

Scientific Advisory Board on Biodiversity and Genetic Resources at the Federal Ministry of Food, Agriculture and Consumer Protection

Product-By-Process Claims for Biopatents in Animal and Plant Breeding – Prerequisites, Problems and Recommendations

Position Paper of the Scientific Advisory Board on Biodiversity and Genetic Resources at the Federal Ministry of Food, Agriculture and Consumer Protection

(Translation of German original paper)

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Summary

Following the broccoli and tomato decision by the Enlarged Board of Appeal of the European Patent Office, so-called product-by-process patents are becoming increasingly significant in biopatenting. Granting product-by-process patents in animal and plant breeding may have the effect of evading the intended legal exclusion of conventional breeding methods from patentability. For on the one hand, granting product-by-process patents does currently not require the patentability of the underlying process. On the other hand, in the prevailing opinion the scope of protection from a product-by-process claim is currently not limited to

products that have been obtained by using the processes specified in the patent. This Position Paper recommends that it be made legally clear that products derived from conventional breeding methods cannot be patented. Moreover, product-by-process patents should only be granted if the structure of the product cannot be fully described and if the description of the product also essentially depends on the production process. Finally, the scope of protection from a product-by-process patent should be restricted to products obtained from the processes specified in the patent.

Introduction

In July 2010, the Scientific Advisory Board on Biodiversity and Genetic Resources published a highly observed opinion on biopatents.¹ It identified numerous problems resulting from current patenting practices in the area of animal and plant breeding. A matter of particular concern was the granting of patents on conventional breeding methods, which are also referred to in the law as “essentially biological processes”.² According to the wording of the European Patent Directive, the European Patent Convention and the German Patent Act, such processes are actually not patentable.³ There was, however, uncertainty over the appropriate interpretation of the question of what precisely constitutes an “essentially biological process” and whether the combination with other, technical

steps can justify the patentability of a traditional breeding method. A decision by the Enlarged Board of Appeal of the European Patent Office in the so-called broccoli and tomato case⁴ of December 2010 has clarified that essentially biological breeding methods which are exclusively based on selection or cross-breeding are excluded from patentability. In particular, marker-based breeding methods as a whole are not patentable, even if the marker-based selection step itself can be patented; the latter is, however, a working and not a production process, with the legal consequence that the patent protection does not pertain to the plants produced.

The broccoli patent EP1069819 by Plant Bioscience, which was the subject of the hearing,

¹The opinion is available at: <http://www.bmelv.de/cae/servlet/contentblob/1124688/publicationFile/90303/Gutachten-Biopatente.pdf> (German). http://www.bmelv.de/SharedDocs/Downloads/EN/Ministry/Biopatents.pdf?__blob=publicationFile (English)

²Section 2a (1) of the German Patent Act in conjunction with Article 4 (1a) of Biopatent Directive 98/44/EC (Official Journal 1998, L 213, p. 13) and Article 53 (b) EPC and Article 27 (3b) TRIPS.

³Ibid.

⁴EPO, EBoA, cases G2/07 and G1/08

claims, in addition to the breeding and selection methods, also the edible *Brassica* plants and parts thereof, the seeds and the cells of the broccoli plant.⁵ These claims are worded in two ways: as a direct product claim on broccoli plants, the inflorescence and the cells of broccoli with specific properties;⁶ and as so-called product-by-process claims on the edible broccoli plant, parts of the plant and the seeds of the broccoli produced using the methods described in the patent.⁷ The verdict by the Enlarged Board of Appeal contains no decision with regard to these product claims. The granting of such product claims depends upon whether the products fulfil the general patent criteria of novelty, inventive step and industrial applicability, which in this case is disputed. A decision by the European Patent Office in this matter is anticipated in autumn 2011.

Currently the eventual granting of a product-by-process claim is not dependent on whether the underlying breeding method is patentable. Furthermore, according to effective case law in Germany, a product-by-process claim is a fully-fledged product claim and would, in the above case, not be restricted to the broccoli that was actually obtained by the processes specified in the patent. Granting product-by-process patents may therefore have the effect of evading the intended legal exclusion of conventional breeding methods from patentability.

