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Recommended Citation

Srividhya Ragavan, *A "Patent" Restriction on Research & Development: Infringers or Innovators?*, 2004 U. Ill. J.L. Tech. & Pol'y 73 (2004).

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A “PATENT” RESTRICTION ON RESEARCH & DEVELOPMENT: INFRINGERS OR INNOVATORS?

*Srividhya Ragavan**

Acquiring a patent in today's patent systems requires in-depth knowledge of the procedure for both product patenting and process patenting. When developing nations create or adopt new policies, they seldom take into account proper policies for patenting. Consequently, their industrial growth is limited by ineffective patent procedures. Recent treaties that address patent procedures, the Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) and the Patent Cooperation Treaty, do not properly assist developing nations in forming adequate patent and claiming procedures. Developing nations must harmonize structural procedures with TRIPS and develop effective patent procedures to achieve stronger industrial growth. India is used as a case study to show how developing nations have unsuccessfully instituted patent procedures in contrast to developed nations such as the United States and, to a lesser extent, the European Union. Until developing nations have proper patent procedures, their industrial growth will be limited. These nations should be given the proper tools to effectively patent new products and thereby stimulate local invention.

I. INTRODUCTION

Patent procedures require sophistication, acquired by a thorough understanding of the functioning of the patent system, for successful implementation. The ability of the patent system to provide a wide range of protection for inventions within the same product classification is one thing that marks such sophistication. Procedural tools like claims, specifications, written descriptions, and patent doctrines all contribute toward building a sophisticated system of patent protection. For

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example, claims induce precision in defining patents. Developed nations achieve industrial growth by supplementing patent legislation with complementing procedural requirements, thus facilitating a wider range of inventions.

Developing nations lack exposure to the role that procedures play, especially patent procedures, in implementing policies. In the past, the lack of proper procedures has resulted in the denial of patent protection for inventions distinguished through functional structural additions or even process innovations. For example, some innovations within India currently labeled as “copies” of Western patents, may, in the United States, be eligible for patents using appropriate patent techniques.¹ Unfortunately, international conventions, especially the Trade-Related Aspects of Intellectual Property Rights (“TRIPS”)² and the Patent Cooperation Treaty,³ do not supplement policy prescriptions with procedural requirements.⁴ Neither treatise edifies developing countries about the finer distinctions of patenting procedures and claiming mechanisms. Thus, developing countries will be impeded in the future from benefiting from patents in spite of embracing the TRIPS patent policy. Consequently, innovations of developing nations could be left unprotected, which affects research and distorts the objectives of the World Trade Organization (“WTO”). Without commenting on the TRIPS patent policy, this Article argues that even if developing nations fully comply with TRIPS, structural harmonization divorced from adequate procedural mechanisms will merely stunt research and development.⁵ Until comparable levels of procedural sophistication are enabled, merely establishing a TRIPS-compliant patent regime will not equip developing nations with the tools to protect all innovations.

India is used as a case study in this paper to demonstrate the consequences for developing countries that lack sophisticated patenting procedures. Without meaning to generalize, India is the choice case study for two reasons. First, India is a prominent developing-nation player in many industries, including the information technology and chemical process industries (such as pharmaceuticals production). Second, patent regimes of important developing nations, such as Brazil,

1. See discussion *infra* Section II.A.2 (highlighting how some of the “copycat” drugs will be eligible for patent protection in the United States).

2. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 33 I.L.M. 81 [hereinafter TRIPS].

3. Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645.

4. The term “procedural requirements” will refer to application standards, such as written description or best mode, and will include, where appropriate, patent doctrines that enable interpretation of the patent.

5. In analyzing developing nations, this Article addresses two periods. The terms “current patent regime” or “pre-TRIPS patent regime” refer to the patent regimes in developing nations before TRIPS-compliant product patent regimes are established. The term “post-TRIPS” refers to the product patent regime that will be established as required under Article 27 of TRIPS.

South Africa, and Thailand, bear remarkable similarity to the Indian patent regime.⁶

Section II introduces the two regimes of patenting: product patenting and process patenting. The process patent regime presumably allows the duplication of an already patented product. A discussion on the patent policy contemplated by TRIPS is followed by an analysis of the procedural tools that will be used in the developed and developing nations to implement TRIPS.

Section III analyzes how claiming mechanisms in the United States enable the benefits of a process patent system within a product patent regime to be realized, as well as the role of claims in facilitating inventions either through functional or structural additions within the same product range. The consequences for developing countries that lack sophisticated patenting procedures are demonstrated by a case study of India.

Section IV examines biotechnology patents in the United States and articulates how procedures create the flexibility required within patent policies to induce industrial development.

In Section V, this Article concludes that until comparable levels of procedural sophistication are enabled, merely establishing a TRIPS-compliant patent regime will not equip developing nations with the tools to protect all innovations.

II. PRODUCT AND PROCESS PATENTS

A. Patent Types

1. Product and Process Patent Regimes

A patent may be granted for either a product or a process. The United States and Europe embrace the product patent regime that protects the end product. Traditionally, developed nations' protection for innovative processes⁷ has been couched in the acclaimed principle

6. See, e.g., Srividhya Ragavan, *Can't We All Get Along? The Case for a Workable Patent Model*, 35 ARIZ. ST. L.J. 117, 135-37 (2003) (discussing Indian and Brazilian law on patents); see also Judy Reh, *International Governance Through Trade Agreements: Patent Protection for Essential Medicines*, 21 NW. J. INT'L L. & BUS. 379, 400-03 (2001) (discussing patent rights for AIDS drugs in South Africa and Thailand).

7. Developed nations like the United States, for example, traditionally protect innovative processes of known patented products using process claims. See Thomas Bilodeau, Case Note, *When Are Pharmaceutical Products Materially Changed from an Intermediate Compound?* *Eli Lilly v. Cyanamid*, 6 GEO. MASON L. REV. 339, 344 (1998) (discussing that if a product is "old" or unpatentable, the only patent protection available to a company could be a process patent). Generally, the process inventor would not seek to claim the product, but would only claim the newly discovered method or process. See generally *In re Tarczy-Hornoch*, 397 F.2d 856 (C.C.P.A. 1968) (discussing process claims).

that a "patent claim addressed towards a process could not be infringed by activities involving a product made by that or another process."⁸ Thus, at all times, developed nations protect the product even if it only embodies a novel process.

The process patent regime of developing nations does not protect the product; instead the method or the process of making the product is protected to the exclusion of the product. Hence, identical products can be produced by several manufacturers who each hold a process patent. Protecting innovative processes encourages innovation in the methods of making known products, although the lack of product patent protection stunts the research and development of new products. Most developing countries encourage the use of process patents for food, drug, and pharmaceutical products, as well as chemical processes.⁹ Developing countries have used the flexibility afforded by process patents to innovate cheaper methods of making expensive patented products, such as pharmaceuticals. They tend to keep inventions in critical subject matters, like food, drugs, and chemicals, away from product patent protection in order to increase market competition through process innovations, cater to public health, and address other social concerns.¹⁰

2. TRIPS Regime

TRIPS seeks to enhance patent protection in developing nations and to prevent distortion in trade arising from the duplication of patented products.¹¹ Article 27 of TRIPS stipulates that "patents shall be available for any inventions, whether products or processes, in all fields of technology."¹² TRIPS standardizes the product patent regime by

8. MARTIN J. ADELMAN ET AL., *CASES AND MATERIALS ON PATENT LAW* 1012 (1st ed. 1998).

9. For example, the Indian Patents Act reads as follows:

In the case of inventions:

- (a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or
- (b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi conductors and inter metallic compounds), no patent shall be granted in respect of claims for the substance themselves, but claims for the methods or processes of manufacture shall be patentable.

Patents Act of 1970, 27 India A.I.R. Manual 450 § 5 (1979) [hereinafter Indian Patents Act].

