

**A GUIDE TO PHARMACEUTICAL PATENTS**

**VOL. II**

**Editor Carlos M. Correa**

**South Centre**

**JULY 2008**



## THE SOUTH CENTRE

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South Centre, POB 228, Chemin du Champ d'Anier 17, 1211 Geneva 19, Switzerland.

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ISBN 92-9162-032-7 Paperback  
ISSN 1607-5323 Paperback

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**Vol. II, July 2008**

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## PREFACE

Pharmaceutical products and processes account for a significant part of patents applied for and granted worldwide. As patents confer exclusive rights and lead to increased prices for such products, they are of particular concern in developing countries. In developed countries, patents provide a stimulus to research and development (R&D) in new medicines or in finding new uses or forms of administration of the existing ones. Their social effects on prices in these countries are attenuated by the role that states and social security systems play in securing access to medicines. In developing countries, however, patents do not encourage R&D needed to address the diseases that most affect them, such as malaria and tuberculosis, while the monopolistic rights they confer, and the ensuing pricing policies, deprive a large part of the population of the possibility of receiving the treatments needed. This leads to an ethically unacceptable situation where many people may not receive treatments that are available and which could cure them or save their lives. The case of medicines to treat HIV/AIDS has provided a dramatic example.

This book is intended to provide policy makers with information and guidance about some important aspects relating to the patenting of pharmaceutical inventions. This theme was chosen on the basis of three main considerations.

First, the adoption of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement represented a resounding victory for the international pharmaceutical industry, as it included an obligation to provide patent protection for pharmaceutical products. However, the Agreement did not include specific rules on all aspects relating to the grant of patents. The determination of how the patentability criteria are applied, the form and breadth of claims and the extent of disclosure are some of the core flexibilities available under the TRIPS Agreement. While there is a number of important post-grant flexibilities, such as parallel imports and compulsory licenses, which have been extensively

explored in the literature,<sup>1</sup> much less effort has been made to identify from the perspective of developing countries the room available to grant a patent or not and to determine the scope of protection. These are crucial aspects of a patent policy which this book explores in some depth.

Second, not only do pharmaceutical patent applications account for a large proportion of total patent applications, but the grant or not of a patent in this field may have important implications for public health. While the number of new chemical entities developed per year has declined dramatically in the past ten years, there is a proliferation of patents on salts, ethers, esters, polymorphs, isomers and other variants of known drugs as well as on formulations and combinations thereof. This type of patents, often called “evergreening” patents, is strategically used to block generic competition. The essential point made in this book is that in many cases such patents could not have been granted if adequate standards to assess the patentability requirements had been applied.

Third, many patent offices have developed practices for assessing patent applications following the advice received from patent offices of developed countries or the World Intellectual Property Organization (WIPO), without proper consideration of such countries’ development needs. This book is premised on the concept that patentability criteria and the scope of protection should be determined, as a basic component of a patent policy, having in view the conditions and objectives of the country concerned. In the absence of a defined government policy on the delicate issues raised by patent protection, the policy is finally made by the patent offices or the courts. Health ministries and other departments, as appropriate, should be able to participate in the crafting of that policy.

The book contains notes prepared by Ravi Srinivas, Santanu Mukherjee and Dalindyabo Shabalala as part of the research undertaken, under my supervision, at the South Centre in the context of a project on intellectual property rights, innovation and development, funded by the Rockefeller Foundation. The notes expand on and supplement the

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<sup>1</sup> See, for example, C Oh and S Musungu *The use of flexibilities in TRIPS by developing countries: can they promote access to medicines* (World Health Organization – South Centre Geneva 2006).

previous South Centre publication *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (Geneva 2000). However, they do not pretend to cover exhaustively all the issues raised by the patenting of pharmaceuticals. They only provide information about how some of such issues are dealt with in developed countries and how much room for manoeuvre is left to developing countries in adopting their own approaches. The aim of the notes is to facilitate the adoption of informed patent policies in developing countries in line with the objective of promoting access to pharmaceutical products for all.<sup>2</sup>

Although a significant portion of the analysis made in the notes is based on the law and jurisprudence of developed countries, this is not to suggest that their practices are to be automatically followed in developing countries but to show their rationale, limitations and how these countries have designed the patent policies to suit their national interests. The reading of the notes, which address several horizontal issues about patentability (applicable to inventions in the pharmaceutical industry and other sectors of technology) should be supplemented with that of *Guidelines for the examination of pharmaceutical patents: developing a public health perspective, Working Paper* (the World Health Organization (WHO), the International Centre for Trade and Sustainable Development (ICTSD) and the United Nations Conference on Trade and Development (UNCTAD), available at [www.ictsd.org](http://www.ictsd.org), Geneva 2006), which deals with certain types of claims particularly relevant to pharmaceuticals.

It must be borne in mind that there is no single “patent system” and that governments can, within the limits imposed by the applicable international obligations, pursue the solutions that are better adapted to their own needs. The notes contained in this book show the diversity of solutions adopted at the national level (for example with regard to the criterion of industrial applicability/utility) and even within the same country (for example the reading of the product-by-process claims in the United States of America (USA)), the evolution that has taken place in some developed countries towards increased protection (for example the Markush claims in the USA), the application of public interest limits

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<sup>2</sup> See the Doha Declaration on the TRIPS Agreement and Public Health (4<sup>th</sup> World Trade Organization Ministerial Conference November 2001), available at [www.wto.org](http://www.wto.org)

(for example in relation to “selection” patents), and the use of legal fictions (such as in the case of the admissibility of patents on “second indications”).

Chapter 1 (S. Mukherjee) elaborates on the concept of novelty, the differences in its regulation in national laws and the acts that may destroy it and consequently prevent the granting of a patent. It examines, in particular, the issue of novelty as applied to pharmaceutical inventions. Developing countries are recommended to apply a concept of “absolute” novelty and to avoid the adoption of legal fictions that unnecessarily expand the space for patenting of pharmaceutical products.

Chapter 2 (D. Shabalala) contains a detailed study of the way in which the standard of inventive step/nonobviousness has been applied in the USA and by the European Patent Office (EPO). It shows that the required level of inventive step/nonobviousness may vary, as it is not determined by the TRIPS Agreement, and that developing countries may opt for the standard that best suits their level of technological development and public policies, including in the area of pharmaceuticals. The experiences in the application of such standards allow interesting lessons to be drawn for developing countries. As a general rule, they should adopt a notion of a qualified “person skilled in the art” and ensure that patents are granted only when a real contribution to the state of the art has been made.

Chapter 3 (R. Srinivas) studies practice in the application of the standard of industrial applicability/utility in developed countries and its implications for the patentability of pharmaceutical inventions. In particular, it considers what degree of knowledge about the therapeutic effects of a product is required to obtain a patent thereon. Developing countries are recommended to apply an industrial applicability standard which avoids the patenting of early or speculative developments that may deter further innovation and production.

Chapter 4 (R. Srinivas) deals with therapeutic, surgical and diagnostic methods. It makes it clear that most countries do exclude such methods from patentability, consistent with the exemption allowed by article 27.3(a) of the TRIPS Agreement. Such methods lack

industrial applicability and may be deemed non-patentable even in the case of an explicit exemption in countries where such standard is applied. Developing countries are advised not to allow for the patentability of therapeutic, surgical and diagnostic methods. Among other advantages, this solution permits the refusal of applications on “second indications” of known drugs, which are equivalent to applications on therapeutic methods.

A review of the patentability of “second indications” of known drugs is undertaken in Chapter 5 (D. Shabalala). This chapter considers four possible options for dealing with the scope of pharmaceutical product patents and with protection of the new use of known products. It considers thoroughly the premises on which patentability of such uses has been accorded in developed countries and the practice of some developing countries (such as India) where patents on second indications are refused. The TRIPS Agreement, in fact, does not require WTO members to recognize those patents. Developing countries are recommended to make full use of this TRIPS flexibility and to exclude patents on new therapeutic uses of known medicines within the framework of policies aimed at promoting follow-on innovation and access to drugs.

Chapter 6 (R. Srinivas) explores the differences between “discovery” and “invention” in the context of the discussion about the patentability of substances occurring in nature. It examines how the dividing line between those two concepts has blurred in some jurisdictions. This chapter makes it clear that developing countries can adopt their own approaches on the matter, as the TRIPS Agreement mandates the grant of patents only with regard to “inventions”, the definition of which is left to the discretion of WTO members. The chapter recommends developing countries to stick to a rigorous concept of invention and to exclude the patenting of substances occurring in nature.

Chapter 7 (D. Shabalala) studies the problems posed by “functional” claims (that is, those describing what an invention does rather than what the invention structurally is) and their limited admissibility even in developed countries. The analysis in this chapter also addresses the applicability of what is known as the “doctrine of

equivalents” and how it may influence the interpretation of functional claims in cases of alleged infringement. Developing countries are recommended to require the description of pharmaceutical products in structural terms and to admit functional language only in very limited and well defined circumstances.

Chapter 8 (S. Mukherjee) deals with another important aspect relating to the assessment and grant of patents: the level of disclosure required to ensure reproducibility of the invention by a person skilled in the art. It considers the practice relating to “sufficient enablement” in the USA and by the EPO. It recommends developing countries to adopt strict requirements of disclosure in order to ensure that patents properly fulfil their informational function. It also warns such countries against supporting the harmonization of rules that may restrain their current space to determine their policies on the matter.

Chapter 9 (S. Mukherjee) deals with a particular type of claim common in the chemical and pharmaceutical fields: the “Markush claims”. These claims may cover thousands or even millions of compounds that share some common characteristics. The admissibility of Markush claims raises issues of sufficient disclosure, since normally the applicant has only empirically obtained and tested a few of the potential embodiments of the invention. Developing countries are advised to apply a strict requirement of disclosure which ensures that patents are granted only with regard to the embodiments of the invention that have actually been obtained by the applicant.

Chapter 10 (S. Mukherjee) discusses a related issue, the “selection patents”, which are often based on previous Markush claims. The admissibility of selection patents is controversial as the members selected from a larger group are already known and, hence, they lack novelty. The chapter reviews the practice in developed countries and suggests a restrictive approach to the subject. As in the case of other issues considered in the notes, there is nothing in the TRIPS Agreement or other international treaties obliging countries to accept such patents.

Chapter 11 (R. Srinivas), finally, addresses another particular form of claim: the product-by-process claim wherein a product is claimed on the basis of the method used to obtain it. This chapter

examines in detail the practices in developed countries and the divergent interpretations that have arisen with regard to the infringement of such claims. While clarifying that there are no international mandatory rules on the matter, the chapter recommends that if developing countries accept such claims, they should be limited to cases where the product cannot be otherwise described.<sup>3</sup> In addition, such claims should be deemed to be infringed only when the same method of production is employed.

The notes included in this volume have been edited by D. Shabalala and later reviewed for consistency in the arguments and presentation within the context of the South Centre's Innovation and Access to Knowledge Programme (IAKP).

*Carlos M. Correa*  
*January 2008*

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<sup>3</sup> For instance, the Chinese patent office has adopted the modality of product-by-process claims to protect traditional medicines, since their characteristics generally make it difficult precisely to determine their active components. See *Patent Application as Indicator of the Geography of Innovation Activities: Problem and Perspectives*, Xuan Li and Yogesh Pai, Paper prepared for Joint Session between South Centre and the World Institute for Development Economics Research of the United Nations University (UNU-WIDER) at Southern Engines of Global Growth: China, India, Brazil and South Africa (CIBS) at WIDER, Helsinki, Finland, 7–8 September 2007 (forthcoming South Centre research paper 2008).



## CHAPTER 6

### SUBSTANCES OCCURRING IN NATURE

#### I. INTRODUCTION

Substances occurring in nature (also called “products of nature”) are not patentable as they are not the result or outcome of any human effort. At the most, finding them can be termed a discovery and not an invention. This may look and sound simple. But, because not all countries have patent laws that clearly differentiate between discovery and invention or provide a coherent definition of both, the picture is much more complicated. Products of nature include micro-organisms, plants found in the wild, uncultivated plants, soil and so on. Naturally-occurring substances are normally unpatentable discoveries, but the products and processes that arise from the human effort in isolating, purifying or modifying these substances may be patentable.

#### II. DEFINING A PRODUCT OF NATURE

A product that occurs naturally does not, as such, fall within the statutory classes of patentable subject matter even though the applicant may be the first to discover or identify that product. In some jurisdictions, however, an applicant may claim an isolated or purified form of a natural product, or claim a process defined as the method of obtaining or using the newly-discovered product to achieve a useful result.<sup>4</sup>

According to the EPO guidelines, if a process is developed which enables a substance found in nature to be isolated and obtained from its

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<sup>4</sup> D Chisum *Chisum on Patents* (Matthew Bender New York 2005) Glossary.

surroundings, the process may be patentable. On the other hand, the mere finding of a substance that occurs freely in nature is only a discovery and is hence not patentable.<sup>5</sup>

The difference between discovery and invention has been explained, for instance, in the draft guidelines published by the Patent Office of India which state:

The mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature; ...

There is a difference between discovery and invention. The discovery adds to the amount of human knowledge by disclosing something, which has not been seen before, whereas an invention also adds to the human knowledge by suggesting an act, to be done and is not patentable. [sic] See also Article 52 of EPC which lists what would not be considered as inventions.<sup>6</sup>

However, most countries do not define what an invention is, or give an indirect definition by specifying what are not considered as inventions under the law, or what subjects are excluded from patentability. Carvalho notes:

The Patents Amendment Act of India likewise excludes “plants and animals in whole or any part thereof other than Micro-organisms, but including seeds, varieties and species” from patentability. ... Brazil's patent law establishes that “all or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germplasm of any natural living being, and the natural biological processes” are “not considered to be inventions or utility models”. Similarly, the decision of the Andean Community on the

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<sup>5</sup> EPO Guidelines Part C ch IV p. 44.

<sup>6</sup> Draft Guidelines of the Indian Patent Office.

In: [www.patentoffice.nic.in/ipr/patent/manual.htm](http://www.patentoffice.nic.in/ipr/patent/manual.htm)

common regime of industrial property states that “any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germplasm of any living thing” shall not be considered inventions.<sup>7</sup>

Some countries give a list of exclusions to what may be patented. For example Mexico’s law states that it does not allow patenting of: “Essentially biological processes for obtaining or reproducing plants and animals; 2. Biological and genetic material, as found in nature; 3. Animal breeds; 4. The human body and its living components; 5. Plant varieties; ...”<sup>8</sup>

Defining an invention is tricky because, due to technological developments and advances in human knowledge and its applications, what was once in the realm of fiction may become a reality in the future. Moreover, patent law is more concerned with inventions that can be patented than with inventions per se or inventive activity as a vocation or hobby. As the eligible subject matter encompasses all branches of technology and the underlying science, only a cryptic and abstract definition that sets a legal standard without going into detail about specific technologies is possible. Otherwise the definition will be too unwieldy to be of any practical use.

### **III. THE CONCEPT OF INVENTION AND THE PRODUCTS OF NATURE DOCTRINE**

The concept of invention as well as the concept of products of nature have been broadened by judicial interpretations. In a landmark decision given in 1969, the German Federal Supreme Court concluded that

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<sup>7</sup> N De Carvalho ‘The Problem Of Gene Patents’ (2004) 3 *Wash. U. Global Stud. L. Rev.* p, 701.

<sup>8</sup> Article 16 of the patent law cited in Norma Garcia-Calderon ‘Mexico: Some Considerations Related With the Ethics in the Patentability of Biotechnology Related Inventions in Mexico’ (2005).

In: <http://www.mondaq.co.uk/article.asp?articleid=33465>

“invention” in the context of patents could include animal breeding methods if it were proved to utilise controllable natural forces to achieve a causal, perceivable result.<sup>9</sup> The Court ruled that even if the starting and end points of an invention were living organisms, that per se, would not make the method unpatentable.<sup>10</sup> The invention in question was a cross-breeding method, which is part of the older and classical method, unlike manipulation at the genetic level, that is, inserting foreign elements or by attenuating some components of the gene or cell. Article 53(b) of the EPC states that essential biological processes are not patentable. However, technical inventions include those which use processes of nature to achieve a technical result.<sup>11</sup>

The law and the judgments in some jurisdictions make a distinction between finding materials in nature and making material found in nature available in a usable form. Making the material available in a usable form involves processing the material found in nature to meet some objective. Thus, under some patent laws there is a distinction between products of nature and products derived from nature. While the former are not patentable, the latter may be. However, there is no hard and fast rule that no patents are possible on any grounds on materials derived from nature. In the USA, for example, in *In re Williams* the court held that “[t]he existence of a compound as an ingredient of another substance does not negate novelty in a claim to a purer compound although it may of course render the claim unpatentable for lack of invention”.<sup>12</sup> Thus, under some circumstances, patent protection is possible on chemical compounds that are found in nature.

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<sup>9</sup> German FSC, GRUR 1969, 677 and IIC 1970, 136 – “Rote Taube” (“Red Dove”). See, for example, Li Westerlund *Biotech Patents - Equivalency & Exclusions under European and U.S. Patent Law* (Kluwer Law International New York 2002) p. 27.

<sup>10</sup> The court observed that an invention “was not rendered unpatentable by the mere fact that its starting point, means and aim were living organisms”. Cited in U Schatz ‘The Patentability of Genetic Inventions in EPO practice’ (paper presented at OECD-BMBF Workshop on Genetic Inventions, IPRs and Licensing Practices, Berlin, 24-25 January 2002).  
In: <http://www.oecd.org/dataoecd/3/27/1820221.pdf>

<sup>11</sup> The EC Directive on Legal Protection of Biotechnological Inventions specifies what is patentable as an invention and the grounds for not granting patents. See Directive 98/44/EC.

<sup>12</sup> *In re Williams* 80 USPQ 150, 151 (CCPA 1948).

In the case of biochemicals found in nature, in some jurisdictions it is possible to get patents on their purified forms. A naturally-occurring substance may be useful but it may not be suitable for any application in the form it is found, or it may be available in quantities that are uneconomical to use. Some patent laws give protection if the same, that is, naturally-occurring, substance is produced in a novel way which is non-obvious and made available in a non-natural form that could be put to use. However, here the laws and guidelines are not uniform. The availability of a purer substance than that found in nature enhances its utility. Structurally, however, the purer substance and the substance found in nature will be the same.

An example of a purified form of a substance occurring in nature is prostaglandin, which is found in small quantities in many animal tissues. Prostaglandins are a group of hormone-like substances; like hormones, they play a role in a wide variety of physiological processes.<sup>13</sup> However, the concentration of prostaglandin is so low in naturally-occurring fluids that it is not medically useful in that form. Extracts from animal glands, while having higher concentrations, also have undesirable side effects. The US inventors in *In re Bergstrom* isolated the compounds in the secretions so that these isolated compounds could be used without resulting in the unwanted side effects. The claim was for compounds “sufficiently pure to give an ideal curve on partition chromatography”.<sup>14</sup> The CCPA held that “by definition, pure materials necessarily differ from less pure or impure materials and if the latter are the only ones existing and available as a stand of reference ... perforce the ‘pure’ materials are ‘new’ with respect to them”.<sup>15</sup>

As the pure material per se did not exist previously, the created material was considered sufficiently “new” to claim a patent. Hence, even if the substance occurred in nature, novelty was not destroyed when the same substance was produced in a purer or more useful form. Many patents relating to substances occurring in nature include claims for isolation and purification. It should be noted that the patent, if granted on the product as such, covers only the isolated and purified

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<sup>13</sup> In: <http://www.medterms.com/script/main/art.asp?articlekey=16461>

<sup>14</sup> *In re Bergstrom and Sjoval* 166 USPQ 256 (CCPA 1970).

<sup>15</sup> *Ibid.* at 1401–1402.

form and not the form occurring in nature. For example, in the case of prostaglandin the patent covers the isolated and purified prostaglandin rather than prostaglandin as found in nature. However, patents that cover “purified” substances and the processes for obtention give the patentee almost total monopoly rights.

In the case of plants, developing a new variety using classical breeding techniques or biotechnology can result in plants with novel features or characteristics that are not found in naturally-occurring plants. However, some countries make intellectual property rights available for discoveries relating to plants. Plant breeders’ rights are available in some jurisdictions (for example, the USA) to those who discover varieties, whether they are found in the wild or occur as a genetic variant, whether artificially induced or not.

In respect of the human body and human genome, some countries provide absolute exclusions from patentability. For instance, article 54(1) of the European Union Biotechnology Directive states, “the human body, at various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute a patentable discovery”. A similar provision is found in the EPC rules.<sup>16</sup> However, isolated and/or purified DNA has been the subject matter of many patents, including the controversial patent on a breast cancer gene.<sup>17</sup> In this case, the concept of “isolated” is equated with “substantially pure” and the patent covers not only the process but the actual sequence as well. Whether such

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<sup>16</sup> Rule 23e: “The human body and its elements; (1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. (2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. (3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

In: <http://www.european-patent-office.org/legal/epc/e/r23e.html>

<sup>17</sup> See R Stephen Crespi ‘Patents on genes – do they have a future?’ (2006).

In: <http://www.law.ed.ac.uk/ahrb/publications/online/Crespi.htm> See also K Jensen and F Murray ‘Intellectual property. Enhanced: intellectual property landscape of the human genome’ *Science* 2005 310 pp. 239–40.

isolation is “invention” is a fundamental question,<sup>18</sup> which we return to later in this chapter.

### III.1 The Doctrine in the United States

In the USA there are many cases involving patents on products of nature or products derived from nature.<sup>19</sup> The settled practice is that if a product of nature is induced to have a new characteristic, then it becomes an invention and is patentable, irrespective of the method of inducement.<sup>20</sup> However, this was not always the case in the USA. Early case law disfavoured such patents. Thus in *In Ex parte Latimer* (1889) it was held:

[E]ven if ... this were the first time that men had discovered that a fiber existed in the leaves and needles of the trees which could be removed by certain processes and made useful for mankind, it is doubtful whether the invention would consist of anything more than the process by which the fiber could be taken from the natural leaf. ... Otherwise it would be possible for an element or a principle to be secured by patent, and the patentee would obtain the right, to the exclusion of all other men, of securing by his new process from the trees of the forest ... the fiber which nature

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<sup>18</sup> See D Kelves and A Berkowitz ‘The Gene Patenting Controversy’ (2001) 67 *Brooklyn L. Rev.* 233 p. 274.

<sup>19</sup> See *In re Mancy*, 499 F.2d 1289, 1294 (CCPA 1974) (dictum) (stating that a strain of micro-organisms found in a soil sample was presumably unpatentable because “the strain, while new in the sense that it is not shown by any art of record, is, as we understand it, a ‘product of nature’”). But also see *In re Bergy*, 563 F.2d 1031, 1036-1038 (CCPA 1977) (declaring finding a biologically pure strain of bacteria used in “an industrial process” to be a “manufacture” or “composition of matter”), D Chisum *Chisum on Patents* (Matthew Bender New York 2005).

