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Patent Judicial Wisdom

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Recommended Citation

Srividhya Ragavan, *Patent Judicial Wisdom*, 20 Nat'l L. Sch. India Rev. 165 (2008).

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PATENT JUDICIAL WISDOM

Srividhya Ragavan*

The project of harmonisation of patent laws around the world under the aegis of the TRIPS Agreement has interacted with national policies and objectives in respect of patents in both developed and developing countries. This interaction has been mediated through the judiciary and the pervasive influence of the judiciary has been essential for the success enjoyed so far. However, the localised perspectives of the judiciary have also hindered the global project of harmonisation to a significant extent as divergent standards and approaches have come forth in spite of similar statutory foundations. This article seeks to analyse specific illustrations that highlight the interplay between harmonisation and localisation in patent laws in developed and developing countries as mediated through the judiciary.

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I. INTRODUCTION

In the milieu of the thoroughly researched Ayyangar Report, the Patents Act of 1970 was a carefully crafted piece of legislation with ambitions to achieve national objectives.¹ The health care needs of the Indian citizens formed the background that prompted the enacting of the statute. In contrast, the patent law amendments patches executed in India from 1999 are the by-product of international pressure and reflect an international trade agenda. The minimum standards outlined under the TRIPS agreement have set the background of the

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1. The Patents Act, 1970.

recent patent law amendments. Thus, these patent law amendments represent India unleashed in the international arena – an India ready to address issues that allegedly clog international trade relating to patented technology. Yet, the patent statute as it exists in India requires clarity on the standards as well as the governing procedures applicable to patents. Such clarity is vital for India to steer the patent law amendments towards a balance between national objectives and international obligations. The key question, now, is to determine which body – patent office, judiciary, or legislature – shall be responsible for bringing clarity and vision to the patent policy that is currently instituted out of a commitment to fulfil international obligations. This question is not unique to India – other countries have faced similar issues. For instance, in the 1980s, when concerns arose with respect to lack of uniform standards for patents and the global competitiveness of the United States, the solution from the legislature involved the judiciary.² Consequently, a centralized court was established to hear patent cases - the Court of Appeals for the Federal Circuit (hereinafter, CAFC).³ It is the CAFC that has been instrumental in charting the highly pro-patent course of the US patent regime.⁴ In India too, the author believes, it is the judiciary that would and should be entrusted with the task of moulding a patent regime that suits its national objectives. Thus, the burden of developing India's patent policy in context of India's national objectives lies with the Indian judiciary.

In India, the challenge of developing patent policy is subject to one important limitation - the Constitution of India. The values in the Constitution obligate India to balance economic values with social needs.⁵ The balance between economic and social development is critical for India to maintain and improve upon its growing reputation and status in the world. Otherwise, a contemporary patent regime disconnected with local realities would merely lead to further marginalization of the poor. Similarly, affordable health care, an area likely to be affected by the patent regime, is essential for India to maintain its niche capital – labour. The promotion of innovation is also important to move towards the next stage of the development paradigm.

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2. A.B. JAFFE & J. LERNER, *INNOVATION AND ITS DISCONTENTS* 4 (2004).
 3. Commission on Revision of the Federal Court Appellate System, *Structure and Internal Procedures: Recommendations for Change*, 67 F.R.D 195 (1975). See United States Court of Appeals for the Federal Circuit, available at <http://www.cafc.uscourts.gov>.
 4. See JAFFE & LERNER, *supra* note 2, at 16, 18.
 5. INDIAN CONST. art. 39(b):
“The State shall, in particular, direct its policy towards securing –
(b) that the ownership and control of the material resources of the community are so distributed as best to subserve the common good.”

This paper discusses the role of the Indian Judiciary vis-à-vis the patent regime, but carefully avoids creating an exhaustive wish list. Instead, this paper uses illustrations from the United States to draw valuable lessons. Importantly, the paper does not advocate that the Indian Judiciary emulate the United States judiciary. In fact, conventional wisdom dictates that copying the policies or precedents of the West does not always work in developing countries given the stark differences in ground realities like poverty, investments, infrastructure, and other such indicators. Instead, the judicial wisdom that characterises each of the illustrations sets the common thread for the paper. The lesson lies in appreciating the wisdom with which courts abroad have spearheaded amendments and set standards for the patent regimes to achieve national objectives. Thus, this paper is a compendium of stories outlining the role of the judiciary and its effects in promoting, streamlining, or even disrupting the patent regime.