10. See Ragavan, *supra* note 6, at 150-52.

11. TRIPS, *supra* note 2, at art. 27. The product patent regime in TRIPS does not necessarily exclude patenting of inventive processes. Article 27 read with Article 28 clarifies that innovative processes are patentable although there is no mention of excluding the product from protection. *Id.* at art. 28(1)(b). Article 28 details that patented processes are infringed by "products obtained directly by that process," thereby suggesting that products obtained by alternate processes do not infringe the process patent. *Id.* Similarly, Article 34 of TRIPS provides that when an identical product is produced without the consent of the patent owner, for the purposes of determining infringement, judicial authorities can "order the defendant to prove that the process to obtain an identical product is different from the patented process." *Id.* at art. 34(1). TRIPS therefore specifically suggests that products using a process not claimed in the patent application will be considered non-infringing.

12. *Id.* at art. 27.

providing a uniform international norm.¹³ TRIPS favors the product patents since developed nations argue that the exclusion of the product in the process patent regimes distorts international trade by allowing duplication of the patented product using different processes.¹⁴ The rhetoric of the developed nations has been that the product patent regime provides more effective protection and prevents all forms of duplication. TRIPS, however, does not suggest any particular claiming mechanism or procedures to provide effective patent protection.

Essentially, TRIPS deprives developing countries of the flexibility to exclude subject matters like food, drugs, and chemicals from product protection. Later sections of this Article will demonstrate that claiming techniques can incorporate flexibilities even within the product patent regime. In effect, it is not the patent law as such, but the various doctrines and claiming mechanisms that balance patent owners' rights with the societal need for the product. The lack of guidance in international treaties on the procedural techniques and patent doctrines will be a disadvantage to developing nations in the post-TRIPS period.

B. Patent Procedures

The following section outlines and compares the development of procedural techniques in India and the United States in order to demonstrate the impact of claiming techniques on successful implementation of patent regimes.

1. U.S. Patent Claims

Claim construction is the heart and soul of the U.S. patent system. Patent applications propose one or more claims which formally state the subject matter of the invention with specificity. The claim is a precise description of an invention's elements and their interactions.¹⁵ U.S. courts measure the scope of patent protection from a careful reading of the various claims. The statutory guidance in 35 U.S.C. § 112¹⁶ is supplemented by the U.S. Patent and Trademark Office guidelines on

13. *Id.*

14. For example, in 1989 alone, estimates of the United States' "exports of goods and services embodying intellectual property amounted to nearly \$60 billion." Robert Pechman, *Seeking Multilateral Protection for Intellectual Property: The United States "TRIPs" over Special 301*, 7 MINN. J. GLOBAL TRADE 179, 183 (1998).

15. Calvin Fan, *Construing Product-by-Process Patent Claims in Scripps and Atlantic*, 28 U.C. DAVIS L. REV. 219, 226 (1994).

16. 35 U.S.C. § 112 (2000). The statute elaborates that:

[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.

Id.

claim drafting and the decisions of the U.S. Court of Appeals for the Federal Circuit on claim interpretation.¹⁷

Here is a sampling of the types of claims: Product-by-process claims describe the product by defining the process of production.¹⁸ The patent will protect the product produced by the patented process. Jepson claims define an invention by reciting the admitted prior art in the preamble and by introducing an improvement clause which recites the ambit of the invention.¹⁹ Claim limitations can be stated either in functional or structural terms. Functional claims describe the product by its function.²⁰ The patent will vest on the product performing the specified function. Structural claim limitations are typically used for biotechnology inventions to describe product structure and limitations.²¹ The means-plus-function claim limitations define the function and the means or mechanism that enables the product to perform the function.²² The patent vests in the product if it performs the function using the specified means described in the claim. Therefore, a product performing the same function with different means is eligible for another patent.

Claims allow for both the broadening and the narrowing of an invention's scope. The precision in defining the scope of an invention leaves room for more innovation. Claims facilitate catering to a wider range of inventions within the same product classification. The use of adequate claiming techniques ensures protection for even minor inventions and provides the incentive for industries working in the same field to evolve and capitalize on the benefits.

2. Claiming Requirements in India

The Indian patent legislation provides that every patent application should embody either a provisional or a complete specification.²³

a. Provisional Specification

A provisional specification, submitted to the patent office when the inventor has a prototype, describes the nature of the invention and its intended manner of working.²⁴ Section 10 of the Patents Act, read with

17. See, e.g., Utility Examination Guidelines Issued by the Patent and Trademark Office, 60 Fed. Reg. 36,263 (July 14, 1995); see also Lisa A. Karczewski, *Biotechnological Gene Patent Applications: The Implications of the USPTO Written Description Requirement Guidelines on the Biotechnology Industry*, 31 MCGEORGE L. REV. 1043, 1064-66 (2000) (detailing the importance of these guidelines).

18. See ADELMAN, *supra* note 8, at 647. See generally *Atl. Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992).

19. ADELMAN, *supra* note 8, at 677.

20. See *In re Donaldson Co.*, 16 F.3d 1189, 1193-96 (Fed. Cir. 1994); 35 U.S.C. § 112(6) (2000) (discussing the means-plus-function approach, which is unique to the U.S. system).

21. See ADELMAN, *supra* note 8, at 680.

22. *Id.*

23. Indian Patents Act, *supra* note 9, § 7(4).

24. *Id.* § 10(1).

Rule 15 of the Patent Rules, states that the title of the provisional specification should mention the area of science, a description, and essential features of the invention.²⁵ The provisional specification secures the benefit of the filing date as the priority date.²⁶ India embraces a first to file system, and therefore the date of filing determines the priority.

b. Complete Specification

A complete specification is filed within twelve months of filing the provisional specification, otherwise the application is deemed abandoned.²⁷ The filing period encourages the inventor to conduct research and incorporate the results into the application.²⁸ Every complete specification should:

- (a) fully and particularly describe the invention and its operation or use and the method by which the invention is to be performed,
- (b) disclose the best method of performing the invention which is known to applicant . . . , and
- (c) end with a claim or claims defining the scope of the invention for which protection is claimed.²⁹

The terms "description of the invention" and "best mode" are not statutorily defined.³⁰ The only statutory guideline for claim construction is in Section 10(5) of the Indian Patents Act,³¹ detailing that claims should be clear, succinct, and fairly based on the matter disclosed in the specification.³²

Lack of adequate statutory definition has left claim and specification construction within the courts' domain.³³ The courts construe specifications and claims as a matter of law.³⁴ The Delhi High Court has held that claims should specify particular features of the device, the distinguishing features from the prior art, and the nature of the

25. *Id.*; Indian Patent Rules, Rules 10, 14–20 (1972) (elaborating the requirements of drawings and models for the specifications).

26. Indian Patents Act, *supra* note 9, § 11(3)(a). The Act states that the patent applicant will get the advantage of the priority date provided the nature, characteristics of the technology, or invention remains unchanged. *Id.* This principle is commonly known as the "Fairly Based Rule."

27. *Id.* § 9(1) (stating that, upon request, the controller can grant up to fifteen months to file the complete specification).

28. *Id.* § 17(1). The Act notes that applicants may request to post-date the application by six months. *Id.* However, the priority dates will also be appropriately post-dated. *Id.* § 11(7).

29. *Id.* § 10(4). The Indian Patent Rules 14–20 (1972) elaborate the requirements for drawings and models included within the specifications.

30. Indian Patents Act, *supra* note 9, § 2. After the complete specification is filed, the examiners determine procedural validity and compliances before prosecuting claims. *See id.* § 10.

31. *Id.* § 10(5).

32. *Id.*

33. *See Lallubhai Chakbhai Jariwalla v. Chinamanlal Chunilal*, 1935 I.L.R. 60 (Bom.) 261, 275–76.

34. *See, e.g., id.*

invention.³⁵ The applicant should describe the nature³⁶ and the limits of the claim with clarity.³⁷ The Bombay High Court has previously noted that the title of the invention claimed has little consequence in controlling the claim.³⁸ No additional guidelines supplement the above broad rules of interpretation laid by the courts, and this leaves unfettered discretion to the patent office and the judiciary to construe patent claims. Thus, claim construction is very subjective and unlimited in India. The lack of a structured claiming mechanism results in unclear definitions and descriptions of the scopes of inventions. Furthermore, it results in the presumption of very broad patents and limits the scope of further inventions.

III. PATENT DISADVANTAGES

The following section traces the role of claims in encouraging innovation by defining the precise scope of patents. Two particular claiming mechanisms are analyzed to demonstrate how inadequate procedural techniques can be detrimental to the successful implementation of patent policies in developing nations.