Against this background this Position Paper provides an overview of the legal concepts and describes the prerequisites and the legal consequences of granting patents on product-by-process claims in the EU, Germany, the United Kingdom and the USA. In particular we discuss the issue of whether the scope of product-by-process claims should be linked to the use of the processes specified in the patent. The final conclusion identifies ambiguities in the legal framework and offers recommendations for amending the EU Biopatent Directive 98/44/EC⁸ to render it more precise.

⁵The patent claims version EP1069819 (B1) can be found at: http://worldwide.espacenet.com/publicationDetails/originalDocument?FT=D&date=20020724&DB=EPODOC&locale=de_EP&CC=EP&NR=1069819B1&KC=B1, last accessed 30.9.2011.

⁶Patent EP1069819 (B1), claims 13-18

⁷Claims 1-8 describe the process, claims 9-11 contain the PbP claims that refer to the process described in claims 1-6.

⁸Official Journal 1998, L 213, p 13

1 General considerations

1.1 Concepts and problems

Patent law differentiates between product and process patents.⁹ A product patent can either refer to a machine or manufacture (*Sachpatent*) or to a composition-of-matter (*Stoffpatent*).^{10,11} Composition-of-matter patents are product patents in the field of chemistry, yet increasingly also in biotechnology.¹² The composition-of-matter patent protects the new substance. Normally this substance is unequivocally identified in the patent claim through specific properties (structural attributes). The new substance can therefore be identified purely through inspection of the matter.

Process patents are distinguished from product patents and describe either a production process or a method. Production processes are processes by which something novel is produced or an existing object is essentially altered.¹³ The product (or composition-of-matter) automatically enjoys a certain protection in the form of so-called secondary product protection (without the product itself having to be patented).¹⁴ For patents in the field of biology, this secondary product protection also covers the ensuing generations of the patented biological material (so-called vertical patent extension).¹⁵ Both derived product protection and vertical patent extension do not apply to methods, that is processes that do not

obtain a new product, but use or manipulate an object without altering it.¹⁶ The selection methods used in animal and plant breeding constitute such working processes, since they select genetic material, but do not alter it.

Occasionally, for instance in synthetic chemistry, it is not possible to precisely identify the structural or physical and chemical attributes of a product, for example if there are no suitable analysis and measuring methods available. Therefore, to precisely demarcate the product, the production conditions are specified in the patent.¹⁷ Such claims are called product-by-process (PbP) claims.¹⁸ For example, in some of the claims for the “broccoli and tomato” patents, the plants are defined as products by taking recourse to the breeding method they have been obtained by (in the case of the broccoli, a so-called smart breeding process).¹⁹ With regard to PbP claims in animal and plant breeding, there is a fundamental question over the significance of the underlying production processes for the legitimacy and the extent of the patent protection. On the one hand, clarification is needed on the extent to which patent protection can be granted for a product based on a non-patentable process, in this case in particular one that is an essentially biological process. On the other hand, it is doubtful whether the protection is limited to those products obtained by the production process that co-

⁹ Cf. Section 9 German Patent Act; Rule 43 (2) EPCIR.

¹⁰ *Scharen*, in Benkard, Patentgesetz, Gebrauchsmustergesetz, 10. Aufl. 2006, § 14 Patentgesetz, comment no. 40.

¹¹ *Mes*, Patentgesetz Gebrauchsmustergesetz, 2. Auflage 2005, § 1 Patentgesetz, comment no. 124 et seq.

¹² *Uhrich*, Stoffschutz, 2010, p 141 f. with further references.

¹³ *Walter*, German Association for the Protection of Intellectual Property (GRUR) Prax 2010, p 329 (330).

¹⁴ *Ibid.*

¹⁵ *Walter*, German Association for the Protection of Intellectual Property (GRUR) Prax 2010, p 329 (330)..

¹⁶ *Ibid.*

¹⁷ *Schrell/Heide*, German Association for the Protection of Intellectual Property (GRUR) 2006, p 383

¹⁸ *Rogge*, Mitteilungen der deutschen Patentanwälte 2005, p 145.

