

PATENT JUDICIAL WISDOM

*Srividhya Ragavan

In the milieu of the thoroughly researched Ayyangar Report, the Indian Patent 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 1970 patent statute. In contrast, the patent amendment patches executed in India from 1999 primarily differs from its 1970 counterpart in being the by-product of international pressure and embodying an international trade agenda. The minimum standards outlined under the TRIPS agreement set the background of the patent amendments. Thus, the patent amendments represent India unleashed in the international arena – an India ready to address issues that allegedly clogged 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. Such clarity is vital for India to steer the patent amendments towards the balance of achieving national objectives while fulfilling its international obligations. The key question now is to determine which body – patent office, judiciary, legislature – is responsible to bring clarity and vision to the patent policy currently instituted out of a commitment to fulfill international obligations. This question is not unique to

* Associate Professor of Law, University of Oklahoma Law Center, Norman, Oklahoma. Professor Ragavan can be reached at sragavan@ou.edu and her faculty profile can be viewed at www.law.ou.edu/faculty.

¹ See Patents Act, 1970, 27 INDIA A.I.R. MANUAL 450 (1979).

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 legislature's solution packet 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 chartering the existing *highly pro-patent course* of the US patent regime.⁴ In India too, it is the judiciary that would and should be saddled with the task of chartering a patent regime that suits its national objectives. Thus, the most important burden of positing the development of the patent policy in the context of India's national objectives lies with the Indian judiciary.

In India, the enormous challenge facing the judiciary is subject to the one important limitation - the Constitution of India, 1947. The values in the Constitution obligate India to balance economic values with social needs. Such a 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

² ADAM B. JAFFE AND JOSH LERNER, *INNOVATION AND ITS DISCONTENTS*, Princeton University Press, (2004) at p. 4.

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 generally, JAFFE AND LERNER, *supra* note 2 at 16-18.

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 –labor – just as promotion of innovation is important to move towards the next stage of the development paradigm.

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 narrates stories from the United States from which one can draw valuable lessons. Importantly, the paper does not advocate that India emulate the United States judiciary. In fact, conventional wisdom dictates that the copying the policies or precedents of the west does not always work in developing countries considering the stark differences in ground realities like poverty, investments, infrastructure and such other indicators. Instead, the judicial wisdom that characterizes each of the stories sets the common thread for the paper. The lessons lies in appreciating the wisdom with which courts abroad have spearheaded amendments and set standards to 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.

Story 1: Development of the American Biotechnology patent regime:

The story of American judiciary's role in fostering biotechnology cannot be fully understood unless contrasted with what happened in Europe. In the 1960s, Europe encountered the issue of patentability modern biotechnology

when a German pigeon breeder sought a patent on a method of breeding a dove with “a considerably larger” red plumage.⁵ 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.”⁶ Patentability required the “technical nature” of the invention to control natural forces and achieve a predicted result.⁷ The *Bundesgerichtshof* reemphasized the “reproduction” requirement, in 1975, to refuse patent protection for a new mutant of baker’s yeast which produced beneficial results in bakery products.⁸ Consequently, biotechnology innovations remained unpatentable in Europe. During the 1970s and 1980s, in some European nations,

⁵ 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*.

⁶ *Id.* at 141. The court explained that 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 Andreas Schrell, Herbert Bauser, Herwig Brunner, *Biotechnology Patenting Policy in the European Union – as Exemplified by the Development in Germany*, *Adv Biochem Engin/Biotechnol* (2007) 107: 13–39, available at <http://www.ncbi.nlm.nih.gov/pubmed/17522818>.

⁷ *Id.* at 140-2. The court added that inventions should comprise of "instruction[s] to [a] systematic acting by utilizing controllable natural forces to achieve a causally predictable result."