A. Product-by-Process Claims and Duplication of Products

1. Product-by-Process Claims in the United States

Traditionally, the use of a product-by-process claim enabled the patenting of a "product produced using the claimed process."³⁹ Since the product-by-process claim merely protects a product produced by the claimed process, the status of an identical product produced by using a different process was left undetermined. Recent U.S. decisions have reiterated that the protection offered by product-by-process claims allowed the duplication of the product using a different process, effectively only protecting the process of making the product.⁴⁰

In 1991, the Federal Circuit in *Scripps Clinic & Research Foundation v. Genentech, Inc.* explained the United States' position at that time regarding the use of product-by-process claims.⁴¹ The patent at issue described a method for purifying and concentrating Factor VIII:C, the blood clotting factor, by using a monoclonal antibody.⁴² Claim 1

35. Ram Narain Kher v. Ambassador Indus., 1976 A.I.R. 63 (Del.) 87, 88.

36. Press Metal Corp. v. Noshir Shorabji Pochk Hanawalla, 1983 A.I.R. 70 (Bom.) 144.

37. See, e.g., Raj Prakash v. Mangath Ram Choudhary, 1978 A.I.R. 65 (Del.) 1.

38. See Lallubhai, 1935 I.L.R. 60 (Bom.) 261, 290.

39. Mark D. Passler, *Product-by-Process Patent Claims: Majority of the Court of Appeals for the Federal Circuit Forgets Purpose of the Patent Act*, 49 U. MIAMI L. REV. 233, 234 (1994).

40. See Atl. Thermoplastics Co. v. Faytex Corp., 970 F.2d 834, 843-46 (Fed. Cir. 1992).

41. 927 F.2d 1565, 1583-84 (Fed. Cir. 1991).

42. *Id.* at 1568-70.

contained a process claim providing for “[a]n improved method of preparing Factor VIII procoagulant activity protein” and the process of preparing the protein.⁴³ Claim 13 was a product-by-process claim and provided for “[h]ighly purified and concentrated human or porcine VIII:C prepared in accordance with the method of claim 1.”⁴⁴ Genentech, the accused infringer, produced Factor VIII:C by a process different from that in the Scripps specification.⁴⁵

The Federal Circuit held that the protection for a product, patented by the use of the product-by-process claims, is “not limited to products prepared by the process set forth in the claims.”⁴⁶ The court noted that the product-by-process claims allow the inherent characteristics of the product to be claimed using the process limitations.⁴⁷ The court authorized Scripps Clinic to claim purified Factor VIII:C whether derived through Scripps’s disclosed process or any other process achieving the same result.⁴⁸ It also noted that both the product and the process were protected by the use of the product-by-process claims. The *Scripps Clinic* decision therefore implied that products protected by the use of product-by-process claims could not be infringed by using another process.

Nonetheless, one year later in *Atlantic Thermoplastics Co. v. Faytex Corp.*,⁴⁹ the Federal Circuit reversed the *Scripps Clinic* position.⁵⁰ In *Atlantic*, the plaintiff owned a patent comprising of process and product-by-process claims for a shock-absorbing shoe innersole made from an elastomeric material and polyurethane foam.⁵¹ The issue involved the defendant’s innersoles with elastomeric heel inserts.⁵² Defendant bought the product from two separate manufacturers using different manufacturing processes.⁵³ The plaintiff brought suit against the defendant for infringing the patent; therefore, the suit related to both of the manufacturing processes.⁵⁴ The Federal Circuit held that the process of one manufacturer infringed the patent because it contained all the

43. *Id.* at 1570.

44. *Id.*

45. *Id.* at 1569. It used recombinant DNA technology, i.e., 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. See Donald S. Chisum, *Patent Law Developments in the United States Court of Appeals for the Federal Circuit During 1991*, 41 AM. U. L. REV. 869, 903 (1992).

46. *Scripps Clinic*, 927 F.2d at 1583.

47. *Id.*

48. *Id.*

49. 970 F.2d 834 (Fed. Cir. 1992), *reh’g en banc denied*, 974 F.2d 1279 (Fed. Cir. 1992).

50. *Id.* at 846–47. See also *Atl. Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1279, 1280 (Fed. Cir. 1992) (Rich, J., dissenting) (commenting harshly on majority’s denial of rehearing en banc). See generally William E. McGowan, Case Comment, *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992), 27 SUFFOLK U. L. REV. 300 (1993).

51. *Atl. Thermoplastics Co.*, 970 F.2d at 835.

52. *Id.*

53. *Id.* at 836.

54. *Id.* at 835.

claim limitations.⁵⁵ The second manufacturer used a different process to achieve an indistinguishable product.⁵⁶ The Federal Circuit ruled that the use of a different process (provided it was not a “substantially identical” process) did not amount to an infringement of the product-by-process claim.⁵⁷ The Federal Circuit overruled *Scripps Clinic* by holding that a product claimed by a product-by-process description is only infringed when the allegedly infringing product is produced using the claimed process.⁵⁸ In clearer terms, the *Atlantic* holding meant that product-by-process claims only protect the product when made by the claimed method.⁵⁹ Accordingly, if a defendant uses a different process to make the same product, the defendant does not infringe a product patented using the product-by-process claims.⁶⁰ Although the court did not consider the issue of the doctrine of equivalents, the judgment allows third parties to use different processes to produce a product patented using the product-by-process claims.⁶¹

Case law after *Atlantic* has opined that it is the controlling law and has ruled that products produced using different processes do not infringe a product-by-process claim.⁶² Authorities on patents, such as Professor Chisum, have interpreted that product-by-process claims are not infringed unless the product is made through a substantially identical process.⁶³

Although the U.S. patent system does not provide for process protection to the exclusion of the product, the use of appropriate interpretive strategies on claiming techniques allow, as non-infringing,

55. *Id.*

56. *Id.* at 837–38.

57. *See id.* at 838–47. Interestingly, the court does not define what would amount to a *substantially identical* process. *Id.* The court gave no guidelines to elevate an alternate process of producing the patented product to a *substantially identical* process capable of infringing the patented product. *Id.*

58. *Id.* at 838–46.

59. *Id.* at 846–47.

60. *Id.*

61. Recent Cases, Trustees of Columbia University v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (D. Mass. 2000), 115 HARV. L. REV. 923, 929 (2002) (arguing that, “[t]aken together, *Atlantic* and *Scripps* define a doctrine of equivalents that applies to the construction of product-by-process claims.”).

62. Tropix Inc. v. Lumigen, Inc., 825 F. Supp. 7, 10 (D. Mass. 1993). *But see* Trustees of Columbia Univ. v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16, 31–32 (D. Mass. 2000) (construing the scope of the product-by-process claims, the court acknowledged that the law was in a “state of uncertainty,” but concluded that, sitting as a lower court, it lacked authority to select a rule based on policy considerations). The court rejected the approach of *Tropix Inc.*, which had held that *Atlantic* states the controlling law, and instead based its conclusions on the reasoning that an *en banc* or higher-court ruling could overrule a panel decision. *Id.* In the absence of such a ruling, the court found the first panel opinion in *Scripps* controlling. *Id.* *See also* Recent Cases, *supra* note 61, at 930 (“The district court in Columbia based its finding of a conflict between *Scripps* and *Atlantic* on an unnecessarily broad and abstract reading of the cases’ holdings, a reading at odds with the policies underlying product-by-process claims.”). *See generally*, Lawrence A. Hymo & Richard A. Anderson, *Product-by-Process Claims: Time for Reexamination*, 3 FED. CIR. B.J. 131 (1993) (arguing that the decisions can be reconciled based on the history of the claims and the rule of necessity).

63. *See* 3 DONALD S. CHISUM, CHISUM ON PATENTS § 8.05 [1] (2002).

the use of different processes of producing patented products. In effect, thanks to the *Atlantic* panel, although the product is allegedly protected, the patent protection is limited to the process of production.⁶⁴ Post-*Atlantic*, industries in developed nations can capitalize through process innovations by competitively marketing same or similar products using different and less expensive processes without infringing the existing patents. This Article later highlights how the *Atlantic* panel used U.S. patent law in a way that patent scholars have vehemently opposed for patent systems in developing nations.

