieties and plant-biotechnological inventions. There are two protection systems available. Plant varieties are protected under the plant variety protection system, whereas other plant-related inventions, including plants, can be protected under the patent system. Both the plant variety protection system and the patent system offer rather weak protection due to wide exemptions from the scope of protection. These exemptions from the scope of plant-related patents and plant variety protection rights have been recently harmonized in Europe.

I. Protection under the plant variety protection system

First, the term plant variety is defined. Then, the conditions and the scope of protection of a plant variety right, including essentially derived varieties, are explained. The exemptions to the scope of a plant variety protection right, especially the breeders' exemption and the farm-saved-seed provision, show that the intellectual property situation concerning inventions related to the production of plant-derived agricultural raw materials is exceptional compared to other fields of technology.

The protection of plant varieties is regulated in the German Plant Variety Protection Act, the *Sortenschutzgesetz* (SortG), on the German level, and in the Regulation (EC) No. 2100/94 on Community Plant Variety Rights (CPVR) on the European level.[378]

1. Plant variety as protectable subject matter

The protectable subject matter of the SortG is a plant variety. A plant variety is legally defined as a "plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be defined by the expression of the characteristics that results from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one of the said characteristics, and considered as a unit with regard to its suitability for being propagated unchanged."[379]

378 SortG of December 19, 1997, Regulation (EC) No .2100/94 on Community Plant Variety Rights of July 17, 1994, OJ L 227, 1.

379 Art. 5, No. 2 CPVR, Sec. 2 (1a) SortG.

This is how the International Union for the Protection of New Varieties of Plants (UPOV)[380] defines a plant variety. The European[381] and U.S. plant variety protection systems are also based on this definition of the UPOV Convention.[382]

2. Conditions of protection

Plant variety protection rights are granted if the plant variety is new,[383] uniform, stable, and distinct,[384] and meets the provisions regarding varietal designation.[385] These criteria fit perfectly for traditional plant breeding. Only distinctness causes difficulty with plant biotechnology aiming to develop economically valuable characteristics.[386]

A plant variety[387] is distinct if it is clearly distinguishable by the expression of at least one determining characteristic[388] from any other plant variety whose existence is a matter of common knowledge on the date of application. In Germany, distinctness is assessed by field trials as part of the examination of dinstinctness, uniformity and stability, the so-called DUS testing, by the Federal Plant Variety Office, the *Bundessortenamt*. The plant variety is examined in comparison with an assortment of other known plant varieties of the same species. This DUS testing is based on the UPOV Convention as well.[389] Many other countries follow a similar procedure.[390]

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380 *Straus&von Pechmann*, Die Diplomatische Konferenz zur Revision des Internationalen Übereinkommens zum Schutz von Pflanzenzüchtungen, GRUR Int. 1991, 507. *Lange*, Abgeleitete Pflanzensorten und Abhängigkeit nach dem revidierten UPOV-Übereinkommen, GRUR Int. 1993, 137.

381 The EU is the first intergovernmental organization that joined UPOV on June 29, 2005, UPOV Press Release No.65 of June 29, 2005, European Communities become first intergovernmental organization to join UPOV, available at www.upov.int/en/news/pressroom/pdf/pr65.pdf.

382 UPOV has 59 members in July 2005, covering most of developed countries, available at www.upov.int/en/about/members/pdf/pub423.pdf.

383 Novelty is linked to commercial launch of the variety, wherein generous novelty protection periods are granted, Sec. 6 SortG, Art. 10 CPVR.

384 Sec. 3 SortG, Art. 7 CPVR.

385 For an overview over the material conditions for the grant of Community Plant Variety Rights see, *Würtenberger et al.*, European Community Plant Variety Protection, New York 2006, 28 ss.

386 „The practice of the CPVO shows the distinctness condition as being the major hurdle for the grant of a PVR.“ *Würtenberger et al.*, European Community Plant Variety Protection, New York 2006, 32, 36.

387 Sec. 2(1a) SortG, Art. 5(2) CPVR.

388 Sec. 3(1) SortG. In contrast, Art. 7(1) CPVR only refers to characteristics in general without the limitation "determining" (*maßgebend*).

389 Beside a "General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants" (UPOV Doc. TG/1/3) UPOV provides test guidelines for 196 plant species with tables for specified characteristics.

390 In contrast, the U.S. Plant Variety Protection Office does not conduct own field trials but performs examination based on data provided by the applicant.

During the DUS testing Approximately 20–25 specified characteristics contained in the characteristics catalog for species of the UPOV are examined. Only one different characteristic is sufficient for distinctness. The catalog of the UPOV Convention covers mainly morphological[391] characteristics, which are usually monogenically[392] inherited, and are sufficiently uniform, stable and usually visually discernible.

Quality characteristics are economically valuable, but they are not considered at all in the DUS testing, being usually inherited polygenically and being strongly dependent on environmental factors. Hence, quality characteristics do not necessarily guarantee morphological distinctness.[393] They are only investigated in the plant variety registration procedure[394] as part of the examination of "value for cultivation and use."[395] As a consequence, plant varieties whose only distinct traits are economically valuable characteristics cannot be protected by plant variety protection rights.[396]

This gap in protection cannot be filled by the patent system.[397] Even though a plant variety can be within the scope of a patent, the lapse of the term of a patent renders protection almost ineffective.

Under the German and the European patent system, a generic patent claim on a plant is admissible.[398] Plant-related inventions are protectable if the technical feasibility of the invention is not restricted to plant varieties. Thus, a plant is patentable as long as the underlying invention is not restricted to one or many plant varieties. Plant groupings of a higher taxonomical unit than a plant variety are consequently patentable. A generic claim on a plant also extends to a specific plant variety.[399]

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391 Morphological means regarding the external shape.

392 Monogenically inherited means a trait caused by a single gene. In contrast, a polygenically inherited trait is caused by multiple genes.

393 A morphologic distinction can arise as a result of genetic change as a coincidental side effect to a value-determining characteristic. This is however neither foreseeable nor reproducible.

394 The plant variety market authorization regulated in Sec. 30 SaatG is a condition for the acceptance of seeds, planting and reproduction material in accordance with Secs. 4, 4a SaatG. This acceptance is again a condition for marketing of seeds, planting and reproduction material according to Sec. 3 SaatG. The conditions for a plant variety authorization are novelty, homogeneity, stability, distinctness and a designation by a suitable denomination (these prerequisites being identical with the conditions for plant variety protection rights) and – in addition - the "Value for Cultivation and Use" (*landeskultureller Wert*). For the examination of said national-cultural value also quality characteristics are assessed according to Sec. 30(1) SaatG.

395 A plant variety possesses "Value for Cultivation and Use" according to Sec. 34 SaatG, if - based on the whole of its value-determining characteristics - it demonstrates a clear improvement for crop farming or for utilization of the harvested crop or of products obtained from the harvested crop in relation to plant varieties registered in the plant variety list. The value-determining characteristics, which relate to cultivation, resistances, yield, quality and application opportunities, are examined under cultivation and in the laboratory.

396 *Willnegger*, Schutz nicht unterscheidbarer Pflanzensorten, GRUR Int. 2003, 815, 817.

397 Although there are much higher material hurdles to protect a plant variety under a patent, protection is possible despite the exclusion of plant varieties *per se*, Art. 53(b) EPC, Sec. 2(2) PatG.

398 EPO, Enlarged Board of Appeal decision G 1/98 of December 20, 1999, OJ EPO 2000, 111.

399 ECJ, Kingdom of the Netherlands v. European Parliament and Council of the EU, Suspension of Directive 98/44/EC, Case-377/98, European Court Reports 2001, I-07079, Reasoning No. 46.

Patent protection, however, begins in the R&D phase. The long development periods for genetically modified plant varieties lead mostly to an exhaustion of the 20-year term of a patent until the new plant variety reaches the market. Therefore, there is hardly enough time for the plant breeder to recoup his investment.[400]

As a last chance, a plant breeder can exceptionally request the Plant Variety Protection Office to include a special quality characteristic in the test for distinctness.[401] Such an examination is at the sole discretion of the respective Plant Variety Protection Office. Hence, a plant breeder faces a certain degree of legal insecurity.

In Germany, a plant variety protection right lasts 25 years starting from the date of grant,[402] at which point the plant variety already exists as a marketable product. A plant variety protection right offers a longer duration of protection than a patent.

3. Scope of protection

A plant variety protection right covers constituents like seed of the plant variety[403] as a concrete material subject,[404] but it does not provide generic protection.[405]

400 *Willnegger*, Schutz nicht unterscheidbarer Pflanzensorten, GRUR Int. 2003, 815, 816.

401 *Willnegger*, Schutz nicht unterscheidbarer Pflanzensorten, GRUR Int. 2003, 815, 820. Representatives of the German Plant Variety Protection Office seem to be open for this approach based on statements made on the 2004 meeting of the GRUR Committee for the Protection of Plant Varieties (Munich, March 19, 2004). Special examinations are also possible after special approval of the CPVO President in proceeding before the Community Plant Variety Protection Office (Angers, France).

402 The plant variety protection term starts in the calendar year following on the grant of a plant variety protection right. For hops, potato, wine and tree varieties the protection term is 30 years according to Sec. 13 SortG, Art. 19(1) CPVR.

403 Art. 13(2) CPVR.

404 *Straus,* Pflanzenpatente und Sortenschutz - Friedliche Koexistenz, GRUR 1993, 794, 801. The scope of protection also extends to other plant material (e.g., harvested material) if the owner has had no reasonable opportunity to exercise his right in relation to the variety constituents according to Sec. 10 (1), No. 2 SortG, Art. 13(3) CPVR.

405 For an overview on the scope of a plant variety right see *Würtenberger et al.*, European Community Plant Variety Protection, New York 2006, 115 ss.

a. Essentially derived plant varieties

The plant variety protection right also extends to plant varieties that are essentially derived from a protected plant variety,[406] which is called initial plant variety.[407] A plant variety is considered essentially derived if the initial plant variety was predominantly[408] used for its breeding. The exact definition of an essentially derived plant variety still depends on a definite interpretation of the respective court. Usually, the overall genetic conformity[409] serves as definition.[410] The transformation[411] of an initial plant variety always leads to an essentially derived plant variety[412], since the overall genetic conformity is only changed minimally by inserting a foreign gene into the genome of the initial plant variety.

In the past, the result of traditional plant breeding generally could not be linked to individual genes. It was assumed that the result was due to an improvement of the entire genome. Today, molecular breeding and plant biotechnology provide economically valuable characteristics such as disease resistance in plant varieties. These characteristics are identifiable within and separable from the genome as they often are linked to individual genes. The out-crossing of such a favorable gene from an initial plant variety by crossing with another plant variety leads to an independent plant variety, because there is conceptually no essential derivation involved in the process.[413] Consequently, an economically valuable characteristic cannot be protected under the plant variety protection system, as the concept of the essentially derived plant variety fails as soon as one crossing step is performed. The rapid isolation and use of economically valuable characteristics or certain genes by competitors is unavoidable, discouraging innovation and investment.

To sum up, economically valuable characteristics are not considered in the DUS testing. However, plant breeders of initial plant varieties should be granted protection for economically valuable characteristics. Inventive step offers a proper remedy for the assessment of economically valuable characteristics.[414]

406 Sec. 10(2) SortG, Art. 13(5) CPVR.

407 The concept of essentially derived varieties is an important exception to the prinicple of independence in plant variety protection. *Würtenberger et al.*, European Community Plant Variety Protection, New York 2006, 121.

408 This requires a genetic conformity of more than 50%.

409 "Overall" in this context means an assessment based on the entire genome but not on specific genetic elements or characteristics.

410 Plant breeders currently try to develop reliable criteria for a limit value for the genetic conformity. The International Seed Federation (ISF) proposes a conformity of 80-85% of the genotype. Available at www.worldseed.org/Position_papers/derivg.htm.

411 Transformation of a plant variety means the genetic modification of a plant by the insertion of genetic elements into its genome.

412 Transformation with a specific genetic element can alternatively also result in a non-distinct plant variety if said genetic element is not linked with a phenotype distinguishable according to the requirements of the plant variety protection regulations.

413 *Lange,* Pflanzenpatente und Sortenschutz - friedliche Koexistenz? GRUR 1993, 801.

414 *Willnegger*, Schutz nicht unterscheidbarer Pflanzensorten, GRUR Int. 2003, 815, 820.

b. Exemptions to plant variety protection

The scope of a plant variety protection right does not extend to plant breeding, discovering or developing other plant varieties, or their commercialization, with the exemption of essentially derived plant varieties.[415] The rationale of the plant breeders' exemption in the context of interest is to guarantee advances in food production by ensuring the free availability of genetic material. The success of plant breeding mainly depends on the genetic variation of the initial plant variety.[416] Traditional plant breeders insist on an unrestricted plant breeders' exemption ensuring genetic variability.[417]

The *de facto* exclusivity of a new plant variety comprising an economically valuable characteristic has now been shortened tremendously. In the past, the initial plant breeder enjoyed a *de facto* exclusivity for 10–15 years after market introduction for new economically valuable characteristics of his plant varieties. Modern technologies speed up plant breeding, including the use of economically valuable characteristics from third parties' plant varieties. Nowadays, it is only 4-5 years, which can be too short for an amortization.[418]

The current plant variety protection system encourages low-risk and inexpensive copying of existing plant varieties leading to small genetic changes. On the other hand, the high expense of screening indigenous plant varieties, that have not been subject to systematic breeding, for new characteristics is hard to justify in view of an unrestricted use by competitors.

A further restriction unique to plant variety protection is the farm-saved seed provision. It is also called farmers' privilege, because it entitles farmers to use harvested seed on their own land for the next crop.[419]

New plant-biotechnological inventions are only profitable if the high investments can be returned, something that depends on the existence of strong intellectual property rights. For this system to work properly, a farmer[420] using harvested seed for his next crop must be obliged[421] to pay the plant breeder a reasonable fee,[422] which must be substantially

415 Sec. 10a(1), No.3 SortG, Art.15(c) CPVR.

416 The initial plant variation is the genetic variation of parental plants used for the plant breeding process.

417 *Le Buanec,* The Management of Intellectual Property Rights in Plant Biotechnology, Doc. WIPO-UPOV/SYM/03/11, 6 (2003).

418 *Meussen,* Commercialization of Transgenic Seed Products, 792 Annals of New York Academy of Sciences 172 (1996). The embryo rescue technique results in a decrease of the development time for new wheat varieties from previously 13 years to 4 years.

Available at www.isaaa.org/kc/CBTNews/2003_Issues/Aprn il/CBT_April_25.htm. For more information see Part III Section A Subsection II.2.

419 Worldwide the extent of farm saved-seed is substantial. In Germany it accounts for 46%. *Toledo,* Saving the Seed: Europe's Challenge (2002), available at www.grain.org/seedling/?id =191.

420 This regulation does not affect small farmers according to Sec. 10a(5) SortG.

421 Sec. 10a(3) SortG, Art. 14 CPVR.

lower than a normal royalty.[423] In its recent judgement of June 8, 2006 the ECJ[424] ruled that a flat-rate remuneration calculated at 80% of the certified seed fee cannot be considered as satisfying the requirement that the remuneration has to be 'sensibly lower' than the normal royalty.[425] Additionally, such a farmer has to inform the plant breeder of the respective plant variety protection right of his use of farm-saved seed of the protected plant variety.[426] However, the ECJ denies the plant breeder a right to information without probable cause of such use.[427] This probable cause should be facilitated by a general right to information for the plant breeder.[428]

4. Assessment

The plant variety protection system is well established and adapted to the plant world. However it does not adequately protect economically valuable characteristics.

The scope of protection and the enforcement of plant variety protection rights is unsatisfactory. Any use of plant breeding results short of plagiarism or product piracy cannot be prevented. The enforcement was not a major concern when plant variety protection laws were being formulated, as business among traditional plant breeders was often based on gentlemen's agreements. However, globalization, product piracy and hard competition are now influencing plant breeding. An appropriate balance between the interests of plant breeders and the public must be sought. Furthermore, the incentive to develop new plant varieties with economically valuable characteristics must be maintained. A modernization of the plant breeders' exemption and the farm-saved-seed provision is overdue. Technological progress makes a modernization of the UPOV Convention necessary.

422 This remuneration accounts – depending on the plant species – up to 50% of the common license fee. Available at www.bayerischerbauernverband.de/sro.php?redid=6050.

423 Art. 5(2)(3), Commission Regulation (EC) No. 1768/95 of July 24, 1995 on the implementing rules on the agricultural exemption provided for in Art. 14(3) of Council Regulation (EC) No. 2100/94 on Community Plant Variety Rights.

424 Joined cases C-7/05 to C9/05, Saatugut-Treuhandverwaltuns GmbH, European Court Reports 2006, available at http://eur-lex.europa.eu.

425 Joined cases C-7/05 to C9/05, Saatugut-Treuhandverwaltuns GmbH, European Court Reports 2006, Reasoning No. 20, 29, available at http://eur-lex.europa.eu. The ECJ seems to regard a remuneration to be paid to plant variety protection right holders, a rate of 50% of the certified seed fee and even transitionally fixed a rate of 40% as adequate in order to encourage the conclusion of agreements between holders and farmers, Reasoning No. 27.

426 Sec. 10a(6) SortG, Art. 14(3) CPVR, Art. 8 Regulation (EC) No. 1768/95.

427 ECJ, Schulin, European Court Reports 2004, I-02263, Reasoning No. 57, 62. The *Bundesgerichtshof* decided similar with regard to national plant variety protection rights (Nachbau-Auskunftspflicht, GRUR 2002, 238, 240).

428 *Würtenberger*, Der Auskunftsanspruch beim Nachbau von geschützten Pflanzensorten, GRUR 2003, 838, 845.

First, a stronger international harmonization of the requirements for the DUS testing, including a deposit system and a generally accessible database[429] of the plant varieties' characteristics, is proposed. Second, amendments to the plant breeders' exemption are necessary, comprising:

- Limitation of the breeders' exemption for hybrid parental lines being coincidentally present in seed,
- Suspension of the breeders' exemption for a certain time after the grant of the plant variety protection right, or the allowance of earlier use of a protected plant variety for appropriate remuneration, and
- Mandatory use of deposited seeds as a condition for plant breeding under the plant breeders' exemption.[430]

Third, a general right to information for the plant breeder regarding reproduction under the farm-saved seed provision is recommended. Fourth, additions to the system of essentially derived plant varieties should be made with regard to the protection of economically valuable characteristics. Fifth, plant variety protection rights should be extended to harvested material. Last but not least, the effective enforcement of plant variety protection rights is crucial. Molecular-biological analyses must replace the lengthy and expensive cultivation of the plant varieties in question for comparison to the protected plant variety, on which the courts still insist.[431] The present burden of proof and probable cause make it difficult to obtain a preliminary injunction.[432]

II. Protection under the Patent System

Innovation related to the production of plant-derived agricultural raw materials comprising new plant varieties and plant-biotechnological inventions can also be protected by patents. Though patents offer generic protection, the intellectual property situation concerning inventions related to the production of plant-derived agricultural raw materials is nevertheless rather weak. This weak intellectual property situation is mainly due to wide exemptions from the scope of protection similar to the exemptions of the plant variety protection system.

429 Available at www.worldseed.org/Position_papers/UPOVdatabasee.htm.
430 This would solve problems of the burden of proof regarding essentially derived varieties.
431 A reversion of the burden of proof and an obligation to disclose breeding books in case of a high genotypic conformity are desirable. The efforts of breeders' federations go into this direction.
432 *Würtenberger,* Beweisrechtliche Fragen im Sortenschutzverletzungsverfahren, GRUR 2004, 566.

1. Scope of protection

The Biopatent Directive[433] of the EU stipulates that patent protection is not exhausted with the first sales of the reproductive material, e.g. in the form of seed.[434] The patent protection therefore extends to any biological material derived from the protected biological material by propagation or multiplication in an identical or divergent form and possessing the same characteristics.[435] Exhaustion by sales of the reproductive material occurs only if the produced material is not used again as reproduction material. Thus, the rights of the patent owner are exhausted if the patented material is consumed as food or feed.[436]

The patent protection for a DNA sequence extends to all materials containing the DNA sequence and performing its functions.[437] The scope of protection for plants only encompasses specific plant varieties, even if these are not patentable as such. Hence, *Moufang* speaks of a rather formal exclusivity of the plant variety protection.[438]

2. Term of protection

The term of a patent lasts 20 years starting from the filing date of a patent application and begins in the R&D phase, when as a rule no marketable product is yet in place. The term of a plant variety right starts with its grant, when a marketable product is already available. A marketable plant variety is achieved after a costly development process of 15 years after the initial invention.

Seed companies invest approximately 12% of their annual turnover in R&D. Development periods of 7–15 years for plant varieties are on a par with pharmaceuticals.[439] Similarly, a genetically modified plant becomes a marketable plant variety only after intensive breeding. The development period of the first glyphosate-resistant soy variety

433 Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998 on the Legal Protection of Biotechnological Inventions (Biopatent Directive), OJ 1998 L 213, 13. Available at www.europa.eu.int/eurlex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf.

434 *Straus,* The Relationship Between Plant Variety Protection and Patent Protection for Biotechnological Inventions from an International Viewpoint, 18 IIC 723 (1987), *Straus,* Patent Protection for New Varieties of Plants Produced by Genetic Engineering – Should "Double Protection" be Prohibited?, IIC 1984, 426. *Hesse,* Zur Patentierbarkeit von Züchtungen, GRUR 1969, 650, *Beier&Straus,* Genetic Engineering and Industrial Property, Ind. Prop. 1986, 447, 456, *Lukes*, Das Verhältnis von Sortenschutz und Patentschutz bei biotechnologischen Erfindungen, GRUR Int. 1987, 318, 322.

435 Art. 8(1) of the Biopatent Directive.

436 Art. 10 of the Biopatent Directive.

437 Art. 9 of the Biopatent Directive.

438 The Interface between Patents and Plant Variety Rights in Europe, Doc. WIPO-UPOV/SYM/ 03/06, 8 (2003).

439 At least 7-12 years for annual plant varieties and 10-15 years for biannual plant varieties. *Meussen,* Commercialization of Transgenic Seed Products, 792 Annals of New York Academy of Sciences 172 (1996).

(Roundup®) was 12 years, of which 7 years were needed solely for traditional plant breeding activities.[440] Plant breeding and plant biotechnology procedures have sped up the development process. However, the necessary regulatory approvals then took up the time this would have saved. As a consequence, even today, the development period of genetically modified varieties still takes 12–18 years.[441]

High commercial risks are inherent in the development of genetically modified plants.[442] The probability that a genetically modified plant will reach the market is very low: 25,000 trials during the period from 1980 to 1996 led only to a few commercially successful plant varieties of corn, oil-seed rape, cotton and soy.[443] Aside from possible technical difficulties, political uncertainty adds to the risks of developing commercially viable plant varieties.[444]

Usually, only 5 years of protection remain once the variety reaches the market. This period is far too short to recoup the investments. For this reason, an "industry-specific patent extension legislation"[445] has been suggested. Supplementary protection certificates (SPCs) provide an established solution for products requiring regulatory approvals. Such SPCs are already used for pharmaceuticals[446] and agrochemicals.[447] They allow the patentee to market his invention before generic products are offered at lower prices. An SPC grants the same rights and is subject to the same restrictions as a patent.[448]

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440 *Meussen,* Commercialization of Transgenic Seed Products, 792 Annals of New York Academy of Sciences 172 (1996).

441 Of these, 5–10 years for R&D, at least 3 years for regulatory approval under the *Gentechnikgesetz*, plus 2–3 years for marketing acceptance under SaatG and testing for plant variety protection.

442 Research costs amount to at least U.S.$1.5 million, development costs to at least U.S.$1-5 million depending on the trait (see No. 12). More recent numbers for development are about U.S.$3-8 million because of increasing regulatory requirements.

443 Out of 25,000 field trials with 10 traits and more than 60 plant species only 51 plant varieties with 4 traits in 15 plant species resulted. However, only herbicide and insect resistance traits can claim commercial success. In: *Phillips,* IPRs an the Industrial Structure of the North American Seed Industry (2003),
available at www.farmfoundation.org/projects/documents/Phillips.iprsandindustry.final_000.pdf.

444 One example are the restrictive regulations for labelling and especially liability. In Germany farmers, which grow genetically modified crops, are facing a general liability even in cases without fault for "pollution" caused by cross-pollination. Farmers, which loose their ecological certification in consequence of the release of a genetically modified crop or become unable to commercialize their harvest, are entitled to compensation.
Available at www.bundesregierung.de/-,413.588691/artikel/Neues-Gentechnikgesetz-vom-Bun.htm. Insurance companies have already declared that the "risk cannot be calculated" and will not provide any corresponding insurance. Available at www.gdv.de/presseservice/24243.htm?IE.

