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17 PATENTABILITY CRITERIA AS TRIPS FLEXIBILITIES: THE EXAMPLES OF CHINA AND INDIA

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Introduction

Much has been said, and much more will be, about TRIPS "flexibilities," which one might loosely define as space available to policymakers making decisions about TRIPS implementation, including in particular exceptions and limitations on rights and/or remedies.[1] A list of such flexibilities typically includes not only patentability criteria and subject matter exclusions (e.g., morality-related exclusions or specific subject matter, such as methods of medical treatment), but also compulsory licenses, government use exceptions, exhaustion of rights, research exemptions, and a regulatory review ("Bolar") regime.[2]

Not surprisingly, the demanders who pushed for TRIPS—mostly pharmaceutical companies with significant support from entertainment and software companies—realized that there may be more there than meets the eye.[3] In response, they have been pushing in bilateral and other

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1. The TRIPS Agreement is the Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 81 (1994). On flexibilities generally, see CAROLYN DEERE, THE IMPLEMENTATION GAME (2009), and on pharmaceuticals in particular, see UNAIDS, *Using TRIPS Flexibilities to Improve Access to HIV Treatment* (2011), *available at* http://www.unaids.org/en/media/unaids/contentassets/documents/policy/2011/JC2049_PolicyBrief_TRIPS_en.pdf.

2. *See* World Intellectual Prop. Org. (WIPO), *Patent Related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels*, WIPO Doc. CDIP/5/4 (Mar. 1, 2010). *See* TRIPS Agreement, supra note 1, arts. 6, 27, 30, 31, 44.2.

3. *See* Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO*

trade agreements for "TRIPS-plus" standards that amount to efforts to cabin such flexibilities.[4]

TRIPS flexibilities stem from three major sources: (1) undefined terms in the Agreement, (2) specified limitations or exceptions (or tests therefor such as the three-step test), and (3) language that imposes a formal requirement only, such as the famous "authorities shall have the authority" phrase used sixteen times in the enforcement part of TRIPS.[5]

The last area of flexibility (adopting facially compliant legislation but with limited application in practice) is possible because the non-violation clause in the GATT does not apply to TRIPS disputes, reinforced by the recent interpretation of enforcement provisions by a WTO dispute-settlement panel in *United States v. China* and, *a contrario,* the Appellate Body's first TRIPS ruling in *United States v India.*[6] Essentially, most WTO members have been able to avoid WTO sanctions by complying with TRIPS as a formal matter, absent evidence that the application of the paper-compliant rule is clearly subpar.[7]

Legal Alternatives Available to Third World Countries, 17 U. PA. J. INT'L ECON. L. 1069, 1096 (1996).

4. On the European Commission, see Henning Grosse Ruse-Khan, Thomas Jaeger & Robert Kordic, *The Role of Atypical Acts in EU External Trade and Intellectual Property Policy*, 21 EUR. J. INT'L L. 901, 925 (2010). On the United States, see Sisule F. Musungu & Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?* (2005), *available at* http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf, at 8; *see also* Carlos M. Correa, *Implications of Bilateral Free Trade Agreements on Access to Medicines* 399–404 (2006), *available at* http://www.who.int/bulletin/volumes/84/5/399.pdf; Thomas A. Faunce & Kathy Shats, *Bilateral Trade Agreements as Drivers of National and Transnational Benefit from Health Technology Policy: Implications of Recent US Deals for Australian Negotiations with China and India*, 62 AUSTL. J. INT'L AFF. 196–213 (2008). They are also using friendly governments to restrict the actual use of available flexibilities.

5. It is also used three more times in Section II. *See also infra* note 8.

6. China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights, WTO Doc. WT/DS362/R (Jan. 26, 2009); India—Patent Protection for Pharmaceutical and Agricultural Chemical Products, WTO Doc. WT/DS50/AB/R (Dec. 19, 1997). In the US–China case, it can fairly be said that the panel required that, in the copyright portion of the case, the Chinese statute be facially TRIPS-compliant, but was more lenient in the application of the phrase "the authorities shall have the authority." This was interpreted as an obligation to have the authority, not to exercise it. In the India case, the Appellate Body did not consider de facto compliance via administrative measures sufficient and similarly required the presence of compliant statutory language. For comments, see DANIEL J. GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 168–72 (3d ed. 2008); Jayashree Watal, *US–China Intellectual Property Dispute: A Comment on the Interpretation of the TRIPS Enforcement Provision*, 13 J. WORLD INTELL. PROP. 605 (2010).