2. *The Purpose-Limited-Product Claims of Europe*

Under the European Patent Office Guidelines (“EPO Guidelines”), “[c]laims for products defined in terms of a process of manufacture are allowable only if the products as such fulfill the requirements for patentability.”⁶⁵ The EPO Guidelines specify that a “product is not rendered novel merely by the fact that it is produced by means of a new process,” which implies by exclusion that such a product may be non-infringing albeit unpatentable.⁶⁶ Europe, however, allows the limited patenting of a known product (even if it is manufactured using a claimed process), provided a *new use* of the product is disclosed. Thus, Europe actually goes one step further than the United States to provide patent protection for identical products, subject to claiming a new use.

In Europe such patents are titled “use innovations” and can be protected using “purpose-limited-product claims.”⁶⁷ These claims limit the scope of patent protection to the particular purpose or *use* of the product. Generally, the purpose-limited-product claims are used only when the product is already patented. For example, a patent application made in 1979 for pyrrolidine derivatives in the European Patent Office (“EPO”) contained active therapeutic substances to reduce cerebral insufficiency.⁶⁸ The Examining Division of the EPO reasoned that public knowledge of pyrrolidine derivatives destroyed novelty even though the pharmaceutical use of the derivatives was unknown.⁶⁹ On appeal, the

64. See generally *Atl. Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992), *reh'g en banc denied*, 974 F.2d 1279 (Fed. Cir. 1992).

65. See EUROPEAN PATENT OFFICE, GUIDELINES OF EXAMINATION IN THE EUROPEAN PATENT OFFICE, pt. C, ch. III, para. 4.7b, at http://www.european-patent-office.org/legal/gui_lines/pdf_2003/gui_03_full_e.pdf (last visited Apr. 15, 2004) [hereinafter EPO GUIDELINES].

66. *Id.* But see ADELMAN, *supra* note 8, at 661 (discussing the EPO Guidelines, which state that “European patent law recognizes ‘product-by-process’ claims to reach the product as obtained by any possible process”).

67. See *How to Claim Medical Methods in the European Patent Office*, at http://www.jenkins-ip.com/serv/serv_7.htm (last visited Apr. 7, 2004).

68. See *Hoffman-La-Roche/Pyrrolidine Derivatives*, Case T128/82, [1984] E.P.O.R. 591, 592 (EPO Technical Bd. App.); see also EPO Patent No. 79 100 378.3 (issued Feb. 9, 1979); U.S. Patent No. 4,239,770 (issued Dec. 16, 1980). The derivative belonged to a general formula containing *o*-methoxybenzoyl, *m*-methoxybenzyl, *p*-methoxybenzyl, or *p*-fluorobenzyl. *Id.*

69. See *Hoffman-La-Roche/Pyrrolidine Derivatives*, [1984] E.P.O.R. at 593 (refusing the application on the grounds that it failed to fulfill the requirements of Article 52(4) and (5) of the

European Patent Board introduced the concept of a purpose-limited-substance claim to extend protection for new discoveries of known substances.⁷⁰ In 1984, the European Patent Board in *EISAI* reiterated that claims directed to the use of a known substance or composition for the manufacture of a pharmaceutical preparation for a specified new and inventive therapeutic application will be eligible for European patent protection.⁷¹ Thus in Europe, the first use (usually medical) of a known product (protected by a product patent) is patentable by the use of a purpose-limited-product claim. The second and further use of the same substance can be patented provided the claims are directed to the use of the substance or composition for the manufacture of the specific inventive application (usually therapeutic).⁷² The required novelty for such pharmaceutical substances is derived from the new use, irrespective of whether there was a previously known pharmaceutical or other use for the same substance.⁷³ The claim format, known as "Swiss claims," falls outside the exclusion under Article 52(4) of the European Patent Convention.⁷⁴ The role of Swiss claims is merely to protect the new use of the known compound or composition.⁷⁵ Thus in Europe, a third party inventing a new use of a patented or known product can get patent protection limited to marketing the product for the new use. By extension, a third party inventing a new process of producing a patented product can, subject to disclosing a new use, get limited patent protection for the product.⁷⁶

3. Comparison with Developing Nations

The current patent regimes of developing nations⁷⁷ protect novel processes of producing known products (in inventions relating to food,

EPC). Article 52(4) of the European Patent Convention states that:

[m]ethods for treatment of the human or animal body by surgery or therapy and diagnostic methods [practiced] on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

European Patent Convention, Oct. 5, 1973, art. 52(4), <http://www.european-patent-office.org/legal/epce/ma1.html#CVN>. Article 54 of the European Patent Convention discusses novelty and preserves the patentability of any substance or composition, comprised in the state of the art, provided its "use" is not comprised in the state of the art. *Id.* at art. 54.

70. See *Hoffman-La-Roche/Pyrrolidine Derivatives*, [1984] E.P.O.R. at 595-96.

71. *EISAI/Second Medical Indication*, Case G 05/83, [1984] E.P.O.R. 241, 246 (EPO Enlarged Bd. App.).

72. *Id.* The court clarified that a European patent with claims directed to the use may not be granted for the "use of a substance or composition for the treatment of the human or animal body [as] therapy." *Id.* ¶ 18.

73. *Id.* ¶¶ 14-20.

74. *Id.* See generally *Pharm. Mgmt. Agency Ltd. v. Comm'r of Patents* [2000] 2 N.Z.L.R. 529.

75. *EISAI/Second Medical Indication*, [1984] E.P.O.R. ¶ 20.

76. See EPO GUIDELINES, *supra* note 65, at pt. C, ch. III, para. 4.7b.

77. See *supra* note 5 (providing definition of "current patent regime").

medicine, and chemicals) although the product is not patent-protected.⁷⁸ The difference is that under the process patent regimes of developing nations, different patents will protect each of the processes of producing one product. The product patent regime of developed nations presumably protects first generation product, while such protection is not available in the process patent regime. However, the interpretation of claims adapted, for instance in *Atlantic*, has resulted in protecting the innovative processes to the limited exclusion (or protection) of the product. In essence, the *Atlantic* judgment creates the same end result that would be derived from a process patent regime in developing nations.⁷⁹ Both the process patent regime used in developing nations and the use of special claiming techniques within a product patent regime used in the developed nations create the same effect of facilitating the duplication of a known product using an innovative process. Thus, the systems in developed nations indirectly tend to facilitate the same results that are obtainable in developing nations which encourage novel methods of producing known products.

Hypothetically, assume that A Corp is the patent owner for a pharmaceutical product MNO claimed using a product-by-process claim, where MNO is manufactured using the formula $X + Y + Z$. If B Corp manufactures MNO using $X^1 + Y^1 + ZC$, under the controlling *Atlantic* ruling, B Corp does not infringe the patent on MNO. Therefore, B Corp will be able to manufacture and effectively market MNO. In Europe, B Corp can obtain a patent on MNO using the purpose-limited-product claim subject to claiming a new use for MNO. However, if A Corp applied for patent protection in a developing country like India, under the process patent regime (which developed nations oppose), A Corp would get process protection for $X + Y + Z$ only and not for the product

78. See, e.g., Indian Patents Act, *supra* note 9, § 5 (stating that “no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable”). For example, in the case of chemical processes, substances that are intended to be used as or capable of being used as food or medicine can garner patent protection for the process, but not the substance. *But cf.* *Atl. Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1279, 1280–81 (Fed. Cir. 1992) (Rich, J., dissenting) (relating to a chemical process).

79. Judge Rich, dissenting from the Federal Circuit’s refusal to examine *Atlantic Thermoplastics en banc*, traces the similarity between the effect of the *Atlantic* panel and the patent regimes of developing nations. *Atl. Thermoplastics Co.*, 974 F.2d at 1280–81. He quotes Roger A. Brooks, assistant vice president of the Pharmaceutical Manufacturers Association, and adds that:

more than 100 research-based members of PMA are highly dependent on intellectual property protection to provide the incentive to invest risk capital. Mr. Brooks stated: “In the pharmaceutical industry, innovation comes at a premium cost. And R&D productivity is measured generally in terms of an individual’s or nation’s ability to develop what we call new chemical entities, or NCEs. The cost of developing an NCE continues to rise each year. For example in 1976, the cost of moving an NCE from laboratory to market was \$54 million. By 1990, this figure has risen nearly fivefold to over \$230 million per NCE.” He then pointed out that only one out of 5,000 or 10,000 compounds discovered ever make it to the market.