445 *Malpass,* Life After the GATT TRIPs Agreement - Has the Competitive Position of U.S. Inventors Changed?, 19 Houston Journal of International Law. 207, 229 (1996).

446 Council Regulation (EEC) No. 1768/92 of June 18, 1992 concerning the creation of a SPC for medicinal products. ABl. EG Nr. L 182, 1.

447 Regulation (EC) No. 1610/96 of the European Parliament and of the Council of July 23, 1996 concerning the creation of a SPC for plant protection products. ABl. EG Nr. L 198, 30. *Schennen,* Auf dem Weg zum Schutzzertifikat für Pflanzenschutzmittel, GRUR Int. 1996, 102.

448 Art. 5 of Council Regulation 1768/92/EEC.

The term of the SPC is the period between the patent application and the market approval for the protected product.[449] The maximum term of an SPC is 5 years.[450]

The SPC compensates for the delay between the patent application and the first marketing approval for a product. For pharmaceuticals, this period lasts 9–10 years,[451] while a similar development time is observed for agrochemicals. The development time for genetically modified plant varieties is, at 15 years, even longer. Genetically modified plants are subject to regulatory approvals under the Directive on the deliberate release of genetically modified organisms[452] and the Seed Marketing Directive.[453] In addition, the directives for genetically modified food and feed products must be observed.[454]

The scope of protection of a SPC for genetically modified plants should be similar to the respective SPCs for pharmaceuticals and agrochemicals. Moreover, the SPC should be limited to the subject matter of the administrative approval, the so-called event. An event is the act of inserting or deleting a gene in a plant's genetic material according to Directive 2001/18/EC.[455] Hence, the event represents a specifiable value for the initial plant breeder and is a suitable point of reference for the SPC.[456]

The event is present in the seed in a replicable and simply isolatable form. After expiration of the term of a patent, competitors can take advantage of the event for their own plant breeding and can market it with the approval of the initial plant breeder. The competitor saves R&D costs and avoids the regulatory approval. This does not apply for pharmaceuticals or agrochemicals due to secondary applicant regulations.[457]

449 Relevant is the time of first authorization for market introduction in an EC member state.

450 *Mühlens*, Das Ergänzende Schutzzertifikat für Arzneimittel, Mitt. 1993, 213, 217.

451 *Suchy*, Patentrestlaufzeit neuerer pharmazeutischer Wirkstoffe, GRUR 1987, 268, 269.

452 Directive 2001/18/EC of the European Parliament and of the Council of March 12, 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

453 Council Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species, Directives concerning respectively the marketing of beet seed (2002/54/EC), fodder plant seed (66/401/EEC), cereal seed (66/402/EEC), seed potatoes (2002/56/EC) and seed of oil and fiber plants (2002/57/EC).

454 Resolution on the proposal for a European Parliament and Council regulation on genetically modified food and feed COM/2001/425 (Novel Food and Feed Regulation), regulation concerning traceability and labeling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms (COM/2001/182).

455 Here, an event refers to insertion of a specific DNA sequence at a specific location within the plant genome. The definition and description requirements for an event are specified in Directive 2001/18/EC Appendix III-B-D.

456 Any other independent type of event is not covered by the approval and should therefore not be the subject of the SPC.

457 The secondary applicant regulation for pharmaceuticals according to Sec. 24a of the German Pharmaceuticals Law and for agrochemicals according to Sec. 20a SortG specifies that a registration is possible by third parties with reference to the initial application after 10 years.

3. Limitations of protection

Research exemption, plant breeders' exemption and the provision on compulsory licenses limit the protection for inventions related to the production of plant-derived agricultural raw materials under the patent system considerably.

a. Research exemption and plant breeders' exemption

The research exemption[458] does not cover the development of new plant varieties using patent-protected plant varieties for further plant breeding. Only in exceptional cases does the research exemption justify the breeding of new plant varieties.[459]

Generally, the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention extends to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.[460] Dependency pyramids are not to be feared if the patent-protected gene is out-crossed in the course of the plant breeding process.[461] However, the first plant breeding step with the patent-protected plant requires permission from the patentee.[462] This restriction of the use of genetic resources is considered a possible threat to future plant breeding efforts. Plant breeders therefore demand a provision equivalent to the plant breeders' exemption in the plant variety protection system for patents allowing the use of the genetic background of patent-protected plant varieties.[463] *Straus* pleads for an amendment to the PatG, because

458 Research relating to the subject matter of the invention is exempted from the patent right, Sec. 11(2) PatG. However, research with the subject of the invention is in general not exempted. BGH, Clinical Trial I *(Klinische Versuche I)*, GRUR 1996, 109, BGH, Clinical Trial II *(Klinische Versuche II),* Mitt. 1997, 253, *Fähndrich&Tilmann,* Patentnutzende Bereitstellungshandlungen bei Versuchen, GRUR 2001, 901, IPR Helpdesk document "Patenting and the Research Exemption" available at www.iprhelp-desk.org/documentos/docsPublicacion/pdf_xml/-8_BP-Patenting-and-the-Research-Exemption[0000003268_00].pdf.

459 Breeding is only in exceptional cases leading to generation of new knowledge about an invention and rarely involves an inventive step, *Lange*, Pflanzenpatente und Sortenschutz - friedliche Koexistenz?, GRUR 1993, 801.

460 Art. 8 para. 1 Biopatent Directive.

461 *Lukes*, Das Verhältnis von Sortenschutz und Patentschutz bei biotechnologischen Erfindungen, GRUR Int. 1987, 328, *Mooney*, Seeds of the Earth, Ottawa 1979. See also *Straus,* Abhängigkeit bei Patenten auf genetische Information - ein Sonderfall?, GRUR 1998, 314

462 *Straus,* Pflanzenpatente und Sortenschutz - Friedliche Koexistenz*,* GRUR 1993, 794, No. 21, *Straus,* Zur Zulässigkeit klinischer Untersuchungen am Gegenstand abhängiger Verbesserungserfindungen, GRUR 1993, 308, 312.

463 ISF, 2003, Position: "Therefore ISF considers that a commercially available variety protected only by Breeder's Rights and containing patented elements should remain freely available for further breeding. If a new plant variety, not an essentially derived variety resulting from that further breeding, is outside the scope of the patent's claims, it may be freely exploitable by its developer. On the contrary, if the new developed variety is an essentially derived variety or if it is inside the scope of

"otherwise molecular plant breeding will be deprived of an important basis for R&D, a disadvantage not only to plant breeders but to the public in general."[464]

The implementation of the Biopatent Directive[465] into the PatG (Implementation Act) regulates the conflict between patent protection and plant variety protection.[466]

Regarding plant variety development, the new paragraph (2a) was added to Sec. 11(2) PatG: "The effect of the patent does not extend to (...) the use of biological material for the purpose of breeding, discovering and developing a new plant variety."[467]

In contrast to the plant breeders' exemption under the SortG, the plant breeders' exemption of the patent system does not extend to the commercialization of the new plant variety if this is within the scope of the patent. The legislature's intent is avoiding any unreasonable obstruction to plant variety development involving the use of patent-protected plant varieties.[468]

This provision of the Implementation Act not only strays from an identical implementation of the Biopatent Directive,[469] but runs contrary to its aim of harmonization.[470] It goes far beyond what is actually required. The exemption applies to the genetic background[471] of a patented plant as well as to the subject matter of the patent *per se*.

The systematic position of the new Sec. 11(2a) PatG after the research exemption in Sec. 11(2) PatG suggests that their contents are related. However, this wording implies a royalty-free compulsory license in practice.[472] It exempts even the commercial development of a plant variety with the subject matter of the invention and prevents any enforcement of a patent in this phase.

The extensive scope of the exemption under Sec. 11(2a) PatG seems to allow an independent and simultaneous development by the competitors, starting with cloning a protected gene, transforming, and breeding the final plant variety. The patentee must expect a commercial launch of a competitor's plant variety as soon as his own patent expires.

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the patent's claims, a consent from the owner of the initial variety or of the patent must be obtained."

464 *Straus*, Optionen bei der Umsetzung der Richtlinie EG 98/44 über den rechtlichen Schutz biotechnologischer Erfindungen, Eidgenössisches Institut für Geistiges Eigentum, Publikation No. 2 (2004), available at www.ige.ch/D/jurinfo/documents/j10015d.pdf.

465 The *Bundestag* passed the Implementation Act of the Biopatent Directive on December 3, 2004.

466 *Haedicke*, Die Harmonisierung von Patent- und Sortenschutz im Gesetz zur Umsetzung der Biotechnologie-Richtlinie, Mitt. 2005, 241.

467 The wording of this regulation is taken from the Regulation (EC) No. 2100/94 on Art. 15(c) CPVR. However, neither the different prerequisites for the grant of a patent (especially autonomous reproducibility) nor divergences in the scope of protection were properly considered. For example, the impact of the exemption on method or use claims is completely ambiguous.

468 No. 1 of the Draft for the Implementation Act, Bundestags-Drucksache (Parliament Publication) 15/1709 (October 15, 2003), available at www.dip.bundestag.de/btd/15/017/1501709.pdf.

469 The Biopatent Directive does not comprise a regulation corresponding to a breeders' exemption.

470 Reasoning 3 of the Biopatent Directive.

471 Genetic background means the genome with exception of the patent protected gene.

472 *Von Pechmann,* Zum Problem des Schutzes gentechnologischer Erfindungen bei Pflanzen durch Sortenschutz und/oder Patente, GRUR 1985, 717.

The plant breeders' exemption in the plant variety protection system is based on different parameters. The competitors start plant breeding under the plant breeders' exemption only after the market introduction of the initial plant variety. This is because a plant variety is not an autonomously repeatable subject, but a unique biological individual. Commercialization of the initial plant variety by the owner of a plant variety protection right and the legal acquisition by the competitor are implicitly presupposed. Thus, competitive plant breeding takes place not simultaneously but subsequently. The owner of a plant variety protection right enjoys a longer period of *de facto* exclusivity.[473] A more appropriate exemption from patent protection for further plant breeding would be bound to material commercially or otherwise deliberately released by the patentee. The corresponding wording could read as follows: "The effect of the patent does not extend to (....) the use of biological material that is released commercially by the patentee or with his consent for the purpose of breeding, discovering and developing a new plant variety."[474]

This is an acceptable compromise. A compulsory right to use the patented invention is only avoided if the patent-protected genetic element or trait is out-crossed and only the genetic background is used for further plant breeding. Accordingly, the newly bred plant variety would no longer fall within the scope of the patent,[475] thus ruling out an intentionally commercial use of the subject matter of the patented invention.

b. Farm-saved seed and coincidental production

If seed of a patent-protected plant variety is grown on the field of a third farmer as a consequence of cross-pollination and that farmer makes no deliberate use of it, that farmer cannot be made liable for any patent infringement.

However, an injunction against commercialization or any other further use of the patent-protected material can be enforced against the farmer *de lege lata* regardless of negli-

473 The Scientific Service of the German Parliament (Wissenschaftlicher Dienst des Deutschen Bundestages) comes to a similar conclusion in a legal opinion dated November 9, 2004. Resolution Recommendation and Report, Bundestags-Drucksache (Parliament Publication) 15/4417 (December 1, 2004), 14-16, available at www.dip.bundestag.de/btd/15/044/15044 17.pdf. Herein the following wording is suggested: "The effect of the patent does not extend to (...) 2a. the use of biological material to the purpose of breeding, discovering and developing of a new plant variety starting from the time, when the biological material can be commercially released by the patentee or with his consent." This solution seems however less suitable due to the material deviation from the plant variety protection rights regulations and conceptual ambiguities.

474 Such a compromise was discussed in the hearing on the draft of the Implementation Act in the legal committee of the *Bundestag* on September 29, 2004. Both the experts of the biotechnology industry (*Wallmeyer*) and the national breeders association (*Herrlinger*) supported such modification.

475 An acceptable exemption could read: "The effect of the patent does not extend to […] the use of biological material, which was commercially released by the patentee or with his consent, for the purpose of breeding, discovering and developing a plant variety, provided that said new plant variety itself is not within the scope of protection of the patent." This wording would allow the breeder to use the genetic background of a patent protected variety but not the invention as such.

gence or fault. In Germany, this natural circumstance is taken into consideration by the Implementation Act, stating in addition to a farm-saved seed provision in accordance with the CPVR Directive 2100/94[476] that patent protection does not extend to biological material that "is obtained in the field of agriculture coincidentally or unavoidably."[477]

This causes legal insecurity, as the exhaustion provisions of the Biopatent Directive concerning the later use of patent-protected material are based on the assumption of protected material. The patent protection cannot be revived in later reproduction cycles if coincidentally obtained material is not subject to patent protection from its genetic source as stipulated in the Implementation Act. In the end, a farmer can use material that has been obtained "coincidentally" without restriction and can even commercialize it as seed. This farmer needs not buy seed of a patent-protected plant variety, and he is not obliged to pay appropriate compensation for any reproduction under the farm-saved seed provision. Furthermore, bringing counter-evidence is difficult when a farmer claims to have coincidentally obtained the respective material.

Clause 2 of the new § 9c(3) PatG stipulates that "(...) a farmer in general cannot be made liable for infringement of a patent if he grows seed or planting material not subject to this patent protection." This formulation is unfortunate, since the interpretation and scope of the term "in general" is completely unclear.

A limitation of the liability payments and the injunction could balance the interests of the patentee and the farmer. In any event, the sale of coincidentally obtained material for seed purposes is to be prevented.

The new § 9c(3) PatG has to be amended at least by reviving patent protection if a farmer takes note of the presence of patent-protected material and intentionally uses it in the next crop. This would subject a farmer who coincidentally obtains seed to the same farm-saved seed provisions as any other farmer who acquires this seed.

c. Compulsory license

The Biopatent Directive introduces a modified compulsory license with regard to interdependence between a plant variety protection right and a patent.[478] The Implementation Act extends this provision to interdependent patents.[479]

A compulsory license can be granted if the owner of the dependent right has unsuccessfully tried to obtain a contractual license from the owner of a patent or a plant variety protection right. Furthermore, the plant variety or the invention must constitute significant technical progress of considerable economic interest compared with the invention

476 Art. 11(1) of the Biopatent Directive. For the conditions and the extent of this exemption Art. 14 CPVR as well as the implementation regulations therefore apply. Any claim of the patentee has to be made in accordance to the implementation regulation for Art. 14(3) CPVR.

477 Art. 1, No. 6 of the Implementation Act, implementation of new Sec. 9c(3) PatG.

478 Art. 12 of the Biopatent Directive.

479 Art. 1, No. 9 of the Implementation Act, amendment of Sec. 24 PatG.

claimed in the initial patent or in the initial plant variety. A public interest is not necessary any more. The term "significant technical progress of considerable economic interest" will be case-specifically interpreted by the court. A significant technical progress may be given if an inventive step of the dependent invention exists. A granted and valid patent acts as an indicator for a significant technical step. Only exceptionally will plant varieties constitute a "significant technical progress," since an inventive step is often denied.[480]

4. Assessment

The patent system is intended to foster all areas of technology including plant biotechnology and plant breeding. The following amendments under the European patent system and the European plant variety protection system seem necessary concerning plants: First, the exemption to patentability and the double protection prohibition for plant varieties should be abolished.[481] Second, the extensive breeders' exemption and farm-saved seed provision under the amended Patent Act should be limited. Third, a SPC for plant varieties should be introduced.

III. Increase in patent applications for non-genetically modified plants

After the analysis of the protection situation for inventions related to the production of plant-derived agricultural raw materials in the section above, a recent phenomenon is explained: the increasing number of patent applications for traditionally bred non-genetically modified plants at the European Patent Office. This phenomenon is particularly striking as traditionally bred plants were typically protected under the plant variety protection system but not under the patent system.

480 *Lange*, Pflanzenpatente und Sortenschutz - friedliche Koexistenz?, GRUR 1993, 801.

481 *Straus*, Patent Protection for New Varieties of Plants Produced by Genetic Engineering – Should "Double Protection" be Prohibited?, 15 IIC 426, 442 s. (1984), The Relationship Between Plant Variety Protection and Patent Protection for Biotechnological Inventions from an International Viewpoint, 18 IIC 723, 736 s. (1987), where Straus explains that "permitting competition between patent and plant variety protection for biotechnological inventions does not mean legal Darwinism (...)"; *Straus*, Pflanzenpatente und Sortenschutz - Friedliche Koexistenz, GRUR 1993, 794, 801.

More and more patents for non-genetically modified plants have been filed at the EPO, like the "biscuit patent,"[482] "corn plants with improved oil composition"[483] or "rapeseed with improved oil composition."[484] These patent applications are not based on genetically modified plants, but rather on traditional breeding methods comprising artificially induced mutation.

Mutation, selection and regeneration are generally considered elements of traditional plant breeding.[485] The European patent system regards essentially biological processes like selection and crossing as not patentable. However, artificially induced mutation combined with selection is patentable.

1. European patent on herbicide-resistant rice

An example of a patent application on non-genetically modified plants is the European patent on herbicide-resistant rice. The Louisiana State University is owner of the European patent on herbicide-resistant rice, particularly on rice resistant to herbicides that normally interfere with the plant enzyme acetohydroxyacid synthase (AHAS), such as imidazolinone herbicides and sulfonylurea. This patent is typical of patent applications on non-genetically modified plants which are based on artificially induced mutation and selection.

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482 EP 445 929 held by Monsanto covered a soft-milling wheat producing flour with favorable baking properties. The patent has been revoked during opposition. Claim 1 has been directed to: "Soft-milling wheat having an SDS-sedimentation volume, measured as in Experiment 2 described herein and corrected to 11% protein, of not greater than about 30ml."

483 EP 744 888 held by DuPont covered corn and products thereof with improved oil composition. The patent has been revoked during opposition. Claim 1 has been directed to: "A corn grain produced by planting in close proximity a corn plant of an agronomically elite highyielding female parent, having high oleic characteristics, and optionally having high-oil characteristics, with a corn plant of a high-oil and high oleic male parent, optionally having high-yielding characteristics and/or agronomically elite characteristics."

484 EP 813 357 held by Pioneer Hi-Bred International Inc covered an improved Brassica oilseed, an improved plant capable of forming the same, and an improved edible endogenous vegetable oil derived from oilseed Brassica. Claim 1 was directed to: "An improved edible vegetable oil having an improved distribution of fatty acids formed by the process consisting essentially of crushing and extracting Brassica napus oilseeds wherein said distribution of fatty acids is endogenously formed and said vegetable oil exhibits (1) an alpha-linolenic acid content of 1 to less than 3.5 percent by weight based upon the total fatty acid content, (2) an oleic acid content of at least 78 up to approximately 84 percent by weight based upon the total fatty acid content, (3) a total saturated fatty acid content of no more than 4.5 percent by weight based upon the total fatty acid content, and (4) an erucic acid content of no more than 2 percent by weight based upon the total fatty acid content, and wherein each of said recited traits of said oil was controlled by genetic means in the absence of cancellation as the result of the formation of the other recited traits."

485 *Willnegger*, Schutz nicht unterscheidbarer Pflanzensorten, GRUR Int. 2003, 815.

Claim 1 of European patent EP 1 126 756 is directed to

> "A rice plant wherein:
> (a) the growth of said plant is resistant to inhibition by one or more of the following herbicides, at levels of herbicide that would normally inhibit the growth of a rice plant: imazethapyr, imazapic, imazapyr, nicosulfuron, sulfometuron methyl, imazaquin, imazamox, chlorimuron ethyl, metsulfuron methyl, rimsulfuron, thifensulfuron methyl, tribenuron methyl, pyrithiobac sodium, or a derivative of any of these herbicides; and
> (b) said plant is a derivative of at least one of the plants selected from the group of plants with ATCC accession numbers 203419, 203420, 203421, 203422, 203423, 203431, 203432, 203433, and
> (c) said plant has the herbicide resistance characteristics of at least one of the plants selected from the group of plants with ATCC accession numbers 203419, 203420, 203421, 203422, 203423, 203424, 203425, 203426, 203427, 203428, 203429, 203430, 203431, 203432, 203433."

ATCC stands for American Type Culture Collection. This collection comprises over 400 strains of patented seeds.[486]

Twenty-seven new rice plants resistant to AHAS-inhibiting herbicides were identified after rice seeds were exposed to the mutagen methanesulfonic acid ethyl ester. Approximately 52 million mutated rice seeds were screened in the process. One hundred seventy kilograms of seed were soaked with the mutagen and then planted, harvested and stored over the winter. The second-generation seed was screened for herbicide-resistance the following spring by application of an AHAS-inhibiting herbicide. The surviving plants had genetic mutations making them resistant to that herbicide.

The experiments were done on the specific rice varieties *Cypress* and *Bengal*. Thus, the invention is solely based on plants of a certain plant variety and is therefore a subject matter inherent to plant variety protection. However, the technical teaching of the patent is not limited to these two rice varieties. Therefore, the EPO granted the European patent EP 1 126 756 on this plant variety-based invention. The patent has not been opposed by any third party during the 9 month opposition period. Claim 1 covers a process for reproducibly producing rice plants resistant to a herbicide, comprising artificially induced mutation, regeneration and selection under presence of an AHAS-inhibiting herbicide, whereas selected plants express an acetohydroxyacid synthase with a resistance to inhibition by said herbicide.

Furthermore, certain individual rice plants resistant to AHAS-inhibiting herbicides with ATCC accession numbers 203419, 203420, 203421, 203422, 203423, 203431, 203432, including their mutants, recombinants, genetically-engineered derivatives or progeny are patented. Finally, a process for controlling weeds in the vicinity of said plants comprising the application of said herbicide has been claimed and granted.

486 Available at www.lgcpromochem-atcc.com/common/catalog/plantSeeds/plantSeedsIndex.cfm.

2. *Exemption to patentability of essentially biological processes and patentability of artificially induced mutation*

Essentially biological processes are excluded from patentability according to Art. 53(b) EPC. The Biopatent Directive defines a process for the production of plants as essentially biological if it consists entirely of natural phenomena such as crossing or selection. Plant-related inventions that are only based on crossing and selection are not patentable *per se*.[487] This legal definition has been implemented in Rule 23(b)(3) EPC.

Inventions that apply artificially induced mutation are patentable, because they are not merely based on selection and crossing. Natural mutations occurring with much less frequency represent mere discoveries and are therefore not patentable. Thus, the mutation has to be man-made meaning artificially induced, e.g. by employing radiation or mutagenic chemicals, to be patentable.

3. *Assessment*

The increasing number of European patent applications for non-genetically modified plants indicates the insufficiency of the European plant variety protection system. Plant variety protection rights are weak.[488] Moreover, the requirements for a plant variety protection right are perfectly adapted to traditional plant breeding, while they do not fit the new developments of plant breeding and plant biotechnology.[489] Plant variety protection does not consider economically valuable characteristics because distinctness is measured mostly in terms of morphological characteristics. Plant varieties with economically valuable characteristics generated by artificial mutation are therefore not always distinct in the sense of the plant variety protection system. The plant breeders' exemption and regulations on farm-saved seed weaken plant variety protection rights. Although, these exemptions have been introduced in the PatG as well as in the patent systems of most other countries of the EU, patents offer a broader scope by not being limited to a specific plant variety. The danger of imitations of plant-related inventions is higher than in other industrial sectors because of the biological material's ability to reproduce itself.

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487 Art. 2(2) of the Biopatent Directive.

488 *Kock, Porzig, Willnegger*, Der Schutz von pflanzenbiotechnologischen Erfindungen und von Pflanzensorten unteer Berücksichtigung des Umsetzung zur Biopatentrichtlinie, GRUR Int. 2005, 183, 192. This weak protection is internationally criticized because it stunts investments in germplasm generation, in: *Willnegger*, ISF International Seminar "Protection of Intellectual Property and Access to Plant Genetic Resources", GRUR Int. 2004, 611, 613, *Straus* points out, that "patents and other industrial property rights are seemingly the only means which could help host countries in generating funds supporting biodiversity in conformity with the principles of the market economy." *Straus*, Patents on Biomaterial – A New Colonialism or a Means for Technology Transfer and Benefit-Sharing, in: *Thiele&Ashcroft* (eds.), Bioethics in a Small World, Heidelberg 2005.

489 *Willnegger*, Schutz nicht unterscheidbarer Pflanzensorten, GRUR Int. 2003, 815.

Consumers in the EU seem to be careful about products made of genetically modified plants.[490] Though a plant derived from artificial mutation is everything but natural, products derived from artificially mutated plants seem to be generally accepted.