7. *See id.* In the US–China case, the panel noted that the United States had failed to provide evidence that behavior exempted from criminal sanctions due to thresholds in Chinese law was "on a commercial scale," as the expression is used in TRIPS Article 61.

Entire books have already been written on the second area of flexibility (limitations and exceptions), and two reports by WTO dispute-settlement panels have now interpreted the three-step test (which, in various incarnations, limits exceptions and limitations to copyright, design, and patent rights in TRIPS).[8] That is a relevant debate and it must continue. The extent to which it is informed by non-WTO norms is an area of particular interest, as the process to determine proper normative interfaces is still in development.[9]

However, exceptions and limitations in TRIPS are made possible by, not imposed on members.[10] Put differently, exceptions and limitations may be considered unregulated policy space at the international level.[11] To a large extent, the geometry of exceptions and limitations (hereinafter referred to as "E&Ls") in a WTO member depends not on TRIPS per se, which offers policy space but little normative guidance, but rather on domestic policymaking, academic and other studies of the role and optimal scope of exceptions, and of course bilateral or plurilateral negotiations aimed at cabining recourse to E&Ls. From that perspective, the TRIPS Agreement acts more as a filter for acceptable domestic measures than as a policy guide.

The first of the three areas mentioned above (namely the role of undefined terms) is, however, the main focus of this chapter. It is also perhaps the least explored of the three.

The matter is complex due to a web of semantic accommodations, sometimes masking unresolved issues. For example, TRIPS negotiators used the fiction of synonymy to declare that WTO members somehow saw eye-to-eye on terminology,

8. *See, e.g.*, EDSON BEAS RODRIGUES JR., THE GENERAL EXCEPTION CLAUSES OF THE TRIPS AGREEMENT: PROMOTING SUSTAINABLE DEVELOPMENT (2012); MARTIN SENFTLEBEN, COPYRIGHT, LIMITATIONS AND THE THREE-STEP TEST: AN ANALYSIS OF THE THREE-STEP TEST IN INTERNATIONAL AND EC COPYRIGHT LAW (2006); M. Ficsor, *How Much of What: The "Three-Step Test" and Its Application in Two Recent WTO Dispute-Settlement Cases*, 192 REVUE INTERNATIONALE DU DROIT D'AUTEUR [RIDA] 111 (2002); Daniel J. Gervais, *Towards a New Core International Copyright Norm: The Reverse Three-Step Test*, 9 MARQ. INTELL. PROP. L. REV. 1 (2005).

9. *See* GRAEME B. DINWOODIE & ROCHELLE C. DREYFUSS, A NEOFEDERALIST VISION OF TRIPS: THE RESILIENCE OF THE INTERNATIONAL INTELLECTUAL PROPERTY REGIME (2012).

10. Because the Berne Convention contains one mandatory exception (Article 10.1), and because the substantive provisions of that Convention were incorporated into TRIPS (Article 9.1), it is arguable that one exception is mandatory for WTO members, subject to how one interprets TRIPS Article 1.1.

11. *See* P. BERNT HUGENHOLTZ & RUTH L. OKEDIJI, CONCEIVING AN INTERNATIONAL INSTRUMENT ON LIMITATIONS AND EXCEPTIONS TO COPYRIGHT: FINAL REPORT (2008), *available at* http://www.ivir.nl/publications/hugenholtz/limitations_exceptions_copyright.pdf; Daniel J. Gervais, *Making Copyright Whole: A Principled Approach to Copyright Exceptions and Limitations*, 5 U. OTTAWA L. & TECH. J. 1 (2008), *available at* http://ssrn.com/abstract=1825342.