II. ILLUSTRATION 1: DEVELOPMENT OF THE AMERICAN BIOTECHNOLOGY PATENT REGIME

The story of the American judiciary's role in fostering biotechnology cannot be fully understood unless contrasted with what happened in Europe. In the 1960s Europe faced the issue of patentability in modern biotechnology when a German pigeon breeder sought a patent on a method of breeding a dove with "a considerably larger" red plumage.⁶ In refusing to grant a patent, the *Bundesgerichtshof* (German Federal Supreme Court) explained that breeding was biological, rather than technical because there was no guarantee of "reproducibility".⁷ Patentability required the "technical nature" of the invention to control natural forces and achieve a predicted result.⁸ The *Bundesgerichtshof* reemphasized the "reproduction"

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6. *Rote Taube* IIC 01/1970 at 136, 137. (Judgment of March 27, 1967, *Bundesgerichtshof*, 52 *Bundesgerichtshof* in *Zivilsachen* [BGHZ] 74 (*Rote Taube*)). A single patent claim sought protection for crossing an *Altdeutscher Kröpfer* with a *Rote Römertaube*. The doves resulting from the selection were crossed with a *Roter Hessenkröpfer*, and then with an *Altdeutscher Kröpfer*.
 7. *Rote Taube*, at 141. The court explained that the German Patent Act § 2(2) explicitly denied patent protection for plant or animal varieties, or essentially biological processes for the production of plants or animals. Arguably, the court's ruling implied that replicable biotechnological inventions can be patented. See A. Schrell et al., *Biotechnology Patenting Policy in the European Union – as Exemplified by the Development in Germany*, 107 *ADV. BIOCHEM ENGIN/BIOTECHNOL.* 13 (2007), available at <http://www.ncbi.nlm.nih.gov/pubmed/17522818>.
 8. *Rote Taube*, at 140. The court added that inventions should comprise "instruction[s] to [a] systematic acting, by utilizing controllable natural forces to achieve a causally predictable result".

requirement in 1975 to refuse patent protection for a new mutant of baker's yeast that produced beneficial results in bakery products.⁹ Consequently, biotechnology innovations remained unpatentable in Germany. During the 1970s and 1980s, in some European nations, particularly Germany, a distrusting and even hostile attitude prevailed towards biotechnology and, in particular, towards genetic engineering.¹⁰

While Europe was fraught struggling with the patentability of biotechnology innovations, Anand Chakrabarty a doctorate from the University of Calcutta, landed in the United States for his post-doctoral work as an associate at the University of Illinois.¹¹ In the United States, Chakrabarty studied the ability of the *pseudomonas* bacteria to use a wide variety of organic compounds as a source of nutrition.¹² During that period, he discovered that the genes that allowed the bacteria to digest compounds such as camphor and octane (which did not reside on the chromosome) resided on separate DNA elements – plasmids – that are transmissible from one bacterium to another.¹³ Much later, as an employee of General Electric, it dawned on Chakrabarty that this ability of the *pseudomonas* bacterium could be used to convert oil (which was then cheap) into biomass.¹⁴ Since crude oil was a mixture of different hydrocarbons, Chakrabarty needed a mixed culture of strains to degrade more components.¹⁵ Soon, Chakrabarty constructed a *pseudomonas* strain with multiple plasmids.¹⁶ Thus, the first oil eating bacterium was born. The invention, as filed for a patent, consisted of genetically transferred (camphor and octane degrading) plasmids into a single *pseudomonas* bacterium to degrade crude oil.¹⁷ Chakrabarty's patent application claimed patents on (1) the process of producing the bacteria, (2) the inoculum of carrier material (e.g., straw to float on water with the bacteria) along with the plasmid-injected *pseudomonas*, and (3) the *pseudomonas* itself.¹⁸

9. See *Bakers Yeast* IIC 02/1975; *Bakers Yeast*, Case X ZB 4/74, 208-211 (1975).

10. See A. Schrell et al., *Biotechnology Patenting Policy in the European Union – as Exemplified by the Development in Germany*, 107 ADV. BIOCHEM. ENGIN/BIOTECHNOL. 13 (2007), available at <http://www.ncbi.nlm.nih.gov/pubmed/17522818>.

11. R.S. Eisenberg, *The Story of Diamond v. Chakrabarty: Technological Change and the Subject Matter Boundaries of the Patent System* in INTELLECTUAL PROPERTY STORIES 327-357 (J. C. Ginsburg & R.C. Dreyfuss eds., Foundation Press 2006).

12. *Ibid* at 332.

13. Eisenberg, *supra* note 11.

14. Eisenberg, *supra* note 11.

15. Eisenberg, *supra* note 11.

16. Eisenberg, *supra* note 11, at 333.

17. *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1972).

18. *Diamond*, 447 U.S. 303, 305 (1972).

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The patent examiner at the USPTO allowed all claims except for the bacteria on the reasoning that “micro-organisms are products of nature and living things are not patentable subject matter under section 101 of Title 35 of the U.S.C.”¹⁹

Section 101 of Title 35, the operative provision, highlights that

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 therefore, subject to the conditions and requirements of this title.²⁰

When Chakrabarty appealed, the larger question for determination was whether micro-organisms fall within the ambit of “manufacture” or “composition of matter” in § 101 of Title 35. If so, the micro-organism would be patentable. It is important to note that the distinguishing feature of the invention was that the subject matter was a non-naturally occurring product of human ingenuity.