<sup>20</sup> K Bozicevic ‘Distinguishing “Products of Nature” from Products Derived from Nature’ (1997) 69 *JPTOS* p. 415. See also Michael D Davis ‘The Patenting of Products of Nature’ (1995) 21 *Rutgers Computer & Tech. L.J.* p. 293.

has produced and which nature has intended to be equally for the use of all men. ... [T]he fiber, when it is made free, is in nowise changed or different from its natural construction. ... I am not aware of any instance in which it has been held that a natural product is the subject of a patent, although it may have existed from creation without being discovered.<sup>21</sup>

In *American Fruit Growers Inc. v. Brogdex*, 283 US 1 (1931) it was held that a modified natural product could not be patented if its essential nature had not been substantially altered.<sup>22</sup>

In *Funk Bros Seed Co. v. Kalo Inoculant Co.*, 76 USPQ 48 (1948) it was held that an unknown compound or composition of materials merely discovered from nature is not patentable.

Discussing the patentability of a “work of nature” the majority rejected the argument that the compound was patentable. The Court observed:

[The patentee] does not create a state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature. ... The qualities of these bacteria ... are part of the storehouse of knowledge of all men.

In *Merck & Co. Inc. v. Olin Mathieson*, 116 USPQ 484 (4Cir. 1958) and *Merck & Co. Inc. v. Chase Chemical*, 155 USPQ 139 (D.N.J. 1967) the issue was whether vitamin B12 as claimed by the applicant was patentable or not. The applicant isolated and produced vitamin B12 in a purer form than that found in nature, that is, in liver extracts. The claim was for a vitamin B12 active composition recovered from a fermentation product and it was argued that the claimed vitamin B12 was different from the natural B12. The Court decided that purified vitamin B12 was not the same as found in nature, but was a new and

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<sup>21</sup> *Ex parte Latimer*, 1889 Comm'n Dec. 13 (1889).

<sup>22</sup> 283 US 1, 11 (1931).

useful composition that could be patented. Thus, if the claim language describes the means of production and the activity of a product occurring in nature being produced in a purer form with more active strength, then the “invention” is different from a product of nature.

This trend in favour of patentability was confirmed with the judgment in *Diamond v. Chakrabarty*, 447 US 303, 65 (1980). In this case, the patent claim was for a genetically-modified organism, a new strain of bacteria with improved capacity for degrading crude oil. The US Supreme Court held that a living, genetically modified micro-organism could be patented as either a manufacture or a composition of matter.

In a 5–4 decision, the Supreme Court made the famous observation about the handiwork of man. It said: “Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under 101.”<sup>23</sup>

The *Chakrabarty* case raised new questions such as whether Congress intended to consider genetically-modified organisms (GMOs) eligible for patents and whether in the absence of a statutory action the Court could extend the scope of the subject matter. It also prompted debates over the pros and cons of genetic engineering. The nascent biotechnology industry argued that patenting was necessary in order to attract investment and promote research.<sup>24</sup>

The rationale expressed in *Chakrabarty* was affirmed in subsequent cases including *Ex parte Hibberd* (227 USPQ 443 (Bd. Pat. App. & Inter. 1985) holding that plants, seeds, and plant tissue culture constituted patentable subject matter, *Ex parte Allen 2* (USPQ.2d (BNA) 1425 (BPAI 1987)) holding that man-made animal life forms constituted

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<sup>23</sup> In: <http://supreme.justia.com/us/447/303/case.html>

<sup>24</sup> Daniel J Kevles ‘*Diamond v. Chakrabarty* and Beyond: The Political Economy of Patenting Life’, in Arnold Thackray (ed) *Private Science: Biotechnology and the Rise of the Molecular Sciences* (University of Pennsylvania Press Philadelphia 1998) pp. 65–79.

patentable subject matter, and the famous Harvard Oncomouse case.<sup>25</sup> By the late 1980s, the product-of-nature doctrine had been transformed beyond recognition and was of little relevance. With respect to biotechnology, as a commentator has pointed out, the products of nature doctrine has been rendered almost inapplicable because of the technical means to isolate and replicate biological materials to produce unnatural levels of purity.<sup>26</sup> Post-*Diamond v. Chakrabarty* and the European Union Biotechnology Directive, it can be assumed that the doctrine is as good as dead in these jurisdictions, or has become irrelevant in the context of changes in judicial interpretations and technology. As Eisenberg has noted, the issue seems to have been reduced to a claim-drafting problem.<sup>27</sup>

### III.2 The Doctrine in Europe

Some decisions in Europe are based on the rationale that when a substance is available in nature in an unusable form, a patent that teaches how to make it available in a usable form is valid, and novelty is not destroyed by the existence of the naturally-occurring non-usable form. In a case on a patent on human relaxin DNA, it was held that, although finding a substance occurring in nature is discovery and therefore unpatentable as such, making it available by a process to

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<sup>25</sup> The “Harvard Oncomouse” was a genetically engineered mouse carrying a specific gene called activated oncogene. This made it more susceptible to cancer and hence useful in cancer research. Patenting this Oncomouse was controversial as the claims allowed in the USA were not allowed in full by the EPO. Moreover, in Canada the Supreme Court ruled against the patent.

In: <http://en.wikipedia.org/wiki/Oncomouse>

See also F Murray *The Oncomouse that roared* (MIT Sloan School of Management Cambridge 2006).

And see:

[http://web.mit.edu/fmurray/www/papers/the%20oncomouse%20that%20roared\\_final.pdf](http://web.mit.edu/fmurray/www/papers/the%20oncomouse%20that%20roared_final.pdf) for a discussion on the history of the invention and patenting of Oncomouse.

<sup>26</sup>JM Golden ‘Biotechnology, Technology Policy and Patentability: Natural Products and Invention in the American System’ (2001) 50 *Emory Law Journal* 101, 121.

<sup>27</sup>RS Eisenberg ‘Re-Examining The Role of Patents in Appropriating the Value of DNA Sequences’ (2000) 49 *Emory Law Journal* 783.

isolate it would make the process patentable.<sup>28</sup> Although DNA occurs in nature, isolating it from nature and properly characterizing it would constitute a patentable invention.<sup>29</sup> Such reasoning is, however, controversial, if not flawed, as the controversies over patenting of DNAs and ESTs show.<sup>30</sup>

### III.3. Implications

From the above discussion on US and European practice we can conclude that:

1. When a process is developed to isolate a substance found in nature and makes it available in a purified form, the process

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<sup>28</sup> Technical Board of Appeal of the EPO, decision T272/95 of 23 October 2002 (“Relaxin” patent EP 112149 B1).

<sup>29</sup> “In 1995, the EPO Opposition Division approved the grant of a patent for a DNA sequence encoding a human protein, produced by pregnant women, that had useful applications during the childbirth process. Relying on the Guidelines for Examination in the EPO, the Opposition Division held that if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is patentable. The substance itself may be patentable if it can be properly characterized by its structure and it is new in the absolute sense of having no previously recognized existence (Hormone Relaxin 1995 O.J. E.P.O. 388 (Opp. Division) as cited in Gitter). So, like the USA, the EPO rejects the products-of-nature doctrine. This is confirmed by the Biotech Directive ‘IPMG Working Document - A detailed overview of the patent system of the European Patent Office’.

In: [www.cipp.mcgill.ca/data/world/00000005.pdf](http://www.cipp.mcgill.ca/data/world/00000005.pdf)

<sup>30</sup> For an overview on gene patents see Wendy H Schacht, ‘Gene Patents: A Brief Overview of Intellectual Property Issues CRS Report For Congress’ 2006. In: [http://www.ipmall.info/hosted\\_resources/crs/RS22516\\_061003.pdf](http://www.ipmall.info/hosted_resources/crs/RS22516_061003.pdf) See also E Kane ‘Splitting the Gene: DNA Patents and the Genetic Code’ (2004) *Tennessee Law Review* Vol. 71, p. 707.

In: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=668628](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=668628)

Dan Burk, ‘The Problem of Progress in Biotechnology’ (2006) 561 *Houston L. Rev.* 43 p. 3.

In: [http://www.houstonlawreview.org/archive/downloads/43-3\\_pdf/Burk.pdf](http://www.houstonlawreview.org/archive/downloads/43-3_pdf/Burk.pdf)

FS Kieff (ed) *Perspectives on Properties of the Human Genome Project* (Elsevier Academic Press Amsterdam 2003).

is patentable. However, purity per se may not guarantee that the claim would be successful.

2. Merely finding a substance is discovery, not invention, and therefore any such discovery would not be patentable.<sup>31</sup>
3. Isolating a substance occurring in nature, characterizing it by the process or by structure, can be deemed to be an invention and hence patentable. The patent claim may include patenting the substance per se.

### ***III.3.1 Chemical compounds***

Under TRIPS it is not necessary that products of nature or substances occurring in nature should be patentable. Countries are free to de-link discoveries from inventions and define inventions using tougher criteria if they so choose. In the case of pharmaceutical patents, countries can prevent misappropriation of knowledge in the public domain by barring patents on products and processes for known uses or medicinal properties of a substance occurring in nature.

In the case of chemicals found in substances occurring in nature and being used in pharmaceutical products, the limitations to patenting imposed by the products-of-nature doctrine are obvious. However, proving the prior art may not be easy in all cases. For plants, which have many uses, the substances that are derived sometimes have a totally new use. For example, rosy periwinkle, which has been used for treatment in many diseases, was examined by scientists who isolated alkaloids from the plant and found a treatment for leukaemia.

Genetic resources have been used extensively in pharmaceutical research, and important chemicals have been extracted from products of nature. In some instances, pharmaceutical research first extracted the chemicals from natural products before synthesizing them. However, the interest in using substances occurring in nature has apparently waxed and waned over the years.<sup>32</sup> According to one commentator, the search

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<sup>31</sup> See, for example, Article 5(1) of the European Union Biotechnology Directive.

<sup>32</sup>AJ Scholz 'From molecules to medicines – The use of genetic resources in

for useful chemicals from natural products is not the only available tool, and its relevance for the pharmaceutical industry has declined over the years. Although pharmaceutical companies are still interested in R&D, natural products are not the primary source for new and potential drugs.<sup>33</sup>

### **III.3.2. Micro-organisms**

“Micro-organism” is a generic term used to denote organisms that are not visible to the naked eye. It is used as a synonym for fungi, protozoa, plasmids, viruses, algae, bacteria, cyanobacteria, yeast. A micro-organism can be defined in terms of its size, structure, function, metabolism, and so on. Neither TRIPS nor most patent laws define “micro-organism”. However, the absence of a definition is not a handicap as micro-organisms are found in nature and the rules and case law applicable to products of nature can be applied to them also.

Micro-organisms are used in the pharmaceutical sector in many processes and products. In some cases, microbes isolated from nature have been patented even without being genetically modified. Here also, the test of isolation and purification applies in some jurisdictions but need not be followed in others. A case in point is the development of cyclosporine from a sample of soil obtained in Norway and patented first in Switzerland. At that time there was no rule regulating the use of such samples and the sample yielded a serious money-spinner for the pharmaceutical company Sandoz (since acquired by Syngenta) with sales approximating one billion US dollars per annum.<sup>34</sup>

Under TRIPS article 27.3(b), micro-organisms cannot be excluded altogether from patentability. But whether micro-organisms found in nature can be patented depends upon the national law. In some

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pharmaceutical research’ in R Schurman and D Kelso (eds) *Engineering Trouble: Genetic Engineering and its Discontents* (University of California Press 2003).

<sup>33</sup> See B Parry *Trading The Genome* (Columbia University Press New York 2004).

<sup>34</sup> H Svarstad, SS Dhillon and HC Bugge ‘From Norway to Novartis: Cyclosporin from *Tolypocladium Inflatum* in an Open Access Bioprospecting Regime’ (2000) 9(11) *Biodiversity and Conservation* pp. 1521–41.

countries an isolated or purified micro-organism is patentable as well as the process of isolation and purification.<sup>35</sup>

Mike Adcock and Margaret Llewelyn point out that there are five possible options available to developing nations:

- a) To adopt an identical patent system to that provided by developed countries. The driving force behind this approach would be the ability of an invention to meet the granting criteria and not the issue of the subject matter making up the invention.
- b) Member states could adopt a revised version of patent protection with refined categories of novelty, inventive step and industrial applicability.
- c) Member states could provide a restricted patent law definition of “micro-organisms”. The exclusion of other material regarded by developed countries as “micro-organisms” could be justified on the grounds that it is in the local economic and technological interest to permit patent protection over only a limited group of inventions of this type.
- d) Member states could adopt both (b) and (c) to include a restrictive definition of a “micro-organism” and use a higher threshold for protection for inventions involving living material.
- e) Member states could refuse to provide patent protection for any form of living material irrespective of the material involved, and fight for a total revision of article 27(3)(b) to permit members to exclude all forms of living material from patent protection.

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<sup>35</sup> For instance, in accordance with the Draft Manual of Patent Practice and Procedure, Patent Office of India 2005, “The living entities of natural origin such as animals, plants, in whole or any parts thereof, plant varieties, seeds, species, genes and micro-organisms may be deemed not patentable. Any process of production relating to such living entities may also be excluded from patentability ... The processes relating to micro-organisms or producing chemical substances using such micro-organisms are patentable.”

It would seem that the WTO is unlikely to accept this last as a viable option.<sup>36</sup>

Their suggestion to use flexibilities available under TRIPS and to enact model provisions is useful. It is difficult, however, to suggest a general strategy that would be suitable for all developing nations. In India, for instance, there is now a race to patent micro-organisms.<sup>37</sup> This is because of the desire to make the maximum use of the microbial biodiversity of India.

In interpreting TRIPS article 27.3(b), some countries have argued that this provision should be essentially applicable only to genetically-modified organisms. The African Group at the WTO has argued that micro-organisms should not be patented.<sup>38</sup> In view of the absence of a definition for invention in TRIPS, countries can opt, for instance, for a rule that micro-organisms can be patented only if they are genetically modified and the genetically-modified organism meets the criteria for patentability.<sup>39</sup> However, the dilemma before developing nations is that, even if they themselves refuse to patent micro-organisms, other countries can always allow such patenting. Even in the case of the existence of benefit-sharing agreements, unless there is a specific provision that micro-organisms cannot be patented, there would be no

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<sup>36</sup> M Adcock and M Llewelyn 'Microorganisms: Definitions and Options Under TRIPS' Occasional Paper 16, Geneva: QUNO 2000.

In: <http://www.quno.org/geneva/pdf/economic/Occasional/Adcock-Llewelyn.pdf> p. 13.

<sup>37</sup> M Somasekhar 'Indian Drug Firms Focus on Micro-organisms' *The Hindu Business Line* (Hyderabad India 15 March 2005) In: <http://www.thehindubusinessline.com/2005/03/15/stories/2005031502640200.htm>

<sup>38</sup> For positions taken by different countries at the Council for TRIPS, see 'Country positions review TRIPS 27.3b' (October 2004) In: [www.grain.org/rights\\_files/trips-review-10-2004-en.pdf](http://www.grain.org/rights_files/trips-review-10-2004-en.pdf)

<sup>39</sup> For instance, in accordance with the Brazilian Industrial Property Code 'transgenic micro-organisms' are patentable if they meet the three patentability requirements. Article 18, sole paragraph defines 'transgenic micro-organisms' as 'organisms, except the whole or part of plants or animals, that present, due to direct human intervention in their genetic composition, a characteristic that can not normally be attained by species under natural conditions'

bar on the part of the individual or company that bio-prospects to patent micro-organisms in a foreign jurisdiction.

#### **IV. CONCLUSIONS**

The product-of-nature doctrine is becoming outdated, or its applicability is very limited these days in developed countries, owing to developments in technology and changes in the law and judicial interpretation.<sup>40</sup> In many jurisdictions, patents on substances occurring in nature, as they relate to the pharmaceutical sector, can be obtained on the process as well as on the isolated and purified product. TRIPS does not mandate patents on products of nature. However, patents on modified micro-organisms have to be provided for under TRIPS, subject to compliance with the patentability requirements. While WTO member countries may differ in interpreting the relevant provision of TRIPS, one country cannot prevent another country from adopting a different position.

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<sup>40</sup> See JM Conley and R Makowski 'Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents in the USA and Perhaps Europe as well' (2004) 13 *Information & Comm. Tech. Law* 3, for a review of developments.

## CHAPTER 7

### FUNCTIONAL CLAIMS

#### I. DEFINING THE CONCEPT

##### I.1. Identifying the Outer Boundaries

A patent claim is a sentence (or two) that unambiguously defines the invention. It should describe the technical advance embodied by the claimed invention.<sup>41</sup> The wording of the claim is the legal basis for determining the scope of subject matter covered by the patent. Therefore, the wording of a claim is crucial to determining how, and with what, third parties may carry out follow-on innovation and inventing around.<sup>42</sup>

Pharmaceutical product patents (as with most product patents) are usually described structurally, that is, by their physical characteristics. Simply put, this is defining something by how it is *shaped*, based on the very reasonable presumption that technical function follows form. Thus anything bearing the same or a trivially different shape would infringe. For chemicals, this is achieved by describing their molecular composition or formula.<sup>43</sup> Another way of describing a product is by what it *does*, without reference to its shape. Thus, where a product solves a particular problem, for example it blocks a virus from entering blood cells, it is then described in the claim as a composition X that does Y. This approach, however, ensures that all compositions that do Y, even though they do not have the same structure and the patent claimant has never considered such a composition, would

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<sup>41</sup> CM Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) p. 31.

<sup>42</sup> *Ibid.*

<sup>43</sup> *Ibid.* p. 32.

be covered by the patent.<sup>44</sup> All ways of doing Y are within the scope of the claim.<sup>45</sup>

In general, functional claims have been admitted in the USA,<sup>46</sup> where the choice of claim is left to the applicant. Such claims are called “means plus function” claims. Wegner notes that such claims found judicial disfavour prior to passage of the 1952 Patent Act, which gave such claims a limited safe haven.<sup>47</sup> While a broader claim may seem more desirable, there is a trade-off in that it provides less certainty about the scope of the claim for the patent-owner and the claimant. Functional claims may therefore be more likely to lead to litigation,<sup>48</sup> especially in new fields. Those patent applicants seeking a clear, strong patent may still prefer a structural claim for its greater certainty and smaller likelihood of litigation.

In the EPO, functional claims are not permitted unless no other way can be found to describe a pharmaceutical by its physical structure more precisely.<sup>49</sup> The reasons for the choice will be described further below but the reasons for restricting their use are similar to the pre-1952 concerns in the USA.

## **II. WHAT ARE THE PUBLIC HEALTH ISSUES IMPLICATED?**

### **II.1. Reduction of Access**

Functional claims broaden the coverage of a patent to encompass large areas of subject matter in which the patent applicant has not even worked. It unduly rewards speculation, as these are areas in which the

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<sup>44</sup> B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 76.

<sup>45</sup> *Ibid.*

<sup>46</sup> *Ibid.* p. 33.

<sup>47</sup> H Wegner *Patent Law in Biotechnology, Chemicals and Pharmaceuticals* (2<sup>nd</sup> edn. Stockton Press New York 1994) 422, citing 35 USC 112 para 6.

<sup>48</sup> B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 63.

<sup>49</sup> CM Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) p. 33.

patent applicant is not in possession of the invention as claimed. The applicant is in possession of only a very small part of the subject matter and has no capacity or ability, or has yet, to consider any other structure or composition which would achieve the same task.

The disadvantages of such broad claims for the patent holder have been briefly outlined above, but such claims also reduce the scope for inventing around by third parties, in addition to creating greater uncertainty about the exact scope of the claim. By allowing such broad patents, a single patent owner can own all solutions to a particular problem and force payment from every person researching that particular issue. This can cripple research, especially in areas crucial to public health. One example may be given in relation to selective serotonin reuptake inhibitors (SSRIs, the first invented being fluoxetine, branded as Prozac),<sup>50</sup> which are used to treat depression. This class of chemicals works to slow the brain's re-absorption of serotonin, which plays a role in maintaining the equilibrium of human moods and behaviour.<sup>51</sup> The drugs function by blocking serotonin uptake in particular serotonin receptors in the brain.<sup>52</sup> A functional claim would lay claim not just to this particular chemical or class of chemicals (defined structurally) but also to any other class of chemicals that are able to block serotonin uptake in these same receptors. Had this been the case, other anti-depression drugs such as Sertraline (brand name Zoloft) or Paroxetine (brand name Paxil) would not have been brought to market to compete with the existing drug, not just on price, but on effectiveness and safety.<sup>53</sup> The issue is especially pertinent for tropical diseases because of the long history of drugs in this area. Many of these drugs were developed during a time when the actual biological mechanisms by which they worked were not known. The advent of biotechnology has made it possible to discover such mechanisms, which could be a boon to the development of more effective and targeted medicines for the developing world. However, if functional claims were

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<sup>50</sup> Mayo Clinic Staff, 'Selective Serotonin Reuptake Inhibitors', The Mayo Clinic. In: <http://www.mayoclinic.com/invoke.cfm?id=MH00066> (11 October 2005)

<sup>51</sup> Ibid.

<sup>52</sup> Ibid.

<sup>53</sup> For example, Paxil and Zoloft do not last as long in the human body as Prozac.

allowed on any such new mechanisms, research paths would be entirely closed off to third parties.

Policy makers should consider what would have happened had the inventor of quinine (the primary preventive and curative drug against malaria) been able to close off all research on other drugs that worked through the same biological mechanism. Allowing functional claims would also pose the same danger for research into HIV drugs and would especially affect research carried out on new chemicals or structural variations of a drug that may be better suited to tropical climates, for example easier and longer storage at higher temperatures.

Simply because one solution to a particular problem has been found does not mean that better solutions do not exist. Once a research path has been identified by one patent applicant, caution should be taken to ensure that all possible consequences of such discoveries are explored and not left to a single patent owner whose rational economic interest would then focus on products that embodied only their own particular solution.<sup>54</sup>

One counter-argument to the reasons for limiting functional claims in this manner is that it encourages what are known as “me-too” products rather than truly new innovation.<sup>55</sup> However, that question is answered by the principle that competition is more likely to produce varied results adjusted to niche populations than is a single actor exploring only those solutions that serve its interests.<sup>56</sup> This is especially true where such competitors may do research and produce new products that are not themselves patentable.

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<sup>54</sup> B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 99.

<sup>55</sup> *Ibid.* p. 85.

<sup>56</sup> *Ibid.* p. 86.

### III. THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY (TRIPS)

#### III.1. What are the TRIPS Requirements?

TRIPS imposes no obligations as to the forms of claims a country must recognize. WTO members have full freedom to determine the nature and limits of allowable claims.<sup>57</sup>

### IV. WHAT ARE THE EXISTING POLICY APPROACHES?

The problem with functional claims is that in the new field of biotechnology it has become increasingly difficult to relate the structure of a chemical product directly to its therapeutic effect.<sup>58</sup> The chemical reactions in question function more as statistical probabilities than as repeatable and predictable certainties. This has made functional claims apparently a more precise way of defining inventions in this field. In a patent system that values precision, such claims may become attractive. However, a counter to this argument is that the lack of predictability about the path from structure to effect is not a constant of the nature of research in the biotechnology field. In fact, there is evidence that researchers in the biotechnology field are rushing to patent before they are fully in possession of the claimed invention. If the chemical as structurally defined can reach its result through several different paths or reactions which the applicant cannot fully predict, this points to a lack of precision in the methods and knowledge of the applicant and researchers in the field. It may be wiser to refrain from broadening admissible patent claims simply to accommodate researchers in fields that are new and require some time to mature before they reach a level of precision and certainty about their results.