such as when TRIPS states in a footnote that the North American and rest of the world patentability criteria "may be deemed to be synonymous" (non-obviousness and utility versus inventive step and industrial applicability).[12] This follows in the footsteps of other arranged marriages, such as the idea that copyright in common law jurisdictions going back to the 1710 Statute of Anne is somehow the same as authors' rights in the rest-of-the-world.[13] In other cases, dispute-settlement panels have turned to the Vienna Convention and the *Oxford Dictionary* to elucidate the "plain meaning" of undefined terms.[14] This has worked, to some degree, such as when everyday terms such as "commercial" or "normal" are used. It may not work as well when technical intellectual property terminology must be defined.

In this chapter, I tackle the lack of definitions of two of the three patentability criterion enunciated in TRIPS Article 27, namely non-obviousness and utility and their deemed synonyms, inventive step and industrial applicability.[15] For a variety of reasons, including space, I will leave aside novelty but it is clear that (1) discrepancies exist as to how it is defined, and (2) there are major policy impacts that result from adopting a particular definition.[16] To mention but one example, in the original patent legislation of India, the geographic scope of the

12. *See* TRIPS Agreement, *supra* note 1, art. 27.1 n.5.

13. The copyright system is a successor to, and helped transition from, the Stationers Company monopoly. Its economic focus is thus unsurprising. By contrast, the authors' rights system was born from Hegelian and other sources that tended to emphasize the author's importance in philosophical and cultural terms.

14. For example, in Section 110(5) of the US Copyright Act, WTO Doc. WT/DS160/R (June 15, 2000), the panel referred to the Oxford Dictionary in ¶¶ 6.108 and 6.109 and to the Vienna Convention in several instances (e.g., ¶¶ 6.37 and 6.43).

15. Readers in the United States might argue that there are four, not three, and add enablement. *See* 35 U.S.C. § 112 (2012). However, TRIPS Article 27.1 only provides that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." A footnote adds that, "For the purposes of this Article, the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with the terms 'non-obvious' and 'useful' respectively." Enablement is addressed in Article 29, which provides in part that "Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art." *See* TRIPS Agreement, *supra* note 1, arts. 27.1, 29.

16. For example, the United States only considers sale or use in the United States as a bar to patentability. *See* 35 U.S.C. §§ 102(a)–(b). On policy impacts, see, e.g., Sean B. Seymore, *Rethinking Novelty in Patent Law*, 60 DUKE L.J. 919, 946–48 (2011):

> The invention landscape changed around the time of World War II, when key breakthroughs in antibiotic, vitamin, and hormone research spawned the "therapeutic revolution" and led to the discovery of many first-generation "wonder drugs." During this period, pharmaceutical companies quickly switched from a manufacturing to a research-based model and secured patents that allowed them to dominate sectors of specific therapeutic markets. This, in turn, quickly forced the Patent Office and the courts to wrestle with fields key to drug research, like organic chemistry. [...] This shoehorning led to nonsensical outcomes and a disconnect between the judicial bench and the laboratory bench. [...] Perhaps the most important unresolved issue is whether and under what circumstances the appearance of a chemical name or structure in the prior art anticipates a subsequent inventor's claim for the compound.

I will also leave aside here the important issue of morality, which, in my mind goes to subject matter eligibility. For a discussion, see Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469 (2003).

novelty inquiry was confined to the United Kingdom and India,[17] rather than to use or publication anywhere in the world.

The backdrop for my analysis is the realization, now also well documented, that TRIPS was initially implemented in many developing countries as a set of standard legislative implants—typically in the form of model laws.[18] The initial focus was *compliance* with TRIPS and avoidance of disputes. After the AIDS/malaria debacle, which led to the adoption of the only (still unratified) amendment to TRIPS (Article 31*bis*)[19], and owing in part to the emergence of more and better economic data and analyses on the role and impact of stronger intellectual property protection in developing countries, several developing countries are now re-implementing TRIPS with a view to fostering domestic innovation and development *and* to reducing the welfare costs of stronger standards.[20] I refer to this process as calibration.