The concept of non-genetically modified, herbicide-resistant plants is well established outside Europe, as the Clearfield® production system shows. BASF Corp. in the U.S. distributes the seed of the Clearfield® production system successfully. According to BASF Corp.: "The system is a combination of herbicides and seeds that are tolerant to these herbicides. The seeds are obtained using traditional breeding methods and not using genetic engineering."[491] The first Clearfield® production system was launched in the U.S. in 1992 for corn. New Clearfield® seed lines are being developed and sold in worldwide partnerships with more than 100 seed companies, in particular for wheat, rice, sunflower and canola.[492] The EU is a new target for such non-genetically modified systems, as genetically modified seed is not accepted there.

The rising number of patent applications of non-genetically modified plants shows that exemptions to patentability are rather doubtable. In practice, the courts allow a circumvention of this exemption. Thus, the exemption to patentability of plant varieties only complicates the application processes and therefore should be abolished.

Patents are the answer to weak plant variety protection rights. Patents grant generic protection and thus guarantee better protection than plant variety protection rights, which are confined only to the protected plant variety as such with exception of essentially derived plant varieties. Patentees are not only interested in protecting seed of their plant variety, but also in products derived from that biological material. These interests are best protected by the generic protection of patents.

490 *Jaeger*, Dr. Jekyll und Mr. Mais, Spiegel Special No. 5, 2005, Besser Essen, besser Leben – Ernährung und Gesundheit, 96.

491 BASF AG, available at www.corporate.basf.com/en/innovationen/preis/2001/clearfield.htm?id =er-5cG7AJKbcp3KK.

492 The group of imidazolinones consists of six active ingredients. As a result, BASF AG can offer custom-designed products that best control typical weeds in a particular crop or region. In the coming years, BASF AG will launch several Clearfield systems and expects them to yield annual sales of approximately U.S.$300 million.
Available at www.corporate.basf.com/en/innovationen/preis/2001/clearfield.htm?id=er5cG7AJKbcp3KK.

B. Protection of inventions related to the production of animal-derived agricultural raw materials

Inventions related to the production of animal-derived agricultural raw materials are protected under the patent system only, as there is no *sui generis* protection system for animal breeding. Art. 53(b) EPC and Sec. 2, No. 2, of the PatG except animal varieties and essentially biological processes for animal breeding from patent protection. Animals are not excluded from patentability, as long as higher taxonomic units than varieties are claimed.[493] The German translation of term animal varieties in Art. 53(b) EPC, as well as in former Sec. 2, No. 2, PatG read *Tierarten*, meaning animal species. Animal species is a higher taxonomical rank than animal variety. But according to the rationale of the EPC based on the Strasbourg Convention, only animal varieties are excluded from patentability. Thus, the German wording *Tierarten* is to be read as animal varieties.[494] Moreover, Art. 4(1)(a) of the Biopatent Directive used the correct term of animal varieties. Meanwhile, the German Implementation Act to the Biopatent Directive introduced a new § 2a(1) PatG also reading *Tierrassen*. So, only animal varieties are excluded from patentability but not animal species.

Up to now, there is no *sui generis* protection system for animal varieties that could compensate for the exemption to patentability of animal varieties. *Straus*[495] has already suggested introducing an animal variety protection system similar to the European or German plant variety protection system.[496]

C. Protection of inventions related to the production of processed food

The protection of inventions related to the production of processed food is considerably more favorable than that of inventions related to the production of agricultural raw materials. There are three areas particularly concerning the production of processed food. On the one hand, savor nuances comprise a field of inventions that is considered characteristic of inventions concerning processed food. Next the product-by-process claim is discussed. Finally, the protection provided by Art. 64(2) EPC for the product directly obtained by the patented process is analyzed and exemplified with three patents on food-related inventions.

493 EPO decision T19/90, Onco-mouse/Harvard II, OJ 1990, 476.

494 *Moufang,* in: *Schulte* (ed.), Patentgesetz mit EPÜ, München 2004, Sec. 2, No. 78, *Hansen&Hirsch*, Protecting Inventions in Chemistry, Weinheim et al. 1997, 273.

495 *Straus*, Ethische, rechtliche und wirtschaftliche Probleme des Patent- und Sortenschutzes für die biotechnologische Tierzüchtung und Tierproduction, GRUR Int. 1990, 913.

496 *Von Pechmann*, Ausschöpfung des bestehenden Patentrechts für Erfindungen auf dem Gebiet der Pflanzen- und Tierzüchtung, GRUR 1987, 475, *Hansen&Hirsch*, Protecting Inventions in Chemistry, Weinheim et al. 1997, 275.

I. Patentability of savor nuances

There are two German decisions relating to savor nuances. The question in these cases was whether aesthetic effects can generally justify the grant of a patent. The outcome of *Käsegericht* decision[497] by the board of appeal of the German Patent and Trademark Office (DPMA) is that a new savor nuance cannot justify the grant of a patent, as savor nuances are in the field of aesthetics rather than in technology. The subject matter of the invention was a production method for a cheese product, or a dish made of cheese, characterized by heating fumed cheese in boiling vegetable fat, usually olive oil, in combination with fresh garlic, until the cheese slices swell and the contiguous slices melt together. The patent application was rejected by the examination department of the DPMA because it lacked of a new and characteristic method. Moreover, there was no progress in another technical field disclosed. The applicant claimed that the creation of a new savor nuance would justify the grant of a patent. He argued that cooking would be enriched by the new savor. Furthermore, he referred to other methods in the food sector, e.g. cocoa processing, where savor nuances regularly justify the grant of a patent. The Board of Appeal states that the creation of a new savor nuance without technical advantages is not sufficient for the patentability of the respective process. It is reasoned that the invention's contribution to the state of the art is not a technical feature, but only a new savor. Savors are a matter of aesthetics and therefore are not patentable.

The legal situation is different if methods lead to clearly distinguishable characteristics of the product. Examples are the roasting of cacao beans in order to improve aroma and taste and the treatment of soybeans to reduce bitter substances. Those improvements can be precisely measured and distinguished, as opposed to other savor nuances.[498]

According to the *Suppenrezept* decision[499] of the German Federal Supreme Court savor nuances alone cannot justify the grant of a patent, as they cannot replace a definite technical effect. The subject matter of the patent application was a method of boiling a "soup" of whole onions roasted or fried in oil, particularly Spanish onions, or chanterelles or other mushrooms roasted or fried in oil, and wheat which has been germinated and afterwards boiled under preservation of the form of its grains by mincing preferably in blended condition, and boiling in vegetable stock. The patent application contained one single claim directed to:

> "Herstellung einer Suppe aus in Öl im Ganzen gebackener unzerkleinerter Zwiebel, insbesondere spanischer Zwiebel, in Öl gebackenen oder gebratenen Pfifferlingen (oder anderen Pilzen), gekeimtem bzw. längere Zeit eingeweichtem und danach unter Erhaltung der Form der Körner gekochtem Weizen, durch Zerkleinern in vorzugsweise vermengtem Zustand und Aufkochen in Gemüsebrühe."

497 German Patent and Trademark Office, board of appeal decision of 5.11.1958, GRUR 1959, 180.

498 Furthermore, the German Federal Supreme Court declared that even the enrichment of kitchen techniques by a new dish is questionable. Such an enrichment of kitchen technique does not justify the grant of a patent on a recipe, because otherwise countless recipes, which are tested every day in the kitchen, could be eligible for patent protection.

499 *Suppenrezept* means recipe for a soup, GRUR 1966, 249 with annotation by *Spieß*.

The application was rejected by the examination department of the DPMA because of lack of an inventive step. The contribution to the state of the art of the invention is only a savor nuance, but no objective savor improvement like bitter or sweet. Savor nuances cannot be measured objectively and therefore are not patentable. The applicant argued that a savor improvement cannot be restricted on reducing bad tastes, e.g. bitterness. Savor improvements are not to be restricted to measurable criteria. He claimed that a recipe with a superior savor effect is a technical advance. The Court stated, that the combination of substances in the soup was new. But novelty alone does not justify the grant of a patent as an inventive step must also be given. An inventive step implies only technical characteristics. Moreover, not every aesthetic effect could justify the grant of a patent, as established in the *Käsegericht* decision.[500]

Generally, savor nuances do not justify the grant of a patent, but they can do so if a non-obvious effect, like the reduction of a bitter taste, is given. To sum up, inventive steps occur not only in technology, but also in aesthetics.[501] A contribution to the state of the art and an inventive step can be based on a characteristic aesthetic effect of a product if there is additionally a special technical effect.[502] Consequently, the patentability of recipes depends on novelty and inventive step, as do all inventions in other fields of technology.

II. Food as a macromolecular substance and product-by-process claims

Food-related substances often represent macromolecular substances that are difficult to describe by a concrete chemical structural formula.[503] These macromolecular substances can often only be described by their way of production, but not by their exact chemical structure. Case law responded to the need to also protect macromolecular substances by developing a claim category of its own, the so-called product-by-process claim. Product-by-process claims make food protectable as substance claims. First the prerequisites of such a claim category are explained. Then the scope of protection of product-by-process claims is analyzed.

500 German Patent and Trademark Office, board of appeal decision of 5.11.1958, GRUR 1959, 180.

501 *Pietzcker*, Patentgesetz und Gebrauchsmusterschutzgesetz, Berlin&Leipzig 1929, No. 39.

502 *Nastelski,* in: *Reimer* (ed.), Kommentar zum Patentgesetz und Gebrauchsmustergesetz, 3rd ed., Köln etc. 1968, No. 5, Sec. 1 PatG, *Tetzner*, Kommentar zum Patentgesetz, 2nd ed., Nürnberg 1951, Sec. 1 No. 47, *Weber,* Ästhetische Wirkungen als Grundlage des Erfindungsschutzes, GRUR 1939, 451**,** *Heine***,** Anmerkung zum Urteil des 5. Beschwerdesenats des Deutschen Patentamts, *Küchenrezept*, GRUR 1959, 180, dissenting opinion: Leitsatz der Entscheidung des 5. Beschwerdesenats des DPA vom 5.11.1958, 1959 Bl. f. PMZ 14.

503 *Schrell&Heide*, Zu den Grenzen des "product-by-process"-Patentanspruchs im Erteilungs- und Verletzungsverfahren, GRUR 2006, 383, citing chocolate whose aroma structure cannot be precisely described other by its process of production.

The Federal Supreme Court of Germany ruled that macromolecular substances must be unambiguously identified in the terms of the patent system, but not down to this exact chemical structure.[504] The Court stated in a landmark case: "(...) it is necessary and also sufficient for the claim, explained by the specification, to contain as many details for characterizing a macromolecular product of unknown structure as are required to differentiate its inventive nature in terms of ascertainable (measurable) characteristics (so-called parameters) from the ascertainable characteristics of other unclaimed macromolecular products, in order to judge the patentability requirements with certainty."[505] The unambiguous identification of macromolecular substances is often only possible by the process of their production. A patent claim referring to such a process of production is hence called a product-by-process claim.[506]

The Federal Supreme Court of Germany has stated with respect to the admissibility[507] of product-by-process claims: "A product claim in which a chemical substance is characterized in terms of its process of preparation (so called product-by-process claim) is admissible whenever the structural formula of a chemical product is not known or the chemical product cannot be identified in terms of characteristics that can be ascertained."[508] The EPO allows product-by-process claims only if the product cannot be sufficiently defined by reference to its composition, structure or some other testable parameter.[509]

The admissibility of product-by-process-claims is obviously necessary, as "this may well be the only way to define certain natural products or macromolecular materials of unidentified or complex composition which have not yet been defined structurally."[510]

504 Bundesgerichtshof (Federal Supreme Court) 06.07.1971 Case:OZB 9/70 "Trioxane," IIC 1972, 226, Headnotes 1 and 2.

505 Bundesgerichtshof (Federal Supreme Court) 06.07.1971 Case:OZB 9/70 "Trioxane," IIC 1972, 226, Headnote 2.

506 The product-by process claim is also called substance-by-process, *Cornish,* Intellectual property: Patents, Copyright, Trade Marks and Allied Rights, 4th ed. London 1999, 170. The resent *Erythropoietin* case decided by the British House of Lords dealt with a product-by-process claim on a hormone used as to enhance the production of erythrocytes. The principles laid down in this judgement also apply to product-by-process claims for food-related inventions. House of Lords, Kirin Amgen Inc. v. Hoechst Marion Russel Ltd. (Erythropoietin), October 21, 2004, [2004] UKHL 46, No. 89. *Welch*, Der Patentstreit um Erythropoietin (EPO), GRUR Int. 2003, 579, 583.

507 *Bühling*, Der "product-by-process-claim" im deutschen Patentrecht, GRUR 1974, 299, *Meier-Beck*, Gegenstand und Schutzbereich von product-by-process-Ansprüchen, in: *Ann et al.* (ed.), Materielles Patentrecht – Festschrift für Reimar König zum 70. Geburtstag, Köln 2003, 323.

508 Bundesgerichtshof (Federal Supreme Court) 06.07.1971 Case:OZB 9/70 "Trioxane," IIC 1972, 226, Headnote 3.

509 UK CIPA 14-07, EPO Decision T 150/82, IFF/Claim categories, OJ EPO 1984, 309.

510 EPO, Flavors&Fragrances Inc, OJ EPO, 309 (1984).

Product-by-process claims present patent offices with considerable difficulties, because an examination of the invention based on the state of the art is virtually impossible. As a result, the applicant has to provide the patent office with experimental data proving that his product can only be characterized by a specific process and differs from the state of the art.[511]

A product-by-process claim is only admissible if the product is new *per se*.[512] The product must be distinguishable *per se* from products of the prior art.[513] Only one production process is required to define the product. Product-by-process claims are applicable to all kinds of products, including chemical substances,[514] anti-bodies,[515] immunomodulators,[516] or plants.[517] With regard to plants the Federal Supreme Court of Germany states, that in case of unsufficient possibilities to describe a plant by directly recognizable features, it is appropriate to describe the plant by chemical or physical parameters or by the method of production.[518]

2. The scope of product-by-process claims

The scope of protection of a product-by-process claim varies from country to country. In Germany, a claim extends to any product having the relevant disclosed characteristics, whereas in the UK, product-by-process claims extend only to substances that have been produced by the disclosed process (further information under a). In the U.S., there is considerable legal uncertainty about the scope of product-by-process claims (further information under b).

511 *Avery&Mayer*, Das US-Patent, 3rd ed., Köln et al. 2003, 97.
512 UK CIPA 14-07, EPO Decision T 434/87, FABRE/Toothbrush fibres (1990) EPOR 141.
513 EPO Decision T 248/85, BICC/Radiation processing, OJ EPO 1986, 261.
514 EPO Decision T 150/82, OJ EPO 1983, 309, EPO Decision T 552/91, Chromanderivates/ MERCK, OJ EPO 1995, 100.
515 EPO Decision T 130/90, Recombinant monoclonal antibody/UNIVERSITY OF TEXAS, EPOR 1996, 46.
516 EPO Decision T 301/87, Alpha-Interferon(Biogene), OJ EPO 1990, 335.
517 EPO Decision T 320/87, Hybrid plants/LUBRIZOL, OJ EPO 1990, 71.
518 "Erweist sich eine eindeutige Kennzeichnung einer Pflanze durch innere oder äußere unmittelbar wahrnehmbare Merkmale als unmöglich oder gänzlich unpraktikabel, so kann die Pflanze durch eindeutig unterscheidbare, zuverlässig feststellbare Parameter ihrer Eigenschaften beschrieben werden. Ist dies nicht möglich, so kann das Erzeugnis durch das Herstellungsverfahren gekennzeichnet werden." Federal Supreme Court of Germany, *Tetrapoide Kamille*, GRUR 1993, 651, 655 = Tetraploid Chamomile, IIC 1994, 580.

a. The scope of product-by-process claims in Europe

Product-by-process claims are considered product claims in Germany. Consequently, their scope of protection extends to the substance independent of its characterization by a process in the claims.[519] The Federal Supreme Court of Germany expressly denied that the scope of a patent on a substance should vary based on its characterization by structure or its process of production.[520] The process serves for the identification of the product. The scope of the product-by-process claim also extends to products that are made by a different process but are similar to the protected product.[521]

The wording of the claim does not necessarily limit the scope of the product-by-process claims. Both wordings "obtainable by" or "obtained by" are possible.[522] Nevertheless, an applicant is free to seek only protection for a precise substance produced by a process that would be indicated by the wording "obtained by."[523] Whereas the formulation "obtainable by" indicates that the process for the production of the protected substance is only meant as an example and not an absolute limitation. A limitation to the product obtained by a specific process only will be necessary if a known substance has characteristics that are caused by the process, like purity, cristallinity and optical or biological activity.[524] This view is also shared by the EPO. Product-by-process claims under the EPC protect products as such, independent of their production process.[525] The scope of a product-by-process claim in the UK is confined to substances made by the defined process.[526]

519 Bundesgerichtshof (Federal Supreme Court) 06.07.1971 Case:OZB 9/70 "Trioxane," IIC 1972, 226, Headnote 4. *Kraßer*, Lehrbuch des Patentrechts, 5th ed., München 2004, 776.

520 Federal Supreme Court of Germany, Trioxan, July 6, 1971, GRUR 1972, 80, 88 = Bundesgerichtshof (Federal Supreme Court) 06.07.1971 Case:OZB 9/70 "Trioxane," IIC 1972, 226.

521 *Schulte*, in: *Schulte* (ed.), Patentgesetz mit EPÜ, 7th ed., Köln et al. 2005, Sec. 34, No. 158.

522 *Meyer-Dulheuer*, Möglichkeiten und Grenzen des product-by-process-Anspruchs, GRUR Int. 1985, 435, 440.

523 Bundesgerichtshof (Federal Supreme Court) 06.07.1971 Case:OZB 9/70 "Trioxane," IIC 1972, 226, 236.

524 *Meyer-Dulheuer*, Möglichkeiten und Grenzen des product-by-process-Anspruchs, GRUR Int. 1985, 435, 441.

525 EPO Decision G 1/98, Transgenic Plant/Novartis II, OJ 2000, 111, T 19/90, Oncomouse/Harvard, OJ 1990, 476.

526 *House of Lords,* Kirin Amgen Inc. v. Hoechst Marion Russel Ltd. (Erythropoietin)*,* October 21, 2004, [2004] UKHL 46, No. 89. *Welch,* Der Patentstreit um Erythropoietin (EPO), GRUR Int. 2003, 579, 583, *Cornish*, Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights, 4th ed., London 1999, 169.

b. The scope of product-by-process claims in the U.S.

Product-by-process claims have been patentable in the U.S. since the *Ex parte Painter* case in 1891.[527] The scope of product-by-process claims in the U.S. is uncertain, as there are two opposing decisions of the Court of Appeals for the Federal Circuit (CAFC) about the limitation of the scope of protection to a simple process claim.[528] Initially, the characterizing process was construed as limiting the scope of a product-by-process claim. In 1991, the *Scripps v. Genentech*[529] decision, which in the following will be called *Scripps,* then stated that substance claims were not to be limited by the process of the production of that substance. Nevertheless, the CAFC decided in *Atlantic v. Faytex,*[530] which in the following will be called *Atlantic*, that process characteristics limit the scope of the claim to substances made by the process of the product-by-process claim. Hence, identical substances produced by a different process were not considered infringing. These contradicting judgements cause a considerable legal uncertainty regarding the scope of product-by-process-claims in the U.S.[531]

aa. The Scripps decision

In *Scripps*, the Court held that product-by-process claims are not limited to products prepared by the process set forth in the claim.[532] Subject of the *Scripps* litigation is U.S. Reissue Patent No. 32,011 on a complex human protein called Factor VIII:C that is essential to the clotting of blood. The inventors had succeeded in isolating Factor VIII:C by a chromatographic absorption using monoclonal antibodies followed by purification. The claims in suit are product-by-process claims. Claim 13 is representative of these claims: What is claimed is a highly purified and concentrated human or porcine VIII:C prepared in accordance with the method of claim 1.[533]

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527 1891, C.D. 200, 57 (Commissioner of Patents 1891), in: *Avery& Mayer*, Das US-Patent, 3rd ed., Köln et al. 2003, 94.

528 *Avery&Mayer,* Das US-Patent, 3rd ed., Köln et al. 2003, 99. *Tian*, Product-by-process claims, IIC 1998, 139, 142.

529 *Scripps Clinic&Research Foundation v. Genentech, Inc*., 927 F.2d 1565, 18 USPY 2d 1001 (Fed. Cir. 1991).

530 *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F. 2d 834, 23 USPQ 2d 1481 (Fed. Cir. 1992). German translation in GRUR Int. 1997, 563 mit Anmerkung *Groebl*.

531 *Groebl*, Anmerkung zur Entscheidung product-by-process-Ansprüche, GRUR Int. 1997, 563, 569: "Hauptangriffspunkt ist jedoch, daß sich die erkennenden Richter einfach über die sie eigentlich bindende Entscheidung Scripps Clinic&Research Foundation v. Genentech. Ind. hinweggesetzt hätten."

532 *Scripps Clinic&Research Foundation v. Genentech, Inc*., 927 F. 2d 1565, 1567, No. 32 (Fed. Cir. 1991).

533 Claim 1 of U.S. Reissue Patent No. 32,04: "An improved method of preparing Factor VIII procoagulant activity protein comprising the steps of (a) adsorbing a VIII:C/VIII:RP complex from a plasma or commercial concentrate source onto particles bound to a monoclonal antibody specific to VIII:RP, (b) eluting the VIII:C, (c) adsorbing the VIII:C obtained in step (b) in another adsorption to concen-

Scripps charged that Genentech's recombinantly produced Factor VIII:C infringed the product-by-process claims. The district court held that the product-by-process claims would not be infringed unless the same process were practised. The Court of Appeals referred to diverging precedent in the context of patent prosecution and pointed out that claims must be construed in the same way for validity and for infringement. Thus, the correct reading of product-by-process claims is that they are not limited to a product prepared by the process set forth in the claims.[534]

bb. The Atlantic decision

In *Atlantic,* the CAFC held that process terms in product-by-process claims served as limitations in determining infringement.[535] The subject of the *Atlantic* litigation was a shock-absorbing foamed plastic innersole protected by U.S. Patent No. 4,674,204 consisting of process claims and a product-by-process claim held by Atlantic Thermoplastics. Faytex did not produce but distributed two different kinds of innersoles. Therefore only the product-by-process claim was considered relevant. Claim 24 was directed to "the molded innersole produced by the method of claim 1."[536] One type of innersole had been produced according to the *Atlantic* process, whose distribution by Faytex was considered infringing, whereas the other type had been produced by a different process. Questioned was only infringement of the product-by-process claim by distribution of innersoles produced by a different process that the district court regarded as non-infringing. The Court of Appeals confirmed that decision.[537]

In the light of Supreme Court case law and the history of product-by-process claims, infringement analysis proceeds with reference to the patent claims. Consequently, process terms in product-by-process claims served as limitations in determining infringement.

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trate and further purify same, (d) eluting the adsorbed VIII:C, and (e) recovering highly purified and concentrated VIII:C."

534 *Scripps Clinic&Research Foundation v. Genentech, Inc*., 927 F.2d 1565, 1583 (Fed. Cir. 1991).

535 *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F. 2D 834.

536 What is claimed in Claim 1 is: "In a method of manufacturing a shock-absorbing, molded innersole for insertion in footwear, which method comprises:
(a) introducing an expandable polyurethane into a mold; and
(b) recovering from the mold an innersole which comprises a contoured heel and arch section composed of a substantially open-celled polyurethane foam material, the improvement which comprises: (i) placing an elastomeric insert material into the mold, the insert material having greater shock-absorbing properties and being less resilient than the molded, open-celled polyurethane foam material, and the insert material having sufficient surface tack to remain in the placed position in the mold on the introduction of the expandable polyurethane material so as to permit the expandable polyurethane material to expand about the insert material without displacement of the insert material; and (ii) recovering a molded innersole with the insert material having a tacky surface forming a part of the exposed bottom surface of the recovered innersole."

537 *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F. 2D 834, 847.