By the time the USPTO's rejection of the patent application reached the Court of Customs and Patent Appeals (CCPA – the predecessor of the CAFC), commercial biotechnology was becoming a significant area of research.²¹ By the time the Supreme Court considered the case in 1979,²² researchers had successfully “used recombinant DNA technology to clone medically important genes in microorganisms”.²³ In fact, Genetech Inc., the biotech company which cloned the first human insulin in 1978, in its *amicus* brief to the Supreme Court asserted that any controversy with respect to biotechnology was “misleading and irrelevant”.²⁴ Further, Genetech added that:

Against a backdrop of active promotion of such research by European governments and concern over possible loss of this country's

19. *Diamond*, 447 U.S. 303, 305 (1972).

20. 35 U.S.C. §101.

21. *In Re Chakrabarty*, 571 F.2d at 40. The defendant appealed USPTO's decision to the Court of Customs and Patent Appeals (CCPA). The CCPA's decision was vacated by a *certiorari* and then the case was remanded to the CCPA. *See Application of Chakrabarty*, 596 F.2d at 952.

22. The government filed for *certiorari* for *Chakrabarty* and *In Re Bergy* – another case that raised similar issues. After the petition was granted, the applicant in *Bergy* cancelled his claims to the micro-organism. Hence, the court merely considered the *Chakrabarty* issue. *See Diamond v. Chakrabarty*, 444 U.S. 1028 (1980).

23. *See Eisenberg*, *supra* note 11, at 348.

24. Brief on Behalf of Genetech Inc as *amicus curiae* at 10 (Filed Jan 28, 1980).

technological lead in the area, a spokesman for Congress' Office of Technology Assessment has suggested that "government's stance may change from regulation to promotion" of the science.²⁵

The Supreme Court, in considering the issue relating to the patentability of living matter, held that the relevant distinction for determining patentability was not between living and inanimate things but between products of nature, whether living or not, and human-made inventions.²⁶ The Court differentiated between the original *pseudomonas* that were a product of nature, and the introduction of a new genetic material capable of degrading oil into the bacterium that constituted an invention.²⁷ Thus, the Court posited the landmark proposition that all human creativity, irrespective of living or otherwise, was eligible for patent protection.²⁸

By holding micro-organisms patentable under 35 U.S.C. §101, *Diamond v. Chakrabarty*²⁹ paved the way for the development of the biotechnology industry. The availability of patent protection for genetic engineering, encouraged research and development and marked the beginning of a new era in biotechnology advances.³⁰ The Supreme Court's decision created tremendous a financial potential for biotechnology companies, that in turn encouraged investment.³¹ Lila Feisee, BIO's Director for Federal Government Relations and Intellectual Property, highlighted that with the help of the Supreme Court decision in *Diamond v. Chakrabarty* and the Bayh-Dole Act, the biotechnology industry had sky-rocketed.³² Due to the forethought of the judiciary, the biotechnology industry, particularly in the United States, was poised for cataclysmic changes after *Chakrabarty*.

Several countries followed the *Chakrabarty* lead. Countries like Canada, for instance, took the cue from *Chakrabarty* but created its own statutory interpretations to suit national requirements. After the *Chakrabarty* decision, the Canadian patent

25. *Ibid.* at 11.

26. *Diamond*, 447 U.S. 303, at 305, 311-313 (1972).

27. *Diamond*, 447 U.S. 303, at 305, 317 (1972).

28. *Diamond*, 447 U.S. 303, at 305, 318 (1972) (Justices Brennan, White, Marshall, and Powell dissented).

29. *Diamond*, 447 U.S. 303, at 305, 311-313 (1972).

30. G. Yonover, *What Hath (Not) Chakrabarty Wrought: From The Mouse That Roared To Hello Dolly And Beyond*, 32 VAL. U.L. REV. 349, 358 (1998).

31. *Id.*

32. L. Feisee, speech titled "*Anything Under the Sun Made by Man*", available at <http://www.bio.org/speeches/speeches/041101.asp> (2001). (Director for Federal Government Relations and Intellectual Property of the Biotechnology Industry Organization discussing the patent's contribution to the development of biotech industry).

office dealt with a patent application concerning a genetically engineered mouse (Harvard OncoMouse) containing an additional gene that makes the mice more susceptible to cancer.³³ The Harvard OncoMouse had already been granted patent protection in the United States.³⁴ In considering that the Oncomouse was patented in the United States and Europe, the Canadian Appeals Court prioritised the uniformity of patent law and held that Canada should also follow suit.³⁵ Commentators have opined that economic pressure to promote the biotechnology industry in Canada might have played a hidden role in the decision.³⁶ At that time, Canada hosted the “second-largest biotechnology industry in the world”, and the absence of patent protection for biotechnology embodied the danger of hindering research and investment.³⁷