¹⁹ Cf. EPO, EBoA, cases G 2/07 and G 1/08, p 4, p 10. Cf. also *Hüttermann/Storz*, Mitteilungen der deutschen Patentanwälte 2009, p 277 ff.

determines the characterization of the product in the patent claim, or whether the patent protection also covers products of identical substances obtained by another process.

1.2 PbP claims in various legal systems

a. Legal situation under the European Patent Convention

In line with the “Guidelines for Examination in the European Patent Office” (Part C, Chapter III, 4.12), the European Patent Office approves PbP claims if they fulfil the requirements for patentability (novelty, inventive step, industrial application). The Board of Appeals at the Patent Office presumes that PbP claims are only permissible if

*“there is no other information available in the application which could enable the applicant to define the product satisfactorily by reference to its composition, structure or some other testable parameter.”*²⁰

This concurs with the prevailing opinion in Germany that the wording of PbP claims is a sort of compromise when the precise structural description of the substances, as required for a composition-of-matter patent, is not possible.

b. Legal situation in Germany

According to German case law PbP claims are only permissible if there is a need for them; hence if definition of the product by means of its structural attributes or its physical and chemical attributes is “impossible or entirely impracticable.”²¹ In this respect, the PbP claim is subsidiary. The reference to the production process in a PbP claim serves to characterize the product. Consequently, the patentability of the underlying process is not relevant.²² The Federal Court of Justice explicates:

*“For, in spite of the description using the production process, the object of the patent is the product as such, which must fulfil the prerequisites for patentability regardless of its production process.”*²³

Since a PbP claim is a product claim, the general requirements for patentability also apply, in particular the “novelty” of the product itself and the “inventive step.”²⁴

c. The legal situation in the United Kingdom

In the United Kingdom PbP claims are accepted.²⁵ Unlike in German or European law, patents in the past referred to the novelty and inventive step of the process and not the product.²⁶ The decision by the House of Lords in the *Kirin-Amgen* case marks a turnabout, making the novelty of the production process on principle not suitable to justify a

²⁰ Technical Board of Appeals, *International Flavours*, Official Journal EPO 1984, p 309 (310).

²¹ Federal Court of Justice, German Association for the Protection of Intellectual Property (GRUR) 1993, p 651 (655) – *Tetraploide Kamille*.

²² *Schrell/Heide*, German Association for the Protection of Intellectual Property (GRUR) 2006, p 383 (383 f.); *Uhrich*, *Stoffschutz*, 2010, p 174 with further references.

²³ Federal Court of Justice, German Association for the Protection of Intellectual Property (GRUR) 1993, p 651 (655) – *Tetraploide Kamille*.

²⁴ *Schrell/Heide*, German Association for the Protection of Intellectual Property (GRUR) 2006, p 383.

²⁵ *Katzka*, MAS-IP Diploma Papers & Research Reports 2007, Paper 10, p 3.

²⁶ *Katzka* (Note 17), p 3.

patent for a product that itself is not novel.²⁷ This implements, for one, harmonization with the prevailing opinion in Germany and Europe that the novelty of the product and not of the process is essential. Secondly, the threshold for the required inventive step has now been significantly raised.

d. The legal situation in the United States

The legal concept of PbP claims has been acknowledged in US law ever since the so-called *Painter* decision of 1891.²⁸ Here, too, the product itself must be a novelty.²⁹ If the structure of the invented product is not entirely known or too complex for analysis, the inventor can use the production process to define the product.³⁰

e. Conclusions

PbP patents are recognized under the European Patent Convention as well as prevailing case law in Germany, the United Kingdom and the United States. In all of these legal systems, they serve as a 'compromise' for describing composition-of-matter patents, for which sufficient structural characterization is not possible or is impracticable. In all of these legal circles today the granting of patents is based on the novelty of the product; the novelty of the process alone is not suitable justification of a PbP claim.