Furthermore, the court held that product-by-process claims were to be treated differently for "administrative patentability determinations than for judicial infringement determinations."[538]

Chief Judge *Nies* requested that the *Atlantic* decision be reheard en banc, which was rejected by the majority of Circuit Judges. Circuit Judges *Lourie*, *Newman*, *Nies* and *Rich* dissented from the denial of rehearing en banc, basically reasoning that the *Atlantic* panel had gone on "an unnecessary excursion beyond the needs of this case, to review, as it sees it, the entire field of product-by-process claims and lay down a universal rule applicable to all such claims."[539]

The very instructive dissenting opinion of Circuit Judge *Newman* referred to the enormous R&D expenditures necessary for producing a new drug, which might be discouraged by the rule laid down in *Atlantic,* and moreover pointed out some interesting differences between the *Scripps* and the *Atlantic* case.[540] *Scripps* dealt with "true" product-by-process claims, in that their patentability and validity depended on the novelty and unobviousness of the *product*, and they were correctly interpreted as product claims, independent of how the product was made.[541] The complex blood clotting protein of the *Scripps* claims was of such structural complexity that the product could not be defined in independent structural terms. For lack of sufficient possibilities of analyzing such a product, the Rule of Necessity justified the grant of a product patent for a product-by-process claim.[542] Otherwise complex chemical or biological products would be *de facto* excluded from patentability.

In contrast to *Scripps,* the *Atlantic* claims were "product of the process" claims, such as may be allowed when the process is found patentable.[543] During prosecution a restriction requirement by the examiner forced Atlantic to separate his product claims into a divisional patent application. The process claims and the "product of the process" claims were grouped together and were issued in one patent, based entirely on examination of the process.[544] *Newman* points out that policy aspects cutting "to the heart of the patent system, raising questions of innovation incentive and fairness" lead to the *Atlantic* judgement, according to which it is contrary to the public interest to permit an inventor

538 *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F. 2D 834, 847.

539 Circuit Judge *Rich*, *Atlantic Thermoplastics Co. v. Faytex Corp. – suggestion for rehearing en banc declined,* 974 Federal Reporter 2d 1279, 1280 (1992).

540 *Atlantic Thermoplastics Co. v. Faytex Corp. – suggestion for rehearing en banc declined,* 974 Federal Reporter 2d 1279 (1992).

541 *Atlantic Thermoplastics Co. v. Faytex Corp. – suggestion for rehearing en banc declined,* 974 Federal Reporter 2d 1279, 1282 (1992).

542 *Atlantic Thermoplastics Co. v. Faytex Corp. – suggestion for rehearing en banc declined,* 974 Federal Reporter 2d 1279, 1282 (1992).

543 *Atlantic Thermoplastics Co. v. Faytex Corp. – suggestion for rehearing en banc declined,* 974 Federal Reporter 2d 1279, 1282 (1992).

544 Counsel for Atlantic argued to the PTO: Such product-by-process claims are process claims with patentable process limitations and would not conflict with any divisional claims containing patentable, structural or compositional limitations. The product claims were rejected on reexamination. *Atlantic Thermoplastics Co. v. Faytex Corp. – suggestion for rehearing en banc declined,* 974 Federal Reporter 2d 1279, 1282 s. (1992).

to have useful patent protection for a new product when the product can not be distinguished in the claim other than by reference to how it was made.[545] According to *Newman* there are three different types of claims that involve product and process terms, which have been treated separately by courts according to their nature.[546] A new and unobvious product that cannot be independently defined constitutes a product-by-process claim, which would be the case with the *Scripps* claims. An old or obvious product produced by a new process constitutes a product by the process claim, which is true for the *Atlantic* claims. The third case is products that are new and unobvious, but are limited by the process. "The Atlantic panel has simply lumped all of these classes and claims and inventions into a one-rule-fits-all law, in a distressingly superficial treatment,"[547] *Newman* writes.

Neither the CAFC case law nor the precedent Supreme Court judgements, nor the regional circuit decisions, support the *Atlantic* thesis that all claims that contain process terms must be read in a single way.[548] The interpretation of claims depends on the particular invention, in light of the specification and prosecution history and prior art for the specific case.[549] Consequently, a novel and unobvious product that is clearly distinguishable from the state of the art must not be limited by process parameters in the product claim.[550] According to the *Atlantic* case, an identical product may not infringe if it has been produced by a different process, meaning that enforceability of a product-by-process claim depends on the process by which the product is made even though the product itself was new and unobvious and distinguishable from the state of the art, and therefore patentable. This seems to break with the general rule of the Federal Circuit that the same law of claim interpretation is applicable to patentability, validity, and infringement.[551]

Circuit Judge *Lourie* also dissented from the court's denial of rehearing en banc the *Atlantic* case. He cited the inventor's own statement that his claim was limited to the process and that the accused infringer did not use that process. Secondly, he referred to the saying that "hard cases make bad law," and added, "and so do cases not limited to their

545 *Newman* further points out that this view is surely not an implementation of 35 U.S.C. 101 and claims that such a policy change aimed at complex chemical and biological inventions, depriving them of useful product patent protection, should be done *en banc*. *Atlantic Thermoplastics Co. v. Faytex Corp. – suggestion for rehearing en banc declined,* 974 Federal Reporter 2d 1279, 1283 s. (1992).

546 *Atlantic Thermoplastics Co. v. Faytex Corp. – suggestion for rehearing en banc declined,* 974 Federal Reporter 2d 1279, 1284 (1992).

547 *Atlantic Thermoplastics Co. v. Faytex Corp. – suggestion for rehearing en banc declined,* 974 Federal Reporter 2d 1279, 1284 (1992).

548 "Indeed, in the Atlantic opinion (...) one observes a collection of dicta lifted out of context, until a new structure has been built on the most tenuous of supports." *Atlantic Thermoplastics Co. v. Faytex Corp. – suggextion for rehearing en banc declined,* 974 Federal Reporter 2d 1279, 1297 (1992).

549 *Atlantic Thermoplastics Co. v. Faytex Corp. – suggestion for rehearing en banc declined,* 974 Federal Reporter 2d 1279, 1296 (1992).

550 *Atlantic Thermoplastics Co. v. Faytex Corp. – suggestion for rehearing en banc declined,* 974 Federal Reporter 2d 1279, 1284 (1992).

551 *Atlantic Thermoplastics Co. v. Faytex Corp. – suggestion for rehearing en banc declined,* 974 Federal Reporter 2d 1279, 1297 (1992).

own facts."[552] He concluded that the broad formulation of the panel that "process terms in product-by-process claims serve as limitations in determining infringement" could have been decided more simply. Though *Scripps* should not be redecided, he wrote, an *en banc* decision would be necessary for the purpose of limiting the *Atlantic* decision to its facts.

In spite of the above-mentioned arguments, the *Atlantic* ruling was twice rejected for an en banc rehearing. Circuit Judge *Rader* explained the rejection, stating that the uniformity of the CAFC's decision was maintained, because *Atlantic* followed with regard to product-by-process claims the uniform rules that claim language identifies the invention and delimits patent protection.[553] Moreover, *Rader* added that attempting to limit the Supreme Court's rule that "nothing can be held to infringe the patent which is not made by that process"[554] to old products would apply aspects of patentability to infringement matters.[555] The labelling as a "true" product-by-process claim has not yet been performed by any court. Finally, the Patent Act would leave the inventor of a product-by-process claim the possibility of reissuance of the claims in broader terms under 35 U.S.C. 251.[556] *Rader* concludes that "if courts did not enforce the only limitations in product-by-process claims, then every patent applicant would have an incentive to claim in process, rather than structural, terms because product-by-process claims would have few, if any, limitations."[557]

552 *Atlantic Thermoplastics Co. v. Faytex Corp. – suggestion for rehearing en banc declined,* 974 Federal Reporter 2d 1279, 1299 (1992).

553 *Atlantic Thermoplastics Co. v. Faytex Corp.*, 974 F. 2D 1299, 1300 (Fed. Cir. 1992).

554 *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293, 310, 4 S.Ct. 455, 464, 28 L.Ed. 433 (1884).

555 *Atlantic Thermoplastics Co. v. Faytex Corp.*, 974 F. 2D 1299, 1303 (Fed. Cir. 1992).

556 "Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue." 35 USC 251. The Omission of product claims was considered a valid basis for reissuance of the Scripps patent for ultrapurification of a blood-clotting factor using monoclonal antibodies; *Scripps Clinic&Research Foundation v. Genentech, Inc.*, 927 F. 2D 1565, 1566, No. 12 (Fed. Cir. 1991).

557 *Atlantic Thermoplastics Co. v. Faytex Corp.*, 974 F. 2D 1299, 1303 (Fed. Cir. 1992).

III. Food as the product directly obtained by a patented process

Food can also be protected under Art. 64(2) EPC, which extends the protection of a process patent to the product directly obtained by that process. Similarly, Art. 28(1(b) TRIPs Sec. 9(3) of the German Patent Act encompass the product directly obtained by a process under the scope of a patent on a process. The patent owner can forbid the unauthorized sale and use of the product directly obtained by a patented process in the same way as for a product patent.[558]

Article 64(2) EPC applies to all processes whose starting materials differ from the end-product.[559] In that way a process for the production of a food also protects the food directly obtained by that process, e.g. a patent on a process for the production of a transgenic plant extends to the transgenic plant resulting therefrom. The question arises in how far processing of the product might influence this extension of patent protection. Does a patent on the production of herbicide-resistant soy bean comprise the oil processed from such soy beans?

This question will be investigated in the following section, beginning with the difference from product-by-process claims, followed by a theoretical analysis of the legal situation in Europe, and concluding with a case study on three food-related patents which differ in one important aspect: the presence of the essential parameter in the processed food product.

1. Comparison with the protection by product-by-process claims

The protection of the product directly obtained by a process is different from the product-by-process claim explained above. The product-by-process claim, under the German Patent Act, also protects products that are produced in a different way than the process described in the claim.[560] Condition for the grant of a product-by-process claim is a new and inventive product. Consequently, the subject of the product-by-process invention is a patentable product.

The protection of a product directly obtained by a process under Art. 64(2) EPC is not a product claim, but a mere process claim.[561] Thus, the product directly obtained by the process neither has to be new, nor does it have to be based on an inventive step. Decisive for patentability is alone novelty and inventive step of the process.[562]

558 *Schennen&Stauder* in: *Singer&Stauder* (eds.) European Patent Convention – A Commentary, 3rd ed., Cologne 2003, Art. 64, No. 14.
559 *Jestaedt* in *Benkard* (ed.), Europäisches Patentübereinkommen, München 2002, Art. 64, No. 22.
560 See Part III Section C Subsection II.
561 *Jestaedt* in *Benkard* (ed.), Europäisches Patentübereinkommen, München 2002, Art. 64, No. 20.
562 *Jestaedt* in *Benkard* (ed.), Europäisches Patentübereinkommen, München 2002, Art. 64, No. 21.

Consequently, the subject of the patent with respect to the product directly obtained by a process is a patentable process.

2. The product directly obtained by a process

Since the extension of protection of process claims to the product directly obtained therefrom, there have been two opposing views on the interpretation of the attribute "directly obtained," briefly called the chronological approach and the parameter approach.[563] A uniform European interpretation has not yet been established.[564] Therefore, the next chapter is dedicated to the question of which interpretation is applicable to food patents, using literal, historical, systematic, and teleological interpretation. The following example will serve to explain both views:

Starting material + steps A, B, and C -----> intermediate product X

Intermediate product X + step D -----> end-product Y

Steps A, B, and C are protected under a process claim for processing a certain starting material into intermediate product X. Intermediate product X is the product resulting from step C. A further step D, which is not described under the process claim, leads to the end-product Y. In the food context, with focus on plant biotechnology, a process for the production of a transgenic soybean plant X comprises steps A, B, and C. The transformation of the seed obtained from the transgenic soybean plant into an oil represents step D, which is not comprised in the process claim. The oil obtained from the transgenic plant represents the end-product D.

3. Interpretation of "directly obtained"

a. Narrow interpretation: chronological approach

A rather narrow time-based observation is performed under the chronological interpretation in order to determine whether a product is directly obtained by a process. First, the steps of the process as described in the claim are analyzed. Only if the product in question is obtained as the result of the last step mentioned in the process claim does the scope of the patent on the process extend to the product.[565]

563 *Reimer*, Patentgesetz und Gebrauchsmustergesetz, 3 ed., München 1968, No. 63 c to Sec. 6 PatG.
564 *Jestaedt* in *Benkard* (ed.), Europäisches Patentübereinkommen, München 2002, Art. 64, 25.

Thus, an end-product that was transformed from an intermediate product by steps that are not mentioned in the process claim is not protected under that process claim.

The chronological interpretation seems to be strictly formal.[566] There is no evaluation of whether the further steps needed to transform the intermediate product into the end-product are essential. Even the smallest step of transformation of the intermediate product would suffice to not render the end-product under the scope of the process claim. In the above-mentioned soybean example, X would only fall within the scope of the process claim under Art. 64(2) EPC. Y would not fall within the process claim under Art. 64(2) EPC.

b. Broad interpretation: parameter approach

A very different approach from the chronological interpretation is the parameter theory.[567] This theory is based on the evaluation of the steps that are involved in the transformation of X into Y. If step C is not regarded as essential, both X and Y fall within the process claim, though the transformation of X into Y requires a further step D not described in the process claim. The evaluation of D as essential depends on whether the parameter of the intermediate product X, which is typical for the patented process comprising the steps A, B, and C, is still present in the end-product Y. Usually this parameter justifies the grant of a patent on the process. According to the parameter theory, the characteristic parameters of the intermediary product X and the end-product Y are compared. Only if the decisive characteristic of the intermediate product is still present in the end-product does the end-product fall within the process claim. Then, it does not matter which further steps must be performed to obtain the end-product Y.

In the above-mentioned example, the oil obtained from the transgenic soybean plant would still be covered by the process patent on the production of the transgenic plant under Art. 64(2) EPC as long as the special characteristic of the transgenic plant were present in the oil.

565 *Krieger,* in: *Beier, Haertel&Schricker* (eds.), Europäisches Gemeinschaftsübereinkommen, Münchner Gemeinschaftskommentar, Köln 1991, Art. 64, *Bruchhausen*, Sind Endprodukte unmittelbare Verfahrenserzeugnisse eines auf die Herstellung eines Zwischenprodukts gerichteten Verfahrens?, GRUR 1979, 743.

566 *Jestaedt* in *Benkard* (ed.), Europäisches Patentübereinkommen, München 2002, Art. 64, No. 24.

567 *Beier&Ohly*, Was heißt "unmittelbares Verfahrenserzeugnis"? - Ein Beitrag zur Auslegung des Art. 64(2) EPÜ, GRUR Int. 1996, 973, *Benjamini*, Patent Infringement in the European Community, München 1993, 162 ss., *Hahn*, Der Schutz von Erzeugnissen patentierter Verfahren, München 1968, 94 ss., *von Pechmann*, Der Schutz für das unmittelbare Verfahrenserzeugnis und der mittelbare Stoffschutz, GRUR 1977, 377, 379, *Jestaedt* in *Benkard* (ed.), Europäisches Patentübereinkommen, München 2002, Art. 64, No. 25 ss, *Pioneer Electronics Capital Inc. v. Warner Music Manufacturing Europe GmbH*, decision of the UK High Court of 24.01.1995, see also *Russell&Hurdle*, What is the Direct Product of a Patented Process?, EIPR 1995, 249 ss.

4. Interpretation applicable to food-related inventions

a. Literal interpretation

The interpretation of the language of Art. 64(2) EPC supports the strict interpretation. The wording "directly obtained" of Art. 64(2) EPC indicates the application of the chronological approach.

Generally, directly has the meaning of without intermediate steps.[568] Consequently, an end-product would not be regarded as directly obtained by the patented process for the intermediate product whenever a further step is required. This result would be independent of the question of the technical effect of this further step on the end-product.

On the other hand, this strict way of interpreting "directly obtained" does not rule out the parameter approach, as the term "directly" does not necessarily relate to a certain period of time. "Directly" can also mean that the further step is of no essential importance to the end-product.[569] Thus the language of Art. 64(2) EPC does not clearly point towards one interpretation of "directly obtained."

b. Legislative history of Art. 64(2) EPC

The historical genesis of Art. 64(2) EPC supports the wide interpretation of the parameter approach.[570] Article 64(2) EPC was drafted according to Art. 29c Community Patent Convention, which has never entered into force.[571] The first President of the European Patent Office *van Benthem* voted during the discussions on the Community Patent Convention clearly in favour of the parameter approach:

> "There seems to be a common understanding that the words "directly obtained" or "directly resulting" do not have to be read in the literal sense of the words, and that to provide reasonable protection for the owner of a patented process, the protection conferred on him should not always be restricted to the first sale or use of the infringing products. When the product embodying the patented process is subjected to other processes before the final product is made, the use or sale of the final product may infringe the patent for the process. According to German law, this is so if the value or

568 The Oxford Advanced Learner's Dictionary defines "directly" as in a direct line or immediately. Oxford Advanced Learner's Dictionary, Oxford 1989.

569 *Beier&Ohly*, Was heißt "unmittelbares Verfahrenserzeugnis"? - Ein Beitrag zur Auslegung des Art. 64(2) EPÜ, GRUR Int. 1996, 973, 983.

570 *Beier&Ohly*, Was heißt "unmittelbares Verfahrenserzeugnis"? - Ein Beitrag zur Auslegung des Art. 64(2) EPÜ, GRUR Int. 1996, 973, 983.

571 The Community Patent Convention intending to create a unitary Community patent title was signed on December 15, 1975 in Luxembourg followed by the agreement relating to the Community patent including a protocol on the settlement of litigation concerning the infringement and validity of Community patents of December 15, 1989. However, these agreements never entered into force because of lacking ratification by its Member Countries. Bericht der deutschen Delegation über die Luxemburger Konferenz über das Gemeinschaftspatent, GRUR Int. 1976, 187.

characteristics of the final product are largely determined by the use of the patented process; and in French law the product must be immediately dependent on the use of the process."[572]

Article 64(2) EPC was proposed by the Swiss delegation and was accepted by the majority of the delegates at the Diplomatic Conference held in Munich in 1973 to agree on the European Patent Convention.[573] Systematically, this provision regarding the scope of protection of a European Patent would not belong to the EPC. The EPC intended to create uniform patent prosecution and left infringement matters to its Members.[574] Nevertheless, the Swiss delegation argued that only this provision could ensure protection of products which could not be described other than by their process of production. Moreover, imports from countries where no patents existed could be prohibited by that provision. This argument has already led to the introduction of a similar provision in the Amending Act of 1981 of the German Patent Act.[575]

The meaning of the term "directly obtained" was not discussed in particular.[576] The Diplomatic Conference has not intended to create new approaches regarding the term "directly obtained" by deviating from the jurisprudence of its Members. Therefore, it can be concluded that the approaches of its Members were applicable.[577] At that time, most European countries, including Switzerland, Austria, the United Kingdom, the Netherlands, Portugal, and partly also Germany[578] had applied the parameter approach.[579] Moreover, the Scandinavian patent systems did not limit the product protection by a patented process to such products that were directly obtained by the patented process.[580] Thus, it can be concluded that the Diplomatic Conference intended the wide interpretation of the term "directly obtained."

572 *Van Benthem*, The Rights Conferred by a Community Patent Under the Community Patent Conventions, in: *Pennington* (ed.), European Patents at the Crossroads, London 1976, 121, 126.

573 Diplomatic Conference Doc. M/67/I (1973), Doc. M/PR (1973), 200.

574 Art. 1 EPC clearly limits the EPC to patent prosecution: A system of law, common to the Contracting States, for the grant of patents for invention is hereby established.

575 See Part I, section A, subsection II.

576 *Beier&Ohly*, Was heißt "unmittelbares Verfahrenserzeugnis"? - Ein Beitrag zur Auslegung des Art. 64(2) EPÜ, GRUR Int. 1996, 973, 975.

577 *Beier&Ohly*, Was heißt "unmittelbares Verfahrenserzeugnis"? - Ein Beitrag zur Auslegung des Art. 64(2) EPÜ, GRUR Int. 1996, 973, 983.

578 The most prominent commentator on the German Patent Act, *Benkard,* still regards the question of how to interpret "directly obtained" as unsolved: "Es ist streitig, ob und gegebenenfalls wann in (Fällen der Weiterbearbeitung eines zunächst geschaffenen Verfahrenserzeugnisses) § 9 S. 2 Nr. 3 eingreift." *Scharen* in *Benkard* (ed.), Patentgesetz Gebrauchsmustergesetz, 10th ed., München 2006, § 9, No. 57.

579 *Beier&Ohly*, Was heißt "unmittelbares Verfahrenserzeugnis"? - Ein Beitrag zur Auslegung des Art. 64(2) EPÜ, GRUR Int. 1996, 973, 976 ss.

580 *Beier&Ohly*, Was heißt "unmittelbares Verfahrenserzeugnis"? - Ein Beitrag zur Auslegung des Art. 64(2) EPÜ, GRUR Int. 1996, 973, 982.

c. Systematic interpretation

The systematic analysis of Art. 64(2) EPC seems to confirm this conclusion. The EPC creates "a system of law, common to the Contracting States, for the grant of patents."[581] In addition to the provisions on the grant of a patent, provisions on the effects of a patent have been included into the EPC in order to improve the protection delivered by a European patent.[582] Clearly, the intention to improve the protection delivered by a process patent supports the broad interpretation of "directly obtained" delivered by the parameter approach.

In contrast, the narrow interpretation would weaken the protection delivered by a patented process. But a narrow protection was not intended. Thus, from a systematic point of view, the wide interpretation seems to be preferred. On the other hand, Art. 64(2) EPC is a provision on the scope of a patent. Thus, Art. 64(2) EPC has to be read in context with Art. 69(1) EPC, according to which the extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims.[583] In the light of Art. 69(1) EPC, end-products that involve steps that are neither mentioned in the claim nor in the description should not be considered as directly obtained by the patented process for an intermediate product.

d. Teleological interpretation

Finally, the teleological method of interpretation supports the broad interpretation of "directly obtained." Based on the *rationale* of a provision, the teleological interpretation evaluates the contradicting interests in order to find an adequate solution.[584] The *rationale* behind Art. 64(2) EPC is to grant the patentee of a process patent effective protection without inappropriately limiting the public's freedom of action.[585] The inventor is granted a patent as a merit for the contribution of his invention to the state of the art. The technical contribution of an invention lies within its essential parameters that render the invention new and inventive over the state of the art. Therefore, it seems justified to include all those products obtained from the patented process that are characterized by these parameters. It should not matter how many steps might be involved in order to obtain an end-product. Consequently, the teleological interpretation results in a broad interpretation of the attribute "directly obtained."

581 Art. 1 EPC.

582 *Haertel*, Die Münchener Konferenz und ihre wesentlichen Ergebnisse, GRUR Int. 1974, 48, 50, *Schennen&Stauder* in: *Singer&Stauder* (eds.) European Patent Convention – A Commentary, 3rd ed., Cologne 2003, Art. 64, No. 15.

583 *Jestaedt* in *Benkard* (ed.), Europäisches Patentübereinkommen, München 2002, Art. 64, No. 27.

584 *Beier&Ohly*, Was heißt "unmittelbares Verfahrenserzeugnis"? - Ein Beitrag zur Auslegung des Art. 64(2) EPÜ, GRUR Int. 1996, 973, 983.

585 *Schennen&Stauder* in: *Singer&Stauder* (eds.) European Patent Convention – A Commentary, 3rd ed., Cologne 2003, Art. 64, No. 15.

e. Parameter approach appropriate

Based on historical and teleological interpretation, the parameter approach seems appropriate for the interpretation of Art. 64(2) EPC. The literal and the systematic interpretation do not expressly contradict or support the parameter approach.

5. Burden of proof with regard to the product directly obtained by a process

The effectiveness of the protection by Art. 64(2) EPC largely depends on the question of the burden of proof. Generally, the burden of proof lies with the person who claims a certain fact.[586] The patentee of a patented process claims that the alleged infringer has used the patented process to produce the product in question. Thus, the burden of proof lies with the patentee.[587] The burden of proof is reversed under Sec. 139(3) PatG[588] only when the product obtained by the patented process is new.[589] According to that provision, there is a presumption that a product put on the market by a third party has been manufactured according to the protected process. It is then up to the third party to refute this presumption.[590]

6. Biological inventions

The question of whether biological products, e.g. seeds derived of a transgenic plant, are considered to be products directly obtained by a patented process for the production of such a transgenic plant is solved by the Biopatent Directive.[591] Art. 8(2) states in this respect:

586 *Heinrichs* in *Palandt*, 65. ed., München, 2006, Vorbemerkung zu § 249, No. 162. "Der Geschädigte hat die Beweislast für die objektiven und subjektiven Voraussetzungen des Schadensersatzanspruchs."

587 *Scharen* in *Benkard* (ed.), Patentgesetz Gebrauchsmustergesetz, 10th ed., München 2006, § 9, No. 57, *Jestaedt* in *Benkard* (ed.), Europäisches Patentübereinkommen, München 2002, Art. 64, No. 35.