Set in this background, it is the decision of the Supreme Court of Canada that provides an important lesson. Unlike the Appeals Division, the Supreme Court of Canada posited public interest considerations ahead of economic issues.³⁸ “Parliament” declared the Supreme Court of Canada, “did not intend higher life forms to be patentable” under the Canadian Patent Act.³⁹ Hence, the Court declared that the OncoMouse was an unpatentable subject matter.⁴⁰

Canada and Europe are not the only examples of nations influenced by the *Chakrabarty* decision. In fact, it is arguable that the *Chakrabarty* buzz caused the Calcutta High Court in India to take the lead in *Dimminaco AG*⁴¹ to protect biotechnology inventions. When a patent was denied the process of manufacturing a vaccine for infectious bursitis in poultry, *Dimminaco AG* appealed the Patent Office decision under section 116 of the Indian Patent Act, 1970.⁴² On appeal, the Calcutta

33. M. Kamber, *Coming out of the Maze: Canada Grants the Harvard Mouse Patent*, 35 *Geo. WASH. INT'L L. REV.* 761 (2003).

34. U.S. Patent No. 4,736,866 (1988).

35. *President and Fellows of Harvard College v. Commissioner of Patents* (2000) 4 F.C. 528 (Can.). See Kamber, *supra* note 33, at 761.

36. See Kamber, *supra* note 33, at 780.

37. Kamber, *supra* note 33, at 780.

38. *Harvard College v. Canada (Commissioner of Patents)*, (2002) 4 S.C.R. 45 (Can.). See Kamber, *supra* note 33, at 780, 781.

39. Kamber, *supra* note 33, 780, 781.

40. Kamber, *supra* note 33, 780, 781.

41. *Dimminaco A.G. v. Controller of Patents Designs*, 2002 I.P.R.L. 255 [Calcutta High Court].

42. See *Kolkata High Court Quashed Patent Controller's Order On Dimminaco AG's Bursitis Vaccine*, available at <http://www.bionews.net/5/0/9/INDEX.HTM>.

High Court held that the definition of “manufacture” in section 2 of the Indian Patent Act, 1970 did not place a statutory bar on the patentability of living organisms.⁴³ In holding in this manner, *Dimminaco AG*⁴⁴ opened India to the world of biotechnology patents.⁴⁵

At the time *Dimminaco AG* was decided, India reserved the right to deny patent protection if the primary or intended use of the invention was contrary to morality or is injurious to public health.⁴⁶ Although no Indian case has addressed the law and morality of the patentability of biotechnology, the “law or morality” phrase in section 3 presumptively raises issues of patentability of biotechnology materials. In reality, the Patents Act, 1970 did not exclude biotechnology patents, but they were never granted. The Patents Act, 1970 in section 2(j) defined inventions as (i) art, process or manner of manufacture, (ii) machine, apparatus or other article, and (iii) substance produced by manufacture.⁴⁷ The Patent Office limited patentability to “manufactured material or substances”, and considered “living organisms” as falling outside the scope of that definition.⁴⁸ Just before the May 2002 *Dimminaco AG* decision, the South African AIDS crisis highlighted the importance of the Indian generic drug industry and its biotechnology potential to the world.⁴⁹ Therefore, the same logic that had applied to the American judiciary to promote biotechnology applied to India as well (subject to considerations of national variations like access to medication). *Dimminaco AG* is a great beginning not because it allowed biotechnology patents, but because it opened up the biotechnology sector at a time when India’s potential in biotechnology was becoming well known around the world.

43. *See Manufacture Applies To Living Organism; HC – Boost To Biotech Patenting*, BUSINESS LINE, available at <http://www.patentmatics.com/news2002/news25.htm> (discussing that patentability requirements like “novelty” were satisfied by the process for preparation, and “utility” was satisfied by the vaccine’s protection against contagious bursitis infection in poultry).

44. *Dimminaco*, 2002 I.P.R.L. 255, 259 [Calcutta High Court].

45. *Dimminaco*, 2002 I.P.R.L. 255, 258 & 293 [Calcutta High Court]. Justice Ashok Ganguly quashed the Controller’s order and directed a reconsideration of the application. The Central Government decided not to challenge the ruling; thus, the judgment of the Calcutta High Court is the authority in India on the issue of biotechnology patents.

46. The Patents Act, 1970.

47. The Patents Act, 1970.

48. Section 2(j), Patents Act, 1970 reads: “The definition of invention includes (i) art, process or manner of manufacture, (ii) machine, apparatus or other article, (iii) substance produced by manufacture”.

49. *See J. Slater, Indian Pirates Turn Partners: Once Copycats, Its Drug Makers Emerge As Industry Power Houses*, WALL ST. J., Nov. 13, 2003, at A14.