²⁷ *Kirin Amgen v. Hoechst Marion Russel* via Lord Hoffmann, [2004] UKHL 46, paras. 88 ff.; 101 = German Association for the Protection of Intellectual Property (GRUR) Int 2005, p 343 ff.:

"The practice in the United Kingdom under the Patents Act 1949 and earlier was to treat the fact that a product was made by a new process as sufficient to distinguish it from an identical product which was already part of the state of the art. This was not particularly logical, because the history of how a product was made is not an attribute which it carries around and makes it something new. It was still the same product, even if made in a different way. But the English practice had practical advantages when the extent of protection conferred by a patent was undefined (as it was until 1977) and it was assumed that a process claim could be infringed only by using that process in the United Kingdom. A product-by-process claim had the advantage of enabling the inventor of a new process to pursue not only the manufacturer who infringed his claim to the process but also, by virtue of the separate "product-by-process" claim, anyone who dealt in a product which had been made by that process. That was particularly useful in the case of the importation of a product made by someone outside the jurisdiction by a process which would have infringed the process claim if it had been made in this country.

[...]

I think it is important that the United Kingdom should apply the same law as the EPO and the other Member States when deciding what counts as new for the purposes of the EPC: compare Merrell Dow Pharmaceuticals Inc v H.N. Norton & Co Ltd [1996] RPC 76, 82. It is true that this means a change in a practice which has existed for many years. But the difference is unlikely to be of great practical importance because a patentee can rely instead on the process claim and article 64(2). It would be most unfortunate if we were to uphold the validity of a patent which would on identical facts have been revoked in opposition proceedings in the EPO. I would therefore allow this part of the appeal and declare claim 26 invalid on the ground of anticipation. "

²⁸ *Fabry*, German Association for the Protection of Intellectual Property (GRUR) Int 2009, p 803 (805).

²⁹ *Grant/Smyth*, European Intellectual Property Review 2010, p 635 (637).

³⁰ See the decision *Abbott v. Sandoz*, 566 F. 3d 1282 (2009): *"In the modern context, however, if an inventor invents a product whose structure is either not fully known or too complex to analyze (...), this court clarifies that the inventor is absolutely free to use process steps to define this product."* (p 20).

2 Product patents despite non-patentability of the production process

2.1 The provisions of the TRIPS Agreement

Under Article 27 (3b) of the TRIPS Agreement, member states may exclude “essentially biological processes” from patentability. Article 28 of the TRIPS Agreement regulates the rights conferred by patents. Section 1b also confers a process patent the right to “the product obtained directly by that process.” In this respect the product protection described in Article 28 (1b) of the TRIPS Agreement is secondary product protection. Articles 27 and 28 of TRIPS do not directly address PbP claims.

2.2 The legal situation under the European Patent Convention and the Biopatent Directive

Under Article 4 (1a) of the EU Biopatent Directive 98/44/EC plant and animal varieties are excluded from patentability. A variety is defined by its whole genome and is defined by the expression of the characteristics resulting from a given genotype or combination of genotypes.³¹ Plants or animals are patentable above and below variety/breed level,³² additionally processes relating to multiple plant varieties or animal breeds are patentable.³³

The Biopatent Directive does not expressly address the issue of PbP claims and their extension to products made using non-patentable (essentially biological) breeding methods. Article 4 of the Biopatent Directive states:

*“(1) The following shall not be patentable
[...]
b) essentially biological processes for the production of plants or animals.”*

The same applies under Article 53 of the European Patent Convention (EPC):

*“European patents shall not be granted in respect of:
[...]
b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof.”*

In the “broccoli and tomato” cases, the Enlarged Board of Appeal commented only on the patentability of the (breeding) process, hence not answering the question of patent protection for the plants as products. Clarification is needed on whether these could possibly be protected by PbP claims even if the underlying production processes, being “essentially biological,” are not patentable.

³¹Recital no. 30 of the EU Biopatent Directive 98/44/EC: “the concept ‘plant variety’ [...], pursuant to which a variety is defined by its whole genome and therefore possesses individuality and is clearly distinguishable from other varieties.” Rule 26 (4) of the EPCIR: ‘Plant variety’ means any 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: (a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes, (b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and (c) considered as a unit with regard to its suitability for being propagated unchanged.”

³²Advisory Board on Biodiversity and Genetic Resources at the BMELV, Biopatents – A Threat to the Use and Conservation of Agrobiodiversity?, 2010, p 11.