The calibration process takes the form of a complex set of policy equations that include a focus on the country's comparative advantages (e.g., solid film or software industry basis; Ayurvedic medicine knowledge in India; or the availability of governmental resources and a large cadre of highly educated researchers as in China), but also on training for key officials, setting up nongovernmental or private–public organizations and partnerships, educational tools, venture capital (private or public), and intellectual- property–specific measures such as patent pooling and making resources available for local inventors.[21] In short, intellectual

17. Peter Drahos, *The Jewel in the Crown: India's Patent Office and Patent-Based Innovation*, *in* INTELLECTUAL PROPERTY POLICY REFORM 80–81 (Christopher Arup & William van Caenegem eds., 2009).

18. *See* Daniel J. Gervais, *Of Clusters and Assumptions: Innovation as Part of a Full TRIPS Implementation*, 77 FORDHAM L. REV. 2353 (2009).

19. The purpose of which is to broaden the scope of patent compulsory licensing for pharmaceutical products needed by least-developed countries.

20. *See* Gervais, *supra* note 18.

21. *See* Ed Levy, Emily Marden, Ben Warren, David Hartell & Isaac Filaté, *Patent Pools and Genomics: Navigating a Course to Open Science?*, 16 B.U. J. SCI. & TECH. L. 75, 87–88 (2010).

property policy has become part of a much broader picture, possibly in the form of an enhanced industrial policy itself ensconced in developmental objectives.

From this perspective, re-implementing TRIPS means setting priorities and implementing those priorities within the flexibilities of TRIPS.[22] This, in turn, requires a determination of the exact scope of available flexibilities, each of which may be portrayed as a decision point for policymakers. It is an almost impossible task at a theoretical level to consider all flexibilities in one fell swoop. In this chapter, I thus limit my analysis to the way in which TRIPS patentability criteria were implemented and are applied in practice in two major emerging nations, China and India, with different but equipollent technological proficiency.[23] This partial look hopefully can serve as an illustration of the use of other similar TRIPS flexibilities.

Getting multilateral deals on substantive patent rules and definitions, especially at WIPO and WTO, may have become irredeemably difficult. Countries such as China and India, but also Argentina, Brazil, South Africa, Thailand, and many others, have become more assertive. It is obvious that their relative clout measured in trade terms has grown exponentially.[24] The work at WIPO on substantive patent harmonization is a testament to the level of difficulty.[25] Additionally, major developing countries now have the same level of sophisticated intellectual property knowledge as more industrialized nations, thus defeating the ignorance narrative to which the TRIPS "deal" has been partially attributed.[26]

Because multilateral efforts to agree on higher hard law standards (e.g., via a TRIPS amendment) seem bound to fail, some countries now resort to other methods. As already mentioned, bilateral trade deals are emerging, in some cases establishing incompatible rules, possibly as a strategy to influence multilateral outcomes.[27] In other cases, countries can produce and try to export soft law.

22. *See* Gervais, *supra* note 18.

23. *See* Shamnad Basheer & Annalisa Primi, *The WIPO Development Agenda: Factoring in the "Technologically Proficient" Developing Countries* 112–13 (2009), *available at* http://ssrn.com/abstract=1289288.

24. *See* Bruno Salama, *Pharmaceutical Patent Bargains: The Brazilian Experience*, 18 CARDOZO J. INT'L & COMP. L. 633 (2010); P.K. Yu, *Access to Medicines, BRICS Alliances, and Collective Action*, 34 AM. J.L. & MED. 345, 355–58 (2008).

25. Indeed this WIPO agenda item has essentially been on hold since 2006. *See* WIPO, *Draft Substantive Patent Law Treaty*, *available at* http://www.wipo.int/patent-law/en/harmonization.htm (last visited Sept. 3, 2013).

26. *See* P.K. Yu, *TRIPS and Its Discontents*, 10 MARQ. INTELL. PROP. L. REV. 369, 375–76 (2006).

27. *See* Gregory C. Shaffer & Mark A. Pollack, *Hard vs. Soft Law: Alternatives, Complements, and Antagonists in International Governance*, 94 MINN. L. REV. 706 (2010).

