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]

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]

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.