³³Ibid, p 10-11. The pertinent legal provisions are Section 2a (2) 1 of the German Patent Act in conjunction with Rule 27 (b) of the EPCIR and Article 4 (2) of the EU Biopatents Directive 98/44/EC.

In April 2011 the European Patent Office (EPO) granted a patent for melons³⁴ possessing resistances to specific viruses (EP1962578).³⁵ The resistance, which originally occurred in an Indian melon variety, can be transferred to other melon varieties both through purely conventional breeding and through genetic modification. The product claim is partially described by a process.³⁶

Apparently, the EPO presently presumes that plants are patentable, even if they are based on conventional breeding. For instance, the EPO apparently has no fundamental objections to patenting a low-seed tomato that is chiefly described by the use of a conventional breeding method (EP1026942).³⁷

2.3 The legal situation in Germany

With regard to the “broccoli and tomato” cases, the question is whether a product patent with a PbP claim can also be granted for a product based on a non-patentable process (for example, an essentially biological breeding method such as smart breeding).

It is conceivable that the products of smart breeding processes gain patent protection through a PbP claim even if the underlying process is not patentable. This is true, however, only under the premise that the general requirements for a product patent (novelty, inventive step, industrial application) are fulfilled and a product definition is not possible using its structure or composition.

2.4 Conclusions

Should future precedence follow the EPO, making product patents possible without consideration to the non-patentability of the production process, the decisions made in the “broccoli and tomato” cases will lose considerable practical significance. For then, a product could be granted protection that could not be obtained through a process patent due to the lack of patentability of a breeding method, through a product patent based on a PbP claim. This would generate considerable tensions between the exclusion of essentially biological processes or methods from patentability and the granting of a PbP claim that is based on a non-patentable breeding method.

The logic behind excluding patentability of “essentially biological” processes under the EU Biopatent Directive and the European Patent Convention is that a product (a manufacture or a composition of matter) should be excluded from patentability when it is characterized in the patent claim by an “essentially biological” process and when this process determines its identity. This contradicts the possibility of granting such PbP claims. This conclusion is also supported by the regulating philosophy of each of the exclusion provisions, for products originating from an “essentially biological” process lack the inventive step (novelty) compared with the naturally occurring substance composition or that attained through other biological selection, for example with regard to enhancing the product with specific ingredients. Fundamentally, the added value of the invention lies not in the structure, but in the reliability of the desired material

³⁴The process claims also made were not granted by the Patent Office.

³⁵<http://www.no-patents-on-seeds.org/de/information/aktuelles/melonen-als-erfindung-von-monsanto>.

³⁶“A *CYSD-resistant plant of the species *Cucumis melo*, said plant comprising an introgression [...], which introgression comprises a [...] QTL or [...] part thereof linked to at least one marker [...] wherein said marker is [...] and wherein said QTL is [...]*.” Said melon is therefore partially described by the use of a marker-based breeding method.

³⁷<http://www.misereor.de/presse/presse-meldungen/presse-meldungen-detals/article/neues-tomaten-patent-fuer-monsanto.html>.

composition (such as enhancing broccoli with anticarcinogenic compounds) and therefore in the scope of the method that allows something accidental in nature to become typical through the breeding process.

Lastly, the following consideration is also relevant to the non-patentability of the broccoli plant in the “broccoli and tomato” cases: if smart breeding

were qualified as a method, similar to a pure screening method, this would consequently exclude primary product protection through a PbP claim. Primary protection can certainly not be possible since not even secondary protection is granted for a method.³⁸

3 Rights conferred by product or composition-of-matter protection: restriction to the identifying production process

If the patentability of the product based on a PbP claim is supported, the consequential question is whether the PbP claim only protects a product based on precisely the process described in the patent or whether it extends to all identical products, regardless of how they were produced.

3.1 The legal situation under the European Patent Convention

The European Patent Convention does not address the issue of the scope of PbP claims. Article 69 (1) of the EPC deems the extent of protection conferred by the patent merely in general terms as “determined by the claims.” Accordingly, a composition-of-matter or product claim determined in part by reference to a process would be treated just as every other product claim.