⁸ See *Bakers Yeast* IIC 02/1975. See also *Bakers Yeast*, Case X ZB 4/74, 208-211 (1975).

particularly Germany, a distrusting and even hostile attitude towards biotechnology and, in particular, against genetic engineering prevailed.⁹

While Europe was fraught struggling with the patentability of biotechnology patents, Anand Chakraborty a doctorate from the University of Calcutta, landed in the United States for his postdoctoral work as an associate at the University of Illinois.¹⁰ In the United States, Chakraborty studied the ability of the *pseudomonas* bacteria to use a wide variety of organic compounds as nutrition.¹¹ During that period, he discovered that the genes that allowed the bacteria to digest compounds such a camphor and octane (did not reside on the chromosome) resided on separate DNA elements - plasmids - that are transmissible from one bacterium to another.¹² Much later, as an employee of General Electric, it dawned on Chakraborty that this ability of the *pseudomonas* bacterium could be used to convert oil (which was then cheap) into biomass.¹³ Since crude oil was a mixture of different hydrocarbons, Chakraborty needed a

⁹ See Andreas Schrell, Herbert Bauser, Herwig Brunner, *Biotechnology Patenting Policy in the European Union - as Exemplified by the Development in Germany*, *Adv Biochem Engin/Biotechnol* (2007) 107: 13-39, available at <http://www.ncbi.nlm.nih.gov/pubmed/17522818>.

¹⁰ Rebecca S. Eisenberg, *The Story of Diamond v. Chakraborty: Technological Change and the Subject Matter Boundaries of the Patent System*, *INTELLECTUAL PROPERTY STORIES*, Foundation Press, (2006) at 330.

¹¹ *Id.* at 332.

¹² *Id.* at 332.

¹³ *Id.* at 332 3.

mixed culture of strains to degrade more components.¹⁴ Soon, Chakrabarty construed a *pseudomonas* strain with multiple plasmids.¹⁵ 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.¹⁶ Chakrabarty's patent application claimed (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.¹⁷ 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 § 101 of Title 35 of the U.S.C."¹⁸

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

"[W]hoever 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."¹⁹

¹⁴ *Id.*

¹⁵ *Id.* at 333.

¹⁶ *Diamond v. Chakrabarty*, 447 U.S. 303 at 305.

¹⁷ *Id.* at 305-6.

¹⁸ *Id.* at 306.

¹⁹ 35 U.S.C § 101.

When *Chakraborthy* appealed, the larger question for determination was whether microorganisms fall within the ambit of “manufacture” or “composition of matter” in § 101 of Title 35. If so, the microorganism would be patentable. Note that the distinguishing feature of the invention was that the subject matter is a non-naturally occurring product of human ingenuity.

By the time the PTO’s rejection of the patent application reached the Court of Customs and Patent Appeals (CCPA – the predecessor of the CAFC) on appeal, commercial biotechnology was becoming a significant area of research.²⁰ By the time the Supreme Court considered the case in 1979,²¹ researchers had successfully “used recombinant DNA technology to clone medically important genes in microorganisms.”²² In fact, Genentech Inc, the biotech company which cloned the first human insulin in 1978, in its *amicus* to the Supreme Court asserted that, any controversy with respect to biotechnology was “misleading and irrelevant.”²³ Further, Genentech added that:

²⁰ *In Re Chakrabarthy*, 571 F. 2d 40 (C.C.P.A 1978). 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 952 (Cust. & Pat. App., 1979).

²¹ The government filed for *certiorari* for Chakrabarthy and *In Re Bergy* – another case that raised similar issues. After the petition was granted, the applicant in Bergy cancelled his claims to the microorganism. Hence, the court merely considered the Chakrabarthy issue. *See Diamond v. Chakrabarty*, 444 U.S. 1028 (1980).

²² *See Eisenberg*, *supra* note 10 at 348.

²³ Brief on Behalf of Genetech Inc As Amicus Curiae at 10 (Filed Jan 28, 1980) (Westlaw Supreme Court Briefs file).

Against a backdrop of active promotion of such research by European governments and concern over possible loss of this country's 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.²⁴

The Supreme Court, in considering the issue relating to the patentability of living matter, in 1980, 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.²⁵ The Court differentiated that the original *Pseudomonas* were a product of nature, but the introduction of a new genetic material capable of degrading oil into the bacterium constituted an invention.²⁶ Thus, the Court posited the landmark proposition that all human creativity, irrespective of living or otherwise, was eligible for patent protection.²⁷

Diamond v. Chakrabarty by holding micro-organisms patentable under 35 U.S.C. § 101 paved the way for the development of biotechnology industries.²⁸ The availability of patent protection for genetic engineering encouraged research and development and marked the beginning of a new era in biotechnology

²⁴ *Id.* at 11.