Id. Judge Rich also adds that, “[t]his kind of innovative R&D is not going to be encouraged by the rule just laid down by the *Atlantic* panel.” *Id.* Thus, Judge Rich specifically identifies that the pharmaceutical industry would be affected if competitors are able to make the same product using a different process. *Id.* Incidentally, this is what third world countries allow and even encourage their pharmaceutical manufacturers to indulge in.

MNO. B Corp can get a process patent for $X^1 + Y^1 + ZC$ and market MNO as well. Ultimately, the bottom line is that in both developed and developing nations, B Corp can manufacture and market MNO subject to not using $X + Y + Z$. Thus, interestingly, the result is the same for B Corp in both the United States and India.

In analyzing the *Atlantic* decision, scholars have observed that:

[a] 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.⁸⁰

Developing a more economic process of producing a patented product is exactly what the third world generic drug industries already do. 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.⁸¹ Developed nations also use other patent doctrines, like the reverse doctrine of equivalents, to protect improvements over existing patents. In effect, developed nations oppose that which they themselves practice.⁸²

4. *Malady After Developing Nations Become TRIPS Compliant*

A malady will arise when the developing nations ultimately move to a product patent regime in 2005 as required by TRIPS. Under a product patent regime, devoid of the use of appropriate claims, innovative processes or uses of known products may be left unprotected. Once developing nations embrace the TRIPS patent regime, unless they incorporate the claiming nuances, process innovations may become unprotected. That is, TRIPS requires developing countries to award only product patents. In effect, novel processes, not necessarily excluded from protection under TRIPS, may become unpatentable in developing countries because of a lack of sufficient claiming or even interpretative techniques. Consequently, inventions patentable in developed nations,

80. Passler, *supra* note 39, at 252.

81. See Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1008 (1997) (discussing how U.S. patent law provides for patenting of improvements, and what improvements qualify for patent protection).

82. *Id.* at 1013 (discussing that patent law has more protection for improvements than copyright law). See generally Ragavan, *supra* note 6, at 154–55.

using sophisticated procedural mechanisms or patent doctrines, will fall outside the TRIPS-compliant patent legislation of developing nations.

Developing countries complying with TRIPS will amend the patent legislation and incorporate a product patent regime without actually strengthening the procedural sophistication.⁸³ Under the post-TRIPS regime, in a developing nation like India, A Corp (in the hypothetical above) will become eligible for a product patent over MNO. Since claiming techniques will not be adequately developed, A Corp will use the general guidelines for claiming in India (as detailed in Section II). The patenting of MNO by A Corp will vest the complete monopoly over MNO in A Corp during the patent term. B Corp's novel process for producing MNO, being $X^1 + Y^1 + ZC$, will infringe A Corp's patent in MNO owing to a product patent regime lacking in procedural sophistication. Thus, A Corp's patent will block further innovations over MNO. The resulting malady is that B Corp's process of making MNO, although not considered infringing in the United States, will be considered infringing in India. Therefore, India (and other similarly placed developing nations) will be deprived of the benefits of process innovations like that of B Corp. It is also possible that the innovative process of B Corp will either fall into the public domain or will be patented in a developed nation depending on the patent sophistication of B Corp. Several developing nations, like India, Brazil, and Thailand, house generic drug industries specializing in process innovation.⁸⁴ After these nations implement the TRIPS-compliant patent legislation, the process innovations in the developed nations may be left unprotected.

The *Hoechst Corporation* case⁸⁵ demonstrates the above proposition. Hoechst owned Indian patent no. 58716 for the "[m]anufacture of New Sulphonyl-Ureas, Salts of those Compounds and of Anti-diabetic Preparations containing such Compounds."⁸⁶ The specification detailed that the invention was comprised of sulphonyl ureas.⁸⁷ Claim 11 related to the "process as claimed in claim 1 wherein thioureas were treated with agents eliminating the sulphur."⁸⁸ The very broad claim 22 referred to the "compounds of the formula . . . [and] the drawings, whenever obtained according to claims 1-15."⁸⁹ One such compound was tolbutamide.

83. It will take the developing nations a long time to understand the nuances of the implementation procedures. In the interim, the product patent regime will function with rudimentary claim and specification requirements.

84. See, e.g., Ragavan, *supra* note 6, at 173.

85. *Farbwerke Hoechst & Bruning Corp. v. Unichem Lab.*, 1969 A.I.R. 56 (Bom.) 255.

86. *Id.* at 263.

87. *Id.* The sulphonyl ureas represented the general formula R-SO₂-NH-CO-NHR.1 in which R represented a phenyl radical with certain limitations in regard to the number of carbon atoms, and R.1 represented a hydrocarbon radical with certain limitations in regard to the number of carbon atoms as well. *Id.* at 264.

88. *Id.* at 264.

89. *Id.* at 263.

The Haffkine Institute, a public sector firm, produced tolbutamide from locally available raw materials and patented the process.⁹⁰ Tolbutamide was used to prepare a drug to reduce blood sugar.⁹¹ The patent for a new process of preparing tolbutamide was licensed to Unichem Labs, a domestic drug producer.⁹² Hoechst filed a suit claiming that the Haffkine patent for tolbutamide lacked novelty since tolbutamide was a by-product of Hoechst's 58716 patent.⁹³

The Bombay High Court verified that the compound tolbutamide was derived from carbutamide, a compound developed in 1955 with hypoglycaemic properties. Carbutamide, however, was withdrawn from the market by 1957 as being unsuitable for prolonged administration.⁹⁴ Hoechst's employee, Dr. Aumuller, removed the amino group in carbutamide and added a methyl group, thereby inventing tolbutamide, which eliminated the defects of carbutamide but preserved the hypoglycaemic properties.⁹⁵ Haffkine Institute, however, produced tolbutamide by desulphurizing benzene sulphonyl thioureas with hydrogen peroxide.⁹⁶ The processes followed by Haffkine and Hoechst to produce tolbutamide were totally different. In spite of the different processes, however, the Bombay High Court found in favor of Hoechst.⁹⁷ Haffkine's process of producing tolbutamide was held to infringe Hoechst's patent only because India, at that time, lacked procedural mechanisms to either limit Hoechst's protection or merely protect innovative processes of making known products.

Notably, the *Hoechst* case was decided in 1969 under the erstwhile Indian Patents and Designs Act of 1911, which embodied a product patent regime.⁹⁸ Once the product patent regime required by TRIPS is established, the operation of the patent regime will be similar to that of the 1911 patent law unless procedural mechanisms are established for protecting innovative processes. Interestingly, had Hoechst applied for a patent in the United States using the product-by-process claim to seek a patent, Haffkine's process would be considered non-infringing. Even if Hoechst did not use product-by-process claims, Haffkine's process could be considered non-infringing under 35 U.S.C. § 271(g), which provides that a "product which is made by a patented process will, for the purposes of this title, not be considered to be so made after—(1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product."⁹⁹

90. *Id.* at 258.

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.* at 268–69.

95. *Id.*

96. *Id.* at 258.

97. *Id.* at 273.

98. Indian Patents & Designs Act, 1911 (1929).

99. 35 U.S.C. § 271(g) (1994).

Unfortunately, developing countries lack the understanding of the complexities of the claiming mechanisms. They are unable to articulate a definitive form of protection or use the existing mechanisms to tailor an effective protection for their knowledge sources. For example, Swiss claims, available in Europe, can be used effectively to protect knowledge of medicinal uses derived from traditional knowledge sources of the indigenous people by construing the knowledge as analogous to either first or second medicinal use. An appropriately modified purpose-limited-product claim may be used to limit the scope of the protection to the *use* of indigenous material and enable the manufacture of medicaments for specified therapeutic applications. Complying with TRIPS could only increase the handicap. For example, while developed nations would facilitate protection of process innovations over known products, developing nations could be denied the luxury post-TRIPS due to the rudimentary patent procedures.¹⁰⁰

Intellectual property harmonization would enable developed nations to appropriate and protect information left unprotected in developing nations simply by using superior procedural techniques. Considering that developing nations have a niche in process innovations, research and development can be stunted by imposing a product-patenting regime without introducing adequate procedural mechanisms. Thus, the TRIPS patent policy by itself has the potential to result in increased inequality of intellectual property protection.