Potentially, however, the different wording used in the patent claim compels differentiated treatment. While some patents in their reference to the process employ the term “obtained by,”³⁹ others use the term “obtainable by.” If this is interpreted in strict terms, the former claims would be restricted to products that are actually produced using the process specified in the patent, while the latter claims in contrast would be significantly broader in scope. The facts that the EPO does not take such differentiation into account in its Guidelines (Part C, Chapter III, 4.12) and the boards of appeal allow for substitution of the wordings speaks against this differentiation.⁴⁰ Thus we must assume that the EPO envisages absolute patent protection for PbP claims, which is not confined to the use of the process specified in the patent claim.⁴¹

³⁸ *Walter*, German Association for the Protection of Intellectual Property (GRUR) Prax 2010, p 329 (331).

³⁹ *Grant/Smyth*, European Intellectual Property Review 2010, p 635 (638).

⁴⁰ *Rogge*, Mitteilungen der deutschen Patentanwälte, 2005, p 145 (147).

⁴¹ This is also generally the opinion of *Benkard*, Europäisches Patentübereinkommen, 2002, Article 69 Rn. 48.

3.2 The legal situation in Germany

More recent case law in Germany points in a similar direction. The Federal Court of Justice's case law extends the scope of protection of PbP claims regardless of the manner of production to all identical products:

*“On the other hand, characterization does not require proof that the product described by the breeding method was also actually produced by means of the specified process. For, in spite of the description using the production process, the object of the patent is the product as such, which must fulfil the prerequisites for patentability regardless of its production process. This manner of description also does not restrict protection of the product to the production process specified for its characterization. The description of the breeding method serves merely to unambiguously characterize the product.”*⁴²

Thus, a product is also protected from other production methods. In its judgement on the *tetraploid chamomile*, the Federal Court of Justice relinquished its original differentiation in the *trioxane* decision according to the respective claim wording (“obtained by” or “obtainable by”).⁴³

The process attributes described in the patent therefore are not a restriction to the claim; in fact the product is protected absolutely. This is justified by the character of PbP claims as fully-fledged product claims. The opinion of the Federal Court of Justice is predominantly shared in the literature.⁴⁴ One considerable opposed opinion adheres to the earlier differentiation.⁴⁵

Pertaining to agrobiodiversity, the prevailing opinion means that citing a process for the production of plants, animals or other biological material may substantiate comprehensive claims to the specified plants, animals or other biological material, even if these were produced using a different process.

3.3 The legal situation in the United Kingdom

In 2004 the House of Lords addressed the question of the extent of a PbP claim in its *Kirin Amgen* decision.⁴⁶ In this case, the patentability of the product (the EPO protein) failed essentially due to its lack of novelty. But, according to *Lord Hoffmann* a patent infringement was already excluded

⁴² Federal Court of Justice, German Association for the Protection of Intellectual Property (GRUR) 1993, p 651 (655) – *Tetraploide Kamille*. See also Federal Court of Justice, German Association for the Protection of Intellectual Property (GRUR) 2010, p 414 (415) – *Thermoplastische Zusammensetzung*.

⁴³ Federal Court of Justice, German Association for the Protection of Intellectual Property (GRUR) 1972, p 80 (88) – *Trioxan*. According to this, the wording “obtained by” (*erhalten durch*) is meant to express that the patentee does not aspire for protection for other types of production as well.

⁴⁴ *Mes*, Patentgesetz, Gebrauchsmustergesetz, 2nd edition 2005, § 14 Patentgesetz, comment no. 94 with further references.

⁴⁵ *Uhrich*, *Stoffschutz*, 2010, p 175 f. with further references; *Hufnagel*, in: *Dieners/Reese, Handbuch des Pharmarechts*, 2010, Section 14 Rn. 136.