²⁵ *Chakrabarty*, 447 U.S. 303, at 305, 311-313.

²⁶ *Id.* at 317.

²⁷ *Id.* at 318. (Justices Brennan, White, Marshall, and Powell dissented).

²⁸ 447 U.S. 303 (1972).

advances.²⁹ The Supreme Court's decision created tremendous financial potential for biotechnology companies, which in turn encouraged biotech investors.³⁰ Lila Feisee, BIO's Director for Federal Government Relations and Intellectual Property, highlights that with the help of the Supreme Court decision of *Diamond v. Chakrabarty* and the Bayh-Dole Act, the biotech industry sky-rocketed.³¹ Thanks 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 office dealt with a patent application concerning a genetically engineered mouse (Harvard Oncomouse) comprising an additional gene that makes the mice more susceptible to cancer.³² The Harvard Oncomouse had

²⁹ Geri Yonover, *What Hath (Not) Chakrabarty Wrought: From The Mouse That Roared To Hello Dolly And Beyond*, 32 VAL. U.L. REV. 349, 358 (1998).

³⁰ *Id.*

³¹ Lila Feisee, speech titled "Anything Under the Sun Made by Man," at <http://www.bio.org/speeches/speeches/041101.asp> (2001) (the Director for Federal Government Relations and Intellectual Property of the Biotechnology Industry Organization discussing the patent's contribution to the development of biotech industry.).

³² Matthias Kamber, *Coming out of the Maze: Canada Grants the Harvard Mouse Patent*, 35 GEO. WASH. INT'L L. REV. 761 (2003) *available at*

already been granted patent protection in the United States.³³ The Appeal Division in Canada granted the patent by specifically focusing on the legal reasoning. In considering that the Oncomouse was patented in the United States and Europe, the Appeals Court prioritized uniformity of patent law and held that Canada should follow suit.³⁴ Commentators have opined that economic pressure to promote the biotechnology industry in Canada may have played a hidden role in the Appeal Division's Harvard decision.³⁵ At that time, Canada hosted the "second-largest biotechnology industry in the world," and lack of patent protection for biotechnology embodied the danger of hindering research and investment.³⁶

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.³⁷ "Parliament" declared the Supreme Court of Canada, "did not intend

http://findarticles.com/p/articles/mi_qa5433/is_200301/ai_n21341363/pg_4?tag=artBoddy;col1.

³³ U.S Patent No. 4,736,866 (1988)

³⁴ *President and Fellows of Harvard College v. Commissioner of Patents* [2000] 4 F.C. 528, *See also* Kamber, *supra* note 32, at 761.

³⁵ *See* Kamber, *supra* note 32, at 780.

³⁶ *Id.*

³⁷ *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R 45. *See generally* Kamber, *supra* note 32, at 780 - 81.

higher life forms to be patentable" under the Canadian Patent Act.³⁸ Hence, the Court declared that the Harvard Mouse was an unpatentable subject matter.³⁹

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*⁴⁰ 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 § 116 of the Indian Patent Act of 1999.⁴¹ On appeal, the Calcutta High court held that the definition of "manufacture" in § 2 of the Indian patent legislation did not pose a statutory bar to the patentability of a living organism.⁴² In so holding, *Dimminaco AG*⁴³ opened India to the world of biotechnology patents.⁴⁴

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Dimminaco A.G., v. Controller of Patents Designs*, 2002 IPRL 255.

⁴¹ See *Kolkata High Court Quashed Patent Controller's Order On Dimminaco AG's Bursitis Vaccine*, SCITARI (July 26, 2002) available at <http://www.bionews.net/5/0/9/INDEX.HTM>.