III. ILLUSTRATION 2: JUDICIARY KEEPING THE PATH CLEAR FOR BIOTECHNOLOGY PATENTING

Judicial interpretations, which outline the second illustration, are naturally influenced by national cultural, social and economic norms. Even in the developed world, the judiciary has had to deal with moral and ethical concerns in biotechnology patents. For example, before the European Patent Office (EPO)⁵⁰ could examine a patent application for the genetically engineered Harvard OncoMouse,⁵¹ it had to deal with massive protests across Europe that delayed the prosecution of the application.⁵² More than two hundred organizations, including animal welfare groups, environmental organizations, and religious societies, had opposed the application on moral and ethical grounds.⁵³ Similarly, in the case of *Relaxin*,⁵⁴ a patent application for the DNA fragment encoding human H2-relaxin (and its precursors) was opposed as offending the provisions of “morality” and “*ordre public*” in Article 53(a) of the European Patent Convention.⁵⁵ The extraction of the DNA encoding the *relaxin* gene, for which the patent was sought, from the tissue of a pregnant woman, was alleged to be immoral, and constituting an offence against human dignity.⁵⁶ In dealing with the question, the EPO clarified that the “morality” requirement of Article 53(a) of the European Patent Convention is violated if “the public would regard the invention as so abhorrent that the grant of patent rights would be inconceivable”.⁵⁷ The patent was eventually granted for *relaxin*, although the decision introduced an element of subjectivity in determining

50. E.P.O. O.J. 6 (1977).

51. Harvard/Onco-Mouse T 0019/90; See 1990 O.J. E.P.O. 476 (Tech. Bd. App.) (1990); Eur. Pat. Off. Rep. 501, 502. The Harvard Onco-Mouse is the first case where the E.P.O. approved patenting a transgenic mammal by holding that the E.P.C. does not exclude the patenting of animals as a category *per se*.

52. See D.M. Gitter, *International Conflicts Over Patenting Human DNA Sequences In The United States And The European Union: An Argument For Compulsory Licensing And A Fair-Use Exemption*, 76 N.Y.U.L. REV. 1623, 1647 (2001).

53. See D.M. Gitter, *Led Astray By The Moral Compass: Incorporating Morality Into European Union Biotechnology Patent Law*, 19 BERKELEY J. INT'L. L. 29 (2001).

54. Howard Florey Institute v. Fraktion der Gronen im europCischen Parlament, V0008/94.

55. Howard Florey Institute v. Fraktion der Gronen im europCischen Parlament, V0008/94.

56. Howard Florey Institute v. Fraktion der Gronen im europCischen Parlament, V0008/94.

57. The European Patent Convention (hereinafter, EPC) created a bundle of European patent rights with effect in European countries designated by the applicant. Article 53 of the EPC specifically discusses “exceptions to patentability”. Article 53(a) exempts from patentability inventions that affect “morality” and *ordre public* as follows:

the issues of morality in patentability. While it is arguable that morality discussions prevented Europe from forging a strong biotechnology patent regime,⁵⁸ it is equally true that economic issues notwithstanding, courts cannot shy away from confronting issues of local importance.

In the United States too, the judiciary was confronted with the moral and ethical concerns regarding the patenting of living organisms, which were raised by the Animal Defense Fund, a non-profit organization comprising several individual farmers.⁵⁹ The Federal Circuit reasoned that under Article III, §2 of the United States Constitution, *locus standi* is established⁶⁰ only for parties with either a threat of personal injury or an actual personal injury.⁶¹ The alleged injury to farmers as a class, the Federal Circuit held, was due to increased competition from commercialization of genetically improved animals and not from the grant of patents.⁶² Since the appellants asserted no other adverse effects on any individual rights under the patent, the suit was dismissed for lack of standing.⁶³ Thus, the CAFC's refusal to indulge into the ethical and social policies underlying patenting of living organisms enabled the U.S. to steer clear of questions that caused a furore in Europe, thus maintaining the focus on promoting biotechnology.⁶⁴ In effect,

[I]nventions the publication or exploitation of which would be contrary to "*ordre public*" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.

58. See Gitter, *supra* note 52, at 1653, 1654. For example, British researchers collaborating with Americans, as part of an international team of scientists, ceased working together because of a disagreement over the ethics of patenting DNA. Mike Stratton, head of the ICR research team, explained that the British researchers "*do not believe pieces of the human genome are inventions; we feel it is a form of colonization to patent them*", adding that he did not believe it "*appropriate for [a disease gene] to be owned by a commercial company because, in contrast to an academic organization or a charity, there inevitably is a demand for profit*".
59. *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 922 (1991).
60. See U.S. Const. art. III § 2 (discussing the scope of Judicial power).
61. *Animal Defense Fund*, 932 F.2d at 925. The court held that standing under Article III § 2 is established when a party "at an irreducible minimum", proves (1) "that he personally has suffered some actual or threatened injury as a result of the putatively illegal conduct" (personal injury), (2) that "the injury 'fairly can be traced to the challenged action'" (causation), and (3) that the injury "is likely to be redressed by a favorable decision" (effective relief).
62. *Animal Defense Fund*, 932 F.2d at 925.
63. *Animal Defense Fund*, 932 F.2d at 935-9.
64. *Animal Defense Fund*, 932 F.2d at 935-9. See M.J. ADELMAN ET AL., *CASES AND MATERIALS ON PATENT LAW* 162 (1998).

while the Supreme Court paved the way for the protection of biotechnology, the CAFC was instrumental in the United States in ensuring that biotechnology was not bogged down by stumbling blocks.