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<sup>57</sup> CM Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000) p. 33.

<sup>58</sup> B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 105.

Domeij notes that with respect to DNA and other proteins, relatively large structural changes can be made without affecting the claimed therapeutic effect. Thus third parties can make irrelevant structural changes to escape the scope of the patent and then compete with the patented structure.<sup>59</sup> However, it may be that the solution does not lie with allowing functional features to be the primary means by which such subject matter is claimed. It may be better to actually require the patent claimant to show *which* fragments of DNA are necessary and sufficient for the invention to work. Without such a demonstration it is clear that the applicant is not fully in possession of the invention and needs to do more research before claiming a patent. The following sections address the approaches of the major patent offices and describe the disapproval with which functional claims are generally treated.

#### **IV.1. The European Patent Office (EPO)**

##### ***IV.1.1. Legislation***

Article 84 of the EPC, which governs the forms of claims for European Patent applications, states:

The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.

It makes no explicit reference to functional claims.

##### ***IV.1.2. Examination and guidelines***

Part C, chapter III, rule 4.7a of the EPO Guidelines states:

As a general rule, claims which attempt to define the invention by a result to be achieved should not be allowed, in particular if they only amount to claiming the underlying technical problem. However, they may be allowed if the

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<sup>59</sup> *Ibid.* p. 107.

invention either can only be defined in such terms or cannot otherwise be defined more precisely without unduly restricting the scope of the claims and if the result is one which can be directly and positively verified by tests or procedures adequately specified in the description or known to the person skilled in the art and which do not require undue experimentation (see T 68/85, OJ 6/1987, 228).<sup>60</sup>

The applicant cannot choose. The determination of whether a structural definition would be better lies with the examiner, and the burden lies with the applicant to show that the structural definition is not the most precise. However, the examiner must balance the requirements of precision and clarity with that of ensuring that disallowing the functional language does not unduly restrict the full scope of protection.<sup>61</sup>

#### ***IV.1.3. Further analysis***

When functional claims are allowed, several standards come into play. The first is the *one-way rule* established in T 292/85 that the applicant must be in possession of at least one structural path leading to the therapeutic effect.<sup>62</sup> Domeij notes that this has been pointed to by applicants as allowing functional claims as long as this standard is met, thus allowing extremely broad claims.<sup>63</sup> He argues that this should be read as a minimum requirement, not as an expansive and permissive standard for broad functional claims.<sup>64</sup> In T 435/91,<sup>65</sup> the Boards of Appeal agreed with Domeij's approach by noting that the one-way rule for functional claims was meant to encourage claimants fully to explore *all* possible mechanisms and solutions before applying for the patent.<sup>66</sup>

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<sup>60</sup> EPO *Guidelines for Examination in the European Patent Office* (EPO Munich 2005).

<sup>61</sup> B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 110.

<sup>62</sup> *Ibid.* p. 107.

<sup>63</sup> *Ibid.* p. 108.

<sup>64</sup> *Ibid.*

<sup>65</sup> OJ EPO 1995, 188.

<sup>66</sup> B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New

In essence, the Boards are asking that the applicant with a functional claim at least show some token attempt actually to try to gain possession of all the solutions to which it would lay claim through a functional claim.

A second test that modifies the one-way rule is whether the person skilled in the art were aware of several structural variants that would perform the same function, based on the knowledge provided in the application.<sup>67</sup> This ensures that a functional claim is not based on speculation about hidden future variants but on knowledge of existing variants that it would be reasonable to claim but which would be difficult to capture under a single structural definition.

From this it can be seen that the EPO attempts to limit functional claims only to those variants which were known or immediately foreseeable at the time of the patent. This is a difficult and complex exercise and it is for developing countries to decide whether a stricter, more certain rule may be more suitable rather than the legal uncertainty that can be created by allowing such claims. The problem of encouraging innovation in new fields may remain, but it is suggested that patents should be made available only in those fields that have sufficiently matured so that researchers are actually in full possession, or largely in possession, of that which they claim. Structural definitions are the best means for ensuring that applicants can predictably make and use the product that they wish to patent. Otherwise, they should claim process patents until such time as they can reliably describe the structure of the product and how it produces its effect. Policy makers should not be influenced by arguments that such a standard is too difficult. Other industries and technological sectors have had to pass through such hurdles and there is no reason why biotechnology and pharmaceuticals should not face the same test. The EPO's difficulty in administering such a nuanced approach should provide fair warning to developing countries, especially those wishing to increase competition and innovation, and maintain and improve access to medicines.

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York 2001) p. 109.

<sup>67</sup> Ibid. p. 112, citing T 740/90.

*The role of the doctrine of equivalents*

In general, the doctrine of equivalents may be considered to be a reply to the worry that limiting claim wording only to structural claims may result in patents that are too narrow. The existence of the doctrine of equivalents is a persuasive counter to the argument that functional claims are necessary to protect against trivial or insubstantial structural changes to a product.

In the EPC, the doctrine of equivalents is an infringement issue and as such is a matter for national courts which is not dealt with at the level of the EPO Boards of Appeal.<sup>68</sup> However, the EPC has dealt with it in the protocol interpreting article 69 which states that:

Article 69 should not be interpreted in the sense that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Neither should it be interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patentee has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties.<sup>69</sup>

Thus, in the EPO the claims are not limited to the literal terms and may encompass equivalents. The extent to which such equivalents are encompassed is left to the case law of each member state except that the claim must be the primary legal basis for determining the scope and not simply a guideline. The existence of this doctrine is a persuasive

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<sup>68</sup> C Martinez and D Guellec 'Overview of Recent Changes and Comparison of Patent Regimes in the United States, Japan and Europe' (2004) in *Patents, Innovation and Economic Performance* OECD Conference Proceedings 25.

<sup>69</sup> EPC art 69. In: <http://www.european-patent-office.org/legal/epc/e/ar69.html#A69> (11 November 2005)

counter to the argument that functional claims are necessary to protect against trivial or insubstantial structural changes to a product.

## **IV.2. The United States Patent and Trademark Office (USPTO)**

### ***IV.2.1. Legislation***

The language that allows functional claims, known as means-plus-function, is found in 35 USC 112 (6), which states:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

It should be noted that Section 112 allows functional language to be used in the claim but that the language must be related to a specific structure, or material described in the specification. The functional language is therefore limited to that described structurally in the specification, *or its equivalents*. Thus, even in the United States, legislation places limits on functional language in the claim, and ensures that it is, at least nominally, related to a structure described in the specification. However, the general principle in the USA is that limitations in the specification should not be read into the claim language.<sup>70</sup> This would suggest that such a limitation would be read narrowly, if at all, into the functional claim language, leaving leeway for the functional language to be broadly interpreted. However, the US courts have stated that the meaning, and therefore the scope of the language, *must* be determined by the structures disclosed in the specification.<sup>71</sup>

In either case, the standard enunciated applies to both patentability requirements and infringement proceedings. US legislation

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<sup>70</sup> *In re Donaldson*, 16F.3d 1189, 29 USPQ2d 1845 (Fed.Cir 1994).

<sup>71</sup> *Ibid*.

on such language appears clearly to disallow broad functional claims. It may seem that it places no limits or conditions on when to choose functional language, and may therefore create uncertainty for third parties who wish to innovate around an invention. One limit that does exist is that the applicant is required to delineate the structure sufficiently clearly that a person skilled in the art would be able to link the functional language to a specific structure described in the specification. Failure to do so would allow the claim to be invalidated for insufficient written description or indefiniteness.<sup>72</sup>

Wegner notes that with respect to chemical entities, especially new biological or chemical entities, this legislation can never apply because there is no such “combination” to speak of.<sup>73</sup> However, even if we accept this argument, access to public health involves delivery systems, dosage regimens and a whole host of other issues which may indeed be patentable as combinations in the USA and may therefore be subject to 35 USC 112. Thus caution should be exercised in allowing such claims, even where they appear to be generally disallowed.

35 USC 112 delineates the types of claims allowed. However, under 35 USC 112 (1) a basic limit is set so that overbroad claims are disallowed.<sup>74</sup> The case law invalidates broad functional claims as “single means” claims, which lay claim to all ways of solving a particular problem without reference to any underlying structure.<sup>75</sup>

#### ***IV.2.2. Examination and guidelines***

Section 2181 of the MPEP governs the interpretation of 35 USC 112(6) by US patent examiners.<sup>76</sup> It follows the ruling in *In re Donaldson*<sup>77</sup>

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<sup>72</sup> USPTO, *USPTO Manual of Patent Examination Procedure*, Section 2181.II: Written description necessary to support a claim limitation which invokes 35 USC 112, sixth paragraph.

<sup>73</sup> H Wegner *Patent Law in Biotechnology, Chemicals and Pharmaceuticals* (2<sup>nd</sup> edn Stockton Press New York 1994) p. 422.

<sup>74</sup> *Ibid.* p. 425.

<sup>75</sup> *Ibid.*

<sup>76</sup> USPTO, *USPTO Manual of Patent Examination Procedure*, Section 2141.01(a).

<sup>77</sup> 16F.3d 1189, 29 USPQ2d 1845 (Fed.Cir 1994).

strictly.<sup>78</sup> Under the guidelines the statute comes into play if the language used meets the following three-prong test:

A claim limitation will be interpreted to invoke 35 USC 112, sixth paragraph, if it meets the following 3-prong analysis:

- A) The claim limitations must use the phrase “means for” or “step for”;
- B) The “means for” or “step for” must be modified by functional language; and
- C) The phrase “means for” or “step for” must not be modified by sufficient structure, material or acts for achieving the specified function.<sup>79</sup>

As can be noted, this is designed to restrict the discretion of the examiner and the applicant to determine when functional language is being used, by insisting on a mechanical use of specific phrases. However, the use of the words, or lack thereof, only creates a presumption which can be overcome.<sup>80</sup> If these do not occur, then the statute cannot be invoked. The third step is to ensure that even where a functional claim is being pursued, if sufficient structural description is given it will not be treated as a functional claim under 35 USC 112, sixth paragraph, and will therefore be treated as a structural claim and tested for indefiniteness as required by 35 USC 112, first paragraph. It will then also be subject to the single means limitation, discussed above.

The language appears to be aimed at disapproval of functional claims and the establishing of strict requirements for the operation of the statute. However, the application of 35 USC 112, sixth paragraph, is a general exception (established in *In re Donaldson*) to the rule that claim language is given the broadest reasonable interpretation.<sup>81</sup> Thus, where there is no discretion for the examiner to characterize a claim as containing functional language, it is possible that claims which may

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<sup>78</sup> USPTO, *USPTO Manual of Patent Examination Procedure*, section 2181.00.

<sup>79</sup> *Ibid.* section 2181.I: Language falling within 35 USC 112, sixth paragraph.

<sup>80</sup> *Ibid.*

<sup>81</sup> *Ibid.* section 2181.

actually be functional while avoiding being characterised as functional will escape the restrictions on claim scope established by 35 USC 112, sixth paragraph. In addition, a distinction is made between functional language and language claiming a process. The language of 35 USC 112, sixth paragraph, is not meant to apply to process claims. A functional claim of this kind provides product protection and thus can provide greater exclusivity than a process patent, which is limited to only one way to achieve a result. The second prong of the test is meant to ensure that the functional language is related to a step of a claim but not the process underlying such a step. The statute applies to functional method claims where the element at issue sets forth a step for reaching a particular result, but not the specific technique or procedure used to achieve the result.<sup>82</sup>

#### ***IV.2.3. Further analysis***

In general, the USA has allowed functional claims reluctantly, and only in specific situations, while providing complex and difficult examination procedures. Such a process may represent the continuous push and pull between the requirements of public interest policy and the desires of pharmaceutical and biotechnology industries to have as broad as possible a scope for their patents. Developing countries should be aware that the difficulties encountered by the USA and the EU in allowing such claims have shown that even sophisticated patent offices have had a difficult time drawing the line between appropriate and inappropriate functional language. The US approach shows that they are very much aware of the policy dangers that functional claims present and have thus hemmed them in with a myriad of restrictions and requirements. In doing so, however, they may also have lowered the standard for the use of functional language in structural claims, such that many applications which should be caught in the more restrictive reading of 35 USC 112, sixth paragraph, are given their broadest reasonable interpretation as structural claims.

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<sup>82</sup> *Ibid.*, section 2181.I: Language falling within 35 USC 112, sixth paragraph citing *O.I. Corp.*, 115 F.3d at 1582-83, 42 USPQ2d at 1782 (Fed. Cir. 1997).

*a. The role of the doctrine of equivalents*

As in the EPO, the doctrine of equivalents may be considered as a reply to the worry that limiting claim wording only to structural claims may result in patents that are too narrow. In the USA, the doctrine states that where a product functions in substantially the same way in order to achieve substantially the same result as a patented product, it will be considered as infringing. This should allay concerns about structural claims being too limited in some cases to provide sufficient protection against minor structural changes that do not affect the core functioning of the product.

*b. The reverse doctrine of equivalents*

In the USA, where a new product performs the same function in a substantially different way but falls within the literal wording of the claim, the claim of the original patentee may be narrowed.<sup>83</sup> This applies in the case of particularly valuable dependent product patents that may embody such significant improvements on the original, or such effective variants, that they surpass the technical contribution made by the original patent. This is also applied in infringement cases to defeat a claim of infringement by the patent holder. It operates from the premise that the improvement is itself not patentable. Domeij argues that the use of such a doctrine negates, to a certain extent, the risks presented by allowing functional claims.<sup>84</sup> He points out that the doctrine is a particularly useful way of narrowing an already-granted patent when it is clear that the patent holder has not explored the very real and useful prospects available within the patent.<sup>85</sup> This would ease the market entry of real innovations that, while dependent, go beyond the original patent and product. The standard as to what period of time should elapse, and the value of the patent, remains in the hands of national courts to determine, and so developing countries may find the doctrine a useful way of limiting functional claims if they are allowed, but also a way of limiting broad structural claims where the accused infringer has

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<sup>83</sup> B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 127.

<sup>84</sup> *Ibid.*

<sup>85</sup> *Ibid.* p. 128.

created a product of real value to the national economy which was not on the horizon of the original patent owner.

## V. THE SITUATION IN DEVELOPING COUNTRIES

Many developing countries have not addressed the issue of functional claims in their policy or legislation. However, requirements for definite descriptive product and process claims can, and should, exclude such claims as inherently characterizing claims to a process, and be treated accordingly. They would be subject to requirements for definiteness and for full descriptions of those elements of the claim that outlined a process. In addition, they will, of course, be limited by the general requirement that a process claim cannot lay claim to all ways of reaching a particular result. The table below represents those countries which do not explicitly allow functional claims, but which have a definiteness requirement, therefore rejecting functional claims for product patents and only allowing them as process patents. Those which require the claim language to be related to a specific structure or element in the specification are also included in this group. It is, however, recommended that developing countries make the prohibition on functional claims explicit in their legislation or regulations.

**Table of Legislative, Regulatory and Examination Guideline Approaches**

<b>Country</b>	<b>Functional claim language explicitly allowed?</b>	<b>Definiteness requirement for claims?</b>	<b>Claim scope limited by description/specification?</b>	<b>Law</b>
Andean Community	No, article 30	Yes, article 30	Yes, article 30	Decision 486 Common Provisions on Industrial Property

Algeria	No, article 22	Yes, article 22	Yes, article 22	Decision n° 03-07 of the 19 Jomada El Oula 1424, corresponding to July 19 2003 on patents
Argentina	No, article 22	Yes, article 20	Yes, article 22	Law No. 24.481 on Patents and Utility Models (as amended by Law No. 24.572) (consolidated text approved by Decree No. 260/96 of March 20, 1996)
ARIPO	No, rule 7	Yes, rule 7	No, rule 7	Regulations For Implementing The Protocol On Patents And Industrial Designs Within The Framework Of The African Regional Intellectual Property (last amended 2004)
Bahrain (see Gulf Cooperation Council)				
Barbados	No, article 17(a)	Yes, article 17(a)	No, article 17(a)	Barbados Patent Act 2001
Belize	No, article 17(5)	Yes, article 17(5)	No, article 17(5)	Patents Act (chapter 253) (Revised Edition 2000)

Gulf Cooperation Council (United Arab Emirates, State of Bahrain, Kingdom of Saudi Arabia, Sultanate of Oman, State of Qatar and State of Kuwait)	No, article 5/2/3 and see also for specific to drugs, article 3/4/2 of the Implementing By-Laws “Where applicable, the chemical formula that, compared to all formulae in the application, best characterizes the invention <i>shall</i> be indicated.”	Yes, article 5/2/4	Possibly, article 5/2/3 and see also article 3/2/2 of the Implementing By-Laws “The claims shall be clear, brief, and shall be in conformity with particulars mentioned in the description.”	Patent Regulation of the Cooperation Council for the Arab States of the Gulf (last amended November 1999)
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## VI. CONCLUSIONS AND RECOMMENDATIONS

Given the difficulties in application, as well as the uncertainty created for third-party innovators and for inventing around, developing countries should limit applicants to structural claims only. Any developing country which chooses the European approach should maintain that the structural definition is paramount and that the functional language is secondary, serving only to clarify the description rather than to define the scope. As in the EPO, it may also be best to ensure that variants which fall within the functional language would have been known to the person skilled in the art at the time of patenting, in the light of the patent application.

Patents should be granted in respect of products only in such cases where the invention is described in structural terms, in both the

claim and the specification. The specification may include functional language referring to elements of the product claim only if, according to the knowledge of the person skilled in the art, a more precise way to describe the invention does not exist and is not likely to exist in the near future. Such a description shall serve to clarify the nature of an invention but may not form the legal basis for determining the scope of the invention.

## CHAPTER 8

### ENABLING DISCLOSURE

#### I. INTRODUCTION

In accordance with an utilitarian vision of intellectual property rights, these deserve protection as they increase utility in society by encouraging artists, authors and inventors through rewards and incentives. Thus, they contribute to the enhancement of arts, science and technology. This philosophy – influenced by the English philosopher and economist John Stuart Mill and elaborated on by other philosophers such as E. Hettinger and A. Kauflik – has inspired many national laws on the subject. In the case of patents, this approach means that the law should ensure that society benefits through the contributions of inventors rather than looking for the later individual benefits.<sup>86</sup>

One of the benefits obtained by society from patents is the disclosure of the invention in order to permit the further development of science and technology. The disclosure function of patents was seen in the nineteenth century as a main justification for the patent system. Even today, it is deemed to be an essential element in such a system. Thus, Justice Aldous stated in *American Home Products v. Novartis Pharmaceuticals*: “I do not believe that the patent system should be used to enable a person to monopolise more than that which he has described in sufficient detail to amount to an enabling disclosure. If it was, it

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<sup>86</sup> An alternative view is the ‘Libertarian’ approach often based on concepts developed by the British philosopher John Locke. According to this approach, all people have natural rights to life, liberty and property, which the government of the land is duty-bound to protect. According to Locke, if a person removes a property from nature and works on it (“mixes his labour”) to add value to it, the result is his property. Because this philosophy highlights the “natural rights” of a person, it is often referred to as “natural rights” philosophy.

would stifle research.”<sup>87</sup> In another case (*Herbert Markman and Positek Inc v. Westview Instruments, Inc. and Althon Enterprises Inc.*), Justice Souter held:

[t]he limits of a patent must be known for the protection of the patentee, the encouragement of the inventive genius of others and the assurance that the subject of the patent will be dedicated ultimately to the public. Otherwise, a zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention only a little less than unequivocal foreclosure of the field, and [t]he public [would] be deprived of rights supposed to belong to it, without being clearly told what it is that limits these rights.<sup>88</sup>

This chapter examines how the requirements are imposed on the patentee regarding the disclosure of the invention in some developed countries, and draws some lessons for developing countries.

### **1.1. Meaning of “Enabling Disclosure”**

A patent application needs to disclose details about the invention for which the patent is applied. Such disclosure should be sufficient that a person skilled in the particular art can build on the invention and enhance public knowledge in the particular area of technology after the expiry of the patent. In exchange for such disclosure, the patentee is allowed monopoly rights to exclude any third party to profit from making, using or selling the invention.<sup>89</sup> This disclosure is known as “Enabling Disclosure” and is sometimes referred to as “Enablement”.

“Enabling Disclosure” refers to the specification of the patent in a patent application which discloses the invention in such a manner that a person skilled in the art can perform it. In other words, it is the details

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<sup>87</sup> (2001) RPC 159, 179.

<sup>88</sup> (1996) 116 Supreme Court 1384,1395.

<sup>89</sup> S Elias and L Goldoftas *Patent, Copyright & Trademark* (Third edition, Nolo Press Berkeley 1999) pp. 228-229.

provided in the patent to allow a person to develop the invention from the knowledge disclosed without applying any further inventiveness.<sup>90</sup>

In most legal jurisdictions, the issue of enabling disclosure is treated in the same way. In the UK, the patent law requires the patent applicant to disclose the invention clearly and completely to enable the person skilled in the art to perform it.<sup>91</sup> The EPC states that “[t]he European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art”.<sup>92</sup> The EPC Rules provide certain specifications with regard to the disclosure:

The description shall:

- a) Specify the technical field to which the invention relates;
- b) Indicate the background art which, as far as known to the applicant, can be regarded as useful for understanding the invention, for drawing up the European search report and for the examination, and, preferably, cite the documents reflecting such art;
- c) Disclose the invention, as claimed, in such terms that the technical problem (even if not expressly stated as such) and its solution can be understood, and state any advantageous effects of the invention with reference to the background art;
- d) Briefly describe the figures in the drawings, if any;
- e) Describe in detail at least one way of carrying out the invention claimed using examples where appropriate and referring to the drawings, if any;

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<sup>90</sup> W Cornish and D Llewelyn *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (5<sup>th</sup> edn, Sweet & Maxwell 2003) p. 225.

<sup>91</sup> Patent Act 1977, Sections 14(3), 72 (1) (c).

<sup>92</sup> Article 83 EPC.

- f) Indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry.<sup>93</sup>

The Japanese Patent Law states, “The detailed description of the invention under the preceding Subsection (iii) shall state the invention in a manner sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the art to which the invention pertains.”<sup>94</sup> The guidelines further elaborate on the meaning of “enablement requirement”, in which they state that the invention shall be described in such a manner that “... a person who has ability to use ordinary technical means for R&D (including comprehension of document, experimentation, analysis and manufacture) and to exercise ordinary creativity in the art (a person skilled in the art) to which the invention pertains can carry out the claimed invention on the basis of matters described in the specification (excluding claims) and drawings taking into consideration the common general knowledge as of the filing (hereinafter referred to as ‘enablement requirement’.”<sup>95</sup>

In the USA the law requires that the enabling disclosure not only allows disclosure in such a manner that the person skilled in the art is able to work it, but also requires the patent applicant to provide the best mode of working the invention. “[1] The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.”<sup>96</sup> This is an additional requirement and is commonly known as “Best Mode requirement”. It entails that the patentee should provide in the specification the best mode of performing the invention; that is,

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<sup>93</sup> EPC Rule 27.

<sup>94</sup> Section 36(4) of the Japanese Patent Law. The English version is sourced from the Patent Examination Guidelines of the JPO – Description Requirements of the detailed description of the Invention (part I, chapter 1).