⁴² See generally *Manufacture Applies To Living Organism; HC – Boost To Biotech Patenting*, BUSINESS LINE, at <http://www.patentmatics.com/news2002/news25.htm> (discussing that other 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).

⁴³ *Dimminaco*, 2002 IPRL at 259.

⁴⁴ *Dimminaco*, *supra note* 47, at 258, 293. Justice Ashok Ganguly quashed the Controller's order and directed a reconsideration of the application. The central government decided

At the time *Dimminaco AG* was decided, India reserved the right to deny patent protection if the primary or intended use of the invention is contrary to morality or is injurious to public health.⁴⁵ Although no Indian case addressed law and morality of patentability of biotechnology, the “law or morality” phrase in § 3 presumptively raised issues of patentability of biotechnology materials. In reality, the Patent Act of 1970 did not exclude biotechnology patents, but they were never granted. The Patent Act, 1970 in § 2 (j) defined inventions as (i) art, process or manner of manufacture, (ii) machine, apparatus or other article, and (iii) substance produced by manufacture.⁴⁶ The Indian patent office limited patentability to “manufactured material or substances,” and considered “living organisms” as falling outside the scope of that definition.⁴⁷ Just before the May 2002 *Dimminaco AG* decision, the South African AIDS crisis showcased the importance of the Indian generic drug industry and its biotechnology potential to the world.⁴⁸ So, the same logic that would have applied to the American judiciary to promote biotechnology applied to India as well (subject to

not to challenge the ruling; thus the judgment of the Calcutta High Court is the authority in India on the issue of biotechnology patents.

⁴⁵ Patent Act, §3(b) (1970) (India).

⁴⁶ Patent Act, §2(j) (1970) (India).

⁴⁷ Patent Act, §2(j) (1970) (India); The definition of invention includes (i) art, process or manner of manufacture, (ii) machine, apparatus or other Article, (iii) substance produced by manufacture.

⁴⁸ See generally Joanna Slater, *Indian Pirates Turn Partners: Once Copycats, Its Drug Makers Emerge As Industry Power Houses*, WALL ST. J., Nov. 13, 2003, at A14.

considerations for national variations like accessibility 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 in the world.

Story 2: Judiciary keeping the Path Clear for Biotechnology patenting:

Judicial interpretations, outlines the second story, are naturally influenced by national cultural, social and economic norms. Even in the developed world, the judiciary had to deal with moral and ethical concerns of biotechnology patents. For example, before the European Patent Office (EPO)⁴⁹ examined a patent application for the genetically engineered Harvard Oncomouse,⁵⁰ massive protests across Europe delayed the prosecution of the application.⁵¹ More than two hundred organizations, including animal welfare groups, environmental organizations, and religious societies, opposed the application on moral and ethical grounds.⁵² Similarly, in *Relaxin*,⁵³ a patent application for a DNA fragment

⁴⁹ EPO O.J. 6 (1977).

⁵⁰ Harvard/Onco-Mouse T 0019/90; see also 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 EPO approved patenting a transgenic mammal by holding that the EPC does not exclude the patenting of animals as a *per se* category.

⁵¹ See Donna 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 n.161 (2001) (hereinafter Gitter).

⁵² See also Donna M. Gitter, *Led Astray By The Moral Compass: Incorporating Morality Into European Union Biotechnology Patent Law*, 19 BERKELEY J. INT'L. 1, 29 (2001) (hereinafter Donna).

encoding human H2-relaxin (and its precursors), was opposed as offending the provisions of “morality” and “*ordre public*” in Article 53(a) of European Patent Convention.⁵⁴ The extraction of the DNA encoding the relaxin gene for which the patent was sought, from the tissue of a pregnant woman was alleged as immoral, constituting an offence against human dignity.⁵⁵ 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.”⁵⁶ The patent was eventually granted for *Relaxin*, although the decision introduced an element of subjectivity for determining the morality issue of patentability. While it is arguable that morality discussions prevented Europe from forging a strong biotechnology patent regime,⁵⁷ it is equally true that economic issues

⁵³ Howard Florey Institute v. Fraktion der Gronen im europCischen Parlament, V0008/94.