588 Sec. 139(3) PatG: "Ist Gegenstand des Patents ein Verfahren zur Herstellung eines neuen Erzeugnisses, so gilt bis zum Beweis des Gegenteils das gleiche Erzeugnis, das von einem anderen hergestellt worden ist, als nach dem patentierten Verfahren hergestellt." = A new product obtained by a patented process is considered as produced by a patented process unless the opposite is proved.

589 Bundesgerichtshof, Alkylendiamine II, BGHZ 67, 38, 42 ss.

590 The same is provided in Art. 35 of the Community Patent Convention, Commission of the European Communities, Proposal for Council Regulation on the Community patent, Doc. COM(2000) 412, 22.

591 Contra the protection of seeds as products directly obtained by the process of production: *Hesse*, GRUR 1969, 644, 659; Pro protection of seeds as products directly obtained by the process of production: *Heydt*, GRUR 1969, 674, 676, *Moufang* in: *Beier, Haertel&Schricker* (eds.), Europäisches Gemeinschaftsübereinkommen, Münchner Gemeinschaftskommentar, Köln 1991, Art. 53, No. 123 ss.

> "The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics."

Basically, this clause embodies the parameter approach when defining that only biological material "possessing those same characteristics"[592] of the biological material directly obtained by a process for the production of biological material is falling under the scope of the patent on that process. The German Patent Act now has clarity on that subject by implementing Art. 8(2) of the Biopatent Directive in Sec. 9a(2) PatG.[593]

7. Case study on food products obtained by a patented process

Three examples of food-related patents are analyzed regarding the scope of protection provided by Art. 64(2) EPC. Two have become rather prominent at the EPO, each causing a press release on the official website of the EPO. Though both being granted plant patents held by the world leader in plant biotechnology Monsanto,[594] they differ in one important aspect regarding the protection for a product directly obtained by a process. EP 445 929, with the title "Plants," became well known under the synonym "biscuit patent." It covers a product which still shows the essential technical characteristic which justified the patentability of the invention: a protein composition of the grains that allows for soft-milling wheat to be processed into biscuits that are normally produced of hard-milling wheat. EP 546 090 covers a process for the production of herbicide-tolerant plants. The essential technical characteristic of herbicide tolerance is present in the plants obtained by the process, but not in the processed plants. The oil or the meal obtained by these herbicide-resistant plants is essentially equivalent to any other oil or meal. The biscuit patent represents the class of output traits. The patent on herbicide-resistant plants is a typical example of an agronomic input trait. Finally, EP 270 615 constitutes the third class dealing with basic technology independent from agronomic or qualitative traits. It is directed at the genetic transformation of the plant of the *Brassica* species, including oilseed rape as its most important representative. Thus the most important fields of plant biotechnology as described in part II.A.I are mirrored in the following case study on the relevance of the protection of the product directly obtained by a process for processed food.

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592 Art. 8(2) Biopatent Directive.

593 §9a(2) PatG: "Betrifft das Patent ein Verfahren, das es ermöglicht, biologisches Material zu gewinnen, das auf Grund einer Erfindung mit bestimmten Eigenschaften ausgestattet ist, so erstrecken sich die Wirkungen von §9 auf das mit diesem Verfahren unmittelbar gewonnene biologische Material und jedes andere mit denselben Eigenschaften ausgestattete biologische Material, das durch generative oder vegetative Vermehrung in gleicher oder abweichender Form aus dem unmittelbar gewonnenen Material gewonnen wird."

594 In addition to Monsanto's seeds and traits business, Monsanto manufactures the world's best-selling herbicide, Roundup®. Available at www.monsanto.com.

a. The biscuit patent – EP 445 929

aa. Background

The biscuit patent aims to protect an invention in the field of wheat breeding. It was originally applied for by one of the globally leading food companies, Unilever PLC and Unilever NV in 1991, going back to the priority date of February 19, 1990. During prosecution the patent application was assigned to Monsanto Technology LLC. The inventor is UK national *Peter Payne*. Its grant was published in Europe on May 21, 2003. In the U.S., an essentially identical patent was granted.[595] The biscuit patent has been opposed by five opponents and has been the focus of public interest in patent law during its opposition.[596]

The biscuit patent was transferred to Société RAGT 2N, seated in Rodez, France from Monsanto Technology LLC on July 28, 2004, as Monsanto sold all its European seed activities in the wheat business to Société RAGT 2N. Immediately after transferral, the new patent proprietor, by statement filed on September 10, 2004, requested that the patent be revoked, leading to the revocation of the patent by the opposition division on September 23, 2006. No appeal was filed against this decision within the time period, rendering the revocation final.

Nevertheless, the question of how far the granted claims of the biscuit patent would have reached is analyzed in the following. Firstly, the claims have not been found invalid by the Board of Appeals, as the patent proprietor revoked the biscuit patent himself. Secondly, the biscuit patent is a good example of a transgenic plant whose essential properties are present in the products made thereof.

bb. The invention of the biscuit patent

The technical teaching underlying the biscuit patent is a soft-milling wheat which produces dough having exceptionally low visco-elasticity. The visco-elasticity of a dough is defined as the balance between extensibility and elasticity. This balance varies significantly between wheat varieties and generally determines the uses of the wheat variety in food production. The ratio of elasticity to extensibility needs to be high for leavened bread, middle for noodles and flat breads and very low for biscuits. The visco-elasticity of a dough is largely influenced by the protein of the endosperm called gluten which occurs from 8% to 15% of the dry weight of wheat flour. High-molecular-weight (HMW) subunits of glutenin are the key components in conferring elasticity and dough-mixing

595 US Patents 5,859,315 and 5,763,741.
596 EPO, Press Release of 27.01.2004, Biscuit Patent.

stability.[597] The inventor backcrossed an Indian landrace called "Nap Hal" which lacks two HMW subunits, into an elite hard-milling wheat germplasm. By a second backcross into a soft-milling wheat a high-performing soft-milling wheat with only two HMW subunits was obtained.

cc. Claims and claim interpretation

The biscuit patent consists of 22 claims comprising all claim categories with 18 product claims, one process claim and 3 use claims. The granted claims are directed at the wheat, the flour and dough obtained from it, and the resulting foodstuff. It is striking that the EPO granted 12 independent product claims, though it is generally recognized within the EPO case law that as a rule there should be not more than one independent claim of each claim category in each case. Nevertheless, unity of the invention under Art. 82 EPC was fulfilled because all the different independent products were linked through a new and inventive common technical concept: the provision of soft-milling wheat which produces dough having exceptionally low visco-elasticity.

Independent claims 1 to 8 each refer to soft-milling wheat with reduced HMW glutenin subunits. Claim 1 claims:

> "Soft-milling wheat with reduced HMW glutenin subunits having an SDS-sedimentation volume, corrected to 11% protein, of not greater than 30ml."[598]

Independent claims 1 to 3 refer to a soft-milling wheat with reduced HMW glutenin subunits having an SDS-sedimentation volume, corrected to 11% protein, of not greater than 30 ml. This means that when being dissolved in water the protein does not form a gel but dissolves more than in usual soft-milling wheat, leading to a low sedimentation value. Independent claim 4 also refers to soft-milling wheat with reduced HMW glutenin subunits, whereas this parameter is measured by a different method.

Independent claims 5 to 8 address the absence or inactivity of the genes that are responsible for high visco-elasticity in wheat, the so-called Glu-D1 locus.Claim 5 is directed to:

597 *MacRitchie & Wrigly*, Journal of Cereal Science, vol. 7, 109-112 (1988).

598 The SDS-sedimentation volume is defined in experiment 2 of EP 445 929: "The SDS(sodium dodecyl sulphate)-sedimentation test, described by Axford, McDermott and Redman, Cereal Chemistry, vol. 56, pages 582-584 (1979), measures the volume of sediment after mixing wholemeal flour in a lactic acid, SDS solution under controlled conditions and then allowing to settle for a specified period. The larger glutenin molecules which are primarily responsible for elasticity and dough strength form a gel and increase the volume of the sediment. The protein molecules imparting extensibility dissolve. The method is used extensively in wheat breeding programmes to select for bread-making quality (large sedimentation volumes) and at wheat mills as a quick test for bread quality prior to accepting a grain load. The SDS volume of the "Galahad-7" (6.0g flour at 15% w/v water content) sample was 22ml (protein content = 14.2%), that of "Galahad" was 51ml (10.2% protein).By contrast the volume of "Apostle", a good bread-quality wheat, was 85ml at about 10.5% protein."

"Soft-milling wheat in which each of the "x" and "y" genes at Glu-D1 is inactive or absent."

Claims 9 to 12 address flour. Claim 9 reads:

"Flour prepared from wheat as claimed in any one of claims 1 to 6."

Dependent claim 9 involves the flour prepared from wheat of independent claims 1 to 6. Independent claim 10 refers to soft wheat flour containing fewer than 3 different HMW glutenin subunits. Dependent Claims 11 and 12 are special embodiments of claims 10.

Dependent claims 13 to 15 finally claim the dough made from the claimed flour, an edible product made from such a dough, and the biscuits prepared from the claimed flour. Claim 13 is directed to:

"Dough or batter prepared from flour as claimed in any one of claims 9 to 12."

Finally, claim 15 claims:

"Biscuits or the like prepared form th flour as claimed in any one of claims 9 to 12."

All in all, the whole food chain of soft-milling wheat with reduced HMW glutenin subunits, from the wheat seed, through the processed wheat and including the final product, biscuits, is claimed.

dd. Impacts for products obtained from the biscuit patent technology

The granted claims protect the wheat, the flour, the dough, and edible products made from the flour. These products are patentable when they differ from the products of the state of the art in a non-obvious way. However, the scope of the process claim is not clear as far as the products obtained by that process are concerned.

Claim 19 of the biscuit patent addresses:

"The production of a strain of wheat, involving the steps of:
a) selecting a hard-milling wheat strain possessing the Glu-D1 double null trait;
b) crossing the hard-milling strain with a soft-milling wheat strain which naturally produces relatively elastic dough;
c) back-crossing the resulting strain into a soft-milling wheat strain;
d) selecting grains exhibiting the Glu-D1 double null trait at half the normal gene dosage, by analysis of embryo-less half grains, the corresponding half-grains being retained for germination;
e) germinating the corresponding half-grain of the selected soft-milling Glu-D1 double null strain, and conducting a further back-crossing and half-grain analysis for the Glu-D1 double null trait;
f) germinating the corresponding half-grains from step (e), and growing and allowing to self-pollinate grains containing the Glu-D1 double null trait in the homozygous state; and
g) determining which of the resulting lines homozygous for the Glu-D1 double null trait are soft."

The scope of claim 19 comprises the wheat obtained therefrom. Regarding the flour obtained from such wheat, further steps which are not expressly described in the process of the claim are involved. According to the chronological approach, the flour would not be protected under the above mentioned claim, as the step of milling the wheat is not claimed. In contrast thereto, the parameter approach would certainly protect the flour obtained from the wheat. This is because the essential parameters that justified patentability are still present in the flour.

For the reasons mentioned above, the parameter approach should be followed in this case. The merits of the biscuit patent lie exactly in the changed baking quality of the wheat. Therefore, the flour characterized by this baking quality should also be protected by the process claim for the production of the wheat.

Finally, it can be concluded that whenever the parameter that led to the patent on a process for the production of a plant is still present in the products obtained from the plant, the parameter theory should be applied. However, in these cases the products themselves will generally be patentable as such. Here, the baking quality was the essential parameter leading to patentability of the invention underlying the biscuit patent. This parameter is present in the flour. Therefore, the flour is patentable as a substance. Thus, the question of whether the flour is protected under Art. 64(2) EPC arises only when the patentee has not drafted a substance claim.

b. Herbicide-tolerant plants – EP 546 090

aa. Background

The patent is titled "Glyphosate Tolerant 5-Enoylpyruvulshikimate-3-Phosphate Synthases," the so-called EPSPS. The applicant is Monsanto, the world's leading transgenic seed company focusing on corn, cotton, and oilseeds. Monsanto also manufactures the world's best-selling herbicide, Roundup®.[599] It is registered in more than 130 countries and approved for weed control in more than 100 crops.[600] The basic ingredient of Roundup is glyphosate. The patent claims the priority of a U.S. patent application of August 31, 1990. It has been opposed by Greenpeace for political reasons, by its competitor, the seed company Syngenta, and by two private persons, *Then* und *Schweiger*. As a result of the opposition an amended set of claims was granted.

bb. Technology underlying the patent

The claims are directed to genes encoding class II EPSPS enzymes. The genes are useful in producing transformed plants which are tolerant to the herbicide glyphosate. The technology underlying the invention is the provision of several novel genes providing more efficient herbicide tolerance than the known Class I EPSPS genes, the so-called Class II EPSPS genes in the presence of glyphosate. Plants transformed with Class II EPSPS genes are also disclosed, as well as a method for selectively controlling weeds in a planted crop field.

599 Available at www.monsanto.com/monsanto/layout/about_us/default.asp.

600 For mor information on Roundup see www.monsanto.com/monsanto/content/products/productivity/roundup/back_history.pdf.

The set of claims that was amended during opposition consists of 33 claims. Four independent and eight dependent claims are directed to the Class II EPSPS genes. Independent Claim 1 as amended during appeal claims:

> "An isolated DNA sequence encoding a Class II EPSPS, said enzyme being an EPSPS enzyme having a Km for phosphoenolpyruvate (PEP) between 1-150 μM and a K(glyphosate)/Km(PEP) ratio between 3-500, which DNA sequence is capable of reacting with antibodies raised against a Class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID NO:3, SEQ IDNO:5."

One independent and five dependent claims address the method of producing genetically transformed plants which are tolerant toward glyphosate herbicide using Class II EPSPS genes. Independent Claim 14 as amended during appeal is directed to:

> "A method of producing genetically transformed plants which are tolerant toward glyphosate herbicide, comprising the steps of:
> a) inserting into the genome of a plant cell a recombinant, double-stranded DNA molecule comprising:
> i) a promoter which functions in plant cells to cause the production of an RNA sequence,
> ii) a structural DNA sequence that causes the production of an RNA sequence which encodes a fusion polypeptide comprising an amino terminal
> chloroplast transit peptide and a Class II EPSPS enzyme capable of reacting with antibodies raised against a Class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID NO:3, SEQ IDNO:5,
> iii) a 3' non-translated DNA sequence which functions in plant cells to cause the addition of a stretch of polyadenyl nucleotides to the 3' end of
> the RNA sequence
> where the promoter is heterologous with respect to the structural
> DNA sequence and adapted to cause sufficient expression of the fusion polypeptide to enhance the glyphosate tolerance of a plant cell transformed with said gene;
> b) obtaining a transformed plant cell; and
> c) regenerating from the transformed plant cell a
> genetically transformed plant which has
> increased tolerance to glyphosate herbicide."

One independent and three dependent claims are directed to a glyphosate-tolerant plant cell. Independent Claim 20 is directed to:

> "A glyphosate tolerant plant cell comprising a DNA molecule of Claims 8, 9, 12 or 13."

One independent and three dependent claims address a glyphosate-tolerant plant. Independent claim 24 as amendend during appeal claims:

> "A glyphosate tolerant plant comprising plant cells of Claim 20."

Finally, a method for selectively controlling weeds in a field containing a crop having glyphosate-tolerant plants is claimed in one independent and five dependent claims. Independent claim 28 adresses:

> "A method for selectively controlling weeds in a field containing a crop having planted crop seeds or plants comprising the steps of:
> a) planting said crop seeds or plants which are glyphosate tolerant as a result of a recombinant double-stranded DNA molecule being inserted into said crop seed or plant, said DNA molecule having::

i) a promoter which functions in plant cells to cause the production of an RNA sequence,
ii) a structural DNA sequence that causes the production of an RNA sequence which encodes a polypeptide which comprises an amino terminal chloroplast transit peptide and a Class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID NO:3, SEQ IDNO:5 ,
iii) a 3' non-translated DNA sequence which functions in plant cells to cause the addition of a stretch of polyadenyl nucleotides to the 3' end of the RNA sequence

where the promoter is heterologous with respect to the structural DNA sequence and adapted to cause sufficient expression of the fusion polypeptide to enhance the glyphosate tolerance of a plant cell transformed with said gene; and
b) applying to said crop and weeds in said field a sufficient amount of glyphosate herbicide to control said weeds without significantly affecting
said crop."

None of the susbstance claims is directed to products derived of the transgenic glyphosate-tolerant plant. Thus crucial for the protection of processed oil as the product obtained by the patented process is the independent method claim 14 directed to the production of genetically transformed glyphosate tolerant plants.

Both the parameter and the chronological approach would render oil obtained from plants transformed according to claim 14 outside the scope of claim 14. Under the chronological approach, the step of oil extraction is not expressly described in claim 14. Thus, an oil obtained from such plants would clearly not fall within claim 14. Under the parameter approach, the essential parameter of the method of claim 14 is the use of genes delivering herbicide tolerance. This parameter is not present in the oil obtained from such plants. Consequently, also under the parameter approach the oil is outside the scope of claim 14.

c. Patent on transformation technology – EP 270 615

Having discussed patents which cover plants with certain useful traits, the third category analyzed with respect to Art. 64(2) EPC comprises patents that cover the technology of generally generating transgenic plants independent of their traits. Here again, the question arises how far the protection delivered by such patents may reach. The so called *Moloney* patent,[601] named after its principal inventor, is directed to a method of transforming plants of a *Brassica* species. It shows that the commercial use of an oil extracted from a plant transformed according to the technical teaching of the *Moloney* patent would not infringe the process claim on the transformation technology under Art. 64(2) EPC. This conclusion is based on the observation that the product in question is not a direct product of the claimed process, as the product would be found materially changed from the transgenic plant. However, production of transgenic oilseed rape falls within the scope of the *Moloney* patent.

601 EP 270 615: Transformation and foreign gene expression in *Brassica* species = US 55,188,958, US 5,463,174, US 5,750,871.

aa. Background

The European *Moloney* patent was revoked after an opposition by 7 parties involved in plant science or the agrochemical business: Novartis, Mogen International N.V., DSM Gist Holding B.V., Groupe Limagrain Holding, Agrigenetics LP, Aventis CropScience S.A. and the Max Planck Society for the Advancement of Science. The fact that so many parties opposed it indicates the importance of the *Moloney* patent. The decision of the Opposition Division was confirmed by the Technical Board of Appeal mainly because the main and auxiliary requests were not in compliance with Art. 123(2) and (3) EPC.[602] Under Art. 123(2) EPC changes ot the patent are only allowed as long as they were originally disclosed in the description. Under Art. 123(3) EPC, claims cannot be changed in a way that would broaden the scope of the patent during opposition. Here, claim 1 was originally filed as follows:

> "Transformed Brassica species cells having a DNA construct resulting from in vitro joining of at least two fragments, wherein said fragments comprise:
>
> (1) a transcription initiation region functional in said Brassica;
>
> (2) a DNA sequence comprising an open reading frame having an initiation codon at its 5' terminus or a sequence complementary to an endogenous transcription product;
>
> (3) a transcription termination region func tional in said Brassica;
>
> (4) a right border of T-DNA;
>
> (5) a structural gene capable of expression in said Brassica providing for selection of transformed Brassica cells; wherein said fragments provide an expression cassette capable of expression in said Brassica cells."

Independent claim 1 was granted as follows:

> "Transgenic Brassica species cells and progeny thereof comprising an expression cassette wherein said cells are characterized as oncogene-free and capable of regeneration to morphologically normal whole plants and wherein said expression cassette comprises in the 5' to 3' direction of transcription
>
> (1) a transcription initiation region functional in said Brassica;
>
> (2) a DNA sequence comprising an open reading frame having an initiation codon at its 5' terminus or a nucleic acid sequence complementary to an endogenous transcription product;
>
> (3) a transcription termination region functional in Brassica species cells; and
>
> (4) a structural gene capable of expression in said Brassica providing for selection of transgenic Brassica species cells;
>
> wherein said expression cassette is capable of altering the phenotype of said Brassica species cells when said cells are grown under conditions whereby said DNA sequence or said nucleic acid sequence is expressed."

602 Decision of the Board of Appeal of 28.07.2000, T289/97 – Brassica/CALGENE, not published, available at http://legal.european-patent-office.org/dg3/pdf/t970289eu1.pdf.

The changes during prosecution to the granted claim 1 were not considered to fulfill Art. 123(2) EPC. During opposition, these changes could not be undone without violating Art. 123(3) EPC leading to the revocation of the patent.

The U.S. and the Canadian patents have not yet been challenged in court. One reason might be that the cost-effective opposition procedure of the EPC is not available in these patent systems and litigation is regarded as consuming tremendous amounts of financial resources. Thus, the U.S. and the Canadian market for transgenic Brassica plants is monopolized by the *Moloney* patent.

bb. The Moloney patent and its scope

The *Moloney* patent claims the priority of a U.S. patent application of May 29, 1986 and has been assigned to Calgene LLC. Calgene LLC is a subsidiary of the U.S.-based seed company Monsanto, which dominates the transgenic seed market.[603] It is titled "Transformation and Foreign Gene Expression in *Brassica* Species." The technical teaching underlying the *Moloney* patent is the Agrobacterium transformation of a cell of a plant of a *Brassica* species. One independent claim and nine claims depending thereon are substance claims directed to transgenic *Brassica* species cells, cell culture of cells, and plants, including a product-by-process claim.

None of the product claims mentions oil or products produced from the claimed transgenic plants or cells. Thus, the substance claims do not cover oil processed from transgenic plants according to the *Moloney* invention. An import of an oil product isolated from a transgenic *Brassica* plant into the EU would not fall within the scope of any of the product claims of the *Moloney* patent. This result is independent of the question of whether a transgenic DNA construct can be analytically determined in the oil, as none of the claims adresses such a DNA construct.

Crucial for the above-raised question on the processed oil are the process claims. One independent method claim with six method claims dependent thereon are directed to a method of transforming *Brassica* species cells to produce morphologically normal whole Brassica plants having an altered phenotype as a result of said transformation. Independent process claim 5 is directed to:

> "A method for transforming Brassica cells to produce Brassica plants, said method comprising:
>
> co-cultivating Brassica cells with disarmed A. tumefaciens comprising a disarmed plasmid containing an insertion sequence resulting from joining in vitro a transcription cassette to at least the right T-DNA border of Ti or Ri plasmid, whereby said-Brassica cells are transformed with said insertion sequence which becomes integrated into the plant cell genome to provide transformed oncogene-free cells;
>
> transferring said transformed oncogene-free cells to callus inducing media containing at least one auxin and selective for cells comprising said marker to produce callus from said transformed cells;

603 Available at www.monsanto.com/monsanto/layout/about_us/timeline/default.asp.

transferring said callus to regeneration media containing less than about 2% sucrose or organic caloric equivalent to produce shoots; and

transferring said shoots to a growing medium to produce plants capable of having an altered phenotype when grown under conditions whereby a DNA sequence in said insertion sequence is expressed."

According to the description, altered oil production is one of the contemplated "altered phenotypes."[604] The oil does not constitute a product directly obtained by the patented process under Art. 64(2) EPC. Both the parameter approach and the chronological approach come to this result. Neither is the transformation method as the essential parameter present in the oil, nor is the step of oil milling mentioned in the process claim. This result seems appropriate, as the *Moloney* patent's contribution to the state of the art is merely a tool independent of an agronomically or physiologically valuable characteristic.

The legal situation in the U.S. seems to be similar to the European situation. According to 35 U.S.C. 271(g),[605] products made by the patented process fall within the process claim unless they are "materially changed by subsequent processes." The products made by the patented process are transformed *Brassica* cells, not an oil extracted from a plant. The question whether the oil product is materially changed is answered by a two-step test. Firstly, "the end product will be deemed to be made by the patented process if it would not be commercially feasible to make the end product other than by using the patented process."[606] The oil produced from plants obtained by the patented process is generally identical to conventional oil which has been obtained from non-transgenic *Brassica* plants. Therefore the oil product will not be regarded as made by the *Moloney* process according to the first step of the test. Regarding the second part of the test for identifying a "material change," the production of oil from a transgenic *Brassica* species would require substantial additional steps. These substantial additional steps are not disclosed in the *Moloney* patent and essentially change the physical and chemical properties of the product produced from the patented process, including extraction of the oil from the harvested seed and its purification and stabilization. However, the product produced by the patented process is limited to transformed cells to produce plants having an altered phenotype. Thus the oil product is physically and chemically completely different than the products produced by the patented process.[607] Therefore, the oil product would not be considered as "made by" the patented process because the patented process

604 EP 270 615 B1, 6 line 20.

605 "Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after -
(1) it is materially changed by subsequent processes; or
(2) it becomes a trivial and nonessential component of another product."