B. Claim Limitations & Protection of Minor Innovations

Procedural mechanisms, especially claims, enable the patent systems of developed nations to be more sophisticated by creating the flexibility to protect a wider range of inventions within the same product classification. Consequently, inventive activity is encouraged, resulting in inventions which are distinguished through functional or structural additions on existing products.¹⁰¹ For example, in *Dolly Inc. v. Spalding & Evenflo Cos.*,¹⁰² the patented device related to a portable and adjustable child's play chair with a stable rigid frame with a seat and back panel.¹⁰³ The claimed invention related to a portable and adjustable child's play chair, but it did not include a stable rigid frame in the claim language. Instead, the seat and back panel of the device fit together to form a rigid frame upon assembly.¹⁰⁴ The court applied the doctrine of equivalents to hold that a stable rigid frame assembled from the seat and

100. *But see* EPO GUIDELINES, *supra* note 65, at pt. C, ch. III, para. 4.7b (stating that a product is not rendered novel merely because it is produced by means of a new process).

101. *See generally* Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605 (1950); Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997) (discussing the doctrine of equivalents).

102. 16 F.3d 394 (Fed. Cir. 1994).

103. *Id.* at 396.

104. *Id.* at 397.

back panels was not the equivalent of a separate stable rigid frame set out in the claim language.¹⁰⁵ Thus the second child's play chair, which was a replica of the patented invention except for the singular feature of a rigid frame, was held to not infringe the patent. In effect, precise claiming furthers innovation by recognizing two similar products performing the same functions differentiated by merely one claim limitation (or sometimes more).

Similarly, in *In re Donaldson Co.*,¹⁰⁶ the patent related to "industrial air-filtering devices often referred to as 'dust collectors.'"¹⁰⁷ Claim 1 was an apparatus claim reciting an "air filter assembly for filtering air laden with particulate matter, said assembly comprising [a plurality of elements]."¹⁰⁸ On appeal, the patentee conceded that a single prior art reference (Swift) met every limitation in claim 1 except for the limitation of a "means, responsive to pressure increases in said chamber caused by said cleaning means, for moving particulate matter in a downward direction."¹⁰⁹ The Board held that the last limitation was also met by the prior art because Swift disclosed the recited function.¹¹⁰ On appeal the Federal Circuit considered the issue *en banc* and unanimously reversed the Board's decision.¹¹¹ The Federal Circuit held that if the prior art does not disclose the same structure, or an equivalent structure, the claim element is not literally met and the claim is not anticipated under § 102.¹¹² If the prior art does not render the claimed structure or its equivalent obvious, the claim is not obvious under § 103.¹¹³ In essence, two dust collectors that differed by only a single element were both patented. Thus, separate patents can protect products performing the same function and manufactured by the same or similar processes by the use of appropriate claims.

A system that has a product patent regime without complementary procedural foundations (like the one contemplated for the developing countries under the WTO) will effectively block the patenting of products within the same range. In the above examples, the patenting of one air-filtering device will effectively stop any other air filters from being patented. Similarly, the patenting of one child play chair may prevent improved chairs, even if safer, from being patented. Such a result can erode the incentive for further research and development. A product patent regime cannot be blindly thrust upon a nation unless there is an adequate understanding of the nuances of working that policy effectively by using the appropriate tools.

105. *Id.* at 400.

106. 16 F.3d 1189 (Fed. Cir. 1994).

107. *Id.* at 1190.

108. *Id.* at 1191 (internal references omitted).

109. *Id.* at 1192.

110. *Id.*

111. *Id.* at 1197.

112. *Id.*

113. *See id.* at 1196-97.

IV. DEVELOPED PRECEDENT

The following section examines efforts in the United States to promote the biotechnology (“biotech”) industry by using patent policies to demonstrate that patent procedures and doctrines create flexibilities within the product patent regime, thus facilitating industrial growth. The development of biotech patenting in the United States exemplifies the effective use of patent mechanisms to further industrial development. The patenting techniques adopted by the United States have furthered industrial development by fostering biotech patenting and then following it with a strong patent regime that sustains industrial development. Understanding the working of these procedural mechanisms may help developing countries in their post-TRIPS legislative attempts to draft patent policies.¹¹⁴

In 1980, *Diamond v. Chakrabarty*¹¹⁵ paved the way for the development of biotech industries by holding microorganisms patentable under 35 U.S.C. § 101.¹¹⁶ The protection offered in *Chakrabarty* enabled the establishment of the biotech industry.¹¹⁷ The invention in *Chakrabarty* was an oil-eating “bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.”¹¹⁸ *Chakrabarty* transferred camphor and octane degrading plasmids into a single *Pseudomonas* bacterium.¹¹⁹ The invention was meant to increase the efficiency of controlling oil spills.

Chakrabarty’s patent application claimed (1) the process of producing the bacteria, (2) the inoculums of carrier material (e.g., straw to float on water with the bacteria) along with the plasmid-injected *Pseudomonas*, and (3) the *Pseudomonas* itself.¹²⁰ The examiner allowed all the claims except for the claim on the bacteria, reasoning that microorganisms are products of nature and living things are not patentable subject matter under the Patent Act of 1952.¹²¹

The Supreme Court granted certiorari to hear the issue relating to the patentability of living matter.¹²² The Court succinctly determined that the relevant distinction for determining patentability was not between living and inanimate things, but between products of nature,

114. See TRIPS, *supra* note 2, at art. 27, para. 3.

115. 447 U.S. 303 (1980).

116. *Id.* at 309; 35 U.S.C. § 101 (2000) (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”).

117. BIOTECHNOLOGY INDUSTRY ORGANIZATION, IMPORTANCE OF INTELLECTUAL PROPERTY, (2004), at <http://www.bio.org/ip> (last visited Nov. 10, 2004).

118. *Chakrabarty*, 447 U.S. at 305.

119. *Id.* at 305 n.1.

120. *Id.* at 305–06.

121. *Id.* at 306.

122. *Id.* at 305.

whether living or not, and human-made inventions.¹²³ The Court highlighted that although the original *Pseudomonas* was a product of nature, the introduction of a new genetic material capable of degrading oil into the bacterium constituted an invention.¹²⁴ Thus, the Court posited the landmark proposition that all human creations resulting from genetic engineering, whether living or inanimate, were eligible for patent protection.¹²⁵

The mere availability of a clear policy providing patent protection for genetic engineering encouraged research and development.¹²⁶ The possibility of patent protection on genetic material created tremendous financial potential for biotech companies and encouraged biotech investments.¹²⁷ Thus, *Chakrabarty* marked the beginning of biotech advances. The biotech industry, particularly in the United States, was poised for cataclysmic changes after *Chakrabarty*.

By 1991, the Federal Circuit, through *Amgen v. Chugai*,¹²⁸ lowered the threshold for biotech patents, thereby encouraging the U.S. biotech industry to file more patent applications.¹²⁹ *Amgen* involved issues of patent validity and infringement with respect to two inventions involving erythropoietin.¹³⁰ U.S. Patent 4,703,008, owned by Amgen Inc., was entitled "DNA Sequences Encoding Erythropoietin," and it claimed "purified and isolated DNA sequences . . . encoding erythropoietin [and] host cells transformed or transfected with a DNA sequence."¹³¹

Genetics Institute, Inc. ("GI") held a product patent for erythropoietin compositions.¹³² Amgen accused GI and its partner Chugai of infringing Amgen's patent.¹³³ Amgen alleged that producing recombinant erythropoietin by transforming mammalian host cells containing vectors with DNA coding for creating human erythropoietin infringed its patent.¹³⁴ GI and Chugai counterclaimed that Amgen's patent was invalid under 35 U.S.C §§ 101, 102, 103, and 112.¹³⁵ The issue under § 102(g)¹³⁶ arose since the defendants alleged that their employee, Fritsch, was the first to conceive the invention in 1981 and was diligent until reducing the invention to practice in May 1984.¹³⁷ GI argued that

123. *Id.* at 303.