<sup>95</sup> Guidelines of the Japanese Patent Office – Description Requirements of the detailed description of the Invention (part I, chapter 1) p. 18.

<sup>96</sup> 35 USC § 112 (1994).

the specific instruments and techniques of performing the claimed invention that is known to the inventor at the time of filing the patent.<sup>97</sup> The best mode requirement prohibits an inventor from applying for a patent while concealing from the public a preferred way of performing the invention which the inventor has conceived.<sup>98</sup>

The patent system is based on certain foundational pillars, “Enabling Disclosure” being one of them. The patent system is often conceived as guaranteeing the owner of the patent restricted monopoly rights as an incentive for his intellectual creativity, time and monetary risk and in exchange for disclosing the details of his invention to the general public. This will enable others to learn from the invention and to be able to gain from the available knowledge after the patent monopoly expires. This means that after the stipulated time when the monopoly expires, anyone will be able to make use of the invention.<sup>99</sup>

Sometimes there is a tendency to confuse the terms “enabling disclosure” and “prior disclosure” since both are at times referred to as “disclosure”. As defined earlier, enabling disclosure is one of the basic requirements of patent law. Lack of enabling disclosure should cause refusal of a patent application and even revocation of an existing patent, whereas “prior disclosure” means a disclosure prior to the filing of a patent which destroys the invention’s novelty. Thus when a prior disclosure is sufficiently enabling, it will be considered as part of prior art.

As in the case of enabling disclosure, even in the case of prior disclosure it will be considered to be sufficient disclosure when the disclosure enables a person skilled in the art to carry on the claimed

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<sup>97</sup> *Glaxo Inc. v. Novopharm Ltd.*, 52 F 3d 1043, 1050 (Fed. Cir. 1995).

<sup>98</sup> SW Halpern, CA Nard and KL Port *Fundamentals of United States Intellectual property Law: Copyright, Patent and Trademark* (Kluwer Law International New York 1999) p. 189.

<sup>99</sup> D Bainbridge *Patent Law – background, basic principles and practical aspects in Intellectual Property* (4<sup>th</sup> edn, Pitman Publishing 1999) pp. 321–322.

invention.<sup>100</sup> If it is possible, then the patent application will be barred due to lack of novelty.<sup>101</sup>

## **II. SUFFICIENT DISCLOSURE IN PRACTICE**

### **II.1. The Issue of Sufficient Enablement**

The importance of enabling disclosure lies in the fact that the grant of a patent depends on it to a considerable extent. A patent application can be denied for lack of sufficient disclosure to enable a person skilled in the art to carry out the invention. At the same time, if prior art has already disclosed the invention, enabling a person skilled in the art to carry out the invention, then the application will be rejected due to the lack of novelty.<sup>102</sup>

Often the issue of enabling disclosure becomes a matter of dispute since, in all jurisdictions, the patent law requires the disclosure to be sufficient for the person skilled in the art to be able to execute it. If the disclosure is not sufficient there might be a pre-grant objection as well as a case for revocation of the patent.<sup>103</sup> However such provisions are elaborated in the national patent laws and may differ procedurally from one jurisdiction to the other.

Whether an invention is sufficiently disclosed or not is actually determined as of the filing date: “The specification must disclose the invention clearly and completely enough for it to be performed by a person skilled in the art. There must be the same “enabling disclosure” as that which justifies a claim to priority and which may amount to an anticipation. It must do so at the date of filing, not when the application is first published. It is this requirement that aims to extract the essential

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<sup>100</sup> AR Miller and MH Davis *Intellectual Property Patents, Trademarks and Copyright in a nutshell* (2<sup>nd</sup> edn, West Publishing Company 1990) p. 46.

<sup>101</sup> G Paterson *The European Patent System The Law and Practice of the European Patent Convention* (2<sup>nd</sup> edn, Sweet & Maxwell London 2001) p. 509.

<sup>102</sup> *Ibid.*

<sup>103</sup> L Bently and B Sherman *Intellectual Property Law* (2<sup>nd</sup> edn, Oxford University Press 2004) p. 489.

“consideration” for the patent grant- revelation of the invention for the information of the rest of industry and any others interested.”<sup>104</sup>

It has been noted that “... the patentee fulfills his duty if in his complete specification he describes and ascertains the nature of the invention, and the manner in which the invention is to be performed, sufficiently and fairly. It is not necessary that he should describe in his specification the manner in which the invention is to be performed, with that wealth of detail with which the specification of the manufacturer of something is usually put before the workman who is engaged to manufacture it”.<sup>105</sup>

**Box 1**

***No Fume v. Pitchford***

In this particular case the claim was defined as “An ash receptacle which, without the use of movable parts, retains the smoke rising from objects thrown into it, characterised by the fact that it consists of a closed container into which extends a shaft of substantially constant cross section, the sides of which, with the sides of the receptacle, form a trapped space closed above, whilst wholly beneath the shaft is provided a deflecting member, which deflects objects thrown in wholly to one side of the lower mouth of the shaft”. Further, an illustrative drawing of the construction of the ash-tray was also provided.

In deciding whether or not the specification described the patent sufficiently, it was held that the patentee did not need to provide details of the particular manner in which the invention was to be performed. It was stated that often specifications could have mistakes or omissions. So the ultimate test of sufficiency is whether the person skilled in the art could rectify the mistakes and omissions while performing the invention. If that were possible then surely the disclosure would be considered sufficiently enabling.

Continued ...

<sup>104</sup> W Cornish and D Llewelyn *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (5<sup>th</sup> edn Sweet & Maxwell London 2003) p. 225.

<sup>105</sup> LJ Romer in *No Fume v. Pitchford* [1935] 52 RPC 231 (CA).

In the *No Fume v. Pitchford* case it was considered that although the claimant had not provided the “relative proportions of the integers”, it would not have been difficult for the person skilled in the art to follow the specifications supported by the illustrative diagram and perform the invention by a trial and error method. Hence, the disclosure was considered to be sufficiently enabling and the patent was allowed.

In the case of mechanical inventions, it is necessary to describe in detail at least one embodiment of the invention to prove that it is not obvious. In the case of chemical inventions, the inventor is expected to provide at least one embodiment featuring the invention. However, if the invention also claims other alternatives, other embodiments, it may be necessary to make the disclosure sufficiently comprehensive.<sup>106</sup> One often-cited case is the invention of a “smokeless ashtray”, which is described above in box 1.<sup>107</sup>

Recently, with the increase in of patents in the pharmaceutical sector, the issue of enabling disclosure has become the central point of a number of patent disputes in all major legal jurisdictions. Generally, the issue of sufficient enabling disclosure as judged by a court from the evidence available is actually a question of fact rather than a question of law. So in such disputes it is usually determined whether the person skilled in the art can perform the claimed invention or not. It is important to note that the enabling disclosure need not educate the person skilled in the art, since he or she will understand how things can be made to work. So the specification need not be used as a mode of rehearsal for their knowledge.<sup>108</sup>

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<sup>106</sup> William Cornish and David Llewelyn *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (5<sup>th</sup> edn, Sweet & Maxwell London 2003) p. 226.

<sup>107</sup> *No Fume v. Pitchford* [1935] 52 RPC 231 (C.A.); for further details see William R Cornish (ed) *Materials on Intellectual Property* (ESC Publishing Limited Oxford 1990) 74–76.

<sup>108</sup> W Cornish and D Llewelyn *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (5<sup>th</sup> edn Sweet & Maxwell London 2003) p. 227.

In an interesting case, the US Federal Circuit held that the person skilled in the art could be required to apply “trial and error” experiment to perform the invention.<sup>109</sup> This would not invalidate the patent claim for lack of disclosure (see box 2).

**Box 2**

***WL Gore and Associates v. Garlock Inc.***

The claimed invention related to an unsintered polytetrafluorethylene (PTFE) tape used to seal water leaks from pipe joints and popularly known under the trade name TEFLON (of E.I. du Pont de Nemours Inc.). WL Gore and Associates Inc. was the assignee in the patent dispute concerned.

In the manufacture of the PTFE tape, there was a problem of tape breaking while it was stretched. An invention by Wilbert L Gore solved the problem by slowing the stretch rate or decreasing the crystallinity of the PTFE rods. This became the conventional wisdom via prior art since this was patented. However, this method was not foolproof and even in this method the PTFE rods broke if they were stretched a relatively small amount.

Dr Robert Gore, son of Wilbert L Gore, experimented further and found that the rods did not break if they were stretched very fast. He found out that if he stretched the rods as fast as possible, then he could stretch them ten times more than their original length without breaking them and also without any virtual change in their diameter. At the same time these rods were transformed from their shiny crystalline nature to soft flexible material. He applied for a patent on this invention which could be used to make different PTFE products.

This patent disclosed in its specification that stretching the PTFE rods at a rate above 10 per cent per second or to a matrix tensile strength in excess of 7,300 psi, and at a temperature between about 35°C and the crystalline melting point of PTFE, would result in the claimed invention.

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<sup>109</sup> *W.L. Gore and Associates v. Garlock Inc.*, 721 F.2d 1540, 220 USPQ 303, cert. denied, 469 US 851, 105 S.Ct. 172, 83 L.Ed. 2d 107 (1984); for further details see P Goldstein *Copyright, Patent, Trade Mark and Related State Doctrines, Cases and Materials on the Law of Intellectual Property* (5<sup>th</sup> edn, New York Foundation Press 2002) pp. 479–483.

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The patent was challenged before the District Court of the Northern District of Ohio on the grounds that the patent did not disclose sufficiently since the language of the claim was not definite. The District Court favoured the plaintiff and held that the application did not fulfil the requirement under §112 of the Patent Act.

The court reasoned as follows:

- (1) There was no definition of “stretch rate” in the specification and a different formula was developed for computing stretch rate and presented at the trial.
- (2) The specification did not teach how to calculate the minimum stretch rate above 35°C.
- (3) The phrase “matrix tensile strength” was indefinite.
- (4) The phrase “specific gravity of the solid polymer” was indefinite.

The dispute over whether or not the disclosure was sufficiently enabling was taken up by the Federal Circuit on appeal, where the court decided that the disclosure was sufficiently enabling. The reasoning of the court is provided below:

- (1) There was no evidence that those skilled in the art would have found the specification non-enabling or the claim indefinite at the date and period when the application was filed (more precisely on 21 May 1970).
- (2) At the time when the patent was filed, “stretch rate” meant (to those skilled in the art), the percentage of stretch divided by the time of stretching, which was measurable with a stopwatch. Hence, the absence of a formula to calculate the stretch rate in the specification is of no importance.
- (3) Calculating stretch rate by actually measuring the time required to stretch the PTFE rods was the only mode used by the inventor and it worked. This would qualify for the “best mode” requirement in the law.
- (4) The use of the phrase “stretch rate” is not indefinite since infringement can be assessed if a stopwatch is used.
- (5) Absence of a method for calculating the minimum rate of a stretch above 35°C does not render the specification non-enabling. At the same time, the fact that the minimum rate of stretch may increase the temperature does not render the application non-enabling.
- (6) Although the District Court found the “matrix tensile strength” to be indefinite, it also acknowledged that the specification disclosed how to compute “matrix tensile strength”. Hence it could not be considered non-enabling.

... continued

(7) There is no dispute with regard to the fact that there were many examples where the specific gravity of solid polymers used for unsintered and sintered PTFE were 2.3 and 2.2 respectively. There was nothing that would have established that a person skilled in the art would not know this specific gravity.

Thus it cannot be concluded that “specific gravity of the solid polymer” is indefinite, or that absence of its definition would result in making the disclosure non-enabling. In addition, the Federal Circuit held as erroneous the District Court’s decision not to allow disclosure by experimentation through a “trial and error” method.

In the case of chemical inventions, especially in the pharmaceutical sector, the issue of enabling disclosure is of particular importance. This is mainly because patents that protect chemical entities quite often encompass more than one compound. In such scenarios, the claims often cover a multitude of compounds which are expected to have similar characteristics in their activity and thus, based on exemplification, only a few compounds are tested. In support of this practice it has been argued that competition in the industry is so sharp that “... some element of prediction is an essential part of drafting a patent specification, especially in these sectors. Otherwise competitors could reap the benefits of another’s invention by minor modification, for example, in the case of NCEs [new chemical entities] replacing a methyl group by a propyl group, just because the patentee had not got round to synthesising all the homologues of a new compound. Such predictive claiming is facilitated by the clear and precise terminology which chemistry employs to characterise structures”.<sup>110</sup>

The issue of enabling disclosure to ascertain the level of disclosure that was required to fulfil the sufficiency requirement was considered in the ICI/Pyridine Herbicide case.<sup>111</sup> In this case it was decided that a chemical synthesis provided in a patent which can only be

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<sup>110</sup> T Cook *A User’s Guide to Patents* (Butterworth London 2002) pp. 299–300.

<sup>111</sup> T 206/83.

located by reference to “Chemical Abstracts” cannot be considered to be enabling disclosure of the product of that synthesis. This is because “Chemical Abstracts” are not part of the common general knowledge that a person skilled in the art is expected to have.<sup>112</sup> Here, the issue of the specification’s being declared insufficient and non-enabling due to errors of commission or omission does not arise since it is dependent on whether the person skilled in the art can rectify such error without performing any additional inventive step.

To qualify under the requirement of sufficient disclosure, it is important that the application provides the necessary know-how through its specification. In a case decided by the Technical Board of the EPO, it was held that the patent claim which defines the particular embodiment must be made available to the person skilled in the art, although it is not essential to provide a detailed specification in such a manner that the invention can be repeated.<sup>113</sup> A patent might be challenged on the enabling disclosure ground based on evidence to this effect, in the absence of which the patent would be considered valid.<sup>114</sup>

An often-cited pharmaceutical patent case involving sufficiency of enabling disclosure is *Biogen v. Medeva*.<sup>115</sup> It was decided by the House of Lords on appeal in the UK and was also taken up at the EPO (see box 3).

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<sup>112</sup> T Cook *A User’s Guide to Patents* (Butterworth London 2002) p. 298.

<sup>113</sup> B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 46, while discussing T 281/86 (OJ EPO 1989) 202.

<sup>114</sup> T 9182/89 (OJ EPO 1991) 391.

<sup>115</sup> *Biogen v. Medeva* [1997] RPC 1, 53–54. For further details see F Abbot, T Cottier and F Gurry *The International Intellectual Property System Commentary and Materials* (Part One, Kluwer Law International New York 1999) pp. 42–44.

**Box 3**

***Biogen v. Medeva***

This case is particularly interesting because when the patent application was being decided in the UK, it had already been granted in the EPO. Medeva challenged the patent before the Technical Board of the EPO in a post-grant opposition and, at the same time, Biogen sued Medeva in the UK alleging infringement of its patent, following which Medeva counter-sued Biogen asking for revocation of the patent.

The test of sufficiency of disclosure required a disclosure that would enable the person skilled in the art to perform the invention as on the date of the filing of the application. The question arose as to whether the claimed method was capable of making both HBcAg and HBsAg and whether it would work in eukaryotic (cells that have a membrane-delimited nucleus, for example algae, fungi, etc.) as well as bacterial hosts. The UK court found that the specification would enable the person skilled in the art. In the opposition proceeding before the Technical Board of the EPO, the same was found.

In the UK the matter was taken up on appeal by the House of Lords and thoroughly re-examined. It was thence considered that although the person skilled in the art should have been able to make HBcAg and HBsAg in bacterial cells, or in any other cells, there was no evidence which justified a claim enabling HBsAg in *E. coli* (or any other host).

The House of Lords decided that the disclosure was not sufficient. However, for the same invention, the EPO considered the disclosure sufficient. While considering the sufficiency of enablement, the Technical Board of the EPO restricted its test to the specific claim on HBcAg and HBsAg although the claim essentially included all recombinant DNA processes by which the synthesized antigen could be produced.

In the USA the law requires the patentee to disclose (in the specification) how to make and use the full scope of the claimed invention. However the law does not specifically mention that if the

claim fails to include any specific process or condition required to perform the invention, “undue experimentation” would be required.<sup>116</sup> But this is established through case law wherein the Federal Circuit has held that undue experimentation would be necessary in such cases. It has said that “... the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art ...”<sup>117</sup>

## **II.2. The Issue of the Person Skilled in the Art**

It has already been discussed whether a disclosure would qualify as enabling only if the person skilled in the art could perform the invention. A person skilled in the art may be considered “a person in the practical field who is informed about what is part of the common general knowledge in the field in question at the relevant time; it is also deemed that he has access to everything that forms the state of the art, in particular the documents cited in the search report, and that he has at his disposal the normal means and skills for routine work and experimentation”<sup>118</sup>.

The issue of ascertaining “who is the person skilled in the art” is complex and often confusing. It is complex because the parameters of judging whether a person is sufficiently skilled or not might vary from case to case and it is confusing because it might need to be ascertained whether the place of work of the person skilled in the art is to be considered as contributing to the performance and aptitude of that person. Questions also arise as to whether the person should be a single

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<sup>116</sup> SW Halpern, CA Nard and KL Port *Fundamentals of United States Intellectual Property Law: Copyright, Patent and Trademark* (Kluwer Law International New York 1999) p. 189.

<sup>117</sup> *Genentech Inc. v. Novo Nordisk*, 108 F.3d (Fed. Cir. 1997) 1361, 1365.

<sup>118</sup> M Singer and D Stauder *European Patent Convention : A Commentary* (Vol. 1, Sweet & Maxwell & Heymanns 2003) pp. 170–171.

person or can be a group of persons. There might be many other such issues that can add to the dilemma.

In the USA, the courts have dealt with this issue for more than a hundred years. In one of the very early judgments it was held that a person skilled in the art is one "... skilled artisan, working under the stimulus of some gain which will come to him from the exercise of his imagination".<sup>119</sup> This can be interpreted as a person who has the ability to make obvious adaptations on the subject matter of the patent claim or who can make improvements for some personal or financial gain. However, if he or she is only a daily wage-earning labourer, he or she might not be qualified enough as a person skilled in the art.<sup>120</sup> In a later case it was decided that a person skilled in the art is a person who has ordinary skills in the specific art which made him or her competent and properly skilled but without "superlative skills".<sup>121</sup> Even in recent times, case laws support the view that "... It is the specification not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute adequate enablement".<sup>122</sup>

Comparing the person skilled in the art in evaluating inventive step with the concept of the skilled person employed to assess sufficiency, they are found to be similar. One difference is that whereas for the purposes of evaluating inventive step the skilled person has knowledge only of the prior art, for the purpose of evaluating sufficiency of disclosure the skilled person has knowledge of the prior art and of the invention as disclosed.<sup>123</sup> Moreover, it is important to note that there is nothing obligating a country to use the same concept of "person skilled in the art" to assess disclosure and inventive step. A developing country may opt, for instance, for a concept of a low-

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<sup>119</sup> *Kennedy Inc. v. Beaver Tile & Specialty Co.*, 232 Fed. (SDNY 1916) 477, 480.

<sup>120</sup> PH Blaustein *Learned Hand on Patent Law* (Pineridge Publishing House 1983) pp. 154–155.

<sup>121</sup> *Dewey & Almy Chemical Co. v. Mimex Co. Inc.*, 124 F. 2d (2<sup>nd</sup> Cir 1942) 986, 990; for further details see Blaustein p. 154.

<sup>122</sup> *Genentech Inc. v. Novo Nordisk*, 108 F. 3s (Fed. Cir. 1997) 1361, 1365; for further details see Halpern et al. p. 189.

<sup>123</sup> L Bently and B Sherman *Intellectual Property* (2<sup>nd</sup> edn, Oxford University Press 2004) p. 490.

qualified person to assess the former in order to ensure that the invention can be performed by a local expert, while adopting the concept of a highly-qualified person to judge the existence of inventive step.

Under the EPC, the issue of a person skilled in the art in determining pharmaceutical patents is defined in the patent examination guidelines which state: “The skilled person is a person in the pharmaceutical field who is informed about what is part of the common general knowledge in the field in question at the relevant time; it is also deemed that he has access to everything that forms the state of the art, in particular the documents cited in the search report and that he has at his disposal the normal means and skills for routine work and experimentation.”<sup>124</sup>

Regarding determination of whether the person skilled in the art is to be a single person or could be a group of persons, the Technical Board of the EPO held that it could be a group of scientists.<sup>125</sup> In this particular case, which involved invention in genetic technology, it was considered that the skilled person could be a team of scientists who had worked in laboratories in which molecular genetics had been developed.<sup>126</sup> In yet another case, it was held by the Technical Board that a team of electronics experts and programmers could be considered as “person skilled in the art”.<sup>127</sup>

The issue of the knowledge of the person skilled in the art has arisen again and again. Under the jurisdiction of the EPO, case law has established that the person skilled in the art will have knowledge obtained from basic handbooks and textbooks in the field of invention, as well as references made in these books.<sup>128</sup> In another decision it was also clarified that more specialised sources such as chemical abstracts are not supposed to be within the knowledge of persons skilled in the art. Existing patents in the field are not usually expected to be known to the person skilled in the art, but if the invention is so new that there is not much written about it in journals, books or in any other literature,

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<sup>124</sup> EPC Examination Guidelines C-IV 9.6).

<sup>125</sup> T 60/89 (OJ EPO 1992) 268.

<sup>126</sup> Ibid.

<sup>127</sup> T 164/92 (OJ EPO 1995) 305.

<sup>128</sup> T 206/83 (OJ EPO 1987) 5.

and the only information available is in previously-published patents, then the person skilled in the art is supposed to have knowledge of such patents.<sup>129</sup> However, if the claimed invention refers to a particular patent, then such patents would be considered to be known to the person skilled in the art.<sup>130</sup>

As inventions become more and more technical within complex and wide fields of technology, a question arises on the knowledge of the person skilled in the art – what should the person skilled in the art know. To answer such a question and clear all doubts, the Board of Appeal of the EPO held: “[W]hile it is indeed perfectly reasonable to expect a person skilled in the art if need be, i.e. in the absence of useful suggestions in the relevant field as to how a given problem might be solved, to look for suitable parallels in neighbouring fields, the question of what is a neighbouring field is one of fact and the solution depends, in the opinion of the Board, on whether the fields are so closely related that the person skilled in the art seeking a solution to a given problem would take into account developments in the neighbouring field. It is furthermore quite reasonable to expect a skilled person to refer to the state of the art in the general field of technology in which the same problems or problems similar to those in the special field of the application extensively arise and which a person skilled in the art must be expected to be aware.”<sup>131</sup>

This means that if required, the knowledge of the person skilled in the art might need to extend to a wider technical field or even to a related but different field, if there is similarity in the technical problems in both these fields.

The other issue is regarding the expectation from the person skilled in the art. It is not just how much the person should know but what he or she is expected to do in order to perform the invention as per the disclosure: “... it is not the technical feasibility of individual steps that is relevant, but the necessary total effort for the man skilled in the art. Even if each of the different steps involved could be considered as

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<sup>129</sup> T 51/87 (OJ EPO 1991) 177.

<sup>130</sup> B Domeij *Novelty in Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) pp. 49, 50.