⁵⁴ *Id.* ¶ 6.

⁵⁵ *Id.*

⁵⁶ 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:

[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.

⁵⁷ See generally Gitter, *supra* note 51, at 1653, 1654. For example, British researchers collaborating with Americans as part of an international team of scientists ceased

notwithstanding, courts cannot shy away from confronting issues of local importance.

In the United States too, the judiciary was confronted with the question when moral and ethical concerns regarding patenting living organisms was raised by *Animal Defense Fund*, a nonprofit organization forming individual farmers, animal husbanders.⁵⁸ The Federal Circuit reasoned that under Article III, § 2 of the United States Constitution, *local standi* is established⁵⁹ only for parties with either a threat of personal injury or an actual personal injury.⁶⁰ 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.⁶¹ Since the appellants asserted no other adverse effects on any individual rights under the patent statute, the suit was dismissed for lack

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."

⁵⁸ *Animal Legal Defense Fund v. Quigg*, 932 F.2d. 920, 922 (1991).

⁵⁹ See U.S. Constitution, Article III § 2 (discussing the scope of Judicial power).

⁶⁰ *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).

⁶¹ *Animal Defense Fund*, 932 F.2d. at 925.

of standing.⁶² 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 furor in Europe, thus maintaining the focus on promoting biotechnology.⁶³ In effect, while the Supreme Court paved the way for protection of biotechnology, the CAFC was instrumental in the US to ensure 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 the biotechnology has ceased to be a contentious issue and also because exclusions are clearly statutorily outlined under § 3.⁶⁴ But, questions repeatedly arise in the 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*⁶⁵ 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 the light of the earlier known *gefatinib*. The decision established that, unlike the

⁶² *Id.* at 935-9.

⁶³ *Id.* see also MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW at 162 (1998) (hereinafter Adelman).

⁶⁴ Patents (Amendment) Act of India (2005) at § 3(d).

⁶⁵ *Hoffman La Roche Ltd and Anr. v. Cipla Ltd.*, 2008(37)PTC71(Del).

United States, the patent holder in India is not automatically entitled to an injunction when the patent validity is challenged, if a generic manufacturer can prove that the patented drug is priced more than the generic, the patented drug is not locally manufactured (several MNC drugs would qualify) ⁶⁶ and the generic has commenced manufacturing the drug.⁶⁷ In doing so, the judgment prevents inventors from protecting minor innovations and then waiting for it 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. 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. ⁶⁸ In India, decisions like the *Roche* judgment and the *Novartis* judgment are absolutely required to draw lines that cater to national objectives.

Story 3: The Judiciary developing the nonobviousness 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 an exclusive or a principled analysis of

⁶⁶ See generally Spicy IP discussions on Roche v. Cipla available at www.SpicyIPIndia.blogspot.com.

⁶⁷ Hoffman La Roche Ltd and Anr. v. Cipla Ltd., 2008(37)PTC71(Del).

⁶⁸ Novartis AG & Anr. v. Union of India & Othrs., (2007) 4 MLJ 1153.

what distinctions over the prior art amounted to an “inventive” activity.⁶⁹ In *Hollister v. Benedict & Burnham Mfg. Co.*,⁷⁰ for example, 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.”⁷¹ 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.”⁷²

Despite the belief that a strong patent system was the central tenet of a free market, economic downturns in the U.S typically caused a mistrust of the patent regime.⁷³ The economic depression of 1873, for instance, increased concerns about the power of “big business” resulting in the Sherman Antitrust Act in 1890.⁷⁴ Similarly, the Great Depression of the 1930s resulted in the patent

⁶⁹ See generally Stephen 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 [r]eluctance to [d]efine a [p]rincipled and [o]bjective [t]est” for patentability prior to the Patent Law of 1954)., for Judge Learned Hand’s conceptual view of “invention,” which he commented is

⁷⁰ 113 U.S. 59 (1885).

⁷¹ *Id.* at 72.

⁷² See *Harries v. Air King Prods. Co.*, 183 F.2d 158, 162 (2d Cir. 1950).