124. *Id.* at 305, 313.

125. *Id.* at 305; *see id.* at 318 (Brennan, White, Marshall, and Powell, JJ., dissenting).

126. *See* Geri J. Yonover, *What Hath (Not) Chakrabarty Wrought: From the Mouse That Roared to Hello Dolly and Beyond*, 32 VAL. U. L. REV. 349, 358 (1998).

127. *See id.*

128. 927 F.2d 1200 (Fed. Cir. 1991).

129. *See generally id.* at 1205-06.

130. *Id.* at 1203-04.

131. *Id.*

132. *Id.* at 1203.

133. *Id.* at 1204.

134. *Id.*

135. *Id.* at 1204-05.

136. 35 U.S.C. § 102(g) (1988).

137. *Amgen*, 927 F.2d at 1205-06.

Fritsch should be held as the prior inventor under § 102(g) over Lin, Amgen's employee, who reduced the invention to practice in 1983.¹³⁸

The court held that the conception of a chemical compound necessitates that the inventor have "a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it."¹³⁹ This idea was enunciated as the doctrine of simultaneous conception and reduction to practice.¹⁴⁰ Essentially, an invention reasonably conceived in the inventor's mind was capable of fulfilling the patentability requirements.¹⁴¹ Additionally, the court did not seek disclosure of the actual DNA sequence, but only that the DNA be "defined" in a manner distinguishing it from other chemicals, along with a description of how to obtain it.¹⁴² *Amgen* enabled patentability of an adequately described DNA although the inventor may be both unaware of its structure and nowhere near disclosing the actual structure.¹⁴³ The Federal Circuit's timely move in *Amgen* made biotech patents easier to obtain, thereby encouraging biotech research. All that was required for scientists to obtain patents was to adequately conceive the DNA sequence and appropriately describe the DNA, distinguishing it from the prior art with details on how to obtain it.

Standards for biotech patenting were further lowered in *In re Deuel*¹⁴⁴ by minimizing the nonobviousness requirement.¹⁴⁵ The *Deuel* court favored the applicants by reducing the obviousness standards from *Amgen* and redefining the legal test of prima facie obviousness.¹⁴⁶ The invention in *Deuel* related to isolated and purified DNA and cDNA molecules encoding heparin-binding growth factors ("HBGF").¹⁴⁷

138. *Id.*

139. *Id.*

140. *Id.* at 1206–07. The court held that conception is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Id.* The doctrine of simultaneous conception and reduction to practice evolved to determine priority of invention. An inventor may be unable to establish conception until the invention has been reduced to practice through experimentation. *Id.*

141. *Id.* at 1209.

142. *Id.* at 1206.

143. *Id.* (requiring merely that the DNA sequence be disclosed in a manner that sufficiently distinguishes it; the DNA sequence could be defined by its actual structure as well as its method of preparation).

144. 51 F.3d 1552 (Fed. Cir. 1995).

145. *Id.* at 1559–60. *Deuel* isolated and purified HBGF from bovine uterine tissue, and determined the first twenty-five amino acids of the N-terminal sequence. *Deuel* then isolated cDNA encoding for the bovine HBGF by screening the bovine DNA library with an oligonucleotide probe. *Deuel* purified the cDNA and found that its sequence consisted of 1196 nucleotide base pairs. The bovine cDNA was then used as a probe to isolate and purify human placental HBGF. *Deuel* isolated, purified, and then determined the sequence of the human placental cDNA which consisted of 961 nucleotide base pairs. With this knowledge, *Deuel* predicted the complete amino acid sequence of the human placental HBGF. *Id.* at 1555.

146. *Id.* at 1557–60; see also *In re Bell*, 991 F.2d 781, 784–85 (Fed. Cir. 1993).

147. *Deuel*, 51 F.3d at 1555. The court also stated that the claims on appeal were independent. *Id.*

HBGFs stimulate mitogenic activity and facilitate repair of damaged tissue.¹⁴⁸ The patent examiner cited a combined teaching of the Bohlen and Maniatis prior art references to reject Deuel's application as *prima facie* obvious under § 103.¹⁴⁹ The court considered "whether the combination of a prior art reference teaching a method of gene cloning, together with a reference disclosing a partial amino acid sequence of a protein, may render DNA and cDNA molecules encoding the protein *prima facie* obvious under § 103."¹⁵⁰ Structural claims were used in the patent application.¹⁵¹ The court agreed that structural similarity between the compounds in the prior art and the claims may provide a basis for an obviousness rejection by establishing a motivation to make the claimed compound.¹⁵² The court added, however, that although a general method of isolating DNA molecules is known, a specific DNA molecule isolated is *prima facie* nonobvious and patentable.¹⁵³ Thus, the court rendered genes isolated from well-known and obvious methods as "nonobvious" and thereby patentable.

The *Amgen* decision rendered an adequately conceived DNA patentable. The *Deuel* decision made obviousness rejections for biotech patents scarcer.¹⁵⁴ *Deuel* also enabled patenting of miniscule inventions by lowering the obviousness bar.¹⁵⁵ Economically, the lowering of the obviousness standard boosted the biotech companies.¹⁵⁶

On the one hand, based on prior art knowledge, the biotechnologists know that sequencing around twenty amino acids is sufficient to obtain the cDNA sequence that codes for a particular protein, absent unforeseen difficulties. On the other hand, under current law, the expected product of this scientifically obvious manipulation is legally unobvious and thus patentable.¹⁵⁷

The lowering of the non-obviousness requirement reduced the minimum threshold that social value inventions were required to contribute to make it worth the trouble of issuing and enforcing a patent. It resulted in biotech companies patenting minor inventions and overclaiming all innovations.¹⁵⁸ The benefit was that it led to several

148. *Id.* at 1554.

149. *Id.* at 1555-56.

150. *Id.* at 1557.

151. *Id.*

152. *Id.*

153. *Id.* at 1559 ("The existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggests the claimed DNAs.").

154. Shradha A. Upadhyaya, *The Postmodern Written Description Requirement: An Analysis of the Application of the Heightened Written Description Requirement to Original Claims*, 4 MINN. INTEL. PROP. REV. 65, 107-09 (2002).

155. *Id.* at 107-08.

156. *See id.* at 109; Sara Dastgheib-Vinarov, *A Higher Nonobviousness Standard for Gene Patents: Protecting Biomedical Research from the Big Chill*, 4 MARQ. INTEL. PROP. L. REV. 143, 178 (2000).

157. Anita Varma & David Abraham, *DNA Is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market*, 9 HARV. J.L. & TECH. 53, 78 (1996).

158. *See Dastgheib-Vinarov, supra* note 156, at 143.

innovations and inventions in biotech and pharmaceuticals. *Deuel* greatly facilitated the United States' growth in biotech patent applications and allowed it to prosper from a rapidly growing biotech industry.¹⁵⁹ *Deuel* together with *Chakrabarty* enhanced the proliferation of intellectual property rights in biomedical research. However, the disadvantage was the underutilization of the resources because too many patent owners blocked each other.¹⁶⁰ The biotech industry was faced with a "spiral of overlapping patent claims in the hands of different owners."¹⁶¹ These realities mandated that the free-for-all biotech patent applications be capped.¹⁶² The cap came in the form of the heightened written description requirement in *Regents of the University of California v. Eli Lilly & Co.*¹⁶³ In an effort to limit the overly broad biotech patents created by *Deuel*, the Federal Circuit decided in *Eli Lilly* to heighten the written description requirement.¹⁶⁴ Thus, the Federal Circuit made a deliberate and conscious effort to slow the race for biotech patents that had been made easier by previous decisions.¹⁶⁵ In the 1990 case, the University of California brought a suit against Eli Lilly alleging infringement of two patents relating to recombinant DNA technology.¹⁶⁶ Specifically, the patents related to recombinant plasmids and microorganisms that produce human insulin.¹⁶⁷ The '525 patent, issued from a 1977 application, related to proinsulin and preproinsulin cDNA sequences in rats.¹⁶⁸ The '740 patent, issued from a 1979 patent application, related to the "cDNA sequences"¹⁶⁹ and the development of 'tailoring' techniques for the incorporation of the human [proinsulin] cDNA into a recombinant plasmid.¹⁷⁰ The district court ruled that claims 1, 2, and 4-7 in the '525 patent were invalid under §112, ¶1,

159. Upadhyaya, *supra* note 154, at 109 ("The *Chakrabarty* and *Deuel* decisions . . . spur[red] biotechnology innovation and progress.")