<sup>131</sup> T 176/84 (OJ EPO 1986) 50.

being feasible with a certain amount of trial and error, the total amount of experimental effort necessary to successfully advance step by step may still be regarded as undue. It is the total effort that must not constitute an ‘undue burden’. This is an important limitation on what may be expected of a man skilled in the art”.<sup>132</sup>

An often-cited pharmaceutical patent case is the Amgen/Erythropoietin case decided by the EPO in favour of sufficiency of disclosure.<sup>133</sup> A similar case was decided by the Federal Circuit in the USA, where the disclosure was not deemed sufficient.<sup>134</sup> The cases decided by the EPO and the Federal Circuit are discussed in brief in boxes 4 and 5.

#### **Box 4**

##### ***Kirin Amgen Inc. & Others v. Avantis & Others***

This case has been of utmost importance not only to the parties involved but also other pharmaceutical companies because of its precedential value. From the enabling disclosure perspective, the issue was whether the person skilled in the art had been able to practise the invention on the priority date, that is, on 13 December 1983. From the nature of the case one might have assumed that the Board would declare the enablement not sufficient but the Board decided to the contrary.

The application was for a claim on glycoprotein (called Erythropoietin – ‘E’) produced by the kidney to enhance red blood cell production. E can be used to treat anaemia, kidney failure and other pathological states.

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<sup>132</sup> B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 55 (footnotes omitted), while discussing T 639/95 of 21.01.1998 and T 994/95 of 18 February 1999 .

<sup>133</sup> T 412/93 of 21. 11. 1994. B Domeij *Novelty in Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) pp. 57–58, D Robertson ‘First round to Amgen in EPO battle’ 18 *Nature Biotechnology* 2000 483 and 19 *Nature Biotechnology* 2001 188.

<sup>134</sup> *Kirin Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 927 F. 2d (Fed. Cir. 1991) 1200, cert. denied, US 856 (1991) 502. See also RJ Berman and AEL Schoenhard ‘The level of disclosure necessary for patent protection of genetic innovations’ 22 *Nature Biotechnology* 2004 1307–1308.

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In this case, the plaintiff alleged insufficient disclosure of the patent since the person skilled in the art was required to do more than the conventional expectation of work to perform the patent.

It is important to note that the specification did not describe the DNA sequence that coded the protein. Instead it provided details of an oligomer (a polymer that consists of two, three or four monomers) which, according to the applicant, could be used to find the E gene from the gene bank.

In such circumstances, the question was whether it was expected of the person skilled in the art to search the gene bank, locate the E probe concerned and then try to perform the invention. Based on expert opinion provided by witnesses, it was considered that it would take considerable time (it could be a few months) to complete all these procedures and perform the invention, even if the invention were performed by a team of persons instead of a single person. According to the Board, such time period is normal and would not place an undue burden on the person skilled in the art. The Board held that the person skilled in the art was expected to complete the procedure and perform the patent.

#### **Box 5**

#### ***Kirin Amgen Inc. v. Chugai Pharmaceutical Co. Ltd***

In this case, Amgen's patent covered DNA-encoding proteins similar to Erythropoietin – 'E'. It was found during the trial that more than 3,600 different analogues of E could be made by the substitution of a single amino acid and more than a million different analogues could be made by substituting three amino acids. However, the patent specification did not disclose all the analogues but disclosed only a few of the E analogue genes.

Chugai sold a protein which was similar to that of E, so Chugai challenged the validity of Amgen's patent on grounds of insufficient disclosure. On re-examination of the patent, the Federal Circuit held that the disclosure was not sufficiently enabling.

It can be concluded that in order to fulfil the requirement of sufficient enablement in a patent over DNA sequences, the written description of the invention in the specification should provide sufficient examples of DNA analogues of the protein concerned on which the patent is applied. Describing one of the analogues, or a few when the claim is over many, will not be considered as sufficient disclosure.

With the very close competition in the pharmaceutical industry where patents rule the turf, patent applicants try different ways to outsmart their competitors. Often they try to avoid providing sufficient disclosure under one guise or another (although this is against the very essence of patent law which is meant to be a tool to encourage innovation instead of being a restrictive commercial tool), with the intention of not enabling the competitor to work on its invention, particularly in the case of process patents.

Since the disclosure needs to be such that the person skilled in the art is able to perform from it, if the invention has never been tried practically it might be impossible to perform it because of its theoretical nature. Patent examiners usually try to determine the nature of the examples to ascertain whether one is a working example or a paper example, by following the description in the specification. The EPO usually rejects an application on grounds of insufficient enablement if the applicant uses words such as “presumably”, “probably”, “will be” and “in principle” to describe the specification.

Hence it can be stated that a person skilled in the art is a person who is skilled in the contemporary technology, having average knowledge and ability. He or she is expected to have the basic knowledge in the state of the art so that he or she can undertake professional-level work in the particular field of technology in order to perform the invention. It must also be noted that he or she might need to extend the work to related fields if there is any common problem.

### III. ENABLING DISCLOSURE IN THE LATEST TECHNOLOGY

#### III.1. Facilitating Enabling Disclosure in Patents on Micro-organisms

Patenting of biotechnology inventions is not a new concept. Even as early as 1873, Louis Pasteur had obtained a US Patent<sup>135</sup> on “[Y]east, free from organic germs of disease, as an article of manufacture”.<sup>136</sup>

Microbiological inventions generally involve “the use of a new strain of micro-organism to produce a new compound or to produce a known compound more efficiently (for example, in higher yield or purity). The new organism may have been found in nature (for example, by screening of soil samples) or may have been produced in the laboratory by artificially induced random mutation or by more specific techniques such as genetic engineering”.<sup>137</sup>

Under article 27.3(b)<sup>138</sup> of the TRIPS Agreement, member countries are required to protect micro-organisms, while plants and animals and the biological process for their obtention may be excluded from protection. In the USA, the trend in patenting micro-organism-based inventions took an upward surge with the US Supreme Court’s landmark decision in *Diamond v. Chakrabarty* which clearly allowed patents on micro-organisms.<sup>139</sup>

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<sup>135</sup> USP 141072.

<sup>136</sup> PW Grubb *Patents for Chemicals, Pharmaceuticals and Biotechnology – Fundamentals of Global Law Practice and Strategy* (Clarendon Press Oxford 1999) p. 225.

<sup>137</sup> *Ibid.* p. 226.

<sup>138</sup> Article 27.3 (b) states, “Members may also exclude from patentability: (a) ... (b) plants and animals other than micro-organisms, 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.”

<sup>139</sup> *Diamond v. Chakrabarty* 447 US 303 (1980), 193.

As in the case of any other patents, the issue of sufficient disclosure becomes extremely important since insufficiently enabling disclosure can be the cause of rejection of an application or revocation of an existing patent. The complexity of disclosure in biotechnology-based inventions is mainly due to the fact that the subject matter may be living organisms and not inert substances. This makes it totally different from chemical inventions: "... [I]t is practically impossible to define a strain of micro-organism unambiguously by a written description observationally; a strain is not of fixed structure and properties, but is a living system, capable of altering its behaviour in response to changes in its environment. It is not always possible to say whether observed differences between two cultures are such as would be expected within a single strain or if they are large enough to compel identification as two different strains".<sup>140</sup>

For this reason, where the invention is on living material, disclosure is nearly impossible through conventional description of the patent claim in the specification. To cater to such inventions, the micro-organism samples needed to perform the invention are generally required to be deposited by the patent applicant with a recognised culture collection. These samples are then made available to the general public through the collection centres.<sup>141</sup> The person skilled in the art or any other interested person can collect the deposited material from the collection bank/centre and perform the invention. The collection centres make these deposited samples available on an undertaking from the requester that the sample will not be transferred to others.<sup>142</sup>

A standardised method of depositing micro-organisms has been established with the Budapest Treaty of 1977 which came into effect in

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<sup>140</sup> PW Grubb *Patents for Chemicals, Pharmaceuticals and Biotechnology – Fundamentals of Global Law Practice and Strategy* (Clarendon Press Oxford 1999) p. 227.

<sup>141</sup> It is important to note that there is a major difference between the practice under the EPC and in the USA. In the USA the samples that are deposited with the collection centre are released only on the grant of the patent, while under the EPC, they are required to be made available from the date of early publication of the application.

<sup>142</sup> W Cornish and D Llewelyn *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (5<sup>th</sup> edn, Sweet & Maxwell London 2003) p. 228.

1980. The treaty provides detailed rules and guidelines on depositing micro-organisms, how requests for the deposits are to be made, procedural details on export and import of micro-organisms, how the deposits are acquired and how they are maintained and all other procedural issues relating to the deposit of micro-organisms. Micro-organisms can be deposited in any of the international depository authorities enlisted with the treaty and a single deposit made in any of the enlisted depository authorities will qualify for all signatory countries.<sup>143</sup> The EPC also provides guidance on how the deposits of micro-organisms are to be made and the time schedule to be followed, and provides other procedural information.<sup>144</sup>

## IV. LATEST LEGAL DEVELOPMENTS

### IV.1. The Enablement Issue in the Substantive Patent Law Treaty (SPLT)

At its fourth session, held in November 2000, the SCP of WIPO decided to draft a harmonized treaty on substantive patent law. It was decided that this future legislation would focus on the main patent issues such as "... the definition of prior art, novelty, inventive step/nonobviousness, industrial applicability/utility, the drafting and interpretation of claims and the requirement of *sufficient disclosure* of the invention. [emphasis added]"<sup>145</sup>

Article 10 of the draft elaborated on enabling disclosure; this is reproduced in box 6.<sup>146</sup>

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<sup>143</sup> Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure 1977. In:

[http://www.wipo.int/treaties/en/registration/budapest/summary\\_budapest.html](http://www.wipo.int/treaties/en/registration/budapest/summary_budapest.html)  
Also see In: <http://bccm.belspo.be/tbu/treaty1.php>

<sup>144</sup> EPC Rule 28. In: <http://www.european-patent-office.org/legal/epc/e/r28.html>

<sup>145</sup> Substantive Patent Law Harmonization: In:  
<http://www.wipo.int/patent/law/en/harmonization.htm>

<sup>146</sup> Article 10, Enabling Disclosure: In:  
[http://www.wipo.int/edocs/mdocs/scp/en/scp\\_10/scp\\_10\\_4.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_10/scp_10_4.pdf)

**Box 6**  
**Article 10: Enabling Disclosure**  
**SCP/10/4**

(1) [*General Principle*] The application shall disclose the claimed invention in a manner sufficiently clear and complete for that invention to be carried out by a person skilled in the art. The disclosure of the claimed invention shall be considered sufficiently clear and complete if it provides information which is sufficient to allow that invention to be made and used by a person skilled in the art on the filing date, without undue experimentation [as prescribed in the Regulations].

(2) [*Parts of Application to be Taken Into Account for Assessing Disclosure*] For the purposes of assessing sufficiency of disclosure under paragraph (1), the disclosure contained in the description, claims and drawings, as amended and corrected, shall be taken into account.

Revisions of the draft treaty were undertaken in different sessions of the SCP on the basis of the proposals submitted by the different member countries. Significant developments were noticed in the tenth session of the SCP when the USA, Japan and the EPO submitted a joint proposal on the harmonization of the draft SPLT. This proposal prioritized certain patent issues, namely prior art, grace period, novelty and inventive step. According to this proposal, these priority issues were to be taken up first by the SCP, and then after there was agreement on these issues other issues could be taken up. Following this a corresponding proposal was submitted to the WIPO General Assemblies in September – October 2004 by the USA and Japan.

Discussions about the SPLT are at an impasse, as a result of outstanding divergences between developed countries and the growing opposition by developing countries to further harmonization of patent law.<sup>147</sup>

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<sup>147</sup> See CM Correa and S Musungu ‘The WIPO Patent Agenda: the risks for developing countries’ Working Paper No. 12 (South Centre Geneva 2002). In: <http://www.southcentre.org/publications/wipopatent/toc.htm>

#### IV.2. Reform of Patent Law in the USA: The Issue of Enabling Disclosure

There has been a move in the USA to reform the patent law<sup>148</sup> to make it more in line with the rest of the world and to make the patent system more effective and less expensive. Apart from issues such as introducing a system of “First to File” instead of “First to Invent” and some other issues, an important proposal is for reform of the rules on “Enabling Disclosure”.<sup>149</sup>

As has already been discussed here, in the USA there is an additional burden on the patent applicant to provide the “best mode” to perform the invention with the intention to have the most practical disclosure enabling the public to perform the invention. The draft legislation proposes to eliminate the best mode requirement on the reasoning that since the issue is very subjective (what is to be considered as the best mode is often disputed), by eliminating the best mode requirement there will be a reduction in patent litigation costs since patent litigation will become more predictable.<sup>150</sup>

The National Research Council also submitted that the best mode requirement is inefficient and costly and is inconsistent with European and Japanese patent practice. It suggested that there is hence no need to have an additional “best mode” requirement.<sup>151</sup> However, this is not a uniform view. There are many start-up companies, even in the high-end

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<sup>148</sup> The United States House of Representatives’ Judiciary Committee’s Subcommittee on Courts, the Internet and Intellectual Property was constituted under the chairmanship of Senator Orin G. Hatch to address the issues of patent law reform. It introduced The Patent (Reform) Act of 2005.

<sup>149</sup> P Geier ‘Bill in Congress to Overhaul Patent Law Seeks to Quell Suits’ *The National Law Journal* 19 August 2005). In: [www.law.com/jsp/law/LawArticleFriendly.jsp?id=1124109330603](http://www.law.com/jsp/law/LawArticleFriendly.jsp?id=1124109330603)

<sup>150</sup> KJ Heintz ‘Significant Patent Law Reform Legislation Pending’ *Michigan Lawyers’ Weekly* 20 June 2005. In: [www.brookskushman.com/News/index.php?id=88](http://www.brookskushman.com/News/index.php?id=88)

<sup>151</sup> The National Academies Press *A Patent System for the 21<sup>st</sup> Century* (Washington D.C. 2004) pp. 117–123.

technology industry sector, which are interested in maintaining the best mode requirement in patent law.<sup>152</sup>

## V. CONCLUSION AND RECOMMENDATIONS

An adequate disclosure of an invention will enable others to learn from the patent and carry the invention ahead and eventually improve on it, thereby nurturing the process of innovation.

In order to establish proper disclosure it is very important to determine the range of knowledge of the person skilled in the art. This is because the knowledge of the person skilled in the art is inversely proportional to the level of disclosure that is required. This means that if the law decides in favour of strict and detailed disclosure, the person skilled in the art need not have a very high level of scientific knowledge and vice versa.

There is a growing tendency in the industrialised nations to attribute a high level of scientific knowledge to the person skilled in the art for the purposes of establishing enabling disclosure (although, as discussed in chapter 2, a very different approach is applied in some jurisdictions to assess inventive step). It is considered that the person skilled in the art has the knowledge to understand an incomplete description of the invention; that is, the person skilled in the art is supposed to have sufficient knowledge about the missing parts. This can be quite problematic where the person with average knowledge may not have the capacity to understand and execute the invention in nations that are not sufficiently industrialised.

For this reason it is especially important for developing countries to introduce strict disclosure requirements for the grant of a patent, as well as procedures for the revocation of a patent if it is found at a later stage that the disclosure was not sufficient. They may establish a

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<sup>152</sup> SR Ludwig, TJ Ebersole and DJ Featherstone *U.S. Patent Reform and the future of Nanotechnology* (Vol. 20 No. 37 *Washington Legal Foundation* 12 August 2005 3.

concept of “person skilled in the art” with the ordinary knowledge available in the country for the purposes of disclosure while adopting the concept of a highly-qualified person to ensure that patents are granted to genuinely inventive contributions to the state of the art. Developing countries also need to consider their position in international forums on this issue so that an enablement practice that is suitable for highly industrialised nations is not forced on them via the harmonization of patent law.



## CHAPTER 9

### MARKUSH CLAIMS

#### I. INTRODUCTION

This chapter explains the meaning of the “Markush Claim” and elaborates on standard practice in allowing or disallowing such claims in Europe and the USA. Further, it concludes with a recommendation as to why caution is to be exercised while considering such claims in developing countries.

Markush claims generally apply in the area of chemistry. Such claims are, however, not restricted to such subject matter, and are sometimes found in cases of mechanical inventions or even in electrical inventions.<sup>153</sup>

The name “Markush Claim” originated from a case in the USA in which the patent application was made by a Hungarian chemist named Dr Eugene A Markush. Dr Markush had migrated to the USA and was the founder of a pharmaceutical company, Pharma Chemical Corporation, in New Jersey in 1919. In 1924 he filed a patent application at the US Patent Office for a class of novel pyrolazone dyes.<sup>154</sup> The examiner did not allow the application since it was too generic and had alternative forms. The rejected application was appealed before the office of the US Commissioner of Patents. Assistant Commissioner Kinnan granted the petition after the claims were re-

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<sup>153</sup> JG Sheldon *How to write a Patent Application* (Practising Law Institute New York 2004) s 6.4.43, s 50.

<sup>154</sup> EA Markush US Patent No. 1506316, 26 August 1924. The claim was for “The process for the manufacture of dyes which comprises coupling with a halogen-substituted pyrazolone, a diazotized unsulphonated material selected from the group consisting of aniline, homologues of aniline and halogen substitution products of aniline”.

phrased using an “R group” construction to show optional groups, and allowed the claim to be examined for patentability.<sup>155</sup>

The practice of allowing specific claims from a broad generic band had started, in fact, in the nineteenth century in decisions regarding German dyestuff laboratories.<sup>156</sup> Such practice moved to the USA when Germans filed similar patents in the US even before they were known as “Markush Claims”.

What is termed a “Markush Claim” is not a doctrine and there is no single rule to determine Markush practice. Each case is judged on its merits as to whether or not it can be allowed for examination for patentability. AS Wegner points out:

In the early years of the development of Markush practice, many of the cases involved the problem of clarity, avoiding the uncertainties of alternatives and the like. More recently, the cases have centered on problems of scope, which are related to enablement. Assuming enablement, however, there remains a body of Markush-practice law regarding Markush-type claims, particularly in the chemical field, concerned more with the concept of what might be better described as the concept of units of invention.<sup>157</sup>

In today’s practice, “the term Markush denotes a substance or substituent agent, reactant or other material that is described as being from a group consisting of certain specified materials. The specified materials can be an element, a chemical structure, a functional group, a class of chemical structures (such as alkyl or aryl), or a class of functional groups (such as esters), and so on. The value of Markush structures in patents is that a number of different chemical compounds can be described in a single patent claim”.<sup>158</sup>

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<sup>155</sup> *Ex parte Markush*, 1925 CD 126 (Comm'r Pat. 1925). See HC Wegner *Patent Law in Biotechnology Chemicals and Pharmaceuticals* (Stockton Press New York 1992).

<sup>156</sup> HC Wegner *Patent Law in Biotechnology Chemicals and Pharmaceuticals* (Stockton Press New York 1992) p. 930.

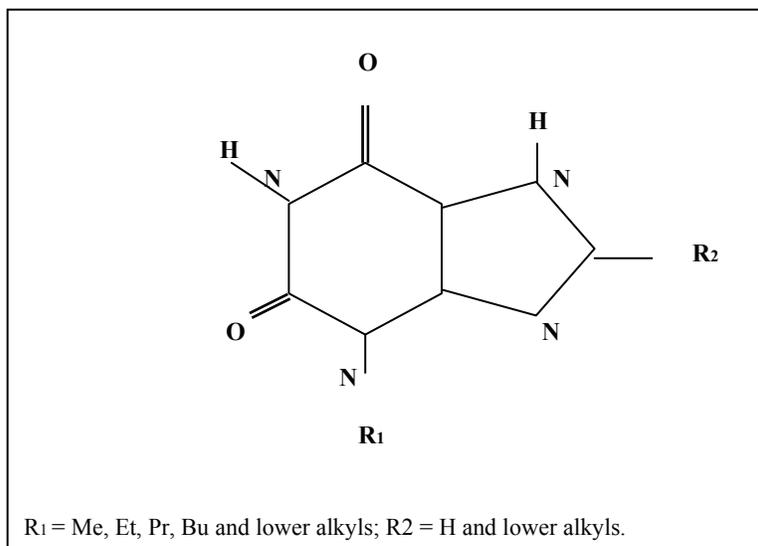
<sup>157</sup> *Ibid.* p. 941.

<sup>158</sup> R Austin *The Complete Markush Structure Search: Mission Impossible?*

An example of a Markush claim accepted by the EPO is provided in box 7.<sup>159</sup>

### Box 7

#### Markush Claim Example



## II. MARKUSH CLAIMS IN EUROPE AND THE USA

The German practice (in the Bundesgerichtshof) has been cautious but has accepted patents on generic claims and EPO practice has been on the same lines.<sup>160</sup> A three-part novelty test was formulated by the EPO

(paper at PIUG North East Workshop 16 October 2001). In: [http://www.stn-international.de/training\\_center/chemistry/piug1.pdf](http://www.stn-international.de/training_center/chemistry/piug1.pdf)

<sup>159</sup> The example is reproduced from B Domeij *Novelty in Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 162.

<sup>160</sup> PW Grubb *Patents for Chemicals, Pharmaceuticals and Biotechnology, Fundamentals of Global Law Practice and Strategy* (Clarendon Press Oxford

while deciding a claim in 1989 and this is generally the present standard practice.<sup>161</sup>

Initially, Markush claims were allowed by the USPTO after the necessary modifications were made to address the problem of its generic nature since it was considered that one claim cannot contain more than one invention.<sup>162</sup> This trend continued until the 1970s. In a landmark case in 1973, generic claims were allowed, reversing the earlier trend of rejecting Markush claims because they were generic.<sup>163</sup> Allowing or disallowing Markush claims was subjected to interpretation in the *Haas* and *Weber* cases. It was decided that where the number of claims in the Markush group is very few or if the claims are closely related, a search and examination of all the claims can be made wherein the examiner needs to examine the claims on their merits even when they are directed to a specific invention or inventions, instead of rejecting them as generic.<sup>164</sup>

In yet another landmark case in 1980, there was a reversal of rejection of a patent claim by the examiner.<sup>165</sup> The claims were rejected on the grounds that the Markush grouping was improper. The contentious claim included "... (1) dyestuffs, (2) intermediates for making dyestuffs, or (3) both ...".<sup>166</sup> The USPTO argued that "... (1) there need not be a specific statutory basis for the rejection, citing by analogy obviousness-type double patenting rejections which are case-law based; (2) the materials set forth in the 'Markush group' ordinarily must belong to a recognized physical or chemical class or to an art-recognized class; and (3) the claimed group must not be 'repugnant to

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1999) p. 199.

<sup>161</sup> B Hansen and F Hirsch *Protecting Inventions in Chemistry: Commentary on Chemical Case Law under the European Patent Convention and the German Patent Law* (Wiley-VCH Berlin 1998) p. 127.

<sup>162</sup> HC Wegner *Patent Law in Biotechnology Chemicals and Pharmaceuticals* (Stockton Press New York 1992) p. 931.

<sup>163</sup> *In re Wolfrum*, 485 F. 2d 588, 179 USPQ 620 (CCPA 1973).

<sup>164</sup> *In re Weber* 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978). For further discussions see Harold C Wegner *Patent Law in Biotechnology Chemicals and Pharmaceuticals* (Stockton Press New York 1992) pp. 932–937.

<sup>165</sup> *In re Harnisch*, 631 F. 2d 716, 206 USPQ 300 (CCPA 1980).