606 Eli Lilly and Co., 82 F .3d at 1575.

was not used directly in the manufacture of the product and because the product is materially changed under both parts of the applicable test. There is at least one known commercial method for making the oil product that does not use the patented process, and the additional processing steps essentially change the physical and chemical properties of the product. In conclusion, the U.S. interpretation of the scope of the *Moloney* patent leads to the same result as the European approach.

8. Summary on Art. 64(2) EPC

Summarizing, Art. 64(2) EPC enhances the scope of method claims, also in the case of food-related inventions. The wide parameter approach leads to reasonable results, as was shown by the biscuit patent in comparison to the patent on herbicide-resistant plants. However, whenever the parameter approach is applicable, independent product claims are generally allowable. Thus, Art. 62(2) EPC provides additional protection only when the patentee has not drafted product claims. In contrast thereto, the chronological approach leads to an inappropriately narrow scope, as it does not acknowledge the essential parameters of the invention. In the case of basic technology, both approaches lead to the same result, which seems appropriate as the essential features of the invention are not present in further processed products.

607 In *Bio-Technology General Corp. v. Genentech, Inc.*the CAFC interpreted "made by" to include a polypeptide expressed by a plasmid where the claim was drawn only to a process for making the plasmid. *Bio-Technology General Corp. v. Genentech, Inc.*, 80 F.3d 1561. This decision can be regarded as distinct from the present case, as the oil product is not a product resulting from the direct expression of a specific sequence used in the claimed method for transforming cells. In *Bayer AG* the CAFC distingushed *Bio-Technology General* by stating that the product could not be made by the patented process because the process was not used in the actual synthesis of the drug product and held that "the process must be used directly in the manufacture of the product." *Bayer AG*, 340 F.3d 1377.

D. Summary

The patentability and the scope of protection of inventions related to the production of agricultural raw materials and the production of processed food vary substantially. There are specific provisions concerning the production of agricultural raw materials, including an exemption to patentability of plant varieties and animal species as well as exemptions from the scope of protection concerning inventions related to the production of plant-derived agricultural raw materials. In contrast to inventions related to the production of agricultural raw materials, there are no specific provisions or exemptions to patentability for inventions relating to the production of processed food. Inventions relating to the production of processed food are treated like inventions in any other industrial sector. The exemptions to patentability and the considerable exceptions from the scope of protection of inventions related to the production of agricultural raw materials lead to a rather weak intellectual property situation, particularly as far as inventions related to the production of plant-derived agricultural raw materials are concerned. The exemption to patentability of plant and animal varieties, the provisions on farm-saved seed and the breeders' exemption in the plant variety protection system and now also in the German patent system are specifically designed for the food sector. These provisions reflect the exceptional position of the production of agricultural raw materials in the German and European patent system. Thus inventions involving the production of agricultural raw materials need to be kept free from restrictions of plant variety protection rights and patents. This is even more astonishing and contradictory as agriculture in Europe is highly industrialized and far from being subsistence farming. All in all, the rather weak protection conferred by the plant variety protection system and the patent system could be a future obstacle to R&D investments in the field of the production of agricultural raw materials.

Final Summary

The food sector has an outstanding position compared to other industrial sectors, as it affects human nutrition. This is reflected in the patent system, where food-related inventions have always had an exceptional position, demonstrated by the exemption to patentability of food in the German Patent Act of 1877, as well as in many developing countries. The TRIPs Agreement has led to the patentability of food, most notably in Brazil, China and India. The economic effects of this change are mirrored in numbers of patent applications, which have almost doubled in Brazil and China since food became patentable. Prospering food sectors, increasing foreign direct investments and declining food prices indicate that patentability of food does not restrict food availability nor negatively influence the food sector. It can thus be concluded that the patentability of food has positive effects on economic welfare.

The food sector of today has faced a rapid technological development, something that is indicated by the amount of plant biotechnology involved in the production of agricultural raw materials and the amount of functional food in the production of processed food. The current protection situation of inventions in the food sector under the European patent and plant variety protection system is rather weak. This weak intellectual property situation is mainly due to wide exemptions under the breeders' exemption and the farm-saved seed provision, which are now implemented in patent law as well as in the plant variety protection system. Though the exemption to patentability of food has been abolished, the food sector thus still has a particular position in the patent system.

Zusammenfassung in deutscher Sprache

Patente in der Nahrungs- und Genussmittelindustrie – Eine Retrospektive unter besonderer Berücksichtigung des TRIPs Übereinkommens

Einleitung

Diese Arbeit untersucht die Rolle und Bedeutung von Patenten in der Nahrungsmittelindustrie als einem der wichtigsten Wirtschaftssektoren. Nahrungs- und Genussmittel (im folgenden abkürzend als Nahrungsmittel bezeichnet) waren in vielen Ländern vom Patentschutz ausgeschlossen, so beispielsweise im deutschen Patentgesetz von 1877. Dieser Patentierungsausschluss wurde erst 90 Jahre später mit der Patentgesetznovelle von 1967 aufgehoben. Der deutsche Gang der Entwicklung hinsichtlich der Patentierbarkeit von Nahrungsmitteln wiederholt sich in vielen Enttwicklungsländern. Das Übereinkommen[608] über handelsbezogene Aspekte der Rechte am Geistigen Eigentum (TRIPs)[609] zwingt nun alle Mitglieder[610] der Welthandelsorganisation[611] (WTO),[612] Patentschutz auch für Nahrungsmittel vorzusehen. Das TRIPs Übereinkommen hat den Nahrungsmittelsektor daher nachhaltig beeinflusst. *Straus*[613] fasst die Auswirkungen für biotechnologische Erfindungen in einer für alle Nahrungsmittelerfindungen gültigen Weise zusammen:

> "Bearing in mind all the specific phases of the food production process it seems clear that under the TRIPs Agreement, WTO Members have to provide patent protection and/or plant variety protection respectively, for all genomic inventions involved in that process at its different stages and their resulting end products including final foods."

608 Vom 15.04.1994, BGBl II 1994, 1730.

609 Agreement on Trade-Related Aspects of Intellectual Property Rights.

610 Ein aktuelles Mitgliederverzeichnis der Welthandelsorganisation ist verfügbar unter www.wto.int/english/thewto_e/whatis_e/tif_e/org6_e.htm.

611 Gesetz zu dem Übereinkommen vom 15. April 1994 zur Errichtung der Welthandelsorganisation vom 30.08.1994, BGBl II 1994, 1438.

612 World Trade Organisation.

613 *Straus*, Genomics and the Food Industry: Outlook from an Intellectual Property Perspective, in: *Vaver&Bently* (eds.), Intellectual Property in the New Millennium – Essays in Honour of William R. Cornish, Cambridge 2004, 124, 134.

Teil I: Die Patentierbarkeit von Nahrungsmitteln im Zeitraum von 1877 bis 2005 in Deutschland im Vergleich zu Brasilien, China und Indien

A. Die Patentierbarkeit von Nahrungsmitteln in Deutschland

I. Der Patentierungsausschluss und seine Abschaffung

Der Patentierungsausschluss für Nahrungsmittel im ersten deutsche Patentgesetz von 1877 lautete wie folgt:

"Patente werden erteilt für neue Erfindungen, welche eine gewerbliche Verwerthung gestatten. Ausgenommen sind: 1. Erfindungen, deren Verwerthung den Gesetzen oder guten Sitten zuwiderlaufen würde; 2. Erfindungen von Nahrungs-, Genuß- und Arzneimitteln, sowie von Stoffen, welche auf chemischen Wegen hergestellt werden, soweit die Erfindugnen nicht ein bestimmtes Verfahren zur Herstellung der Gegenstände betreffen."[614]

Dieser Ausschluss sollte die Volksernährung sicherstellen und die irreführende Werbung mit Patenten unterbinden, wurde jedoch im Schrifttum weitestgehend kritisiert. Die Patentierungsaunahme umfasste nur Nahrungsmittel, nicht aber Verfahren zu deren Herstellung.[615] Folglich konnten Nahrungsmittel, die nach einem patentgeschützten Verfahren hergestellt wurden, ungehindert vom Ausland eingeführt werden, solange dort kein Schutz bestand.[616] Um diesem Misstand der sogenannten illoyalen Importe abzuhelfen, wurde im Patentgesetz von 1891 der Schutz von Verfahrenspatenten auf das unmittelbare Verfahrensprodukt erweitert.[617] Die *Kongorot*[618] Entscheidung des Reichsgerichts verbesserte die Schutzmöglichkeiten für Nahrungsmittel. Danach wurden bekannte chemische Verfahren, die zu einem neuen Produkt führten, patentierbar.[619] Das Europäische Patentübereinkommen von 1973 sah keine Patentierungsausnahme für

614 §1 Patentgesetz vom 25.05.1877, Reichsgesetzblatt 1877, 501.

615 *Kohler*, Handbuch des Deutschen Patentrechts in rechtsvergleichender Darstellung, Mannheim 1900, 176.

616 So sah beispielsweise die Schweiz bis 1907 keinen Patentschutz für chemische Stoffe vor. *Stolz*, Der Aufbruch der Schweiz ins Industriezeitalter, 7, in: *Stolz*, Industrialisierung und Innovation in Großbritannien und der Schweiz, Basel 2004,
verfügbar unter www.wwz.unibas.ch/wige/-lehre/skripten_stolz/Stolz_Vorl2_Schweiz_im_Industriezeitalter.pdf.

617 Bericht der Enquete-Kommisssion zur Revision des Patentgesetzes, Berlin 1887, 16, *Klöppel*, Patentrecht und Gebrauchsmusterrecht, Berlin 1908, 43. §4 PatG: Ist der Patentschutz für ein Verfahren erteilt, so erstreckt sich die Wirkung auch auf die durch das Verfahren unmittelbar hergestellten Erzeugnisse. Patentgesetz, 7.4.1891, Reichsgesetzblatt 1891, 501.

618 Reichsgericht vom 20.03.1889 = 7 Gareissche Sammlung 47.

619 *Kreisler*, Für und wider den Schutz von chemischen Stoffen, Arznei-, Nahrungs- und Genussmitteln, GRUR 1951, 534, 537.

Nahrungsmittel mehr vor. Seine Umsetzung führte folglich zwangsläufig zu einer Abschaffung des Patentierungsausschlusses im deutschen Patentgesetz im Jahr 1967.[620] Zudem hatten sich die dem Patentierungsausschluss zu Grunde liegenden Befürchtungen nicht realisiert. Weder war die Volksernährung durch Patente gefährdet worden, noch konnte der Patentierungsausschluss einen unlauteren Wettbewerb mit Patenten verhindern.[621] Schließlich bedingte die fehlende Möglichkeit des absoluten Stoffschutzes eine Vielzahl an Verfahrenspatentanmeldungen, die die Prüfungskapazität des deutschen Patentamtes zusehends ausschöpfte.[622]

620 *Rheinfelder,* Die Bedeutung des im Vorentwurf für ein europäisches Patentrecht vorgesehenen Patentschutzes für chemische Stoffe, GRUR 1964, 354, 358, Die Lissabonner Konferenz, Bericht von Mitgliedern der deutschen Delegataion, GRUR Int. 1959, 58, 67. The U.S. allowed substance patents for chemical inventions before 1877. England hat seinen Stoffschutz für chemische Erfindungen im Jahre 1919 abgeschafft, jedoch bereits im Jahre 1949 wieder eingeführt. *Zutrauen*, Über den Schutz chemischer Erfindungen in Frankreich, GRUR Int. 1958, 331.

621 *Metzger*, Nahrungsmittel und Erfindungsschutz: Eine Zusammenstellung patent- und erfinderrechtlicher Gesichtspunkte für die Lebensmittelindustrie, Doktorarbeit, Universität Erlangen 1951, 2.

622 "(...) das Patentamt (wird) mit Verfahrensanmeldungen belastet..., die möglichereweise nicht oder jedenfalls nicht in diesem Ausmaß eingereicht werden würden, wenn die Möglichkeit bestünde, für den Stoff selbst Patentschutz zu erlangen.", and "Der Ausschuß ist aber der Auffassung, daß bei Einführung des Stoffschutzes die Wahrscheinlichkeit oder jedenfalls die Möglichkeit einer nicht unerheblichen Entlastung des Patentamts gegeben ist.", *Nastelski,* in: *Reimer* (ed.), Patentgesetz und Gebrauchsmustergesetz, 3rd ed., Köln 1968, 127.

II. Die Folgen der Patentierbarkeit von Nahrungsmitteln

Als Nahrungsmittelerfindungen gelten in diesem Zusammenhang diejenigen technischen Klassen nach der Internationalen Patentklassification (IPC)[623], die der wirtschaftlichen Klasse der Nahrungs- und Genussmittel nach der *Statistical Classification of Economic Activities in the European Community* (NACE)[624] zuzuordnen sind. Tabelle 13 zeigt die nahrungsmittelbezogenen, Tabelle 14 die biotechnologiebezogenen IPC Unterklassen nach der Konkordanzuntersuchung von *Schmoch et al.*[625] Nahrungsmittelpatentanmeldungen weisen eine IPC-Unterklasse nach Tabelle 13 auf. Biotechnologiebezogene Nahrungsmittelpatentanmeldungen weisen zusätzlich eine Unterklasse aus Tabelle 14 auf.

623 Die Internationale Patentklassifikation wurde im Strasburger Übereinkommen im Jahre 1971 vereinbart und wurde im Jahre 1975 wirksam. Mitglieder können alle Mitglieder der Pariser Verbandsübereinkunft zum Schutz des Geistigen Eigentums werden. Im Jahre 2005 waren insgesamt 55 Mitgliedsstaaten zu verzeichnen, WIPO, 2005, verfügbar unter www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=11. Die Patentämter von mehr als 100 Staaten, vier regionale Patentämter und das Internationale Büro der WIPO verwenden jedoch die Internationale Patentklassifikation, WIPO, 2004, verfügbar unter www.wipo.int/classifications/-ipc/en/preface.htm. Nur wenige Länder, wie die U.S.A nutzen parallel zur Internationalen Patentklassifikation ihr eigenes Klassifikationssystem.

624 *Nomenclature des Activités dans la Communauté Européenne (*NACE) Rev.1. Statistical Classification of Economic Activities in the European Community, ISBN 92-826-8767-8, verfügbar unter www.europa.eu.int/comm/eurostat/. Diese Klassification ist der englischen SIC und dem U.S. Standard Industrial Classification Manual sehr ähnlich, in: *Schmoch et al.,* Linking Technology Areas to Industrial Sectors, Final Report to the European Commission, DG Research, Karlsruhe etc. 2003, verfügbar unter www.isi.fraunhofer.de/p/Downloads/Microsoft%20Word%20-%20Report%20Technology%20Industry%20.pdf.

625 *Schmoch et al.,* Linking Technology Areas to Industrial Sectors, Final Report to the European Commission, DG Research, Karlsruhe etc. 2003, 16, verfügbar unter www.isi.fraunhofer.de/p/-Downloads/Microsoft%20Word%20-%20Report%20Technology%20Industry%20.pdf.

Tabelle 13:
Nahrungsmittelbezogene IPC Unterklassen.[626]

IPC Unterklasse	Titel und Beispiele der betreffenden IPC Unterklasse	Bezeichnung im folgenden
A01H	Neue Pflanzen oder Verfahren zu deren Gewinnung;	Pflanzen
A21D	Behandeln, z.B. Konservieren von Mehl; Backverfahren; Bäckereierzeugnisse; deren Haltbarmachung	Backwaren
A23B	Konservieren, z.B. durch Eindosen; chemisches Reifen von Obst oder Gemüse; die so entstandenen Produkte	Konservierung
A23C	Molkereierzeugnisse, deren Herstellung	Milchprodukte
A23D	Speiseöle oder -Fette, z.B. Margarine, Backfette, Backöle	Öle und Fette
A23F	Kaffee; Tee	Kaffee und Tee
A23G	Kakao; Kakaoerzeugnisse, Konfekt; Kaugummi; Speiseeis; deren Herstellung	Süßwaren
A23J	Protein-Zusammensetzungen für Lebensmittel; Phosphatid-Zusammensetzungen für Lebensmittel	Proteine
A23K	Futtermittel	Futtermittel
A23L	Lebensmittel oder nichtalkoholische Getränke, soweit nicht von A21D oder A23B-A23J umfasst;	Gemischtes
A23P	Formen oder Bearbeiten von Lebensmitteln	Formen
C12C	Bierbrauen	Bierbrauen
C12F	Gewinnung von Nebenprodukten von fermentierten Lösungen; Vergällen von Alkohol oder vergällter Alkohol	Distillation
C12G	Wein; Andere alkoholische Getränke; deren Bereitung	Alkoholische Getränke
C12H	Pasteurisieren, Sterilisieren, Haltbarmachen, Reinigen, Klären, Altern von alkoholischen Getränken oder Entfernen von Alkohol daraus	Pasteurisierung
C12J	Essig; seine Bearbeitung	Essig
C13F	Gewinnung oder Verarbeitung von Rohzucker, Zucker oder Sirup	Zucker
C13J	Extraktion von Saccharose aus Melasse	Zucker
C13K	Glucose; Invertzucker; Lactose; Maltose; Synthese von Zuckern durch Hydrolyse von Di- oder Polysacchariden	Zucker

626 Field Definitions by IPC, 7th ed., in: *Schmoch et al.,* Linking Technology Areas to Industrial Sectors, Final Report to the European Commission, DG Research, Karlsruhe etc. 2003, 67.

Tabelle 14:
Biotechnologische IPC Unterklassen.[627]

IPC Unterklasse	Titel und Beispiele der betreffenden IPC Unterklasse	Bezeichnung im folgenden
C07H	Zucker; deren Derivate; Nucleoside; Nucleotide; Nucleinsäuren (DNA oder RNA, die genetische Verfahrenstechnik betreffend, Vektoren, z.B. Plasmide, oder ihre Isolierung, Herstellung oder Reinigung)	Nucleinsäuren
C12N	Mikroorganismen oder Enzyme; Zusammensetzungen aus Mikroorganismen oder Enzymen; Züchten, Konservieren oder Lebensfähigerhalten von Mikroorganismen; Mutation oder genetische Verfahrenstechnik; Kulturmedien	Microorganismem
C12P	Gärungsverfahren oder Verfahren unter Verwendung von Enzymen zur gezielten Synthese von chemischen Verbindungen oder Zusammensetzungen oder zur Trennung optischer Isomerer aus einer racemischen Mischung	Fermentation

Tabelle 15 zeigt die zunehmende Wahrnehmung der Patentierungmöglichkeit für Nahrungsmittel seit der Abschaffung des Patentierungsausschlusses in Deutschland. Waren im Jahr 1970 gerade 97 Patentanmeldungen jährlich zu verzeichnen, so verfünfachte sich diese Zahl bis zum Jahr 2001 auf 535 Patentanmeldungen.[628] Das Maximum wurde im Jahr 1997 mit 726 Nahrungsmittelpatentanmeldungen erreicht. Die Abnahme in den folgenden Jahren mag auf die noch laufende Bestückung der Datenbank durch das Patentamt zurückzuführen sein. Im Zeitraum von 1970 bis 2001 wurden insgesamt 13.206 Nahrungsmittelpatentanmeldungen getätigt. Die meisten Patentanmeldungen waren in der Unterklasse der Süßwaren (A23G) mit insgeamt 1.479 Patentanmeldungen zu verzeichen, gefolgt von den Futtermitteln (A23K) mit 1.325 Patentanmeldungen, den Backwaren (A21D) mit insgesamt 866, der Konservierung (A23B) mit insgesamt 865 und den Milchprodukten (A23C) mit insgesamt 837 Patentanmeldungen.[629]

627 Field Definitions by IPC, 7th ed., in: *Schmoch et al.,* Linking Technology Areas to Industrial Sectors, Final Report to the European Commission, DG Research, Karlsruhe etc. 2003, 67.

628 Der Überglick in Tabelle 15 bezieht sich auf nationale Deutsche Patentanmeldungen. Europäische Patentanmeldungen mit Benennung Deutschlands sind nicht inbegriffen.

629 Diese Daten wurden von der Autorin in Zusammenarbeit mit *Schmoch* im Jahre 2004 am Fraunhofer Institut für System- und Innovationsforschung in Karlsruhe erhoben unter Verwendung von PLUS-PAT, eine Datenbank von Questel-Orbit. Für einen Überblick wird auf Tabelle 15 verwiesen. Zum technologischen Hintergrund siehe Teil II.

Table 15:
Deutsche Nahrungsmittelpatentanmeldungen mit Priorität im Zeitraum von 1970 bis 2001.[630]

Jahr	A01H	A21D	A23B	A23C	A23D	A23F	A23G	A23J	A23K	A23L	A23P	C12C	C12F	C12G	C12H	C12J	C13F	C13J	C13K	Summe
70	0	11	4	7	2	6	5	1	17	25	2	8	1	3	1	0	2	0	2	**97**
71	0	9	15	11	1	11	21	7	18	29	1	26	2	6	4	2	4	1	2	**170**
72	2	13	18	11	4	8	26	1	27	44	0	19	5	10	5	1	3	2	8	**207**
73	14	15	23	26	0	10	35	6	22	70	7	22	4	10	9	0	2	2	5	**282**
74	4	17	23	15	3	8	32	4	30	65	3	17	6	16	5	0	1	1	4	**254**
75	0	16	30	24	5	6	39	11	35	70	2	27	1	9	6	1	2	2	7	**293**
76	0	27	25	19	1	7	19	6	32	59	1	22	3	4	8	0	2	0	4	**239**
77	4	25	30	20	2	11	31	8	39	47	0	16	1	6	2	1	6	1	7	**257**
78	15	25	21	27	2	18	49	5	27	92	23	22	5	29	5	1	8	0	3	**377**
79	3	18	27	22	4	4	44	8	41	80	4	30	1	17	6	0	9	1	7	**326**
80	1	19	21	28	6	11	33	18	60	88	11	30	3	18	5	0	2	0	5	**359**
81	3	25	21	29	1	17	36	4	50	101	11	30	7	20	4	0	10	0	15	**384**
82	2	25	26	21	2	15	47	10	55	113	11	21	3	9	5	0	12	0	7	**384**
83	2	23	26	34	2	9	42	8	40	101	11	27	2	16	7	2	8	0	7	**367**
84	8	25	32	27	2	14	47	9	43	117	13	19	2	19	7	0	13	0	1	**398**
85	6	25	27	19	0	7	47	7	55	106	16	32	2	38	5	0	7	0	5	**404**
86	10	34	47	32	5	18	56	4	66	137	31	25	10	24	16	0	18	1	2	**536**
87	16	24	24	31	3	17	65	2	53	128	27	15	5	19	9	1	2	0	4	**445**
88	15	25	21	27	2	18	49	5	27	92	23	22	5	29	5	1	8	0	3	**377**
89	8	27	18	21	3	9	54	4	22	115	19	21	1	15	6	0	3	0	1	**347**

630 Deutsche Patentanmeldungen, die als Haupt- oder Nebenklasse mindestens eine der in Tabelle 13 definierten IPC Unterklassen aufweisen. Zeitlicher Anknüpfungspunkt ist das früheste Prioritätsdatum der jeweiligen Patentanmeldung. Diese Daten wurden von der Autorin in Zusammenarbeit mit *Schmoch* im Jahre 2004 am Fraunhofer Institut für System- und Innovationsforschung in Karlsruhe erhoben unter Verwendung von PLUSPAT, einer Datenbank von Questel-Orbit. PlusPat ist die weltgrößte internationale Patentdatenbank. Diese Datenbank vereinigt die Datenbestände des Europäischen Patentamts, des US Patentamts und der WIPO sowie des Japanischen Patentamts. Sie deckt insgesamt mehr als 50 Millionen Patentdokumente von 75 Patentämtern ab. Verfügbar unter www.questel-orbit.com/EN/Prodsandservices/PlusPat.htm.