⁴⁶ *Kirin Amgen v. Hoechst Marion Russel via Lord Hoffmann*, [2004] UKHL 46.

because the defendant used a different process for the production of the substance than that described in the patent claim.⁴⁷ In *Generics (UK) Ltd. v. Lundbeck*⁴⁸ the court, by contrast, decided that citing *one* production process in the patent claim is sufficient for comprehensive protection of the product.⁴⁹ In this case, however, it was not a matter of the validity of a PbP claim, but of the production of a product the contents of which were completely described (through structural attributes).⁵⁰ Therefore, the extent of composition-of-matter protection for PbP claims in the United Kingdom is not yet specified.⁵¹

3.4 The legal situation in the United States

Until recently, the extent of protection of PbP claims in the United States was not yet conclusively clarified.⁵² After contradictory decisions by the Court of Appeals in *Scripps v. Genentech*⁵³ and *Atlantic v. Faytex*⁵⁴ the court recently adhered to a restrictive view in *Abbott v. Sandoz*.⁵⁵ According to this decision, reference to a specific production process in the scope of a PbP claim is understood as confining the content of the patent protection. If a product is produced using a different process than that specified, the patent is not infringed.⁵⁶

⁴⁷ "It may be clear from the language, context and background that the patentee intended to refer in general terms to, for example, every way of achieving a certain result, even though he has used language which is in some respects inappropriate in relation to a new way of achieving that result: compare *Regina (Quintavalle) v Secretary of State for Health* [2003] 2 AC 687. In the present case, however, I agree with the Court of Appeal (and with the judge, before he came to apply the Protocol questions) that the man skilled in the art would not have understood the claim as sufficiently general to include gene activation. He would have understood it to be limited to the expression of an exogenous DNA sequence which coded for EPO." (*Kirin Amgen v. Hoechst Marion Russel*, [2004] UKHL 46, para 80). See also *Brandi-Dohrn*, *Mitteilungen der deutschen Patentanwälte* 2005, p 337 (343); *Grant/Smyth*, *European Intellectual Property Review* 2010, p 635 (638).

⁴⁸ [2009] UKHL 12; on this Wechsler, *German Association for the Protection of Intellectual Property (GRUR) Int* 2009, p 363 f. and *Whitehead/Jackson/Kempner*, *Bio Science Law Review* Vol. 10 (2009), p 108 ff.

⁴⁹ Lord Neuberger elucidated: "[...] it appears clear to me that, [...] the product claim in the present case is valid. I appreciate that this means that, by finding one method of making a product, a person can obtain a monopoly for that product. However, that applies to any product claim. Further, where (as here) the product is a known desideratum, it can be said (as Lord Walker pointed out) that the invention is all the more creditable, as it is likely that there has been more competition than where the product has not been thought of. The role of fortuity in patent law cannot be doubted: it is inevitable, as in almost any area of life. Luck as well as skill often determines, for instance, who is first to file, whether a better product or process is soon discovered, or whether an invention turns out to be valuable. Further, while the law must be principled, it must also be clear and consistent." ([2009] UKHL 12 para 90).

⁵⁰ Cf. [2009] UKHL 12, para 94 via *Lord Neuberger*.

⁵¹ For absolute composition-of-matter protection by contrast, see *Fabry*, *German Association for the Protection of Intellectual Property (GRUR) Int* 2009, p 803 (804) with further references.

⁵² *Grant/Smyth*, *European Intellectual Property Review* 2010, p 635 (637).

⁵³ 927 F.2d 1565 (1991).

⁵⁴ 970 F.2d 834 (1992).

⁵⁵ 566 F.3d 1282 (2009).

⁵⁶ „This court’s rule regarding the proper treatment of product-by-process claims in infringement litigation carries its own simple logic. Assume a hypothetical chemical compound defined by process terms. The inventor declines to state any structures or characteristics of this compound. The inventor of this compound obtains a product-by-process claim: ‘Compound X, obtained by process Y.’ Enforcing this claim without reference to its defining terms would mean that an alleged infringer who produces compound X by process Z is still liable for infringement. But how would the courts ascertain that the alleged infringer’s compound is really the same as the patented compound? After all, the patent holder has just informed the public and claimed the new product solely in terms of a single process. Furthermore, what analytical tools can confirm that the alleged infringer’s compound is in fact infringing, other than a comparison of the claimed and accused infringing processes? If the basis of infringement is not the similarity of process, it can only be similarity of structure or characteristics, which the inventor has not disclosed. Why also would the courts deny others the right to freely practice process Z that may produce a better product in a better way?’ (566 F.3d 1282 (2009), p 20 f.).