⁷³ See generally *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 147 (1989) (citation omitted). See also 13 Writings of Thomas Jefferson 335 (Memorial ed. 1904).

⁷⁴ See Ladas & Parry, *A Brief History of the Patent Law of the United States*, <http://www.ladas.com/Patents/USPatentHistory.html> (last visited Dec. 21, 2001). See also Sherman Act, 15 U.S.C.A § 2, 26 Stat. 209 (July 2, 1890).

system being viewed as assisting monopolies.⁷⁵ During this time, even the judiciary viewed patents with limited enthusiasm.⁷⁶ The Supreme Court's propensity to strike down patents was so high that Justice Jackson lamented in *Jungerson v. Ostby & Barton Co*,⁷⁷ "[T]he only patent that is valid is one which this court has not been able to get its hands on."⁷⁸

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-publicized *Novartis* dispute itself stands as an example of the cautious undertone of the Indian judiciary to avoid patenting 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 Glivac under § 3(d) of the Patents (Amendment) Act of 2005 (the Act).⁷⁹ Section 3(d) excludes new forms of a known substance - like salts, esters, ethers, polymorphs, metabolites, pure form, particle size, ... etc., from patentability -

⁷⁵ *Id.*

⁷⁶ ADELMAN, *supra* note 63, at 23 (addressing how misplaced antitrust priorities and the subjective inventiveness test ultimately caused general mistrust of patents).

⁷⁷ 335 U.S. 560 (1949).

⁷⁸ *Id.* at 572.

⁷⁹ Ashling O'Connor, *Activists Protest at Novartis's Patent Law Challenge*, TIMES (U.K.), March 7, 2007, at 59. See also Patents (Amendment) Act 15 of 2005 § 3(d), available at http://www.patentoffice.nic.in/ipr/patent/patent_2005.pdf (last visited Mar. 21, 2007).

unless it embodies an *enhanced efficacy*.⁸⁰ As it turned out, Glivac was an isomer of an existing compound and the examiner's opinion that it lacked the requisite efficacy was sustained, on appeal, by the Chennai High Court.⁸¹ The *Novartis* dispute underlines the Indian judiciary attempt to standardize the *efficacy* requirement to determine nonobviousness.

In the United States, 35 U.S.C under § 103 directs the courts to determine patentability by an objective comparison of the claimed invention and prior art.⁸² The Supreme Court, in 1966 conceptualized the test for nonobviousness 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.⁸³ In 1969, however, another Supreme Court decision, *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, developed the test of "synergism."⁸⁴ The Court held that a mere combination of old elements

⁸⁰ *Id.*

⁸¹ *Novartis AG v. Union of India*, available at <http://www.piercelaw.edu/ipproflist/Novartis.doc>.

⁸² 35 U.S.C § 103

⁸³ 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); See also *Graham v. John Deere Co.*, 383 U.S.1, 12, 19 (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, 48, 52 (1966). See generally Kathleen N. McKereghan, Comment, *The Nonobviousness of Inventions: In Search of a Functional Standard*, 66 WASH. L. REV. 1061 (1991).

⁸⁴ 396 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

would become obvious and unless it produces a “synergistic effect.”⁸⁵ The synergism rule increased subjectivity of interpretation resulted in conflicting and uncertain decisions from the regional circuits.⁸⁶ The conflicts within the regional circuit courts led Congress, to appoint the Hruska Commission,⁸⁷ which resulted in the establishment of the CAFC in 1982.⁸⁸ The Federal Circuit evolved a new test for determining *prima facie* obviousness. Under this test, an invention (that is a combination of known elements) would be nonobvious and therefore patentable, unless there is some specific teaching, suggestion or motivation (TSM) in the prior art references to make that combination. The TSM test, especially relevant to pharmaceutical formulations, resulted in some questionable inventions clearing the nonobviousness threshold. As recently as in 2007, the Supreme Court weighed in unfavorably on the TSM test in *KSR v.*

separately.”). Although the invention (an asphalt paving machine) was a commercial success, the Court determined that it lacked “synergism.” *Id.*

⁸⁵ *Id.* at 61.

⁸⁶ ADELMAN, *supra* note 63, at 24.