A salient example is the use of patent examination guidelines issued by major patent offices trying to influence the meaning of patentability criteria.[28] One might argue that developing countries will increasingly look to other, more advanced developing nations when considering which set of rules to adopt or follow. As we will see below, China is an increasingly active player at that game.

Let us start, then, by considering, in Section I, the non-obviousness/inventive step requirement. In Section II, I turn to utility/industrial applicability. In Section III, I consider lessons that one might draw from the analysis of both topics. Wherever possible, existing reports by WTO dispute-settlement panels and the Appellate Body will be included in the analysis.

I. Non-Obviousness/Inventive Step

This patentability criterion matters a great deal. In fact, non-obviousness/inventive step has been referred to as the "ultimate condition of patentability"[29] and as "one of the most critical aspects of a patent regime, as it determines the level of technical contribution required to obtain a patent and the corresponding limitation on competition."[30] It is, or could be, the filter that separates inventions worthy of patent protection (which one might be tempted to describe as essential "consideration" if patents are looked at from a contractarian perspective) from the normal, incremental advances in technology that would likely happen anyway.[31] A glut of "unworthy"

28. A number of examples are given in the following sections of this chapter.

29. G.S. RICH, NONOBVIOUSNESS: THE ULTIMATE CONDITION OF PATENTABILITY 1:201–213 (John F. Witherspoon ed., 1980).

30. Carlos Correa, *Guidelines for the Examination of Pharmaceutical Patents* 4 (Int'l Ctr. for Trade and Sustainable Dev. Working Paper, Jan. 2007), *available at* http://ictsd.org/downloads/2008/06/correa_patentability20guidelines.pdf.

31. *See* WILLIAM ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 22 (1890); Jennifer Nock & Sreekar Gadde, *Raising the Bar for Nonobviousness: An Empirical Study of Federal Circuit Case Law Following* KSR, 20 FED. CIR. B.J. 369, 373–74 (2011):

> The requirements for patentability are designed to make patent protection available only to beneficial inventions that would not otherwise have been devised or disclosed. . . . The nonobviousness requirement ensures that a patented invention represents a substantial technical contribution to society. . . . A low standard for patentability harms the public because granting monopoly rights for obvious inventions "withdraws what already is known into the field of [the patent] monopoly and diminishes the resources available to skillful men."

It has also been suggested that:

> [the] nonobviousness requirement serves another very important purpose where, as is realistically nearly always the case, the social value of research projects substantially exceeds their private value. When this is the case, the socially preferable level of invention exceeds the privately optimal choice even when patents are available at both levels.

patents may, in fact, slow innovation, thereby reducing a nation's overall competiveness.[32] As a more practical matter, this criterion will directly affect whether patents are granted on genes (simply for discovering that a given gene may have a role to play in susceptibility to a particular disease) or on combinations or preexisting objects.[33]

Based on a desire to maintain incentives to discover genes, the US Court of Appeals for the Federal Circuit has "force[d] the square peg of the obviousness analysis of chemical compounds into the round hole of the obviousness analysis of claims to genetic sequences."[34] It may be, in fact, that non-obviousness is not one concept, but rather many different things depending on the type of invention.[35] One thing is

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The nonobviousness threshold may be used as a "stick" to induce researchers to pursue more difficult, socially preferred research projects.

Michael J. Meurer & Katherine J. Strandburg, *Patent Carrots and Sticks: A Model of Nonobviousness*, 112 LEWIS & CLARK L. REV. 547, 549 (2008).