<sup>166</sup> *Ibid.*

accepted principles of scientific classification”<sup>167</sup>. Further, the USPTO argued that since there was no such doctrine as the “Markush doctrine” and there was no statutory basis for such a doctrine, it was not proper to impose a judicial precedent creating such a doctrine.<sup>168</sup> It was admitted by the USPTO that since all the claimed compounds are dyestuffs, some of them could be used as intermediates to make other dyestuffs.

In its opinion the court stated that it is true that there is no single doctrine which can be stated to be the “Markush doctrine” but that there were many tenets that could be derived from precedents. It further stated that previous precedents<sup>169</sup> showed that there was a possibility of having an “improper Markush grouping” which might not follow any particular statutory basis. It was up to the applicant to define his or her invention. The court opined that in a Markush-type claim, the compounds would differ from each other in certain respects and so must be taken up on a case-by-case basis. In line with the USPTO’s guidelines, the Markush groups must be considered as wholes and should not be broken down to specific elements or other compounds. Considering all these, the court concluded that the USPTO board had erred in not considering all claimed compounds of the appellant to be dyes (since the intermediates can also be used to make dyes). It stated that all the claimed compounds belonged to a subgenus<sup>170</sup> which is not repugnant to scientific classification. Hence, the claimed compounds were to be considered part of a single invention as there was unity of invention.<sup>171</sup>

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<sup>167</sup> HC Wegner *Patent Law in Biotechnology Chemicals and Pharmaceuticals* (Stockton Press New York 1992) p. 938.

<sup>168</sup> *Ibid.*

<sup>169</sup> *In re Weber*, 580 F. 2d 455, 459, 198 USPQ 328 (CCPA 1978) and *In re Haas II*, 580 F. 2d 461, 198 USPQ 334 (CCPA 1978).

<sup>170</sup> Subgenus Claim – In circumstances where the claimant has presented a number of examples where the examiner finds sufficient representation in support of a generic claim but the court might consider the claim invalid because of its being too broad. In such circumstances, the applicant is often limited to specific claims that might not suit him. Here a Markush-type claim under a true genus claim would appear to be beneficial to the applicant since the applicant would be able to claim all the disclosed operative embodiments and afford an intermediate level of protection in the event the true genus claims are held invalid. See HC Wegner *Patent Law in Biotechnology Chemicals and Pharmaceuticals* (Stockton Press New York 1992) p. 943.

<sup>171</sup> *Ibid.* pp. 940–942.

At present, in the case of Markush claims the examiner might prefer to hold a provisional election of a single species before examining the claim on its merits, and if the Markush claim is found not allowable, the provisional election will be given effect. After this, the Markush claim will be examined fully with respect to the elected species to determine patentability. If the examination shows that the prior art discloses the invention and the Markush claim is not allowable, examination will be limited to the elected species and the claims that are distinct from the elected species are to be held as withdrawn.<sup>172</sup> If the prior art does not anticipate the elected species, the search of the Markush claims will be extended. If the prior art is found to anticipate the Markush claim with respect to the non-elected species, the Markush claim will be rejected and the other claims held withdrawn. If the applicant prefers to amend the Markush claim to exclude the anticipated species, the amended Markush claim will be re-examined.<sup>173</sup>

### III. CONCLUSION

In sum, the Markush claim is a generic expression of a group of elements having some physical or chemical relationship to one another.

Markush claims can pose problems in general mainly because of their broad nature and its possible use (through “selection patents”)<sup>174</sup> in prolonging the life of protection on subject matter that would otherwise fall into the public domain. Such claims may affect innovation negatively since the next generation of present and future inventors “... must try to design around patents that are to be granted long in the future with terms that may extend to various times extending well into the next millennium”.<sup>175</sup> This is mainly because of the so called “artichoke theory” where a single leaf is plucked each time from the artichoke. In this case a specific invention is actually carved out in such a manner that

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<sup>172</sup> Manual of Patent Examining Procedure *Section 803.02, Restriction – Markush Claims* (Bitlaw 1998). In: [www.bitlaw.com/source/mpep/803\\_02.html](http://www.bitlaw.com/source/mpep/803_02.html)

<sup>173</sup> *Ibid.*

<sup>174</sup> See chapter 10.

<sup>175</sup> Harold C. Wegner *Patent Law in Biotechnology Chemicals and Pharmaceuticals* (Stockton Press New York 1992) p. 951.

it consists of a large number of inventions. This permits a multiple division of a patent application in such a manner that the parts are not applied for at the same time but over a period of time. Hence each subgenera of patent is applied once, and in this way it is possible to prolong the entire period of protection.<sup>176</sup>

At present developed countries allow Markush claims and selection inventions provided the selection is qualified as inventive and is not just an extension of the available state of the art. In a case where the existing patent lapses, its entire scope should be in the public domain so that the patent monopoly is not unjustifiably prolonged. Developing countries can establish their own practice relating to this type of claim. Typically, the patent applicant has only empirically obtained a few of the sometimes millions of claimed compounds. Thus, developing countries may require that all claimed embodiments of the invention have been effectively obtained and tested as a condition for the grant of a patent.<sup>177</sup>

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<sup>176</sup> Ibid.

<sup>177</sup> For instance, section 15.2(a) of Pakistan's Patents (Amendment) Ordinance 2002 provides that the patent specification shall be specific to one chemical product only.



## CHAPTER 10

### SELECTION PATENTS

#### I. INTRODUCTION

This chapter explains the nature of “selection” patents and how the traditional concepts of novelty are applied in Europe and the USA, and includes recommendations on the subject for developing countries.

A “selection patent” can be defined as “a patent under which a single element or a small segment within a large group is ‘selected’ and independently claimed, based on a particular feature not specifically mentioned in the larger group”.<sup>178</sup> For example, a range of products having N carbon atoms can already be covered by a patent, but under a selection patent a particular range, such as C1–C4, may be further patented in some jurisdictions.<sup>179</sup>

In accordance with the law and practice in some countries, even when the invention is actually disclosed as a part of a larger group, it is still not considered as technically disclosed and thus regarded as patentable.<sup>180</sup> Selection inventions are sometimes differentiated as “genuine” and “non-genuine”.

“Genuine” selection inventions are said to claim a specific invention which lies within a larger group which is already known. A “non-genuine” selection invention would be one which partially overlaps with the known art; hence only that part which does not overlap

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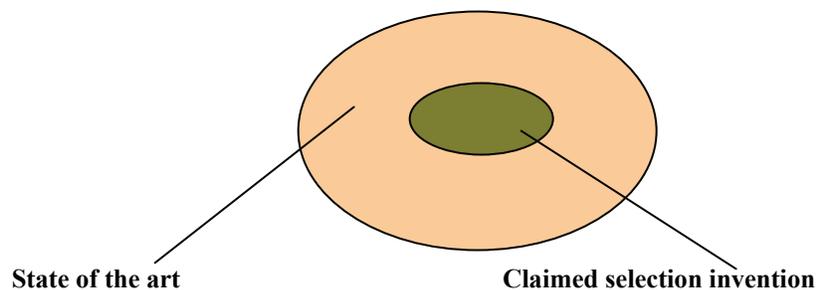
<sup>178</sup>CM Correa *Integrating Public Health Concerns into Patent Legislations in Developing Countries* (South Centre Geneva 2000) pp. 51–52.

<sup>179</sup> *Ibid.* p. 51.

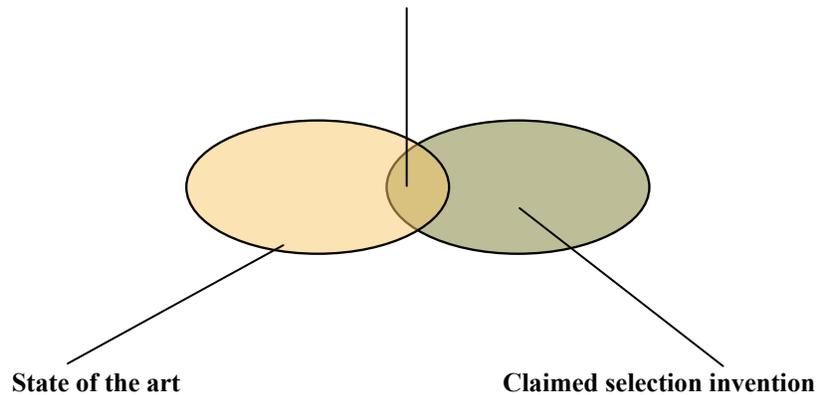
<sup>180</sup> B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 157.

may be claimed to be patentable.<sup>181</sup> The diagrams below will clarify this distinction.<sup>182</sup>

**FIGURE 1 - GENUINE SELECTION INVENTION**



**FIGURE 2 - NON-GENUINE SELECTION INVENTION**



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<sup>181</sup> B Hansen and F Hirsch *Protecting Inventions in Chemistry: Commentary on Chemical Case Law under the European Patent Convention and the German Patent Law* (Wiley-VCH Berlin 1998) pp. 125–126.

<sup>182</sup> *Ibid.* p. 127.

## II. EVOLUTION OF PRACTICES ON SELECTION INVENTION

Patents on selection inventions, where granted, require an adaptation of the standard concept of novelty since they are already part of the prior art. A patent application on items selected from an already-disclosed larger group can be refused on the basis of lack of novelty.<sup>183</sup> There is also a view that "... the selection of one particular compound out of a broad disclosure in a generic compound claim provides advantages over and above those previously known to be shared by the members of the class the subject of the broad disclosure. In such situations, separate contribution to knowledge merits protection".<sup>184</sup> So, in essence, although these inventions are not novel, they are deemed to be so due to a legal fiction.

There is no internationally accepted approach towards selection inventions. The issue of novelty has been a matter of discussion and debate with regard to selection inventions. However, case law tends to treat selection inventions in the light of nonobviousness instead of novelty considerations, thus allowing them if they pass the nonobviousness test.

Historically, it was in 1930 that the English courts first addressed the issue of selection patents in the *IG Farben* case.<sup>185</sup> This case laid down rules to govern selection invention patents for the first time, as follows:<sup>186</sup>

- 1) There must be some substantial advantage to be secured by the use of the selected members.
- 2) All of the selected members must possess the advantage (although a few exceptions would not invalidate the patent).

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<sup>183</sup> G Keller 'Summary of some recent decisions of the Board of Appeal of the EPO regarding questions of Novelty, Inventive Step and Structural Obviousness' (1993) 75(3) *Journal of the Patent and Trademark Office Society* pp. 237–242.

<sup>184</sup> T Cook *A User's Guide to Patents* (Butterworth London 2002) p. 291.

<sup>185</sup> I. G. Farbenindustries Patents (1930) 47 RPC 239–289.

<sup>186</sup> *Ibid.*

- 3) The selection must be in respect of a property which can fairly be said to be peculiar to the selected group.

Although the first two would still be valid in present practice, there is doubt regarding the third rule.<sup>187</sup>

In a case decided by the House of Lords in the UK (DuPont de Nemour's (Witsiepe's) application), the Court allowed a patent claim to use glycol having four atoms even when prior art in an earlier patent had disclosed the use of a four-carbon glycol. The court had opined that the patent was allowed since it was not an example of the claimed invention.<sup>188</sup>

The recent practice in Europe follows criteria formulated through case law:<sup>189</sup>

- 1) The chosen sub-range must be narrow.
- 2) It must be sufficiently distant from the preferred known range (as possibly defined by examples).
- 3) The chosen range may not be an arbitrarily chosen section of that which is known, and cannot be a simple embodiment of what has been previously described, but must lead to a new invention (purposive selection).

A prominent case was *Copolymers/DuPont* where it was stated:

If a prior document describes a process for the production of a class of compounds, the members of the class being defined as having any combination of values of particular

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<sup>187</sup> PW Grubb *Patents for Chemicals, Pharmaceuticals and Biotechnology, Fundamentals of Global Law Practice and Strategy* (Clarendon Press Oxford 1999) p. 197.

<sup>188</sup> [1981] FSR 377, CA ; affd [1982] FSR 303, HL and discussed in T Cook *A User's Guide to Patents* (Butterworth London 2002) p. 291.

<sup>189</sup> T279/89 of 3.7.1991, ref. O.J. Supplement 6/1992 and discussed in B Hansen and F Hirsch *Protecting Inventions in Chemistry: Commentary on Chemical Case Law under the European Patent Convention and the German Patent Law* (Wiley-VCH Berlin 1998) pp. 127–128.

parameters within numerical ranges for each of those parameters, and if all the members of the defined class of compounds can be prepared by a skilled man following such teaching, all such members are thereby made available to the public and form part of the state of the art, and a claim which defines a class of compounds which overlaps the described class lacks novelty. This holds even when the specifically-described examples in the prior document only prepare compounds whose parameters are outside the claimed class. The above does not imply any deviation from the principle of selection invention.<sup>190</sup>

In yet another case decided by the EPO,<sup>191</sup> detailed principles for patenting of selection invention were provided, wherein the Board of Appeal distinguished between the extent of the technical concepts and their intentions.<sup>192</sup> Finally, the EPO formulated its own guidelines for treating patent claims on selection inventions, which are now the standard rules. These state, “In considering novelty it should be borne in mind that a generic disclosure does not usually take away the novelty of any specific example falling within the terms of that disclosure, but that a specific disclosure does take away the novelty of a generic claim embracing that disclosure e.g. a disclosure of copper takes away the novelty of metal as a generic concept, but not the novelty of any metal other than copper and one of rivets takes away the novelty of fastening means as a generic concept, but not the novelty of any fastening other than rivets.”<sup>193</sup>

Further, the guidelines highlight what are to be considered obvious, that is, non-inventive and what are to be considered non-obvious, that is, inventive selections as discussed below:<sup>194</sup>

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<sup>190</sup> Copolymers/DuPont – T124/87 of 9.8.1988, OJ 1989, 491 discussed in B Hansen and F Hirsch *Protecting Inventions in Chemistry: Commentary on Chemical Case Law under the European Patent Convention and the German Patent Law* (Wiley-VCH Berlin 1998) p. 128.

<sup>191</sup> T374/94 of 19.03.1996.

<sup>192</sup> B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 2001) p. 158.

<sup>193</sup> EPO Examination Guidelines chapter IV 7.4.

<sup>194</sup> EPO Examination Guidelines chapter IV and reproduced in T Cook *A User's*

*Obvious or non-inventive selections*

- i) The invention consists merely in choosing from a number of equally likely alternatives.
- ii) The invention resides in the choice of particular ... parameters from a limited range of possibilities, and it is clear that these parameters could be arrived at by routine trial and error or by the application of normal design procedures.
- iii) The invention can be arrived at merely by a simple extrapolation in a straightforward way from the known art.
- iv) The invention consists merely in selecting particular chemical compounds or compositions ... from a broad field ... [where] ... the resulting compounds are not described as having, nor shown to possess, any advantageous properties not possessed by the prior art examples, or ... are described as possessing advantageous properties compared with the compounds specifically referred to in the prior art but these properties are ones which the person skilled in the art would expect such compounds to possess, so that he is likely to be led to make this selection.

*Non-obvious or inventive selections*

- i) The invention involves special selection in a process of particular operating conditions ... within a known range, such selection producing unexpected results in the operation of the process or the properties of the resulting product.
- ii) The invention consists in selecting particular chemical compounds or compositions ... from a broad field, such compounds or compositions having unexpected advantages.

An important case involving selection patents in the field of pharmaceuticals is the *DRACO/Xanthines* case<sup>195</sup> relating to a pharmaceutical formulation wherein the first claim was for “(1) A pharmaceutical preparation for use in the treatment of chronic obstructive airway disease or cardiac disease comprising as active ingredient an effective amount of a compound of the formula [3 - propylxanthine] or a therapeutically acceptable salt thereof, in association with a pharmaceutically acceptable carrier” and the second claim was “... in corresponding, first medical use form: (2) A compound of the formula [3 - propylxanthine] or a therapeutically acceptable salt thereof, for use in the treatment of chronic obstructive airway disease or cardiac disease”. It is interesting to note that although 3 - propylxanthine had been specifically disclosed in a prior document and a variety of disubstituted xanthines were also disclosed via another document, the Technical Board of Appeal opined that there was no specific disclosure of each of the individual compounds and that the documents did not teach the pharmacology activity; hence the invention could be considered novel and thus patentable.<sup>196</sup>

In Germany, the Bundesgerichtshof has held that even in a relatively large generic group of compounds, disclosure of the group is, to the skilled chemist, fully equivalent to a disclosure of each compound within the group.<sup>197</sup> Selection inventions in the normal sense of the word may, hence, be regarded as unpatentable in Germany<sup>198</sup>.

In the USA, initially the courts decided disallowed selection inventions. However the treatment of selection inventions at present is

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<sup>195</sup> T 7/86 *DRACO/Xanthines* (OJEPO of 1988) 381 and discussed in T Cook *A User's Guide to Patents* (Butterworth London 2002) p. 293.

<sup>196</sup> T Cook *A User's Guide to Patents* (Butterworth London 2002) p. 293.

<sup>197</sup> “A compound, in the sense of Patent Law, is every chemical entity that can be reliably differentiated from another chemical entity, through the provision of sufficient, suitable parameters. Fundamentally, compounds having the same chemical composition are identical. This does not apply for special forms of compounds having the same chemical composition, if these forms could not be produced, despite their chemical composition being known.” PW Grubb *Patents for Chemicals, Pharmaceuticals and Biotechnology – Fundamentals of Global Law Practice and Strategy* (Clarendon Press Oxford 1999) pp. 197–199.

<sup>198</sup> See, for example, CM Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre Geneva 2000).

rather lenient: "... if the disclosure from which the invention is selected is very broad, it is not even necessary to show any advantages".<sup>199</sup> Now the question arises as to whether a person with ordinary skill in the art would be able to derive sufficient information from the prior art to obtain the selected invention. In the case where the person is able to do so, then the selected invention would not be patentable due to obviousness.

For instance, in one case it was considered that "... a prior art disclosure for a method of taffy pulling might teach that the taffy<sup>200</sup> can be heated to a temperature of anywhere from 25°C to 250°C, when pulling it. The applicant might discover that a narrow range, say from 70°C to 110°C, is far superior to any other point of the range for taffy pulling, noting that at temperatures below that range, the taffy becomes solid and unpullable, and that above that range the taffy turns into liquid and eventually chars. The question is whether the prior art broad temperature disclosure would have provided one of ordinary skill in the art with enough information to give rise to a case of prima facie obviousness, which the applicant would then have the opportunity to rebut ... If there were a reasonable expectation of success, based on the prior art, then the applicant's invention might very well be prima facie obvious".<sup>201</sup>

The US case law on selection inventions in the field of chemical inventions is split due to diverse decisions. In the *Susi* case which is based on structural similarity, it was held that if the broad prior art that disclosed the invention included at least some compounds that were common to the applicant's compounds and both were used for the same purposes, then the selection invention would be considered obvious.<sup>202</sup>

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<sup>199</sup> PW Grubb *Patents for Chemicals, Pharmaceuticals and Biotechnology, Fundamentals of Global Law Practice and Strategy* (Clarendon Press Oxford 1999) p. 197.

<sup>200</sup> Taffy is a type of sweet made of molasses.

<sup>201</sup> A Varma and D Abraham 'DNA is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market' (1996) 9 *Harvard Journal of Law & Technology* pp. 54–85.

<sup>202</sup> 440 F.2d 442 (CCPA 1971) and discussed in A Varma and D Abraham 'DNA is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market' (1996) 9 *Harvard Journal of Law & Technology* 54,

Similarly, in a subsequent case involving Merck, the same argument was followed.<sup>203</sup> In this case the patent claim on the selection invention included only 1 out of 1200 embodiments from the prior art. But the prior art instructed the person skilled in the art to be able to work from any of the 1200 embodiments. The court held that the claim lacked novelty because the "... claimed composition was used for the same purpose taught by the prior art..."<sup>204</sup>

This strict interpretation became gradually diluted and a shift in the approach was noticed in the *Jones* case. In this case the Federal Circuit diverted from existing case law and decided that there was no prima facie case of obviousness. It opined that although the prior art might be broad, it did not disclose the claimed species in the selection invention.<sup>205</sup> This was closely followed by another case – the *Baird* case, where the court rejected the argument of obviousness and allowed the patent. This case involved a claim on ‘bisphenol A’ from more than 100 million ‘diphenols’ contained in the broad genus disclosed in the prior art. The court decided that “[a] disclosure of millions of compounds does not render obvious a claim to three compounds, particularly when that disclosure indicates a preference leading away from the claimed compounds”.<sup>206</sup>

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p. 70.

<sup>203</sup> *Merck & Co. v. Biocraft Laboratories Inc.*, 874 F.2d 804 (Fed. Cir. 1989), cert. denied, 493 US 975 (1989) and discussed in A Varma and D Abraham ‘DNA is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market’ (1996) 9 *Harvard Journal of Law & Technology* 54, p. 71.

<sup>204</sup> A Varma and D Abraham ‘DNA is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market’ (1996) 9 *Harvard Journal of Law & Technology* 54, p. 71.

<sup>205</sup> 958 F.2d 347 (Fed. Cir. 1992) and discussed in A Varma and D Abraham ‘DNA is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market’ (1996) 9 *Harvard Journal of Law & Technology* 54, p. 71.

<sup>206</sup> 16 F.3d 380 (Fed. Cir. 1994) and discussed in A Varma and D Abraham ‘DNA is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market’ (1996) 9 *Harvard Journal of Law & Technology* 54, pp. 71–72.

### III. CONCLUSION

By their very nature, selection inventions could allow patentees to extend the term of their patents beyond the mandated period since the selection patent might be selected from a large group of elements which are already covered under a patent (maybe when the existing patent/s are nearing expiry).<sup>207</sup> The recent trend in developed countries is to allow selection inventions. This in effect means that even when certain claims are not novel, they are allowed to be patented. There are, however, exceptions as exemplified by the German approach.

The TRIPS Agreement does not provide any guidance as to how selection inventions are to be treated or whether at all they are to be allowed or disallowed. As a result of this, WTO members can decide on such cases according to their municipal laws and being guided by their own policy objectives. If developing countries intend to exclude patent monopolies, where no genuine inventions are present, in order to allow, for instance, for a broader access to medicines, then developing countries may disallow selection inventions. This would be unobjectionable under the TRIPS Agreement.

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<sup>207</sup> CM Correa *TRIPS and R & D Incentive in the Pharmaceutical Sector* (CMH Working Paper Series, Paper No. WG2: 12) p. 11.

## CHAPTER 11

### PRODUCT-BY-PROCESS CLAIMS

#### I. INTRODUCTION

A “true” product claim is one in which the product is defined in terms of structural characteristics only.<sup>208</sup> This has been affirmed by courts in many cases.<sup>209</sup> A Product-by-Process Claim (PPC) defines a product in the terms of the process used to make the product. The examples given by the UK Patent Office for a PPC are:

- a) A polypeptide which is the product of the method according to claim ...
- b) A polypeptide (when) obtained by the method of claim ...

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<sup>208</sup> “Product-by-process claims differ from conventional product or composition claims, which claim the product or composition by describing its structure. They also differ from process claims, which claim a method by describing the steps in it. The hybrid nature of product-by-process claims has caused a good deal of confusion over the years. In particular, there has been confusion over how much, if any, of the process described in the claim has to be copied in order to establish infringement, and how far the process described in the claim can support patentability.” Catherine P Katzka *Comparative Analysis of Product-by-Process Patent Claims in Europe, Japan and United States* MAS-IP Diploma Papers & Research Reports (2007).