In developing countries like India, biotechnology questions rarely relate to patentability of the subject matter. Partly, patentability of biotechnology has ceased to be a contentious issue and also because exclusions are clearly outlined under section 3(d).⁶⁵ Nevertheless, questions repeatedly arise in context of the balance required between promoting trade and protecting national welfare issues. To its credit, the Indian judiciary has shown a remarkable ability to draw the welfare lines, where required. Justice Bhat's decision in *Roche v. Cipla*⁶⁶ that enunciated a judicial compulsory licensing is an excellent example. Cipla, the generic drug maker, challenged Roche's patent on *erlotinib* - sold as *Tarceva* and priced at Rs.4,800 per tablet – on the grounds that the compound was obvious in light of the earlier known *gefitinib*. The decision established that, unlike the United States, the patent holder in India is not automatically entitled to an interim injunction when the validity of the patent is challenged. If a generic manufacturer can prove that the patented drug is priced more than the generic drug, or that the patented drug is not locally manufactured (several MNC drugs would be covered)⁶⁷ or that the generic has commenced manufacturing the drug,⁶⁸ then an interim injunction can be obtained. In doing so, the judgment prevents inventors from protecting minor innovations and then waiting for such patents to be squashed by the courts at the cost of judicial time and tax-payer's money. It also establishes that in India, access to medication will remain an important consideration in patent law and policy. Other decisions, like the *Novartis* decision, have clarified the standards of what kind of *efficacy* is required for unknown forms of known compounds to be elevated as an invention.⁶⁹ In India, decisions like the *Roche* judgment and the *Novartis* judgment are absolutely essential to create a balance that caters to national objectives.

65. The Patents (Amendment) Act, 2005.

66. *Hoffman La Roche Ltd and Anr. v. Cipla Ltd.*, 2008 P.T.C. 71 [Delhi High Court].

67. See Spicy IP discussions on *Roche v. Cipla*, available at www.SpicyIPIndia.blogspot.com.

68. *Hoffman La Roche*, 2008 P.T.C. 71.

69. *Novartis AG & Anr. v. Union of India & Ors.*, 4 M.L.J. 1153 (2007).

IV. ILLUSTRATION 3: THE JUDICIARY DEVELOPING THE NON-OBVIOUSNESS JURISPRUDENCE

Just like India's struggle in *Novartis* over the question of what qualities elevate a novel and useful material to an invention, the United States has dealt with similar questions during the initial stages of patent development, and even later. Before the enactment of §103 of Title 35, the United States' patent regime was characterized by a distinct lack of a principled analysis of what distinctions with respect to the prior art amounted to an "inventive" activity.⁷⁰ In *Hollister v. Benedict & Burnham Mfg. Co.*,⁷¹ the Court held that patentable inventions "spring from that intuitive faculty of the mind put forth in the search for new results, or new methods, creating what had not before existed".⁷² Justice Hand characterized the conceptual view of an "invention" as "fugitive, impalpable, wayward, and vague a phantom as exists in the whole paraphernalia of legal concepts".⁷³

Despite the belief that a strong patent system was the central tenet of a free market, economic downturns in the United States typically caused a mistrust of the patent regime.⁷⁴ The economic depression of 1873, for instance, increased concerns about the power of "big business" resulting in the Sherman Antitrust Act in 1890.⁷⁵ Similarly, the Great Depression of the 1930s resulted in the patent system being viewed as assisting monopolies.⁷⁶ During this time, even the judiciary viewed patents with limited enthusiasm.⁷⁷ The Supreme Court's propensity to strike down patents was so high that Justice Jackson lamented in *Jungerson v. Ostby & Barton Co.*,⁷⁸ "The only patent that is valid is one which this court has not been able to get its hands on".⁷⁹

70. See S.G. Kalinchak, *Obviousness and the Doctrine of Equivalents in Patent Law: Striving for Objective Criteria*, 43 CATH. U.L. REV. 577, 582-583 (1994) (discussing the "Supreme Court's reluctance to define a principled and objective test" for patentability prior to the Patent Law of 1954).

71. *Hollister v. Benedict & Burnham Mfg. Co.*, 113 U.S. 59 (1885).

72. *Hollister*, 113 U.S. 59, 72 (1885).

73. See *Harries v. Air King Prods. Co.*, 183 F.2d 158, 162 (2d Cir. 1950).

74. See *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 147 (1989). See 13 Writings of Thomas Jefferson 335 (1904).