32. *See* ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS (2004); NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., A PATENT SYSTEM FOR THE 21ST CENTURY 1–2 (Stephen A. Merrill, Richard C. Levin & Mark B. Myers eds., 2004); Joshua D. Sarnoff, *Bilcare, KSR, Presumptions of Validity, Preliminary Relief, and Obviousness in Patent Law*, 25 CARDOZO ARTS & ENT. L.J. 995, 1051 (2008); FED. TRADE COMM'N (FTC), TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

33. The former issue was recently addressed by the US Supreme Court in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*,133 S. Ct. 2107 (2013), and the latter was dealt with in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

34. Mark Polyakov & Eugene Goryunov, *(Non)Obviousness of Claims to Genetic Sequences: Finding the Middle Ground*, 26 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1 (2009–10). The authors explain:

> By way of background, the CAFC devised a special test for chemical compounds, under which a prima facie case of obviousness requires "structural similarity between claimed and prior art subject matter . . . where the prior art gives reason or motivation to make the claimed compositions." Once the prima facie case is established, an examiner must show some motivation to modify the prior art compound. Usually, this prong does not present a high burden since the motivation may be found in the knowledge that structurally similar compounds often display similar properties. . . . [T]his framework is ill-suited for genetic sequences because it does not consider the special nature of genes. A PHOSITA attempting to determine the DNA sequence of a protein does not generally start his search by looking at structurally similar DNA sequences. Instead, he starts by determining the amino acid sequence of the protein. Once the amino acid sequence has been determined, a PHOSITA can design and use nucleotide probes to uncover the protein's DNA sequence. It is irrelevant to the analysis whether the prior art discloses a structurally similar cDNA molecule.

Id. at 21–22.

35. *See* Gregory Mandel, *The Non-Obvious Problem: How the Indeterminate Nonobviousness Standard Produces Excessive Patent Grants*, 42 U.C. DAVIS L. REV. 57, 111–12 (2008):

certain: there is no shortage of critiques of the Federal Circuit's approach, and other countries might want to take a fresh look at their own approach instead of copying the US one (whatever it might be as of this writing).[36]

By contrast, the European Patent Convention provides that[37] an invention "shall be considered as involving an inventive step if, having regard to the state of the art, it is *not obvious to a person skilled in the art*." Thus in the EPO context the synonymy established by TRIPS between inventive step and non-obviousness seems defensible. Still, the term "inventive" arguably points beyond nonobviousness, especially in the case of discoveries. Finding and isolating a DNA sequence requires much work but it is (arguably at least) not "inventive."[38] However, in an effort to harmonize with Japanese and US practice, a Directive was adopted by the European Union (and implemented by the EPO) to make isolated or artificially produced natural substances patentable.[39]

Inventive step has also been used in Europe as a reason to exclude computer programs "as such" from patentability.[40] In addition, it has also been used in a famous case to exclude from patentability a claimed invention where a large

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> Some inventions may be non-obvious in their conception, though once conceived may be easy to achieve. Post-It notes provide an example . . . Other inventions are obvious to conceive, but identifying operative means for carrying them out is non-obvious. An HIV vaccine is an example. . . . A third nonobviousness category concerns inventions where potential operative means are obvious, but the field is uncertain enough that actually reducing the invention to practice is non-obvious. This could occur where certain operative means appear obvious, but do not actually work . . . For example, other inventors developed incandescent light bulbs before Edison, but their filaments burned out quickly, rendering the light bulbs impractical.

36. In a paper proposing substantial reforms, Professor Barton noted that non-obviousness has been "greatly weakened" in the United States in recent years and failed "the common-sense test," adding that "[i]f these patents are non-obvious to the person of reasonable skill in the art, that person simply isn't very bright." John Barton, *Non-Obviousness*, 43 IDEA 475, 477, 482 (2003). The patentability of unmodified but isolated gene sequences obviously raises subject matter questions as well.

37. Convention on the Grant of European Patents of 5 October 1973, as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000, Article 56 [hereinafter European Patent Convention or EPC] (emphasis added).

38. This is reminiscent of the debate on copyright applying to sweat of the brow works, which, though non-creative, required a significant investment of time and/or effort. The EPC, *supra* note 37, specifically excludes discoveries (Article 52(2)). *See* Gerard Porter, *The Drafting History of the European Biotechnology Directive*, *in* EMBRYONIC STEM CELL PATENTS: EUROPEAN LAW & ETHICS 1, 8–9 (Aurora Plomer & Paul Torremans eds., 2009).

39. *See id.*; Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, [1998] OJ L213/13.