In: <http://www.bepress.com/ndsip/reports/art10> p. 3.

<sup>209</sup> D Chisum *Chisum on Patents* (Matthew Bender New York 2005) pp. 3–8. Supplement to chapter 8 referencing *3M Innovative Properties Co. v. Avery Dennison Corp.*, 185 F. Supp.2d 1031, 1038 n.3 (D. Minn. 2002) (citing Treatise: “A ‘true’ product claim is one in which the product is defined by structural characteristics only.”), *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp.2d 69, 101, 57 USPQ2d 1449 (D. Mass. 2001), *aff’d in part, vacated in part & remanded*, 314 F.3d 1313, 65 USPQ2d 1385 (Fed. Cir. 2003) (“[T]he process by which a patented product is obtained is ordinarily irrelevant to a product patent”).

## c) A polypeptide (when) produced by the method of claim ...

These are “product by process” claims which protect, for example, the polynucleotide product of a specific method. The claimed polypeptide is distinguished by virtue of its origin rather than in its own right. In other words, the claimed polypeptide is characterized by the way in which it is produced.<sup>210</sup> PPCs can be found in DNA-related patents as well. The invention can be claimed as a product, that is, a product patent; as a means for achieving a specific objective, that is, a use patent; as a process of producing a recombinant or genetically modified product, that is, a process patent. A PPC can be made for the recombinant or genetically modified product.

How the invention is claimed depends on the nature of the permissible claims and the scope of the patentable subject matter according to the law. Not all countries permit PPCs, nor is it required that all countries should allow them. It seems that some countries permitted product-by-process claims before the availability of product patents in pharmaceuticals (Canada for example).<sup>211</sup> As PPCs are not generally mentioned in patent statutes, they were developed to meet some specific needs.<sup>212</sup>

As pointed out by Justice Newman, PPCs can be classified into three types:

- 1) The product is new and unobvious but is not capable of independent claim.

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<sup>210</sup> UK Patent Office Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the UK Patent Office (November 2003). In: <http://www.ipo.gov.uk/biotech.pdf> p. 37.

<sup>211</sup> “Canada further modified its patent laws by the Patent Act Amendment Act, 1992 (Bill C-91), which entered into force in February 1993. While inventions in the area of pharmaceuticals were under the pre-C-91 patent regime only patentable as process patents (or what is termed ‘product-by-process patents’), product patents for pharmaceutical inventions were only introduced by C-91 in 1993.” WTO Panel Report ‘Canada – Patent Protection Of Pharmaceutical Products’ (WT/DS114/R 2000), p. 21.

<sup>212</sup> IH Donner ‘Combating Obviousness Rejections under 35 U.S.C Section 103’ (1996) *Alb. L.J. Sci. & Tech.* 159.

- 2) The product is old or obvious but the process is new.
- 3) The product is new and unobvious but has a process-based limitation.<sup>213</sup>

According to Domeij, “[In] general it is naturally occurring chemical compounds, catalysts, enzymes, macromolecules, and products of microbiological process that are defined by how they are manufactured. These compounds are particularly susceptible to structural variations, which makes it difficult to define them unambiguously by their structure.”<sup>214</sup>

Sometimes product-by-process recitation is used to define one component of a product in a claim rather than the entire claim. A common example of this is the description of a structure in terms of the production/manufacturing process. For example, if a novel electrical component is described as a PPC, then the PPC limitation will be mentioned in the body of the claim. Process-based limitations are denoted by words such as “moulded” or “frozen”, and these are interpreted as structural limitations. The words “moulded” or “frozen” are used in a non-process sense and they indicate the physical characteristics of the product.<sup>215</sup> Thus PPCs can be restricted to a part alone.

PPCs can be used to patent living forms and biological processes. In the *Oncomouse* case it was opined, “Since in the present case the claimed products are not individually definable biological entities, which could be characterized by their physiological or morphological features, there is no way of defining the animals other than by process of their production”.<sup>216</sup> In the USA a patent was granted for a PPC on a non-naturally occurring oyster.<sup>217</sup>

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<sup>213</sup> *Atlantic Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1279 (Fed. Cir. 1992) 1284.

<sup>214</sup> B Domeij *Pharmaceutical Patents in Europe* (Kluwer Law International New York 1998) p. 68.

<sup>215</sup> T Takenaka ‘What Japan Should Learn from U.S. Experiences: Tests of Equivalence, Means-Plus-Function Claims and Product-By-Process Claims’ (2002) 9(1) CASRIP Newsletter, 6.

In: <http://www.law.washington.edu/casrip/Newsletter/Vol.9/newsv9i1Takenaka.pdf>

<sup>216</sup> *Oncomouse* application V 4/89 OJ EPO 1989, 451 cited in B Domeij, op. cit.

A true PPC is one in which the product specified in the claim is new and non-obvious from prior art and the product is independent from the specified process. If the product is obvious or anticipated by prior art then the PPC will not be patentable, for instance, in the USA. Normally there is no limitation on the number of PPCs that may be used in an application. It is also possible to use PPCs in an application which has a regular product claim.<sup>218</sup>

## II. PRODUCT-BY-PROCESS PATENTS IN THE USA

### II.1. Admissibility of PPCs

In the USA, courts have given important guidelines and opinions on PPCs. Acceptance of product-by-process patent claims began over a century ago, in *Ex parte Painter*, and was based on the inability of patent lawyers to describe effectively the end product that resulted from the inventor's mechanisms. Painter's claim was for a bottle-stopper that could only be described through product-by-process terms. The *Painter* court noted, "[W]hen a man has made an invention, his right to a patent for it, or his right to a claim properly defining it, is not to be determined by the limitations of the English language." The court therefore determined that when an invention "cannot be properly defined and discriminated from prior art otherwise than by reference to the process of producing it, a case is presented which constitutes an exception to the rule [that inventions should not be described in process terms]". Thus, *Painter* established the necessity rule, whereby inventions could be protected through process terms, but only if process terms were the most accurate manner in which to describe the invention.<sup>219</sup>

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p. 68.

<sup>217</sup> *In re Lowry* 2 USPQ.2d 1425 (BPAI 1987) PTO extended protection to a multi-cellular organism that is a non-naturally occurring altered oyster (a product-by-process claim).

<sup>218</sup> *In re Certain Steel Rod Treating Apparatus & Components Thereof* 215 USPQ 237 (International Trade Commission 1981).

<sup>219</sup> MD Passler 'Product-By-Process Patent Claims: Majority of the Court of Appeals for the Federal Circuit Forgets Purpose of the Patent Act' (1994) 49 *U. Miami L. Rev.* 233.

Some representative cases and the key observations from the US courts on PPCs may be summarised as follows:

*In re Brown*, 173 USPQ 685 (CCPA 1972):

It must be admitted, however, that the lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claims and not of the recited process steps which must be established. (*Brown* at 688)

*In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985):

Product-by-process claims are not specifically discussed in the patent statute. The practice and governing law have developed in response to the need to enable an applicant to claim an otherwise patentable product that resists definition by other than the process by which it is made. For this reason, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. (citing *In re Brown* 173 USPQ 685 (CCPA 1972); *In re Pilkington* 162 USPQ 145 (CCPA 1969); *Buono v. Yankee Maid Dress Corp.*, 26 USPQ 57 (2d Cir. 1935). “The patentability of a product does not depend on its method of production.” (citations omitted). “If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” (citations omitted) (*Thorpe* at 966).<sup>220</sup>

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<sup>220</sup> Claim was directed to a novolac colour developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in

It is important to understand the position in US law regarding PPCs. A PPC is expected to satisfy 35 USC 102 and 103. A completely new process may be patentable but the product is not patentable if it is not new.<sup>221</sup> For example, the process to manufacture a shaving razor may be novel and may meet the criteria for patentability, but a PPC on a shaving razor is not patentable as the shaving razor is an old and well-known product. If the product is novel and the process is also novel, and if both meet the criteria for patentability, then the PPC will be allowed.<sup>222</sup> However, it is for the patentee to prove that the product was not anticipated by prior art or was not a known product (cf. *In re Marosi*, 218 USPQ 289 (Fed.Cir. 1983)).

Although it may appear that PPCs give a broader scope than a process claim, this need not be so. Prior to the 1988 Process Patent Amendment Act, such assumptions had some validity. However, post-1988, when process protection was extended to the final product, it no longer made sense to include PPCs if the PPCs did not cover products that might result from different processes.

Another problem with PPCs is that anticipation in prior art and nonobviousness of the product may be grounds for rejection. Novelty and nonobviousness should be independent of the method by which the

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situ, does not change the end product.

Chapter 2100 'Patentability' *MPEP Manual of Patent Examining Procedures* § 2113.

<sup>221</sup> *Ex parte Edwards* 231 USPQ 981 (Bd. Pat. App. And Interferences 1986).

<sup>222</sup> "A product-by-process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper." *In re Luck* 476 F.2d 650, 177 USPQ 523 (CCPA 1973); *In re Pilkington* 411 F.2d 1345, 162 USPQ 145 (CCPA 1969); *In re Steppan* 394 F.2d 1013, 156 USPQ 143 (CCPA 1967). "A claim to a device, apparatus, manufacture, or composition of matter may contain a reference to the process in which it is intended to be used without being objectionable under 35 USC 112, second paragraph, so long as it is clear that the claim is directed to the product and not the process. An applicant may present claims of varying scope even if it is necessary to describe the claimed product in product-by-process terms." *Ex parte Pantzer* 176 USPQ 141 (Bd. App. 1972). *USPTO Manual of Patent Examining Procedures* § 2173.05(p).

product is produced.<sup>223</sup> The applicant has to differentiate the physical features of the recited product from the prior art, and proving that the claim could meet the criteria for novelty and non obviousness may not be easy.<sup>224</sup> From the point of view of the patent examiner, PPCs are difficult to examine as they lack the description of the structure, and examining a product in terms of its physical features is difficult in the absence of a facility to manufacture and test.<sup>225</sup>

In the USA, a PPC should meet the enablement, written description and also the best mode requirements, as with any true product claim. Regarding enablement, the applicant has to disclose how to make and how to use the product specified in the claim. While

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<sup>223</sup> *In re Pilkington* 411 F.2d 1345 (CCPA 1969).

<sup>224</sup> *In re Stephens* 345 F.2d 1020 (CCPA 1965). In *In re Stephens*, the CCPA held that process limitations in a product claim are not to be given patentable weight in determining patentability over the prior art.

<sup>225</sup> "...[e]xamination of a product-by-process claim is very difficult since the Examiner must determine whether the product is new and non-obvious without considering the process limitations even though the process limitations may substantially define the product which is being claimed. As summarised by the CCPA: In order to be patentable, a product must be novel, useful and unobvious. In our law, this is true whether the product is claimed by describing it, or by listing the process steps used to obtain it. This latter type of claim, usually called a product-by-process claim, does not inherently conflict with the second paragraph of 35 USC 112. It must be admitted, however, that the lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. *Ibid*.

"[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. ... As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown* 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

disclosing how to make is not difficult, regarding the “how to use” requirement USPTO guidelines stipulate that utility specific to the product should be disclosed. The utility should be credible to one skilled in the art and it should be substantial enough to be of utility in the real world.<sup>226</sup> Thus, meeting the first requirement would be easy if the applicant could produce the product using the process and demonstrate that it has a utility. Describing the invention in such a manner that any one skilled in the art can practise it is a challenging task, particularly in the case of biological or genetic material where the applicant may not be able to describe it in the required manner. In unpredictable technological fields,<sup>227</sup> or in the case of inventions where the patent applicant is unable to prove that they can be practised without undue experimentation, failure to meet the criteria for enablement can be a ground for rejection.<sup>228</sup> Another ground for rejection can be the undue breadth doctrine. The claims should not be too broad or extended to non-enabled embodiments. The correlation between the disclosure and the claim is the crux of the issue here. If the disclosure in the specification is too narrow in relation to the broad claim, then the specification cannot be deemed to meet the requirement of enablement.<sup>229</sup>

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<sup>226</sup> “The patent specification does not enable one skilled in the art to make or obtain ACTHs with other than 39 amino acids in the chain, and there has been no showing that one of ordinary skill would have known how to make or obtain such other ACTHs without undue experimentation. As for Appellant's conclusion that the 25th to 39th acids in the chain are unnecessary, it is one thing to make such a statement when persons skilled in the art are able to make or obtain ACTH having other than 39 amino acids; it is quite another thing when they are not able to do so.” *In re Fisher* 427 F.2d 833 (CCPA 1970).

<sup>227</sup> “Inventions within the unpredictable arts present unique challenges in meeting the Patent Act's disclosure requirements. Applications claiming an invention possessed of unpredictable factors will be carefully scrutinized for compliance with the utility, written description, how-to-make-and-use, and enablement requirements. Even if the applicant's disclosure facially complies with those requirements, courts or the PTO might still challenge the applicant for evidence to support enablement.” BP O'Shaughnessy ‘The False Inventive Genus: Developing a New Approach for Analyzing the Sufficiency of Patent Disclosure Within the Unpredictable Arts’ (1996) 7 *Fordham Intell. Prop. Media & Ent. L.J.* 147.

<sup>228</sup> *In re Wright* 999 F.2d 1557 (Fed. Cir. 1993).

<sup>229</sup> *In re Fisher* 427 F.2d 833 (CCPA 1970).

In the case of unpredictable arts, the undue breadth doctrine can work against the claims of the patent applicant. A patent applicant may prefer a PPC, as that is the best way to claim protection for an invention that cannot be adequately defined structurally or functionally. However, the mere fact that the claim relates to unpredictable arts does not lessen the burden of the applicant to show that he/she could meet all the conditions for fulfilling the enablement requirement. When the enablement requirement is invoked to limit the claim scope of an application in an unpredictable art, a claim might fail to fulfil the requirement if the product relates to a highly unpredictable technology.<sup>230</sup> This happens because of the tendency to file early patents in new and unpredictable technologies where scientific understanding has yet fully to unravel the functioning and structure of systems. Product-by-process patents are issued in new fields such as nanotechnology, and such patents are likely to be useful in pharmaceutical or drug delivery methods as well.<sup>231</sup>

The written description requirement can be another barrier to PPCs when the structure or physical characteristics are not known and not disclosed in the specification. The Federal Circuit had held that a description of the method of producing the DNA sequence was insufficient to describe a DNA sequence.<sup>232</sup> The precise physical definitions have to be disclosed to fulfil the description requirement. In this case, the Federal Circuit remarked that to protect a sequence the patentee had to provide a precise definition of that sequence.

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<sup>230</sup> *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362 (Fed. Cir. 1999).

<sup>231</sup> For instance, “Labopharm Inc. (TSX: DDS) has been granted a fundamental patent by the US Patent and Trademark Office for Contramid(R), a controlled-release, hydrophilic starch platform that enables the Company to formulate oral and implantable products that provide improved dosing and clinical effect for pharmaceuticals in a wide range of therapeutic categories. The product-by-process patent extends Labopharm’s existing intellectual property protection of Contramid(R), the technology’s process of manufacture and its use in controlled-release pharmaceutical products. The patent, Labopharm’s seventh issued US patent on Contramid(R), extends the Company’s patent protection on its core technology through 2020.” In:

<http://www.nanoxchange.com/NewsFinancial.asp?ID=71>

<sup>232</sup> *Univ. of California v. Eli Lilly* 119 F.3d 1559 (Fed. Cir. 1998).

Application of the disclosure requirement under Section 112, paragraph 2 can be another hurdle for PPCs. In the case of unpredictable arts the PPCs may fail to meet the claim definiteness requirement. In the absence of any definite structural feature it will be difficult for those skilled in the art to understand the claim, even when read in light of the specification.

When a substantially identical product is found and the claim is rejected under 35 USC 101/103 the onus is on the patent applicant to show that there is an unobvious difference. When the examiner rejects a claim based on the rationale that a claimed product appears to be the same or similar to one in the prior art, although it is produced by a different process, the onus is on the applicant to show that there is an unobvious difference between the claimed product and the prior art product.<sup>233</sup>

Irrespective of the technique or process used, the PPC should result in a product that is not identical to or not nearly identical to (that is, only slightly different from) the product disclosed by prior art. The applicant should establish that the product has some unexpected properties when compared to the prior art product. The mere fact that the applicant used a new technique does not overcome this limitation of a PPC.

For example, in a claim on human nerve growth factor (b-NGF) the prior art disclosed b-NGF isolated from human placental tissue. The claim related to the same product produced through genetic engineering techniques. However, the resulting product was substantially the same as that of the product isolated from the tissue. Although the applicant raised the question of the purity of the prior art factor, an unobvious difference between the two could not be demonstrated by the applicant. The Board took the view that the issue was whether there were any unexpected properties that distinguished one product from another. When the answer was negative, the claim was disallowed. In this case,

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<sup>233</sup> “Where a product-by-process claim is rejected over a prior art product that appears to be identical, although produced by a different process, the burden is upon the applicants to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product.” (citations omitted). *In re Marosi*, 218 USPQ 289 (Fed.Cir. 1983), 293.

the PPC does not result in a new product that was not disclosed by prior art, as the claimed product was identical or nearly identical to that of the prior art. Had the claim related to b-NGF which had different properties when compared to the prior art product, or was vastly superior to the prior art product in terms of purity and this level of purity had not before been attained, the claim might have been allowed.<sup>234</sup>

When this rationale is extended to microbiological processes it becomes clear that a hybrid plant that is disclosed by prior art cannot be claimed in a PPC unless the latter results in a hybrid plant which is different from that disclosed by prior art in an unobvious way. This rationale is significant as it prevents patenting of prior art products using

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<sup>234</sup> *Ex parte Gray* 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989). Cf. *Ex parte Aggarwal* 23 USPQ2d 1334, 1336 (Bd. Pat. App. & Int'l 1992) (method claims to treat tumours using recombinant lymphotoxin; “whether extracted from humans or prepared recombinantly, lymphotoxin is essentially the same material or a minor modification thereof which would have been expected to effectively treat at least the tumors described in the references, all of which are concerned with natural lymphotoxin extracted from mitogen-stimulated lymphocytes”).

Recent cases dealing with patents on purified biological materials, such as blood factor proteins, confirm that a product patent claim covers the defined material produced by any means, including patentably new and significantly more efficient techniques, such as recombinant technology. For example, *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 706 F. Supp. 94, 103-104, 9 USPQ2d 1833, 1840-1841 (D. Mass. 1989), aff'd in part, rev'd in part, vacated in part, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), cert. denied, 502 U.S. 856 (1991) (one party's patent disclosing and claiming a nonrecombinant method for purifying erythropoietin (a blood factor that induces differentiation of cells into red blood cells) and compositions of highly purified erythropoietin covers erythropoietin produced by another party, using its patented recombinant technology (purified and isolated DNA sequences encoding erythropoietin in addition to host cells transformed or transfected with a DNA sequence); “[A] fundamental principle of patent law is that a product patent claim covers only the product itself, not the method or process for making the product. ... Although the development of recombinant technology provides the scientific and commercial communities with innovative techniques for manufacturing certain products and compositions, the patent protection of product claims has not changed. That is, a product claim still protects the use and sale of the product, regardless of whether the product was produced by traditional or recombinant technology.”) From Chisum *On Patents*, op. cit.

new or novel techniques. The logic that the product should meet all the criteria for patentability need not be overemphasized.

In assessing the difference between prior art and the claimed invention, the USPTO manual states that the following will be taken into account:

- 1) The claimed invention as a whole must be considered. Here the question is whether the invention as a whole would have been obvious to those skilled in the art.
- 2) Distilling the invention down to a “gist” or “thrust” of an invention disregards “as a whole” requirement.
- 3) Discovering source/cause of a problem is part of “as a whole” inquiry.
- 4) Applicants alleging discovery of a source of a problem must provide substantiating evidence.
- 5) Disclosed inherent properties are part of “as a whole” inquiry.
- 6) Prior art must be considered in entirety including disclosures that teach away from the claims.

If a claim is directed to a non-patentable subject matter under 35 USC 101 then that claim will be invalid. In a claim for producing a “random fade effect” on fabric the court found that the “claims were more similar to claims in design patent as the appearance of the random faded effect on jeans attracts attention but does not affect the utility of the jeans”.<sup>235</sup> The question is whether the process of producing jeans is more novel or unobvious over existing processes than patentability of jeans per se. In this case the product was old and the outcome of the process did not result in a new product as the random faded effect did not affect the utility of jeans.

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<sup>235</sup> *Levi Strauss & Co. v. Golden Trade* SRL DCSNY 1995 US Dist. LEXIS 4899 cited in ‘The Winning Mechanical Claim’ Robert C Faber PLI Workshop 2004.

## II.2. Infringement

Having discussed the requirements of an allowable PPC and the limitations in using a PPC claim, let us look at the issue of infringement. The Federal Circuit gave two important verdicts regarding determining infringement in PPC. However, as the verdicts were in conflict they created a controversy.

In *Scripps*<sup>236</sup> the court held: “In determining patentability we construe the product as not limited by the process stated in the claims.” However, in *Atlantic Thermoplastics*<sup>237</sup> it was held that “Process terms in product-by-process claims serve as limitations in determining infringement.”

In *Scripps* the patent related to human blood-clotting factor VIII:C.<sup>238</sup>

Claim 1: An improved method of preparing Factor VIII pro-coagulant 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 concentrate and further purify same,
- d) eluting the adsorbed VIII:C, and
- e) recovering highly purified and concentrated VIII:C.

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<sup>236</sup> *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991).

<sup>237</sup> *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834, 23 USPQ2d 1481 (Fed. Cir. 1992).

<sup>238</sup> *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991).

Claim 13: Highly purified and concentrated human or porcine VIII:C prepared in accordance with the method of claim 1.

The scientists in *Scripps* invented a process for preparing a highly purified and concentrated human or porcine Factor VIII:C. The patent contained process claims (for example claim 1) and product-by-process claims (for example claim 13). The same product Factor VIII:C was produced by the accused infringer through recombinant technology.<sup>239</sup> With regard to the District Court's observation on infringement in the case of PPCs the Federal Circuit observed that:

In determining patentability we construe the product as not limited by the process stated in the claims. Since claims must be construed the same way for validity and for infringement, the correct reading of product-by-process claims is that they are not limited to products prepared by the process set forth in the claims.

In plain words this meant that for infringement purposes PPCs are *not* limited to products prepared by the process set forth in the claims. The case was remanded for examining infringement under the reverse doctrine of equivalents.<sup>240</sup>

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<sup>239</sup> That is, by isolating the gene encoding the protein, inserting it into a host cell, replicating the cell, causing the cell to excrete the protein into a culture medium, and purifying the protein from the medium using Factor VIII:C monoclonal antibodies.