75. See Ladas & Parry, *A Brief History of the Patent Law of the United States*, available at <http://www.ladas.com/Patents/USPatentHistory.html>. See also Sherman Act, 15 U.S.C.A. §2 (1890).

76. Ladas and Parry, *supra* note 75.

77. Adelman, *supra* note 64, at 23 (addressing how misplaced antitrust priorities, and the subjective inventiveness test, ultimately caused general mistrust of patents).

78. *Jungerson v. Ostby & Barton Co.*, 335 U.S. 560 (1949).

79. *Jungerson*, 335 U.S. 560, 572 (1949).

Interestingly, the cautious steps that the United States judiciary took during periods of depression are similar to those that the Indian judiciary is currently taking. The well-publicised Novartis dispute stands as an example of the cautious undertone of the Indian judiciary adopted to avoid patents with respect to frivolous and minor innovations. The dispute relates to a rejection by the Indian patent office of an application filed by drug manufacturer Novartis for a cancer drug named Glivec under section 3(d) of the Patents (Amendment) Act of 2005 (the Act).⁸⁰ Section 3(d) excludes new forms of a known substance - like salts, esters, ethers, polymorphs, metabolites, pure form, particle size, ... etc., from patentability - unless it embodies an *enhanced efficacy*.⁸¹ The facts indicate that Glivec was an isomer of an existing compound and the Madras High Court sustained the examiner's opinion, that is, that it lacked the requisite efficacy to make it patentable.⁸² The Novartis dispute *inter alia* underlines the attempt of the Indian Judiciary to standardize the *efficacy* requirement to determine non-obviousness of innovations.

In the United States, 35 U.S.C under §103 directs the courts to determine patentability by an objective comparison of the claimed invention with prior art.⁸³ The Supreme Court, in 1966, conceptualized the test for non-obviousness in a trilogy of cases based on the scope and content of prior art, the differences between prior art and the claims at issue and the level of "ordinary skill" in the art at the time the invention was made.⁸⁴ In 1969, however, another Supreme Court decision, *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*⁸⁵ developed the test of

80. A. O'Connor, *Activists Protest at Novartis's Patent Law Challenge*, TIMES (U.K.), March 7, 2007, at 59. See Patents (Amendment) Act (2005), available at http://www.patentoffice.nic.in/ipr/patent/patent_2005.pdf.

81. *Id.*

82. *Novartis AG v. Union of India* 4 M.L.J. 1153 (2007) [Madras High Court].

83. 35 U.S.C. §103.

84. See *Calmar Inc. v. Cook Chemical Co.*, 383 U.S. 1, 26 (1966) (refusing patentability to a sprayer since the invention was based on non-technical differences well known in the art); *Graham v. John Deere Co.*, 383 U.S. 112 (1966) (invalidating a plow clamp due to lack of operative mechanical distinctions between the invention and prior art); *United States v. Adams*, 383 U.S. 39 (1966). See K.N. McKereghan, Comment, *The Nonobviousness of Inventions: In Search of a Functional Standard*, 66 WASH. L. REV. 1061 (1991).

85. *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 61 (1969) (explaining the "synergism" test by stating that "[A] combination of elements may result in an effect greater than the sum of the several effects taken separately") Although the invention (an asphalt paving machine) was a commercial success, the Court determined that it lacked "synergism".

“synergism”. The Court held that a mere combination of old elements would become obvious unless it produces a “synergistic effect”.⁸⁶ The synergism rule increased the subjectivity of interpretation, resulting in conflicting and uncertain decisions from the regional circuits.⁸⁷ The conflicts within the regional circuit courts led Congress to appoint the Hruska Commission,⁸⁸ which resulted in the establishment of the CAFC in 1982.⁸⁹ The CAFC evolved a new test for determining *prima facie* obviousness. Under this test, an invention (that is a combination of known elements) would be non-obvious and therefore patentable unless there is some specific teaching, suggestion or motivation (TSM) in the prior art that refers to that combination. The TSM test, especially relevant to pharmaceutical formulations, has resulted in some questionable inventions clearing the non-obviousness threshold. As recently as 2007, the Supreme Court weighed in unfavourably on the TSM test in *KSR v. Teleflex* by declaring that the “combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results”⁹⁰

Particularly in biotechnology, the judiciary in the U.S has had to calibrate its standards and closely relate it to practical effects and industrial development taking place. For example, after the *Chakrabarty* decision, the CAFC held in *Re Deuel*, that an isolated DNA molecule is *prima facie* nonobvious and hence patentable although a combination of *prior art* references about the general method of gene cloning, together with a reference disclosing a partial amino acid sequence of the protein were present.⁹¹ The lowering of the obviousness standard for biotechnology patents in *Deuel* promoted patents and caused companies to race

86. *Anderson's-Black Rock, Inc.*, 396 U.S. 57, 61 (1969).