Table 15 - Fortsetzung:
Deutsche Nahrungsmittelpatentanmeldungen mit Priorität im Zeitraum von 1970 bis 2001.[631]

Jahr	A01H	A21D	A23B	A23C	A23D	A23F	A23G	A23J	A23K	A23L	A23P	C12C	C12F	C12G	C12H	C12J	C13F	C13J	C13K	Summe
90	22	28	23	25	5	14	28	5	32	115	19	11	0	15	8	0	4	0	2	**356**
91	12	28	18	29	7	4	38	8	34	93	19	11	2	15	5	2	3	0	1	**329**
92	19	35	26	21	5	7	44	10	43	134	24	28	1	18	6	2	8	2	2	**435**
93	15	31	45	40	4	8	53	7	30	176	30	26	2	16	11	0	4	0	1	**499**
94	18	39	41	39	6	18	56	15	51	194	29	30	1	22	14	0	5	0	2	**580**
95	17	33	37	31	5	16	53	13	35	206	29	37	0	26	16	0	7	0	0	**561**
96	32	47	26	41	5	20	95	11	52	239	36	40	0	27	11	0	6	1	3	**692**
97	23	50	37	38	5	9	82	21	46	265	58	44	2	27	11	0	7	0	1	**726**
98	27	53	38	40	6	18	68	16	62	261	44	28	1	19	12	1	9	0	1	**704**
99	41	34	31	36	3	18	83	16	48	235	40	19	0	17	7	1	5	0	1	**635**
00	38	44	36	27	1	10	50	8	70	265	37	20	2	26	13	0	3	0	1	**651**
01	37	16	28	19	2	8	52	7	63	192	34	32	1	31	8	0	5	0	0	**535**
Total	**414**	**866**	**865**	**837**	**104**	**374**	**1479**	**265**	**1325**	**4054**	**615**	**777**	**81**	**576**	**242**	**16**	**188**	**14**	**114**	**13206**

631 Deutsche Patentanmeldungen, die als Haupt- oder Nebenklasse mindestens eine der in Tabelle 13 definierten IPC Unterklassen aufweisen. Zeitlicher Anknüpfungspunkt ist das früheste Prioritätsdatum der jeweiligen Patentanmeldung. Diese Daten wurden von der Autorin in Zusammenarbeit mit *Schmoch* im Jahre 2004 am Fraunhofer Institut für System- und Innovationsforschung in Karlsruhe erhoben unter Verwendung von PLUSPAT, einer Datenbank von Questel-Orbit. PlusPat ist die weltgrößte internationale Patentdatenbank. Diese Datenbank vereinigt die Datenbestände des Europäischen Patentamts, des US Patentamts und der WIPO sowie des Japanischen Patentamts. Sie deckt insgesamt mehr als 50 Millionen Patentdokumente von 75 Patentämtern ab. Verfügbar unter www.questel-orbit.com/EN/Prodsandservices/PlusPat.htm.

Ein bedeutender Teil der deutschen Nahrungsmittelpatentanmeldungen weist einen Bezug zur Biotechnologie auf (siehe Tabelle 16). Im Zeitraum von 1970 bis 2001 waren ca. 8,2% der Nahrungsmittelpatentanmeldungen der Biotechnologie zuzuordnen.[632] Der Höchstand von 73 wurde im Jahr 1999 erreicht.[633] Dieser Anstieg ist der steigenden Bedeutung der Biotechnologie in der Nahrungsmittelindustrie zu verdanken. Einerseits erleichert sie durch molekulare Züchtungsverfahren die Herstellung von landwirtschaftlichen Erzeugnissen. Andererseits ermöglicht sie neue und verbesserte Verarbeitungsverfahren durch gentechnisch veränderte Mikroorga-nismen. Die sog. "Grüne Biotechnologie" (IPC Unterklasse A01H) bestreitet den Großteil der Nahrungsmittelpatentanmeldungen mit Biotechnologiebezug mit einem Anstieg von Null im Jahr 1970 auf 35 im Jahr 2000. Insgesamt sind seit 1999 ca. 45% aller biotechnologiebezogenen Nahrungsmittelpatentanmeldungen der Grünen Biotechnologie zuzurechnen.

632 Die in Tabelle 16 abgebildeten Patentanmeldungen beziehen sich auf nationale Deutsche Patentanmeldungen. Europäische Patentanmeldungen mit Benennung Deutschlands sind nicht inbegriffen.

633 Diese Daten wurden von der Autorin in Zusammenarbeit mit *Schmoch* im Jahre 2004 am Fraunhofer Institut für System- und Innovationsforschung in Karlsruhe erhoben unter Verwendung von PLUS-PAT, einer Datenbank von Questel-Orbit. Einen Überblick bietet Tabelle 16.

Tabelle 16:
Deutsche biotechnologiebezogene Nahrungsmittelpatentanmeldungen mit Priorität im Zeitraum von 1970 bis 2001.[634]

Jahr	A01H	A21D	A23B	A23C	A23D	A23F	A23G	A23J	A23K	A23L	A23P	C12C	C12F	C12G	C12H	C12J	C13F	C13J	C13K	Summe
70	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
71	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	**1**
72	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
73	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	**1**
74	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	**1**
75	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	**2**
76	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	**1**
77	0	0	0	0	0	0	0	0	4	2	0	2	0	0	0	0	0	0	0	**8**
78	10	3	2	7	0	0	0	0	8	11	2	1	2	3	0	1	2	0	3	**55**
79	1	0	1	1	0	0	0	1	1	1	0	2	0	0	0	0	0	0	1	**9**
80	0	1	0	3	0	1	0	2	9	5	0	4	1	1	3	0	0	0	0	**30**
81	0	0	0	1	0	0	0	1	6	2	0	2	1	1	2	0	0	0	4	**20**
82	1	1	0	1	0	0	0	0	2	5	0	0	0	1	0	0	0	0	0	**11**
83	0	4	1	8	0	0	0	4	7	8	0	0	0	0	1	0	0	0	1	**34**
84	1	1	0	0	0	0	0	1	6	8	0	0	0	2	0	0	0	0	0	**19**
85	3	2	2	3	0	0	0	4	6	8	0	2	1	4	0	0	0	0	2	**37**
86	8	1	0	5	0	0	1	1	13	9	0	5	5	5	1	0	0	1	1	**56**
87	13	2	2	2	0	0	1	1	5	8	0	1	2	2	1	0	0	0	1	**41**
88	10	3	2	7	0	0	0	0	8	11	2	1	2	3	0	1	2	0	3	**55**
89	7	0	0	0	0	0	0	1	2	3	1	0	0	2	0	0	0	0	0	**16**

634 Deutsche Patentanmeldungen, die als Haupt- oder Nebenklasse mindestens eine der in Tabelle 13 definierten IPC Unterklassen sowie mindestens eine der in der in Tabelle 14 definierten IPC Unterklassen aufweisen. Zeitlicher Anknüpfungspunkt ist das früheste Prioritätsdatum der jeweiligen Patentanmeldung. Diese Daten wurden von der Autorin in Zusammenarbeit mit *Schmoch* im Jahre 2004 am Fraunhofer Institut für System- und Innovationsforschung in Karlsruhe erhoben unter Verwendung von PLUSPAT, einer Datenbank von Questel-Orbit.

Tabelle 16 - Fortsetzung:
Deutsche biotechnologiebezogene Nahrungsmittelpatentanmeldungen mit Priorität im Zeitraum von 1970 bis 2001.[635]

Jahr	A01H	A21D	A23B	A23C	A23D	A23F	A23G	A23J	A23K	A23L	A23P	C12C	C12F	C12G	C12H	C12J	C13F	C13J	C13K	Summe
90	19	1	2	2	0	0	0	1	3	4	0	0	0	0	0	0	0	0	0	**32**
91	7	0	1	1	0	0	0	0	3	3	0	1	0	0	1	0	0	0	1	**18**
92	18	7	2	1	0	0	0	0	1	10	0	6	0	1	0	2	0	0	0	**48**
93	15	1	0	2	0	0	1	0	3	19	0	5	0	0	1	0	2	0	1	**50**
94	17	4	2	6	1	0	2	1	7	15	1	3	0	2	0	0	1	0	0	**62**
95	16	4	2	2	0	0	2	2	5	21	1	0	0	1	1	0	2	0	0	**59**
96	29	5	0	1	0	1	0	1	8	24	0	2	0	1	1	0	0	0	2	**75**
97	21	3	0	2	1	0	1	0	6	16	1	1	0	1	1	0	1	0	1	**56**
98	22	4	1	1	1	0	1	2	9	17	0	4	0	1	0	0	0	0	1	**64**
99	33	1	1	2	0	1	2	5	9	15	1	1	0	2	0	0	0	0	0	**73**
00	35	2	1	0	0	0	0	1	14	17	1	3	0	0	2	0	0	0	0	**76**
01	32	0	0	0	0	0	0	0	24	10	0	1	0	1	0	0	0	0	0	**68**
Total	**318**	**50**	**22**	**58**	**3**	**3**	**11**	**29**	**171**	**253**	**10**	**48**	**14**	**34**	**15**	**4**	**11**	**1**	**23**	**1078**

635 Deutsche Patentanmeldungen, die als Haupt- oder Nebenklasse mindestens eine der in Tabelle 13 definierten IPC Unterklassen sowie mindestens eine der in der in Tabelle 14 definierten IPC Unterklassen aufweisen. Zeitlicher Anknüpfungspunkt ist das früheste Prioritätsdatum der jeweiligen Patentanmeldung. Diese Daten wurden von der Autorin in Zusammenarbeit mit *Schmoch* im Jahre 2004 am Fraunhofer Institut für System- und Innovationsforschung in Karlsruhe erhoben unter Verwendung von PLUSPAT, einer Datenbank von Questel-Orbit.

Der deutsche Nahrungsmittelsektor prosperierte seit der Abschaffung des Patentie-rungsausschlusses für Nahrungsmittel im Jahr 1967. Dies zeigen auch die zu-nehmenden Patentanmeldungsaktivitäten (siehe Tabelle 15 und 16). Er umfasste 5.970 Unternehmen mit über einer halben Million Angestellten im Jahr 2004. Sein Umsatz stieg von €116.9 Milliarden im Jahr 1998 auf €133.6 Milliarden im Jahr 2005.[636] Die Lebensmittelpreise sind dagegen gefallen. So verringerte sich der Anteil der Ausgaben für Lebensmittel an den Gesamtverbraucherausgaben von 16,7% im Jahr 1980 auf 12,2% im Jahr 2004.[637] Darüber hinaus sind auch die Preise für landwirtschaftliche Erzeugnisse stetig gesunken. Der Anteil dieser an den Gesamtnahrungsmittelausgaben fiel von 50% in den frühen 70er Jahren auf 26% im Jahr 2004, während die Gewinne der Lebensmittelverarbeiter und des Handels ständig gestiegen sind.[638] Diese verbraucherfreundlichen Preisentwicklungen zeigen, dass die Patentierbarkeit von Nahrungsmitteln nicht die Nahrungsmittelverfügbarkeit be-schränkte. Die dem Patentierungsausschluss zu Grunde liegenden Bedenken haben sich somit nicht bestätigen lassen.

B. Die Patentierbarkeit von Nahrungsmittel unter dem TRIPs Übereinkommen

Die Patentsysteme vieler Entwicklungsländer sahen oder sehen teils noch immer einen Patentierungsausschluss für Nahrungsmittel vor. Zu Beginn der TRIPs Verhandlungen im Jahr 1988 hatten 35 Länder der 92 Mitglieder der Pariser Verbands-übereinkunft Nahrungsmittel vom Patentschutz ausgeschlossen.[639] Weiterhin schlossen neun Länder

636 Bundesvereinigung der deutschen Ernährungsindustrie, 2006, verfügbar unter www.bve-online.de/.

637 Ein repräsentativer Korb mit 24 Lebensmitteln ist im europäischen Vergleich sogar in Deutschland am preisgünstigsten mit nur 80% der europäischen Durchschnittskosten im Jahre 2004. Landesbauernverband Niedersachsen, Nahrungsmittel in Deutschland besonders preiswert, Pressemitteilung vom 09.03.2005, verfügbar unter www.landvolk.net/3747.htm.

638 Informationsdienst Wissenschaft, Anteile der landwirtschaftlichen Erzeugererlöse an den Verbraucherausgaben für Nahrungsmittel in Deutschland leicht gestiegen, 2005, verfügbar unter www.idw-online.de/pages/de/news97492.

639 Nahrungsmittelanmeldungen waren in folgenden Ländern entweder ausdrücklich oder mittelbar als chemische Erfindungen vom Patentschutz ausgenommen, wobei teilweise auch nur eine Ablehnungsmöglichkeit vorgesehen war: Australien, Bolivien, Brasilien, Bulgarien, Kanada, China, Tschechoslowakei, Kolumbien, Kuba, Dänemark, Ecuador, Ägypten, Finnland, Deutschland, Ungarn, Island, Indien, Lybien, Malawi, Mexico, Mongolei, Neuseeland, Norwegen, Peru, Polen, Portugal, Korea, Romänien, Thailand, Tunisien, Venezuela, Vietnam, Yugoslavien, Zambia, Zimbabwe, WTO, Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property, Negotiating Group on TRIPs, Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property, Doc. MTN.GNG/NG11/W/24 (1988), p. 31.

Verfahren zur Herstellung von Nahrungsmitteln[640] und Mikroorganismen[641] vom Patentschutz aus. Bis Ende 1989 waren die Ansichten zu der Patentierbarkeit von Nahrungsmitteln in der TRIPs-Verhandlungsgruppe gespalten.[642] Indien wollte die Frage der patentierbaren Gegenstände den Mitgliedsstaaten überlassen. Die U.S.A., Japan und Australien plädierten für die Patentierbarkeit von Erfindungen auf allen technischen Gebieten gleichermaßen. Brasilien stimmte ebenfalls für eine grundsätzliche Patentierbarkeit aller technischen Gegenstände, schlug aber zum Ausgleich weitgehende Ausnahmen im öffentlichen Interesse vor.[643] Die Europäische Delegation stimmte dem grundsätzlich zu. Hinsichtlich Pflanzensorten und Tierarten schlug sie aber eine dem Art. 53(b) EPÜ vergleichbare Regelung vor. Kanada und einige Schwellenländer schlossen sich dem Standpunkt der Europäi-schen Delegation im wesentlichen an.[644] Der Standpunkt der Entwicklunsländer bezüglich der Patentierbarkeit von Nahrungsmitteln lässt sich wie folgt zusammenfassen:

> "... mit steigenden Schutzniveaus sollten maßgebliche öffentliche Interessen wie die Armutsbekämpfung, die Gesundheitsversorgung, die Ernährung und die die Nahrungsmittelerzeugung sowie technologische Erwägungen, wie die Förderung von Forschung und Technik (...) betrachtet werden um den Schutz der Rechtsinhaber auszugleichen."[645]

Zum Ausgleich für die Einführung des Stoffschutzes forderten die Entwicklungsländer Übergangsregelungen für Nahrungsmittel.[646] Einige Ent-wicklungsländer nahmen auf die Entwicklung des Patentsystems in Deutschland Bezug und forderten eine vergleichbare Entwicklungsmöglichkeit für ihr eigenes Patentsystem.[647] Die entscheidenden Verhandlungen im Dezember 1991 führten schließlich zu einem Kompromiss basierend auf dem europäischen Vorschlag mit einer Revisionsoption hinsichtlich der Ausnahmemög-

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640 Verfahren zur Herstellung von Nahrungsmitteln waren in folgenden Ländern vom Patentschutz ausgenommen, wobei teilweise auch nur eine Ablehnungsmöglichkeit vorgesehen war: Australien, Brasilien, Kolumbien, Dänemark, Malawi, Mexico, Neuseeland, Zambia, Zimbabwe, Negotiating Group on TRIPs, Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property, Doc. MTN.GNG/NG11/W/24 (1988), S. 32.

641 Mikroorganismen waren teils unter Einschränkung in folgenden Ländern vom Patentschutz ausgeschlossen: Brasilien, Kuba, Tschecheslowakei, Deutschland, Ungarn, Malaysia, Spanien, Rumänien, Yugoslavien, WTO, Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property, Negotiating Group on TRIPs, Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property, Doc. MTN.GNG/NG11/W/24 (1988), 32.

642 Negotiating Group on TRIPs, Synoptic Tables Setting Out Existing Standards and Proposed Standards and Principles, Doc. MTN.GNG/NG11/W/32/Rev.2 (1990).

643 "Patents should be granted to those inventions which satisfy the criteria of patentability, with the exception of inventions that are contrary to morality, religion, public order, public health and bearing in mind public interest and technological and economic development conside-rations."Negotiating Group on TRIPS, Doc. MTN.GNG/NG11/W32/Rev.2, 85.

644 WTO Committee on Trade and the Environment, Doc. WT/CTE/W/8, Environment and TRIPs, 24.

645 Übersetzt aus dem Englischen, Negotiating Group on TRIPs, Meeting of Negotiating Group of 11-12 May 1989, Doc. MTN.GNG/NG11/12 (1989), 1.

646 Negotiating Group on TRIPs, Meeting of Negotiating Group of 12-14 July 1989, Doc. MTN.GNG/NG11/14 (1989), No. 74.

647 Negotiating Group on TRIPs, Meeting of Negotiating Group of 2, 4, and 5 April 1990, Doc. MTN.GNG/NG11/20 (1990), No. 31.

lichkeit für Pflanzen und Tiere vier Jahre nach dem Inkrafttreten des TRIPs Übereinkommens:

> "(Es) (...) ist vorzusehen, daß Patente für Erfindungen auf allen Gebieten der Technik erhältlich sind, sowohl für Erzeugnisse als auch für Verfahren, vorausgesetzt, daß sie neu sind, auf einer erfinderischen Tätigkeit beruhen und gewerblich anwendbar sind. (...) Die Mitglieder können von der Patentierbarkeit auch ausschließen (...) b) Pflanzen und Tiere, mit Ausnahme von Mikroorganismen, und im wesentlichen biologische Verfahren für die Züchtung von Pflanzen oder Tieren mit Ausnahme von nicht-biologischen und mikrobiologischen Verfahren. Die Mitglieder sehen jedoch den Schutz von Pflanzensorten entweder durch Patente oder durch ein wirksames System sui generis oder durch eine Kombination beider vor. Die Bestimmungen dieses Buchstabens werden vier Jahre nach dem Inkrafttreten des WTO-Übereinkommens überprüft."[648]

Zusammenfassend ist festzustellen, dass die Industrieländer die TRIPs Verhandlungen entscheidend prägten. Die Entwicklungsländer setzten dagegen die Möglichkeit von Zwangslizenzen und großzügige Übergangsregelungen durch.[649] Mit *Straus*[650] kann das TRIPs Übereinkommen als entscheidender Meilenstein für die Entwicklung des internationalen Patentrechts angesehen werden:

> "Mit diesem Übereinkommen ist es endlich gelungen, die Schutzdefizite abzubauen, die in Ermangelung von entsprechenden Mindestrechten über 100 Jahre der PVÜ immanent geblieben sind und nur im Kontext regionaler Patent-rechtsharmonisierung in Staaten mit vergleichbarem Entwicklungsstand, ver-gleichbarer Gesellschafts- und Wirtschaftsordnung sowie vergleichbaren Rechtstraditionen, und darüber hinaus einer ausgeprägten Integrationstendenz, behoben werden konnten."

I. Die Patentierbarkeit von Nahrungsmitteln in Brasilien, China und Indien

Das erste brasilianische Patentgesetz von 1809 schloss Nahrungsmittel von der Pa-tentierbarkeit aus.[651] Dies änderte sich erst in Folge der Umsetzung des TRIPs Übereinkommens, das per Dekret am 30.12.1994 ratifiziert wurde und am 01.01.2005 in Kraft trat.[652] Brasilien genoss als Entwicklungsland eine vierjährige Übergangsfrist nach Art. 65(4) TRIPs Übereinkommen. Weitere fünf Jahre wurden nach Art. 65(4) TRIPs Übereinkommen für die Einführung des Stoffschutzes einge-räumt. Brasilien änderte sein Patentgesetz daraufhin bereits im Jahr 1996.[653] Nach Art. 8 des brasilianischen Patentgesetzes ist

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648 Art. 27 TRIPs Übereinkommen.

649 *Abbott,* The TRIPS-Legality of Measures Taken to Address Public Health Crises: Responding to USTR-State-Industry Positions that Undermine the WTO, in: *Kennedy et al.* (eds.), The Political Economy of International Trade Law: Essays in Honor of Robert E. Hudec, Cambridge 2002, 311, 314.

650 *Straus*, Bedeutung des TRIPS für das Patentrecht, GRUR Int. 1996, 179, Rn. 87.

651 *Graca Aranha*, The Challenge for the Medium Sized Office, WIPO Conference on the International Patent System, Geneva, March 25-March 27, 2002,
verfügbar unter www.wipo.int/patent/-agenda/ en/meetings/2002/presentations/gracaaranha.pdf.

652 Dekret Nr.1355.

653 Industrial Property Law vom 14.05.1996, das am 15.05.1997 in Kraft trat.

jede Erfindung patentierbar, soweit sie die Voraussetzungen der Neuheit, der erfinderischen Tätigkeit und der gewerblichen Anwendbarkeit erfüllt. Damit sind auch Nahrungmittel grundsätzlich dem Patent-schutz zugänglich.

Art. 25(1) des ersten chinesischen Patentgesetzes von 1984 schloss Nahrungsmittel vom Patentschutz aus, Patente für Verfahren zu deren Herstellung waren jedoch schützbar.[654] Der Patentierungsausschluss für Nahrungsmittel sollte die Volks-ernährung und die Nahrungsmittelverfügbarkeit sicherstellen.[655] Diese anfänglichen Bedenken konnten nicht bestätigt werden, so dass der Patentierungsausschluss für Nahrungsmittel im Patentgesetz von 1992 abgeschafft wurde.[656]

Das indische Patentsystem wurde nach britischem Vorbild etabliert.[657] Das Patentgesetz von 1911 erlaubte die Patentierung von Nahrungsmitteln. Der Patentierungsaus- schluss für Nahrungsmittel wurde erst nach Indiens Unabhängigkeit im Jahr 1947 mit dem Patentgesetz von 1970 eingeführt.[658] Verfahren zur Herstellung von Nahrungsmitteln waren zwar schutzfähig, jedoch war die Laufzeit solcher Patente auf nur sieben Jahr begrenzt. Mit dem TRIPs Übereinkommen war Indien nun ver-pflichtet, als Entwicklungsland innerhalb einer Übergangsfrist von zehn Jahren ab dem 01.01.1995 die Patentierbarkeit von Nahrungsmitteln vorzusehen. Mit der dritten Patentgesetznovelle infolge der Umsetzung des TRIPs Übereinkommens am 05.04.2005 wurde rückwirkend zum 01.01.2005 der Stoffschutz für Nahrungsmittel eingeführt.

II. Folgen der Patentierbarkeit von Nahrungsmitteln

Die Auswirkungen des Abbaus des Patentierungsausschlusses für Nahrungsmittel werden durch den Gebrauch der nationalen brasilianischen, chinesischen und indischen Patentsysteme (Tabelle 17) dargestellt. Die brasilianischen Nahrungmittelpa-tentanmeldungen zählten 35 im Jahr 1990 und stiegen stetig bis zu 128 im Jahr 2000 an. Der starke Anstieg von 50 Patentanmeldungen im Jahr 1996 auf 118 im Jahr 1997 wurde durch den Abbau des Patentierungsausschlusses verursacht, der in Brasilien 1997 wirksam wurde.[659] Die chinesischen Nahrungsmittelpatentanmeldungen stiegen rasch von 471 im

654 *Yu*, The Second Amendment of the Chinese Patent Law and the Comparison between the New Patent Law and TRIPS, 4 The Journal of World Intellectual Property 137, 145 (2001).

655 "Pharmazeutische Erzeugnisse, Nahrungsmittel, chemische Stoffe und andere Substanzen sowie neue Tierarten und Pflanzensorten stehen in einem engen Zusammenhang mit Leben und Gesundheit der Menschen (...)." *Guo*, Entstehung und Grundzüge des chinesischen Patentgesetzes, GRUR Int. 1985, 1.

656 *Ganea*, Die Neuregelung des chinesischen Patentrechts, GRUR Int. 2002, 686, 706.

657 Act of Protection of Inventions, *Mukherjee*, The Journey of Indian Patent Law towards TRIPS Compliance, IIC 2004, 125.

658 Sec. 5(1)(a) of the Indian Patent Act of 1970.

659 Diese Daten wurden von der Autorin in Zusammenarbeit mit *Schmoch* im Jahre 2004 am Fraunhofer Institut für System- und Innovationsforschung in Karlsruhe erhoben unter Verwendung von PLUS-PAT, einer Datenbank von Questel-Orbit.

Jahr 1990 bis auf 2.210 im Jahr 2001 an. Zwischen 1992 und 1993 betrug der Anstieg sogar nahezu 80%. Dies entspricht der Abschaffung des Patentierungsaussschlusses im Patentgesetz von 1992.[660] Die indischen Nahrungsmittelpatentanmeldugen erreichten ausgehend von 22 im Jahr 1990 ihr Maximum mit 76 im Jahr 1995. Die Abschaffung des Patentierungsausschlusses erfolgte erst im Jahr 2005, so dass dessen Auswirkung erst zukünftig an den Patentanmeldungszahlen messbar sein wird. Nichtsdestotrotz waren in Indien vergleichsweise wenige Nahrungsmittelpatentanmeldungen zu verzeichnen.[661]

Tabelle 17:
Brasilianische, chinesische und indische Nahrungsmittelpatentanmeldungen mit Priorität im Zeitraum von 1990 bis 2001.[662]

Jahr	Brasilien	China	Indien
90	35	471	22
91	39	605	44
92	46	981	35
93	54	1751	49
94	46	1569	53
95	52	1467	76
96	50	1537	43
97	118	1527	55
98	119	1561	41
99	119	1579	23
00	128	1945	3
01	96	2210	0

660 Diese Daten wurden von der Autorin in Zusammenarbeit mit *Schmoch* im Jahre 2004 am Fraunhofer Institut für System- und Innovationsforschung in Karlsruhe erhoben unter Verwendung von PLUSPAT, einer Datenbank von Questel-Orbit.