160. See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anti-Commons in Biomedical Research*, SCI. MAG., May 1, 1998, at 698, available at <http://www.sciencemag.org/cgi/content/abstract/280/5364/698>.

161. *Id.*

162. *Id.* at 698-99; see also Dastgheib-Vinarov, *supra* note 156, at 165, which states:

[B]etween 1990 and 1998, the total number of [biotechnology] patents granted to U.S. corporations has quadrupled. In contrast, between 1990 and 1998, the total number of patents issued increased by about sixty percent. This large disparity is cause for concern. It suggests that the biotechnology industry is using the relaxed nonobviousness standard to obtain genomic patents simply for corporate gain.

163. 119 F.3d 1559 (Fed. Cir. 1997); see Upadhyaya, *supra* note 154, at 109.

164. *Eli Lilly*, 119 F.3d at 1567.

165. *Id.* at 1566-69.

166. *Id.* at 1562.

167. *Id.* A person unable to produce insulin suffers from diabetes. Prior to recombinant technology for producing human insulin to treat diabetes, animal insulin was used, which caused allergic reactions. *Id.*

168. *Id.*

169. The patent covered human proinsulin and preproinsulin. *Id.* at 1563.

170. *Id.* Eli Lilly produced human proinsulin by using "semi-synthetic DNA to yield a cleavable fusion protein." *Id.* The produced fusion protein "consists of a bacterial protein, a 'cleavable linkage' consisting of a single methionine residue and human [proinsulin]." *Id.* The human proinsulin was obtained by cleaving it from the fusion protein. *Id.*

because the specification did not provide an adequate written description of the cDNA covered in the claims.¹⁷¹ The Federal Circuit affirmed, basing its holding upon lack of written description.¹⁷²

The Federal Circuit held that for claims relating to genetic material, “a generic statement such as ‘vertebrate insulin cDNA’ or ‘mammalian insulin cDNA,’ . . . is not an adequate written description of the genus.”¹⁷³ Such a written description “does not distinguish the claimed genus from others, except by function.”¹⁷⁴ The Federal Circuit required that genes be specifically defined along with distinguishing structural features of the genus.¹⁷⁵ It was here that the court articulated the “precise definition” test.¹⁷⁶ The Federal Circuit held that a specification should have an adequate written description of a DNA molecule with “a precise definition, such as by structure, formula, chemical name, or physical properties,” not a mere wish or plan for obtaining the claimed chemical invention.¹⁷⁷ Finally, the Federal Circuit held that “[w]ithout the heightened specificity requirement, a genus defined entirely by function fails to establish an adequate written description of the specification.”¹⁷⁸

Earlier the Federal Circuit in *Fiers v. Revel*¹⁷⁹ had “created an exception to the rule that a claim included in the application cannot be rejected for lack of description.”¹⁸⁰ The *Fiers* court emphasized on specificity by holding that “[w]hile one does not need to have carried out one’s invention before filing a patent application, one does need to be able to describe that invention with particularity.”¹⁸¹ Thus, the court in *Eli Lilly* used the *Fiers* rule effectively.

The U.S. patent policy on biotech patenting since the 1980s has been uniformly stringent. The intervention by the Federal Circuit in fine-tuning application requirements, in effect, diluted the stringency of the policy and facilitated investments. When biotech investments increased, the United States raised the application standards to streamline biotech patents. Procedural requirements were used to induct the required flexibility into the seemingly stringent patent policy to achieve the required industrial growth. Without amending the policy, the patenting bar that was reduced in *Deuel* was increased in *Eli Lilly* using the written description requirement. In summary, *Chakrabarty* facilitated the establishment of biotech industry; *Deuel* promoted proprietary rights

171. *Id.* at 1566.

172. *Id.* at 1562.

173. *Id.* at 1568.

174. Karczewski, *supra* note 17, at 1078 (quoting *Eli Lilly*, 119 F.3d at 1568).

175. *Eli Lilly*, 119 F.3d at 1566–67 (quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)) (“A definition by function . . . does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.”); *see also* Karczewski, *supra* note 17, at 1078–79.

176. *Eli Lilly*, 119 F.3d at 1566.

177. *Id.* at 1566–67 (quoting *Fiers*, 984 F.2d at 1171).

178. *Id.*; *see also* Karczewski, *supra* note 17, at 1078.

179. 984 F.2d 1164 (Fed. Cir. 1993).

180. ADELMAN, *supra* note 8, at 611.

181. *Fiers*, 984 F.2d at 1169.

that benefited the biotech industry; and *Eli Lilly* streamlined the industry by ultimately regulating the free-for-all biotech patents.

Therein lays the model for developing countries for inducing clarity and vision that will focus policies on national needs. TRIPS advocates the application of a harmonized patent policy for developing countries. These countries are at the crossroads of development and need flexibility in sectors with industrial growth. Since developing countries are new to the workings of patent policies, they are unaware of the various modes of creating flexibility within systems. Much to their disadvantage, developing countries are more likely to use the TRIPS patent policy without fully exploiting the opportunities to use such flexibility. Developing countries need to understand that amendments made in compliance with international treaties should incorporate appropriate standards and procedures to retain the national focus of the policies.

V. CONCLUSION

If developing nations lack the procedural pillars to support the structure of patent policies, certain inventions and innovations will be denied patent protection. Thus, harmonizing patent systems without the supporting procedural backup will not create the economic incentive for which developing nations embraced TRIPS. Domestic industries will be encouraged to invest when local inventions become protected. In turn, third world governments will be provided with an incentive to take a stronger stance against intellectual property infringements.¹⁸² Developing nations, if unable to effectively protect local innovations, may reduce research and development initiatives. Demanding recognition for the intellectual property of the developed nations without educating developing nations on corresponding mechanisms to protect local innovations will weaken government willingness to enforce intellectual property laws strictly. The government's willingness to enforce is one of the key factors for intellectual property harmonization since conscious government involvement is required to reject the industrial bases offered by counterfeit markets.¹⁸³ The solution for intellectual property harmonization lies in adequately equipping developing nations with appropriate tools to promote growth by encouraging local invention.¹⁸⁴ Unfortunately, patent harmonization will

182. See generally *In Praise of the Real Thing*, THE ECONOMIST, May 17, 2003, at 12.

183. *Id.* The strongest proponents of intellectual property rights, Europe and the United States, built their industrial base a century ago by copying others. *Id.* See also Ruth Gana Okediji, *Copyright and Public Welfare in Global Perspective*, 7 IND. J. GLOBAL LEGAL STUD. 117, 123, 136 (1999).

184. There are several examples to prove that industrialization improves intellectual property protection. The embracing of copyright laws by the Indian computer industry is a case in point. Once the Indian computer industry realized its global competence, it canvassed the government for intellectual property legislation. See A.K. CHAKRAVARTI, *Protecting Proprietary and Security Rights in Cyberspace: Initiatives in India*, at http://www.unesco.org/webworld/infoethics_2/eng/papers/paper_15.htm (last visited Nov. 10, 2004). The computer industry in India aided the government in

ultimately suffer unless developing countries can benefit from it. Otherwise, even developing countries that amend patent legislation to become TRIPS compliant will relax implementation.

amending the copyright legislation to suit industrial needs. *Id.* See also *Imitating Property Is Theft*, THE ECONOMIST, May 17, 2003, at 54 (noting that until Japan became industrialized, it was the hot spot for counterfeit products in the 1960s, followed by Hong Kong in the 1970s, and Taiwan and South Korea in the 1980s; significantly, industrialization had a direct correlation with these countries clamping down on intellectual property infringement).