87. Adelman, *supra note* 64, at 24.

88. Commission on Revision of the Federal Court Appellate System, *Structure and Internal Procedures: Recommendations for Change*, 67 F.R.D. 195 (1975).

89. By 1978, the Department of Justice proposed merging the Court of Claims with the Court of Customs and Patent Appeals into a single appellate structure with national jurisdiction over all patent appeals. In 1979, the Senate Judicial Committee approved the Improvements in the Administration of Justice Bill which, in 1982, established the Federal Circuit. See Judge R. Rader, *Specialized Courts: The Legislative Response*, 40 AM. U. L. REV. 1003 (1991) (discussing whether the Federal Circuit is a specialized court); R.C. Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1 (1989) (critically appraising the role of the Federal Circuit).

90. *KSR International Co., v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007).

91. *In re Deuel*, 51 F.3d 1552, 1557-8 (Fed. Cir. 1995). Structural claims were used in the patent application. The Court noted 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.

to obtain biotechnology patents resulting in several innovations.⁹² Deuel greatly helped the United States to lead in the field of biotechnology patents and prosper from a rapidly growing biotechnology industry.⁹³

In making the standard of obviousness weaker for biotechnology patents, Deuel also enabled the patenting of miniscule inventions.⁹⁴ It later resulted in a “spiral of overlapping patent claims in the hands of different owners”.⁹⁵ Patent owners blocked each other’s research resulting in the under-use of resources.⁹⁶ Consequently, the system of free-for-all biotechnology patent applications had to be halted.⁹⁷ Again, the CAFC stepped in to limit the overly broad biotechnology patents in *Regents of the University of California v. Eli Lilly & Co.* by creating a heightened written description requirement.⁹⁸ In doing so, the Court created a specific written description requirement for biotechnology patent applications. Every biotechnology patent application now required a detailed written description with a specific description of the genes along with their distinguishing structural features.⁹⁹

The fine-tuning of the biotechnology patent regime and the non-obviousness standards in the United States by various courts – the Supreme Court and Federal Circuit – exemplifies the burden on the judiciary to cautiously guide policies to

92. S.A. Upadhyaya, *The Postmodern Written Description Requirements: An Analysis of the Application of the Heightened Written Description Requirement to Original Claims*, 4 MINN. INTELL. PROP. REV. 65, 107-9 (2002). See S. Dastgheib-Vinarov, *A Higher Non-obviousness Standard for Gene Patents: Protecting Biomedical Research from the Big Chill*, 4 MARQ. INTELL. PROPER. L. REV. 143, 178 (2000).

93. Upadhyaya, *supra* note 92, at 109.

94. Upadhyaya, *supra* note 92, at 109.

95. Upadhyaya, *supra* note 92, at 109.

96. M.A. Heller & R.S. Eisenberg, *Can Patents Deter Innovation? The Anti-Commons In Biomedical Research*, SCIENCE MAG., MAY 1, 1998, available at <http://www.sciencemag.org/cgi/content/abstract/280/5364/698>.

97. Upadhyaya, *supra* note 92, at 109.

[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.

See also Dastgheib-Vinarov, *supra* note 92.

98. *University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (1997); See Upadhyaya, *supra* note 92, at 109.

99. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566-7 (1997) (quoting *Fiers v. Revel*, 984 F. 2d 1164 (Fed. Cir. 1993)).

achieve national objectives. In developing nations like India, the judiciary should adopt a clear objective, that is, to focus policies on national needs. The judiciary should ensure that statutory amendments that are made to comply with international treaties incorporate appropriate standards and procedures to achieve national objectives.

V. CONCLUSION

The lessons from the illustrations above lie in appreciating the nature of judicial interpretation. Lord Denning termed judges as by-products of "predilections and preconceived notions" These predilections and preconceived notions are reflections of the national socio-economic and political influences. Judgments rendered without due consideration to national social, cultural and policy differences lack the degree of realism required to achieve national objectives. In the area of patents in particular, where all members of the WTO subscribe to minimum standards of protection, it is easy for the legislature or the judiciary to emulate another country. However, "drafting similar laws does not necessitate making the same interpretive decisions".¹⁰⁰ In fact, case law can develop in wholly different ways despite similar statutory construction and despite the influence of another country's jurisprudence.¹⁰¹ Reckless judgments rendered without the full appreciation of realities cause more harm than good. In fact, the problem of the anti-commons in biotechnology patents in the United States itself is a reflection of ambitious judgments that failed to balance economic considerations with other reasonable considerations. While it is important for the judiciary in India to not create stumbling blocks for investments, it is equally important that the judiciary does not act as an investment promoter to the detriment of social issues. The burden on the Indian judiciary is high but there is every reason to believe that it can fully stand up to the challenge.

100. See Kamber, *supra* note 33, at 779.

101. Kamber, *supra* note 33, at 779.