661 Diese Daten wurden von der Autorin in Zusammenarbeit mit *Schmoch* im Jahre 2004 am Fraunhofer Institut für System- und Innovationsforschung in Karlsruhe erhoben unter Verwendung von PLUSPAT, einer Datenbank von Questel-Orbit.

662 Patentanmeldungen, die als Haupt- oder Nebenklasse mindestens eine der in Tabelle 13 definierten IPC Unterklassen aufweisen. Zeitlicher Anknüpfungspunkt ist das früheste Prioritätsdatum der jeweiligen Patentanmeldung. Diese Daten wurden von der Autorin in Zusammenarbeit mit *Schmoch* im Jahre 2004 am Fraunhofer Institut für System- und Innovationsforschung in Karlsruhe erhoben unter Verwendung von PLUSPAT, einer Datenbank von Questel-Orbit.

Der Anteil der in Tabelle 18 gezeigten brasilianischen, chinesischen und indischen Nahrungsmittelpatentanmeldungen mit Bezug zur Biotechnologie an den gesamten Nahrungsmittelpatentanmeldungen betrug ca. 5% zwischen 1990 und 2001. Die brasilianischen fluktuierten von 0 im Jahr 1990 bis zu ihrem Maximum von 19 im Jahr 1997. Der Anstieg von einer Anmeldung im Jahr 1996 auf 19 im darauffolgenden Jahr entspricht dem Abbau des Patentierungsausschlusses im Jahr 1997. Ent-sprechend war der Anteil der biotechnologiebezogenen an den gesamten brasilianischen Nahrungsmittelpatentanmeldungen mit 16% im Jahr 1997 am größten. Die chinesischen biotechnologiebezogenen Nahrungsmittelpatentanmeldungen stiegen konstant von 10 im Jahr 1990 auf 57 im Jahr 1996 an, nivellierten bei 50 zwischen 1997 und 2000, bis sie sich im Jahr 2001 auf 105 verdoppelten. Der Abbau des Pa-tentierungsausschlusses im Jahr 1992 führte zu einem leichten Anstieg von 19 auf 25 im folgenden Jahr. Durchschnittlich 3% der chinesischen Nahrungsmittelpatentanmeldungen im Zeitraum von 1990 bis 2001 wiesen einen Bezug zur Biotechnologie auf. Die indischen beliefen sich auf maximal drei im Jahr 1997.[663]

663 Diese Daten wurden von der Autorin in Zusammenarbeit mit *Schmoch* im Jahre 2004 am Fraunhofer Institut für System- und Innovationsforschung in Karlsruhe erhoben unter Verwendung von PLUS-PAT, einer Datenbank von Questel-Orbit.

Tabelle 18:
Brasilianische, chinesische und indische Nahrungsmittelpatentanmeldungen mit Biotechnologiebezug mit Priorität im Zeitraum von 1990 bis 2001.[664]

Jahr	Brasilien	China	Indien
90	0	10	0
91	1	19	0
92	1	19	1
93	6	25	0
94	1	21	0
95	2	34	0
96	1	57	1
97	19	47	3
98	5	41	1
99	8	49	0
00	5	45	0
01	3	105	0

Die Nahrungsmittelindustrie in Brasilien, Indien und China prosperierte in den vergangenen Jahren. So bestritt die brasilianische Nahrunsmittelindustrie 17% des Bruttoinlandprodukts im Jahr 2000 mit einem Umsatz von rund U.S.$100 Milliarden.[665] Die brasilianischen Nahrungsmittelpreise sind zwischen 1994 und 2001 um nahezu 30% gefallen.[666] Der chinesische Nahrungsmittelsektor erwirtschaftete 1999 einen Umsatz von U.S.$80 Milliarden und erreichte in den ersten sieben Monaten des Jahres 2004 bereits U.S.$104.8 Milliarden.[667] Auch Indiens Nahrungsmittelsektor machte in den letzten Jahren beachtliche Fortschritte mit einem Umsatz von U.S.$69.4 Milliarden im Jahr

664 Patentanmeldungen, die als Haupt- oder Nebenklasse mindestens eine der in Tabelle 13 definierten IPC Unterklassen sowie mindestens eine der in der in Tabelle 14 definierten IPC Unterklassen aufweisen. Zeitlicher Anknüpfungspunkt ist das früheste Prioritätsdatum der jeweiligen Patentanmeldung. Diese Daten wurden von der Autorin in Zusammenarbeit mit *Schmoch* im Jahre 2004 am Fraunhofer Institut für System- und Innovationsforschung in Karlsruhe erhoben unter Verwendung von PLUSPAT, einer Datenbank von Questel-Orbit.

665 Ieinschließlich Tabakverarbeitung und Transportkosten, In: *Azevedo et al.*, The Food Industry in Brazil and the United States: The Effects of the FTAA on Trade and Investment, Buenos Aires 2004, 4, Table 2, using data from the Central Bank of Brazil, verfügbar unter www.iadb.org/intal/Publicaciones/Azevedo-Chaddad-Farina_WP-SITI-07.pdf.

666 *Azevedo et al.*, The Food Industry in Brazil and the United States: The Effects of the FTAA on Trade and Investment, Buenos Aires 2004, 5, 10, verfügbar unter www.iadb.org/intal/Publicaciones/Azevedo-Chaddad-Farina_WP-SITI-07.pdf.

667 *Wang Wenzhe*, cited in: People's Daily Online, September 12, 2004, verfügbar unter www.english.people.com.cn/200409/12/eng20040912_156 701.html.

2000.[668] Insgesamt lässt die florierende Entwicklung des Nahrungsmittelsektoren in Indien, Brasilien und China auf positive Auswirkungen der Patentierbarkeit von Nahrungsmitteln schließen.

C. Nestlé und die Patentierbarkeit von Nahrungsmitteln

Die Auswirkungen der Patentierbarkeit von Nahrungsmitteln in Folge des TRIPs Übereinkommens werden am Beispiel des weltgrößten Nahrungsmittelkonzerns Nestlé erläutert. Nestlés Nahrungsmittelanmeldungen sind – wie in Tabelle 19 dargestellt – seit 1990 ständig gestiegen.[669] Die meisten Nahrungsmittelpatentanmeldungen hat Nestlé dabei in Brasilien eingereicht, wo Nestlé bereits eine starke Marktstellung innehat. In Brasilien hat Nestlé beginnend mit 11 im Jahr 1990 bis zu 58 Patentanmeldungen im Jahr 1998 getätigt. Der Abbau des Patentierungsaus-schlusses für Nahrungsmittel im Jahr 1997 führte allerdings zu keinem Anstieg der Anmeldungsaktivität, die von 54 im Jahr 1886 auf 42 im Jahr 1997 fiel. Diese Ent-wicklung steht im Widerspruch zum allgemeinen Trend mit einem 80%igen Anstieg der Nahrungsmittelpatentanmeldungen von 1996 bis 1997. Die chinesischen Pa-tentanmeldungen von Nestlé stiegen von 7 im Jahr 1990 stetig an. Der Abbau des Patentierungsausschlusses in China im Jahr 1992 führte zu einem Anstieg der Nahrungsmittelpatentanmeldungen von 9 auf 15 im Jahr 1993. Nestlé hat weit weniger Anmeldungen in Indien als in Brasilien und China seit 1990 getätigt. Ausgehend von zwei Anmeldungen im Jahr 1990 wurden maximal 19 im Jahr 1997 erreicht.

668 Indian Ministry of food production Industries 2000, using data from Source - APEDA Export Statistics and Annual Report 1999-2000 of the Indian Ministry of food production Industries, verfügbar unter www.mofpi.nic.in/industryspecificinformation/index.htm.

669 Diese Daten wurden von der Autorin in Zusammenarbeit mit *Schmoch* im Jahre 2004 am Fraunhofer Institut für System- und Innovationsforschung in Karlsruhe erhoben unter Verwendung von PLUS-PAT, einer Datenbank von Questel-Orbit.

Tabelle 19:
Nestlés deutsche, brasilianische, chinesische und indische Nahrungsmittelpatentanmeldungen mit Priorität im Zeitraum von 1990 bis 2001.[670]

Jahr	Deutschland	Brasilien	China	Indien
90	30	11	7	2
91	29	16	12	9
92	27	15	9	9
93	31	18	15	5
94	49	33	21	9
95	55	29	36	18
96	75	54	39	11
97	47	42	30	19
98	43	58	43	17
99	26	57	43	6
00	16	43	31	0
01	1	32	3	0

Nestlés Nahrungsmittelpatentanmeldungen mit Bezug zur Biotechnologie in Deutschland, Brasilien, China und Indien sind in der Tabelle 20 dargestellt.[671] Nestlé hat jährlich maximal fünf deutsche Anmeldungen zwischen 1990 und 2001 getätigt. Die brasilianischen und die chinesichen übertrafen die deutschen sogar ab dem Jahr 1993 mit jeweils zwei Anmeldungen und maximal sieben Anmeldungen in Brasilien in den Jahren 1999 und 2000 und sechs in China im Jahr 1999. Die Abschaffung des Patentierungsausschlusses für Nahrungsmittel hatte keinen nachweislichen Effekt auf die Patentanmeldungszahlen in Brasilien mit einer im Jahr 1996 und drei im Folgejahr. Dies gilt auch für die Abschaffung des Patentierungsausschlusses in China im Jahr 1992. Die Aktivitäten von Nestlé hinsichtlich Nahrungsmittelpatentanmeldungen mit Bezug zur Biotechnologie waren insgesamt vergleichsweise gering.

670 Patentanmeldungen, die als Haupt- oder Nebenklasse mindestens eine der in Tabelle 13 definierten IPC Unterklassen aufweisen. Zeitlicher Anknüpfungspunkt ist das früheste Prioritätsdatum der jeweiligen Patentanmeldung. Diese Daten wurden von der Autorin in Zusammenarbeit mit *Schmoch* im Jahre 2004 am Fraunhofer Institut für System- und Innovationsforschung in Karlsruhe erhoben unter Verwendung von PLUSPAT, einer Datenbank von Questel-Orbit.

671 Diese Daten wurden von der Autorin in Zusammenarbeit mit *Schmoch* im Jahre 2004 am Fraunhofer Institut für System- und Innovationsforschung in Karlsruhe erhoben unter Verwendung von PLUSPAT, einer Datenbank von Questel-Orbit.

Tabelle 20:
Nestlés deutsche, brasilianische, chinesische und indische Nahrungsmittelpatentanmeldungen mit Biotechnologiebezug mit Priorität im Zeitraum von 1990 bis 2001.[672]

Jahr	Deutschland	Brasilien	China	Indien
90	1	0	0	0
91	1	1	1	0
92	5	1	0	0
93	1	2	2	0
94	2	3	3	0
95	3	2	4	0
96	1	1	3	0
97	2	3	2	0
98	0	3	2	0
99	3	7	6	0
00	3	7	2	0
01	0	3	0	0

D. Beurteilung

Das TRIPs Übereinkommen hat den Nahrungsmittelsektor im Hinblick auf die Pa-tentierbarkeit von Nahrungsmitteln nachhaltig beeinflusst. Nahrungsmittelerfindungen sind nun in den meisten Ländern der Welt patentierbar mit Ausnahme von pflanzen- und tierbezogenen Erfindungen. Das TRIPs Übereinkommen führte ent-sprechend zu einem Anstieg der Nahrungsmittelpatentanmeldungen in Brasilien, China und Indian, wo Nahrungsmittel vormals vom Patentschutz ausgenommen waren.

672 Patentanmeldungen, die als Haupt- oder Nebenklasse mindestens eine der in Tabelle 13 definierten IPC Unterklassen sowie mindestens eine der in der in Tabelle 14 definierten IPC Unterklassen aufweisen. Zeitlicher Anknüpfungspunkt ist das früheste Prioritätsdatum der jeweiligen Patentanmeldung. Diese Daten wurden von der Autorin in Zusammenarbeit mit *Schmoch* im Jahre 2004 am Fraunhofer Institut für System- und Innovationsforschung in Karlsruhe erhoben unter Verwendung von PLUSPAT, einer Datenbank von Questel-Orbit.

Teil II. Innovation im heutigen Nahrungsmittelsektor

Der Nahrungsmittelsektor weist zahlreiche technologische Entwicklungen und Inno-vationsfelder auf, allen voran die Biotechnologie. Sie hat sowohl die landwirtschaftliche Erzeugnisse als auch die Nahrungsmittelverarbeitung verändert. Die Pflanzenbiotechnologie ermöglicht die Optimierung der agronomischen Eigenschaften, der verarbeitungstechnischen und der ernährungsphysiologischen Eigenschaften der Pflanzen.[673] Das erfolgreichste Beispiel für die Verbesserung der agronomischen Eigenschaften sind herbizidresistente Pflanzen, die in der Regel nur eine Einmalbehandlung mit einem Totalherbizid erfordern und somit die Kosten der landwirtschaftlichen Erzeugung beträchtlich senken können. Die weltweite Anbaufläche mit gentechnisch veränderten Pflanzen betrug 90 Millionen Hektar im Jahr 2005 und stieg im Vergleich zum Vorjahr um 11% an.[674] Die U.S.A., Argentinien, Brasilien, Canada, China, Paraguay und Indien sind dabei führend. Der globale Markwert der gentechnisch veränderten Pflanzen wurde auf U.S.$5.25 Milliarden im Jahr 2005 ausgehend von U.S.$ 4,7 Milliarden im Vorjahr geschätzt und beläuft sich auf 15% des weltweiten Pflanzenschutzmarktes und 18% des weltweiten Saatgutmarktes.[675] Die Tierbiotechnologie steht vergleichsweise noch am Anfang. So werden Züchtungsverfahren schon durch den Einsatz von molekularen Markern und Reproduktionstechnologien wie der künstliche Befruchtung und dem Embryonentransfer beschleunigt.[676] Die Biotechnologie hat die Nahrungsmittelverarbeitung schon weitestgehend durchdrungen. So werden zahlreiche Mikroorganismen teilweise auch genetisch veränderter Natur in bestehenden Verarbeitungsprozessen eingesetzt. Ein breites Band an Nahrungsmittelzusatzstoffen und Prozessierungshilfen werden bereits mit Hilfe von Mikroorganismen hergestellt, so beispielsweise Aminosäuren, Zitronensäure, Vitamine, Farbstoffe, Gummis und auch Enzyme.[677]

Die Akzeptanz der Konsumenten entscheidet letztlich über die Verwendung neuer Technologien im Nahrungsmittelsektor. Hinsichtlich gentechnisch veränderter Pflanzen sind die Meinungen gespalten, wobei insbesondere in Europa eine starke Vorsichtshaltung

673 Eine Überblick verschafft Tabelle 9. Weitere Hinweise in *McElroy*, Sustaining Agbiotechnology through Lean Times, 21 Nature Biotechnology 996, (2003). Siehe auch *Chua&Tingey*, Plant Biotechnology: Looking Forward to the Next Ten Years, 17 Current Opinion in Biotechnology 103 (2006). Hinsichtlich Weizen siehe *Bhalla*, Genetic Engineering of Wheat – Current Challenges and Opportunities, 24 Trends in Biotechnology 305 (2006).

674 *James*, Executive Summary of Global Status of Commercialized Biotech/GM Crops: 2005, ISAAA Briefs No. 34, Ithaca, NY 2005, 3.

675 *James*, Executive Summary of Global Status of Commercialized Biotech/GM Crops: 2005, ISAAA Briefs No. 34, Ithaca, NY 2005, 7. Weitere Hinweise bei *Brookes&Barfoot,* GM Crops: The Global Economic and Environmental Impact - The First Nine Years 1996-2004, AgBioForum, Vol. 8 (2&3) (2005), Article 15.

676 FAO, Electronic Forum on Biotechnology in Food and Agriculture, Conference 3: The Appropriateness, Significance and Application of Biotechnology Options in the Animal Agriculture of Developing Countries, June 12–August 25, 2000, verfügbar unter www.fao.org/biotech/C3doc.htm.

677 Einen Überblick verschafft Tabelle 11.

herrscht.[678] Gentechnisch veränderte Mikroorganismen in der Lebensmittelverarbeitung haben sich dagegen auch in Europa durchgesetzt und stoßen auf keine vergleichbaren Verbraucherbedenken.

Teil III: Die Schutzrechtssituation des Nahrungsmittelsektors

A. Schutz von pflanzenbezogenen Erfindungen unter dem Sortenschutz

Der Schutz von pflanzenbezogenen Innovationen ist durch den Sortenschutz wie auch durch den Patentschutz möglich. Die Voraussetzungen des Sortenschutzes sind Neuheit, Homogenität, Beständigkeit, Unterscheidbarkeit und eine eintragbare Sortenschutzbezeichnung. Diese Beurteilungskriterien eignen sich hervorragend für die tranditionelle Pflanzenzüchtung. Für die pflanzenbiotechnologischen Erfindungen und deren Verwertung in einer Pflanzensorte bereitet nur die Unterscheidbarkeit Schwierigkeiten. Die Prüfung erfolgt dabei im Feldanbau auf der Grundlage eines für die jeweilige Art fest definierten Merkmalskataloges. Der Sortenschutz dauert 25 Jahre ab seiner Erteilung und erfasst das Vermehrungsmaterial als konkrete körperliche Materie. Er bietet anders als das Patentrecht keinen generischen Schutz, sondern erstreckt sich nur auf Pflanzensorten, die von der geschützten Pflanzensorte im wesentlichen abgeleitet sind. Die Züchtung neuer Pflanzensorten und deren Kommerzialisierung ausserhalb der wesentlichen Ableitung ist dagegen nicht erfasst. Die Nachbauregelung im Sortenschutzrecht gewährt dem Landwirt weiterhin die Verwendung von Erntegut als Saatgut in der nächsten Generation gegen eine ange-messene Vergütung. Eine Einschränkung des Züchtervorbehalts, die Anpasung des Konzepts der im wesentlichen abgeleiteten Sorte an die technischen Entwicklungen sowie die Verbesserung der Auskunftsverpflichtung bei dem Nachbau von Pflanzensorten könnten den Sortenschutz erheblich stärken.

B. Schutz von pflanzenbezogenen Erfindungen unter dem Patentrecht

Die Erteilungsvoraussetzungen für Patente sind Neuheit, erfinderische Tätigkeit und gewerbliche Anwendbarkeit. Zudem muss die Erfindung so ausreichend offenbart sein, dass der Fachmann sie ausführen kann. Hinsichtlich transgener Pflanzen und Pflanzensorten stellen sich die erfinderische Tätigkeit und die ausreichende Offenbarung als schwierigste Hürden dar. Der Schutzbereich eines Patents auf biologisches Material er-

678 *Gurau&Randhod*, The Atlantic Divide in Food Biotechnology: Differences in Industry, Market and Consumers' Perception between the U.S. and the UK, 5 Int'l J. Biotechnology 141, 153 (2003).

streckt sich auf jedes biologische Material, das von dem geschützten Material durch Vermehrung gewonnen wurde, soweit es dieselben wesentlichen Eigenschaften enthält. Die Nachbauregelung und der Züchtervorbehalt haben nun auch in das Patentrecht als Schutzbereichsausnahmen Eingang gefunden. Die Patentlaufzeit beträgt 20 Jahre. Angesichts der langen Entwicklungszeiten für gentechnisch veränderte Pflanzensorten bleiben meist nur noch wenige Jahre zur Amortisierung der Entwicklungskosten. Ein ergänzendes Schutzzertifikat zum Ausgleich des Zeitverlusts durch die Zulassungserfordernisse für gentechnisch veränderte Pflanzen wird daher vorgeschlagen. Zusammenfassend stellt das Patentrecht ein etabliertes Schutzsystem auch für pflanzengezogene Erfindungen dar, das mit der Aufhebung des Doppelschutzverbotes für Pflanzensorten und mit der Eindämmung der weitreichenden Patentierungsausnahmen sowie der Einführung eines ergänzenden Schutzzertifikats noch erheblich verbessert werden könnte.

C. Schutz von Erfindungen in der Nahrungsmittelverarbeitung

Der Patentschutz für Erfindungen, die der Nahrungsmittelverarbeitung dienen, ist mangels weitreichender Schutzbereichsausnahmen stärker als hinsichtlich der pflanzenbezogenen Erfindungen. Nahrungsmittelerfindungen stellen aus chemischer Sicht meist makromolekulare Substanzen dar. Diese sind nur schwer durch eine exakte chemische Strukturformel zu beschreiben. Die richterrechtlich entwickelte An-spruchskategorie des Product-by-process Anspruchs ermöglicht nun auch die Bean-spruchung von makromolekularen oder anderweitig schwierig charakterisierbaren Stoffen. Die Kennzeichnung erfolgt dabei allein durch das Verfahren zur Herstellung dieses Stoffes. Der Schutzbereich von Product-by-process Ansprüchen wird in den betrachteten Rechtskreisen Deutschland, England und USA jedoch unterschiedlich gesehen. Während in Deutschland keine Begrenzung auf die Verfahrensparameter erfolgt, beschränken die Verfahrensparameter den Schutzumfang eines Product-by-process Anspruches nach der englischen Rechtsprechung. In den U.S.A herrscht bezüglich des Schutzumfangs von Product-by-process Ansprüchen erhebliche Rechtsunsicherheit, die auf den entgegengesetzten Entscheidungen des *Court of Appeals for the Federal Circuit* (CAFC) *Scripps v. Genentech*[679] und *Atlantic v. Faytax*[680] be-ruht. Während der Product-by-process Anspruch ein neues Produkt unabhängig von der Neuheit seines Verfahrens schützt, setzt der Schutz des unmittelbaren Ver-fahrensprodukts nach Art. 64(2) EPÜ zwingend ein neues und erfinderisches Verfahren voraus. Der Schutz nach Art. 64(2) EPÜ hängt entscheidend davon ab, welche Produkte noch als unmittelbar nach dem patentierten Verfahren hergestellt gelten. Nach dem chronologischen Ansatz umfasst er nur solche Produkte, die zeitlich unmittelbar nach dem letzten beanspruchten Verfahrensschritt

679 *Scripps Clinic&Research Foundation v. Genentech, Inc*., 927 F.2d 1565, 18 USPY 2d 1001 (Fed. Cir. 1991).

680 *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F. 2d 834, 23 USPQ 2d 1481 (Fed. Cir. 1992). German translation in GRUR Int. 1997, 563 mit Anmerkung *Groebl*.

entstehen. Die nach der historischen und der teleologischen Auslegung zu bevorzugende Eigenschaftstheorie stellt dagegen auf die technischen Effekte der wesentlichen Verfahrensparameter ab. Solange diese vorhanden sind, gilt das Erzeugnis als unmittelbares Verfahrensprodukt und wird vom Schutzumfang des Verfahrensanspruchs mitumfasst. Anhand zweier pflanzenbezogener Patente werden diese Unterschiede verdeutlicht.

Zusammenfassung

Der Nahrungsmittelsektor nimmt insgesamt eine im Vergleich zu anderen industriellen Sektoren aussergewöhnliche Stellung ein, die sich im Patentrecht wiederspiegelt und die sich nicht zuletzt im Patentierungsauschluss für Nahrungsmittel in Deutschland bis 1967 und in vielen Entwicklungs- und Schwellenländern zur Sicherung der Volksernährung bis in jüngster Zeit zeigt. Das TRIPs Übereinkommen hat nun Nahrungsmittel dem Patentschutz auch in Schwellenländern wie Brasilien, China und Indien zugänglich gemacht. Die durchaus gute wirtschaftliche Entwicklung der betreffenden Nahrungsmittelsektoren zeigt, dass die Patentierbarkeit von Nahrungsmitteln, die Nahrungsmittelverfügbarkeit nicht spürbar beschränkt. Der Nahrungsmittelsektor behält auch weiterhin dank umfassender Schutzbereichsausnahmen wie der Nachbauregelung und des Züchtervorbehalts im europäischen Patent- und Sortenschutzrecht eine besondere Position im Recht des Geistigen Eigentums.

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