<sup>240</sup> Under the reverse doctrine of equivalents, where a person has literally infringed a patent, the person may nevertheless escape liability for infringement. *SRI International v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1123 (Fed. Cir. 1985) (en banc). "Thus, where a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement." (quoting *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 US 605, 608-09 (1950)). Cf. "Just as the purpose of the doctrine of equivalents is to prevent pirating of the patentee's invention, so the purpose of the reverse doctrine is to prevent unwarranted extension of the claims beyond a fair scope of the patentee's invention." *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1581 (Fed. Cir. 1991)

In contrast, in *Atlantic Thermoplastics* a different panel ruled that the *Scripps Clinic* statement that “the correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims” is not controlling because it is contrary to Supreme Court case law and “would require this court to directly ignore basic patent principles”. ... “[P]rocess terms in product-by-process claims serve as limitations in determining infringement.”<sup>241</sup> In other words, the panel in this case took a diametrically opposite view and concluded that product-by-process claims are limited to the particular processes that produce the product.<sup>242</sup> The *Atlantic Thermoplastics* panel reviewed previous rulings of the CCPA and the evolution of PPCs in the USPTO and the Supreme Court rulings on patent infringement and validity. It refused to follow the rationale outlined in *Scripps* and observed:

[T]he Supreme Court stated in a line of cases that the infringement inquiry for product claims with process limitations focuses on whether the accused product was made by the claimed process or its equivalent. ... In *Cochrane* (“BASF”), the Supreme Court addressed both infringement and validity (in terms of patentability) of product claims containing process limitations. In judging infringement, the Court treated the process terms as limitations on the patentee’s exclusive rights. In assessing validity in terms of patentability, the Court forbade an

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(citation and internal quotation marks omitted).

In *Scripps*, the Federal Circuit remanded the case for further examination of infringement under the reverse doctrine of equivalents because it was very likely that a new process developed by the infringer resulted in a product with purity and activity different from those of the product resulting from the *Scripps* process. Accordingly, infringement of a true product-by-process claim is very likely to be limited, under the reverse doctrine of equivalents, by physical characteristics that are not recited in the claim (Takenaka, op. cit.).

<sup>241</sup> *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834, 23 USPQ2d 1481 (Fed. Cir. 1992), suggestion for rehearing en banc declined, 974 F.2d 1279, 23 USPQ2d 1801, 974 F.2d 1299, 24 USPQ2d 1138 (Fed. Cir. 1992). (Nies, dissenting; Rich, dissenting; Newman, Rich & Lourie dissenting; Lourie, Rich & Newman dissenting; Rader, concurring.)

<sup>242</sup> “The patent in suit contained process and product-by-process claims relating to shock absorbing shoe inner soles.”

applicant from claiming an old product by merely adding a new process. The infringement rule focused on the process as a limitation; the other rule focused on the product with less regard for the process limits.

The regional circuits “followed the rule that the process limits a product-by-process claim”. In *Hide-It Leather*, the First Circuit stated, “[A]lthough a product has definite characteristics by which it may be identified apart from the process, still, if in a claim for the product it is not so described, but is set forth in the terms of the process, nothing can be held to infringe the claim which is not made by the process.”

In substance, the ruling meant that product-by-process claims extend only to the end product made by the process recited.

This ruling created a controversy and many lower courts chose the ruling in *Atlantic Thermoplastics*. The larger question is what is the objective of patent law and how to reconcile the patentee’s rights including the applicability of the doctrine of equivalents vis-à-vis the rights of competitors and the public regarding over-broad claim interpretation and scope. If the view adopted in *Scripps* is taken as the correct approach, the possibility of the patentee’s getting more protection than his contribution warranted or than was disclosed in the patent cannot be ruled out. If the view adopted in *Atlantic Thermoplastics* is taken as the right approach, then the public interest gets precedence over the rights of the patentee. Takenaka has properly summed it up:

The *Atlantic Thermoplastics* view should prevail over the *Scripps* view if examined with respect to two competing interests: (1) interests of the inventor who is entitled to a fair reward and tries to overcome the difficulty of defining a new and non-obvious product in an unpredictable technology area; and (2) interests of the patent office and public with respect to definitional function and the notice function of claims. The inventor’s interest tends to be supported by the broad scope of protection given by the *Scripps* view, whereas in contrast, the public interest tends to be supported by the *Atlantic Thermoplastics* view that

secures room for further developments. As discussed with respect to the tests for equivalents, recent case law after *Markman* and *Warner-Jenkinson* reflects a significant shift away from the inventor's interest and toward the public interest.

In addition, many product-by-process claims are adopted only for convenience and very little justification remains for allowing inventors to use product-by-process claims. Particularly, the Supreme Court emphasized that each element in a patent claim is deemed material to defining the scope of the patented invention and thus forbids lower courts from using the doctrine of equivalents to effectively eliminate any element in its entirety. (citation omitted) This rule should also apply to claim interpretation. Accordingly, under current case law developments, it is very difficult to justify the *Scripps* view that undermines claims' notice and definitional functions by ignoring process limitations in product claims.<sup>243</sup>

In *Scripps* the PPC was for a new and unobvious product and the product was difficult to describe for patentability purposes. In *Atlantic* the claims pertained to product claims with process limitations and these were the basis for patentability over the prior art. In *Scripps*, a PPC was used to overcome the difficulty in defining the product for patentability purposes. In *Atlantic*, however, the PPC seems to have been added to avoid the rejection of the patent; that is, the PPC was used more as a strategy than anything else whereas, in contrast, in *Scripps* the PPC was perhaps the only option available for the patentee.

In *Scripps* the court held that the accused product could infringe even if it was made through a non-infringing process. In *Atlantic* it was ruled that only if the product were the same and was made by the same process would there be an infringement. The two judgments were discussed extensively in law reviews and journals.<sup>244</sup> In the absence of clarification from the Federal Circuit, different courts have adopted

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<sup>243</sup> Takenaka, *op. cit.*

<sup>244</sup> See, for example, AI Cohen 'A Prescription for the Treatment of Product-by-Process Patent Infringement' (1993) 67 *St. John's L. Rev.* 923.

either of the two as guiding cases.<sup>245</sup> In *Stryker*, the Federal Circuit declined to impute functional limitations from the specification into a claim term when the claim term was defined structurally and not functionally in the claims.<sup>246</sup> In *Vanguard*<sup>247</sup> it was held:

The method of manufacture, even when cited as advantageous, does not of itself convert product claims into claims limited to a particular process. We agree with the district court that the word “integral” describes the relationship between the elastomeric layers, not the means of joining them. This word did not limit the claim to the manufacturing process set forth in the specification. A novel product that meets the criteria of patentability is not limited to the process by which it was made (*Vanguard* at 1372).<sup>248</sup>

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<sup>245</sup> For example, cases where *Atlantic* was held as the guiding case: *Tropix, Inc. v. Lumigen, Inc.*, 825 F.Supp. 7, 10; 27 USPQ2d 1475 (D. Mass. 1993). *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 163 F.Supp.2d 426 (D. Del. 2001). *Scripps* was used as the guiding case in: *Trustees of Columbia Univ. v. Roche Diagnostics GmbH* 126 F.Supp.2d 16, 57 USPQ2d 1825 (D. Mass. 2000). The District Court for the District of Massachusetts has also applied *Scripps* to interpret product-by-process claims as not being limited to the product prepared by the process set forth in the claims. “Accordingly, the product by process claims shall be interpreted so that ‘they are not limited to product prepared by the process set forth in the claims.’” *Columbia* at 49 (quoting *Scripps* 927 F.2d 1565, 1583). *DeKalb Genetics Corp. v. Northrup King Co.* 1997 US Dist. LEXIS 14275 (ND Ill. 14 August 1997). The District Court for the Northern District of Illinois, Western Division applied *Scripps* to deny a motion for partial summary judgment for patent infringement *Smithkline Beecham Corp. v. Geneva Pharms.*, 2002 US Dist. LEXIS 25275 (ED Penn. 2002). (*Scripps* was applied to find product-by-process claims invalidate for anticipation based on prior art product.) Jan Embretson et al. ‘Claim Drafting: Bio/Pharma’ In: <http://www.slwk.com/CM/PhoneSeminars/biopharma.pdf>

<sup>246</sup> *Stryker Corp. v. Davol, Inc.*, 234 F.3d 1252, 1258, 57 USPQ2d 1133 (Fed. Cir. 2000).

<sup>247</sup> *Vanguard Products Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 57 USPQ2d 1087 (Fed. Cir. 2000).

<sup>248</sup> *Vanguard Products Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 57 USPQ2d 1087 (Fed. Cir. 2000).

In this case the allegedly infringed product was produced by a different process and it had the same properties as the claimed one. The Federal Circuit affirmed that it was infringing and declined to accept the view that the scope of the claim was limited to the method of manufacture.

The decisions and the contradicting views can be analysed in terms of the role of the patent system.<sup>249</sup> According to one commentator writing in the context of SPLT:

In addition, many product-by-process claims are adopted only for convenience and very little justification remains for allowing inventors to use product-by-process claims. In particular, the US Supreme Court established the all-elements rule by holding that each element in a patent claim is deemed material to defining the scope of the patented invention, forbidding lower courts from using the doctrine of equivalents to effectively eliminate any element in its entirety. This rule should also apply to claim interpretation. The expansive claim interpretation rule in the SPLT clearly conflicts with this all-elements rule by ignoring process limitations recited in the claim.

In short, product-by-process claims only introduce confusion in determining patentability and validity, while giving the same protection as process claims. Product-by-process claims fail to accomplish their public notice function. Such claims have little value to applicants and

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<sup>249</sup> The tension between encouraging invention and preventing unfair competition is a century-old battle fought in the federal courts. The question of whether product-by-process claims should be limited to the process described in the claims illustrates this ongoing struggle, as the debate over the necessity rule did in the past. If, as *Scrapps* suggests, the product is protected notwithstanding a difference in process, improvement in processes will be discouraged. If differences in processes are considered, as *Atlantic Thermoplastics* suggests, then the invention of products may be discouraged. The Constitution is deceptively clear in describing where the battle line must be drawn: the courts must offer as much protection as is necessary to further the promotion of science and the useful arts. Passeler, op. cit.

patent offices. Thus, the current Rule 12(4)(c) should be replaced with a clear prohibition of such claims or alternatively provide a restrictive claim interpretation rule to cover only products resulting from the process recited in the claim.<sup>250</sup>

Although the SPLT is in limbo the points raised by the author are relevant as they question the relevance of PPCs and why harmonization initiatives should be careful about extending PPCs in all jurisdictions.

### **II.3. PPCs and Drug Registration**

Regarding pharmaceutical patents, the Federal Trade Commission (FTC) took the stand that PPCs that do not claim a novel product should not be listed in the “Orange Book”. The rationale is that they are not true PPCs. According to the FTC:

Rather, as the FDA has stated, product-by-process claims are those in which the patented invention is the product, as opposed to the process used to make the product. A new and patentable process cannot make a known product, which results from that process, patentable. The most essential requirement for a product-by-process claim is that the end product of the process be new and patentably distinct from prior products.

When a claim relies solely on a novel process for patentability, even if such a claim is drafted in product-by-process format, it is not a product claim, and therefore, does not satisfy the first prong. Neither the listing statute nor FDA’s proposal allows the listing of patents based on claims in which the patentee only relied on the process as the novel invention. The Commission in its Study identified

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<sup>250</sup> T Takenaka ‘The Best Patent Practice or Mere Compromise? A Review of the Current Draft of the Substantive Patent Law Treaty and a Proposal for a “First-To-Invent” Exception for Domestic Applicants’ (2003) 11 *Tex. Intell. Prop. L.J.* 259.

several patents listed in the Orange Book based on claims drafted in a product-by-process format for which, according to the patent itself, the novel aspect of the invention was the process, not the product. For example, the FTC Study identified that certain patents listed for the drug product Paxil contained only process claims and claims drafted in the product-by-process format. The latter claims recited an admittedly known drug substance made according to a purportedly novel process. Such claims are not “true” product-by-process claims of the type identified in the FDA’s proposal.

... [T]he FDA should revise the text of the proposed regulation to reflect the fact that only product-by-process claims in which the product is novel should be listed.<sup>251</sup>

This resulted in the revision to the FDA’s listing rules in June 2003 and under this revision it was stipulated that PPCs were to be listed only if the product were novel. According to the revised rules product-by-process patents may also be listed in the Orange Book provided that the request is accompanied by a certification that the patent is actually a product-by-process patent. The purpose of this certification is to differentiate product-by-process patents from pure process patents that are excluded from the Book by law.<sup>252</sup>

### III. PRODUCT-BY-PROCESS PATENTS IN EUROPE

Under the case law of the EPO the process functions only as a definition; it is not the invention. Thus the compound or the product should meet all the patentability requirements and the mere fact that the process is novel is not enough.<sup>253</sup> As chemical reactions need not

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<sup>251</sup> See FTC’s comments. In: <http://www.ftc.gov/be/v030002.pdf> P-13 See also FTC Study at A-42–A-44.

<sup>252</sup> H A Sayeed ‘A Summary of recent changes to the Drug Price Competition and Patent Term Restoration Act of 1984’ (2004). In: [http://leda.law.harvard.edu/leda/data/662/Sayeed\\_paper\\_redacted.pdf](http://leda.law.harvard.edu/leda/data/662/Sayeed_paper_redacted.pdf)

<sup>253</sup> B. Domeij, *Pharmaceutical Patents in Europe* (Kluwer Law International

follow only one path and some by-products may be produced, the process and the final product need to be separated in the end. This obviously creates more uncertainty than a structural claim. Thus, wherever possible it is better to use structural claims. However, when the applicant is left with little option or has mistakenly opted for a PPC where structural claim would have been more apt, defining the product by the manufacturing process might be possible.

While parameters in PPCs are permitted, they may create ambiguities. According to the EPO guidelines, if the parameters are unusual or require special or tailor-made instruments, the examiner has to exercise caution as the parameters might have been chosen to hide lack of novelty. Generally new parameters should not be used unless they are absolutely necessary or the known means of characterization are inadequate. Characterization by biological effect is also permissible in some cases<sup>254</sup> but these characterizations are acceptable only if they are not ambiguous or do not place undue burden on the skilled person.<sup>255</sup> In different cases the question of ambiguity has been discussed and even when it was bothersome to test, if it was possible with routine tests to verify, such claims were accepted. For example, claims that defined a feature of a compound as one that should be used in a “contraceptively effective amount” or “physiologically effective amount” were accepted. Thus the rationale is that ambiguity per se will not be a bar unless it is too ambiguous to put into practice or it is not

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New York 2001) p. 69. T 124/93 of 10 08 of 1995 ‘According to the established case law of Boards of Appeal ... product-by-process claims give protection for products as such, independent from the process by which they were made, and the said products, therefore, likewise have to fulfil the requirements of patentability such as novelty and inventive step independent from the novelty and inventive step of the process.’

<sup>254</sup> *Ibid.*, p. 70–71. In T 301 / 87 the application concerned a recombinant DNA molecule characterized by the fact that it coded for a polypeptide of IFN Alpha (alpha-interferon fulfils a function in the human immune defence and is used in cancer treatment). The Board of Appeal accepted the wording of the claims.

<sup>255</sup> According to Bostyn, “The Board takes the view that in order to minimise uncertainty, the form for a claim to a patentable product as such defined in terms of a process of manufacture (i.e. ‘product-by-process claims’), should be reserved for cases where the product cannot be satisfactorily defined by reference to its composition, structure or some other testable parameters.” Bostyn *supra*.

possible for a person skilled in the art to assess it.<sup>256</sup> For products known from the prior art that are produced by new processes, the definition by the process does not automatically make it novel unless it confers to the product features that make it a different product.<sup>257</sup> This solution rules out the “analogy processes”.

In *Amgen* it was held that using a PPC to claim what was a product of nature was not acceptable, however novel or useful the process was.<sup>258</sup> In other words, unless the product of the PPC fulfils the novelty criteria, the claim that the process is innovative or novel or very useful will not make it patentable.

The relevant case laws and decisions in Germany and the UK may be summarised as follows:

According to the decision “Trioxan”, it is irrelevant whether the product is described in the claims by means of its structural formula or by means of its way of preparation (“product-by-process”). An identical product which is prepared “by a different process is ... [still] within the scope of protection of a product-by-process claim. An explanatory indication of a purpose or effect in a product claim ... generally does not

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<sup>256</sup> Domeij, op. cit., p. 72.

<sup>257</sup> T 0748 / 98 dated 23 May 2001 “According to established jurisprudence of the EPO, a product-by-process claim can be allowed only if the claimed product **as such** fulfils the requirements for patentability, i.e. inter alia that of novelty (cf., for example, T 150/82, OJ EPO 1984, 309, and T 248/85 OJ EPO 1986, 261). If a product known from the prior art is produced by a new process, it does not necessarily acquire novelty only by the fact that it is defined in terms of this process, unless the latter confers to the product features which make it a different product.”

<sup>258</sup> Lord Hoffman in the *Kirin Amgen* case [2004] UKHL 46, stated, “Standing back from the detail, it is clear that Amgen have got themselves into difficulties because, having invented a perfectly good and ground-breaking process for making EPO and its analogues, they were determined to try to patent the protein itself, notwithstanding that, even when isolated, it was not new. Hence the patenting of the two product-by-process claims which have failed, one because the last-minute amendment to distinguish the product from the natural EPO turned out to be based upon the false premise that all EPO had the same molecular weight and the other because the factual basis on which the European Patent Office allowed it turned out to be wrong.’

have a [limiting] effect”. From the decision *Oberflächenactives Material*, it can be extracted that in the case of product-by-process claims, the use of a different process does not necessarily lead away from the protective scope. If the process features in the product claim impart a specific characteristic to a claimed product, this characteristic has to be read into claims.<sup>259</sup>

Product-by-process claims are also admissible under UK practice in cases where a product is not novel. The position of UK courts is that if the product cannot be characterised by means other than by the process used for its preparation, the claim shall be regarded as a classic product claim. If that process is novel, but the product as such is not novel, the claim should be given the meaning and effect of a process claim. In such a case, the protection conferred by a product-by-process claim should extend to the products obtained by a novel process or an equivalent.”<sup>260</sup>

#### IV. PRODUCT-BY-PROCESS CLAIMS IN JAPAN

PPCs are accepted in Japan but the practice with respect to the interpretation of claims and patent infringement differs widely from that of the USA.<sup>261</sup> According to Takaneke:

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<sup>259</sup> S Bavec ‘Scope of Protection : Comparison of German and English Courts’ Case Law’ (2004) 8 *Marq. Intell. Prop. L. Rev.* 255.

<sup>260</sup> Ibid.

<sup>261</sup> “In Japan, the theory applied to the interpretation of product-by-process claims in the establishment of a patent right is that a product identical to the patented invention shall be included in the technical scope of the patented invention even if it is produced by a different process (‘Identical Product Theory’), instead of the theory that such a product shall not be included in the technical scope if it is produced by a different process (‘Process Limitation Theory’). However, in the case of claim interpretation in infringement litigation, Japanese courts have applied either (1) the Identical Product Theory, (2) limitation by process under special circumstances, or (3) the Process Limitation Theory, but have never affirmed infringement.” IIP Bulletin, Study on Patent Claim Interpretation (2003).

In: [http://www.iip.or.jp/e/summary/pdf/detail2002/e14\\_07.pdf](http://www.iip.or.jp/e/summary/pdf/detail2002/e14_07.pdf)

Currently, Japanese courts adopt the *Scripps* view and find infringement of a product-by-process claim independent from the process recited in the claim. However, patentees almost always fail to show infringement if infringing products are made by different processes than those recited in the claim because Japanese courts also apply a doctrine similar to the reverse doctrine of equivalents and require identity of physical structures between the claimed product and the infringing product. ... In addition, product-by-process claims are difficult for the JPO to examine. Japanese courts and the JPO therefore should discourage the use of product-by-process claims by making such claims difficult to issue and limiting the protection of patents issued on such claims.<sup>262</sup>

## V. CONCLUSIONS AND RECOMMENDATIONS

Although PPCs are useful in some circumstances, it is desirable to weigh the pros and cons of allowing such claims. From a public policy perspective, the use of PPCs to claim overly broad patents or using it as a strategy to patent what is in the public domain should be discouraged. Striking a balance between the public interest and protecting the rights of inventors regarding PPCs is difficult but possible to do through appropriate rules and guidelines.

In terms of efficiency and incentive to innovate, if both judgments (*Scripps* and *Atlantic Thermoplastics*) are compared, the interpretation in *Atlantic* is more in favour of fostering competition. According to Pressler,

[E]ven though it is inconsistent with precedent, the *Atlantic Thermoplastics* holding is not without merit. Under its narrow view, the process in the product-by-process claim is the claim's limitation when determining infringement. A

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<sup>262</sup> Takaneka, *op. cit.*

complex biological or chemical claim would be limited to the exact process by which the claimant described it, permitting other inventors to develop new, and possibly more economical, processes for making the same product. The limitation provides greater incentive to create more efficient processes because the discoverer of the new process can profit from both the process and the end product. Clearly, the right to market the end product of drug and chemical research is more valuable to an inventor than having to sell the new process to the patent holder of the end product.<sup>263</sup>

While switching over to a product patent regime, developing nations had to extend patent protection in all fields of technology as envisaged under the TRIPS Agreement. If they permitted the patenting of enzymes, catalysts, naturally occurring substances and products of microbiological processes using PPCs, it would result in a broad scope of protection. The same would occur if PPCs on new chemical entities were allowed. However using the lack of definitions for key terms in the Agreement, and using other flexibilities, they could develop suitable patent laws and policies. The problem is that in many developing countries, patent examination and judges' capacity is not adequate to deal with such claims. It is possible to draft PPCs that are for old products or for products anticipated by prior art under the guise of a novel process or method of manufacture.

In the case of pharmaceuticals it has been pointed out that:

Viewed in light of the *Atlantic* decision, some of the generic drugs from developing nations, currently termed "copycat" drugs, may actually be valid process innovations since they use a different process for producing the patented products. Whether a particular generic drug actually amounts to a patentable innovation can only be resolved on a case-by-case basis depending on the extent of the improvement's contribution to the existing material. Developed nations also use other patent doctrines, like the

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<sup>263</sup> Pressler, op. cit.

reverse doctrine of equivalents, to protect improvements over existing patents. In effect, developed nations oppose that which they themselves practice.<sup>264</sup>

When developed countries recognized PPCs, they also ensured that the patent offices and the judicial system had the capacity to deal with them. We have highlighted some of the problems with PPCs elsewhere in this chapter. We have also examined the problems such claims pose to patent examiners. It has been pointed out that the FTC suggested that in the case of patents having PPCs, they should be listed in the Orange Book only if they covered novel products. The patent system in developed nations is well equipped to handle such claims. The development of various doctrines (doctrine of equivalents, the reverse doctrine of equivalents) and rules is another important factor. Thus, while PPCs do give a broad protection and are often used in unpredictable arts, there are checks and balances in the system to ensure that PPCs are scrutinized thoroughly. The question is whether developing nations can really handle PPCs in the absence of a well-developed system.

Thus developing countries should not opt for PPCs unless they are equipped enough to handle them. They may require that, in order to be patentable as such, a product must be structurally defined. Even when PPCs are permitted by law, it is essential to interpret them in such a way that the incentive to develop more efficient processes is not reduced. It is also essential that there should be a pre-grant or post-grant opposition system. In the case of pharmaceutical products, caution should be exercised as PPCs can be used to stifle competition.

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<sup>264</sup> S Ragavan 'A "Patent" Restriction on Research & Development: Infringers or Innovators?' (2004) *U. Ill. J.L. Tech. & Pol'y* 73.



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