⁸⁷ Commission on Revision of the Federal Court Appellate System, Structure and Internal Procedures: Recommendations for Change, 67 F.R.D 195 (1975).

⁸⁸ 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 generally* Judge Randall Rader, *Specialized Courts: The Legislative Response*, 40 AM. U. L. REV. 1003 (1991) (discussing whether the Federal Circuit is a specialized court); Rochelle Cooper 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).

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.”⁸⁹

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. 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 a *prior art* references taught the general method of gene cloning, together with a reference disclosing a partial amino acid sequence of the protein.⁹⁰ The CAFC’s lowering of the obviousness standard for biotechnology in *Deuel* promoted patents and caused companies to race to obtain biotechnology patents resulting in several innovations.⁹¹ *Deuel* initially greatly helped the United States to lead in biotechnology patents and prosper from a rapidly growing biotechnology industry.⁹²

⁸⁹ *KSR International Co., v. Teleflex, Inc*, 127 S. Ct. 1727 (2007).

⁹⁰*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. *Id.*

⁹¹ Shraddha 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, 107–09 (2002). See also Sara Dastgheib-Vinarov, *A Higher Nonobviousness Standard for Gene Patents: Protecting Biomedical Research from the Big Chill*, 4 MARQ. INTELL. PROP. L. REV. 143, 178 (2000).

⁹² *Id.* at 109.

In making obviousness rejection scarcer for biotechnology patents, *Deuel* also enabled patenting of miniscule inventions.⁹³ Soon, it resulted in a “spiral of overlapping patent claims in the hands of different owners.”⁹⁴ Patent owners blocked each other’s research resulting in an under-use of the resources.⁹⁵ Consequently, the free-for-all biotechnology patent applications had to be capped.⁹⁶ Again, the CAFC stepped in to limit the overly broad biotechnology patents in *Regents of the University of California v. Eli Lilly & Co.* (“*Eli Lilly*”), by creating a heightened written description requirement.⁹⁷ In doing so, the Federal Circuit created a specific written description requirement for biotechnology patent application. Every biotechnology application, held the Federal Circuit, required a detailed written description with a specific description of the genes along with its distinguishing structural features.⁹⁸

⁹³ *Id.* at 109.

⁹⁴ *Id.*

⁹⁵ Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anti-Commons In Biomedical Research*, SCIENCE MAGAZINE, MAY 1, 1998 available at <http://www.sciencemag.org/cgi/content/abstract/280/5364/698>.

⁹⁶ Upadhyaya, *supra* note 91, 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 generally Sara Dastgheib-Vinarov, *A Higher Nonobviousness Standard for Gene Patents: Protecting Biomedical Research from the Big Chill*, 4 MARQ. INTELL. PROPER. L. REV. 143, 165 (2000).

⁹⁷ 119 F.3d 1559, 1566–69 (1997); see also Upadhyaya, *supra* note 91, at 109.

⁹⁸ *Id.* at 1566, 1567 (quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)).

The fine tuning of the biotechnology patent regime and nonobviousness standards in the U.S by the various courts – the Supreme Court and Federal Circuit – exemplifies the burden on the judiciary to cautiously guide policies to achieve national objectives. In developing nations like India, the judiciary should have a clear vision to focus policies on national needs. The judiciary should ensure that statutory amendments made to comply with international treaties incorporate appropriate standards and procedures to achieve national objectives.

Conclusion:

The lessons from the stories above lie in appreciating the nature of judicial interpretation. Lord Denning termed judgments as by-products of “predilections and preconceived notions.” The 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. Especially in patents, 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.”⁹⁹ In fact, case law can develop in wholly different ways despite similar statutory construction and despite influence of

⁹⁹ See Kamber, *supra* note 32, at 779.

another country's jurisprudence.¹⁰⁰ Reckless judgments rendered without full appreciation of the realities causes more harm than good. In fact, the problems of the anti-commons in biotechnology patents in the United States itself is a reflection of ambitious judgments that failed to balance economic 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 investment promoters 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.

THE END.

¹⁰⁰ *Id.*