In the field of agrobiodiversity, the extent of a PbP claim would therefore be limited to those animals or plants that were produced using the processes described in the patent. Nonetheless, a dissenting opinion rejected this narrow interpretation.⁵⁷

3.5 Conclusions

In Germany and at the EPO a broad interpretation of the extent of protection from PbP claims

dominates, which, however, is subjected to grave criticism in Germany. In the United Kingdom the extent of composition-of-matter protection from PbP claims is presently not specified. In the USA a narrow interpretation has recently become established, which links the scope of protection from a PbP claim to the use of the process specified in the patent.

4 Conclusions and recommendations

Based on these accounts, the Board has come to the following conclusions:

4.1 Exclusion of PbP claims based on essentially biological processes:

In order to facilitate unambiguous clarification of the legal situation, we recommend an explicit provision in the Biopatent Directive 98/44/EC, which excludes not only “essentially biological processes” but also composition-of-matter patents based upon them. Therefore, the patentability also of such products that are based on a traditional breeding method would be excluded through a teleological reduction of Article 4 Abs. 1 (b) of the EU Biopatent Directive and the corresponding national implementing act. Such a clarification would be based upon the regulatory intent of

Article 4 (1b) to exclude conventional breeding practice and its products from patentability. Hence, according to the EU Biopatent Directive no patents should be granted for products based on essentially biological breeding methods. In the light of the analogous content of the European Patent Convention (EPC) and the Biopatent Directive, modification of the EPC does not appear imperative.

4.2 Narrow interpretation of the scope of PbP patents:

As long as a patented production process does not lead to a patent that the patentee describes completely with regards to content (structure) and the description of the product also is substantially dependent on the production process, product

⁵⁷ „Today the court rejects this expedient and discards this practice, ruling that all claims containing a process term under the rule of necessity now must be construed, for purposes of infringement, as limited to use of any process term that was used to assist in defining the product. That is, such a product is not patented as a product, however it is produced, but is limited to the process by which it was obtained. This is a new restraint on patents for new products, particularly today’s complex chemical and biological products whose structure may be difficult to analyze with precision. It is a change of law with unknown consequences for patent-based innovation.” (566 F.3d 1282 (2009), minority vote by Judges Newman, Mayer, Lourie, p 3).

protection should be confined to the production process. Should the protection resulting from a PbP claim also extend to other production processes than that described in the patent claim, the patentee would virtually have a monopoly on the product. In animal and plant breeding this by far exceeds the appropriate reward for innovativeness of the inventive step.⁵⁸ In this respect we recommend a clarifying provision in EU law (for example, when transferring the Biopatent Directive to an EU regulation) and – in general – for PbP claims in the German Patent Act.

4.3 Restraint in granting patents based on PbP claims:

Moreover, product-by-process patents should strictly be granted only in cases in which the structure of the product cannot be completely described and in which the description of the product also depends to a large extent on the production process. In addition, it should be taken into consideration that product-by-process patents were originally designed for the patenting of chemicals.⁵⁹ Chemical substances can, however, demonstrate different qualities than those that are the object of biotechnological inventions. For

instance, unlike other substances, proteins have very large molecules and are therefore also known as macromolecules. The problem here is that the precise properties of the recombinant protein are highly dependent, on the one hand, on the amino acid sequence, the folding and possibly other modifications, and on the other hand from the specific cell line used.⁶⁰ Granting a product-by-process patent for a protein can then substantiate the claim not to a product, but to a whole series of similar products, depending on which cell line is used. Conversely, the uniqueness of each cell line leads to uncertainties in the verifiability and the reproducibility of the underlying processes.⁶¹ For these reasons, at all events, restraint is indicated in granting patents with PbP claims for such complex molecules, since they potentially do not always fulfil the requirements for complete disclosure in adherence with Article 83 of the EPC.

⁵⁸ Also 304 U. S. at 373 (1938).

⁵⁹ *Walter*, German Association for the Protection of Intellectual Property (GRUR) Prax 2010, p 329 (331).

⁶⁰ *Karshedt*, Hastings Science & Technology Law Journal 2011, p 109 (135).

⁶¹ *Ibid.*

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