

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.<sup>500</sup>

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.<sup>501</sup> 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.<sup>502</sup> 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.<sup>503</sup> 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.

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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, 3<sup>rd</sup> ed., Köln etc. 1968, No. 5, Sec. 1 PatG, *Tetzner*, Kommentar zum Patentgesetz, 2<sup>nd</sup> 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.

## 1. Patentability of product-by-process claims

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.<sup>504</sup> 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.”<sup>505</sup> 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.<sup>506</sup>

The Federal Supreme Court of Germany has stated with respect to the admissibility<sup>507</sup> 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.”<sup>508</sup> 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.<sup>509</sup>

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.”<sup>510</sup>

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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, 4<sup>th</sup> ed. London 1999, 170. The recent *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.<sup>511</sup>

A product-by-process claim is only admissible if the product is new *per se*.<sup>512</sup> The product must be distinguishable *per se* from products of the prior art.<sup>513</sup> Only one production process is required to define the product. Product-by-process claims are applicable to all kinds of products, including chemical substances,<sup>514</sup> anti-bodies,<sup>515</sup> immunomodulators,<sup>516</sup> or plants.<sup>517</sup> With regard to plants the Federal Supreme Court of Germany states, that in case of insufficient 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.<sup>518</sup>

## 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).

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511 *Avery&Mayer*, Das US-Patent, 3<sup>rd</sup> 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, *Tetraploide 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.<sup>519</sup> 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.<sup>520</sup> 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.<sup>521</sup>

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.<sup>522</sup> 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.”<sup>523</sup> 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, crystallinity and optical or biological activity.<sup>524</sup> This view is also shared by the EPO. Product-by-process claims under the EPC protect products as such, independent of their production process.<sup>525</sup> The scope of a product-by-process claim in the UK is confined to substances made by the defined process.<sup>526</sup>

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519 Bundesgerichtshof (Federal Supreme Court) 06.07.1971 Case:OZB 9/70 “Trioxane,” IIC 1972, 226, Headnote 4. *Kraßer*, Lehrbuch des Patentrechts, 5<sup>th</sup> 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, 7<sup>th</sup> 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, 4<sup>th</sup> 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.<sup>527</sup> 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.<sup>528</sup> Initially, the characterizing process was construed as limiting the scope of a product-by-process claim. In 1991, the *Scripps v. Genentech*<sup>529</sup> 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*,<sup>530</sup> 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.<sup>531</sup>

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.<sup>532</sup> 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.<sup>533</sup>

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527 1891, C.D. 200, 57 (Commissioner of Patents 1891), in: *Avery& Mayer*, Das US-Patent, 3<sup>rd</sup> ed., Köln et al. 2003, 94.

528 *Avery&Mayer*, Das US-Patent, 3<sup>rd</sup> 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 *Groebel*.

531 *Groebel*, 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.<sup>534</sup>

*bb. The Atlantic decision*

In *Atlantic*, the CAFC held that process terms in product-by-process claims served as limitations in determining infringement.<sup>535</sup> 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.”<sup>536</sup> 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.<sup>537</sup>

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.”<sup>538</sup>

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.”<sup>539</sup>

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.<sup>540</sup> *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.<sup>541</sup> 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.<sup>542</sup> 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.<sup>543</sup> 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.<sup>544</sup> *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

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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.<sup>545</sup> 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.<sup>546</sup> 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,”<sup>547</sup> *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.<sup>548</sup> The interpretation of claims depends on the particular invention, in light of the specification and prosecution history and prior art for the specific case.<sup>549</sup> 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.<sup>550</sup> 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.<sup>551</sup>

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

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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.* – suggestion 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.”<sup>552</sup> 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.<sup>553</sup> 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”<sup>554</sup> to old products would apply aspects of patentability to infringement matters.<sup>555</sup> 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.<sup>556</sup> *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.”<sup>557</sup>

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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.<sup>558</sup>

Article 64(2) EPC applies to all processes whose starting materials differ from the end-product.<sup>559</sup> 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.<sup>560</sup> 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.<sup>561</sup> 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.<sup>562</sup>

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558 Schennen&Stauder in: Singer&Stauder (eds.) European Patent Convention – A Commentary, 3<sup>rd</sup> 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.