40. *See* Peter Stone, *Copyright Protection of Computer Programs in Europe*, *in* Law, Computer Science and Artificial Intelligence 146–47 (1998).

number of people were all working toward one goal and the means of achieving the goal. Getting there first was not necessarily a sign of an inventive step.[41]

Let us now consider how the criterion is applied in China and India.

A. China

China has tried to craft a patentability policy with particular attention to pharmaceuticals. Although desiring to provide access to products by consumers, it also wanted to develop both a "Western-style" biotechnology industry *and* an industry based on traditional medicinal knowledge.[42] That is not an easy task.

"Inventiveness," the Chinese application of the TRIPS "non-obviousness/inventive step" criterion,[43] is defined as meaning that "compared with the technology existing before the filing date of the application, the invention has prominent and substantive distinguishing features and represents a marked improvement, or the utility model possesses substantive distinguishing features and represents an improvement."[44] As with the non-obviousness requirement in the United States, the purpose of the inventiveness requirement is to "distinguish major innovations worthy of government-granted monopolies from ordinary and pedestrian advances that are not."[45] The *Chinese Patent Examination Guidelines* provide that the question arises only after a determination of novelty has been made.[46]

In examining the substantive features of a patent application, an examiner inquires "whether or not there exists such a ***technical motivation*** in the prior art as to apply the said distinguishing features to the closest prior art in solving the existing technical problem (that is, the technical problem actually solved by the invention), where such motivation would prompt a person skilled in the

41. *Genentech Inc.'s Patent*, [1998] RPC 147.

42. *See* C. Grace, *Update on China and India and Access to Medicines*, Dep't for Int'l Dev. (Nov. 2005); Xuan Li & Weiwei Li, *Inadequacy of Patent Regime on Traditional Medicinal Knowledge: A Diagnosis of 13-Year Traditional Medicinal Knowledge Patent Experience in China*, 10 J. WORLD INT. PROP. 125 (2007).

43. Louis S. Sorell, *A Comparative Analysis of Selected Aspects of Patent Law in China and the United States*, 11 PAC. RIM L. & POL'Y J. 319, 326 (2002).

44. Patent Law of the People's Republic of China, *as revised by* Decision Regarding the Revision of Patent Law of the People's Republic of China, art. 22, promulgated by the Standing Comm. Nat'l People's Cong., Aug. 25, 2000 [hereinafter China Patent Act], *available at* http://www.sipo.gov.cn.

45. Some International Aspects of Patent Protection § 2A.06, 2004 WL 3804734.

46. *See* Li & Li, *supra* note 42, at 136; *see also* Cheng Wenting & Zhang Feifei, *Third Revision of China's Patent Law: Patent Examination Guidelines: A Comparative Analysis (2006 and 2010)*, IPR2 (Dec. 2010), *available at* http://www.ipr2.org/storage/Patent_Examination_Guidelines_comparative_2006_and_2010845.pdf.

art, when confronted with the technical problem, to improve the closest prior art and thus reach the claimed invention. If there exists such a technical motivation in the prior art, the invention is obvious and thus fails to have prominent substantive features (emphasis added)."[47] In assessing "notable progress," an examiner inquires "whether or not the invention produces ***advantageous technical effects*** (emphasis added)."[48] In addition to prior art, examiners may also take into account secondary indicia of inventiveness, including "providing a solution to a long-felt problem, overcoming technical prejudice, unexpected results, and commercial success."[49] Put differently, if the invention can be arrived at by a simple extrapolation in a straightforward way from the known art, it does not involve an inventive step.[50] Although "prominent substantive features" and "notable progress" carry equal weight in the examination process, the judiciary's assessment of inventiveness tends to place more emphasis on "prominent substantive features" than "notable progress."[51]

The *Examination Guidelines* provide three sets of factors beyond the general assessment criteria explained above. First, they differentiate among inventions opening up a whole new field, invention by combination, invention by selection, invention by diversion, invention of a new use of a known product, and invention by changing elements (changing relations between elements, replacing elements, or omitting elements).[52] On inventions by combination, one might wonder whether the *Guidelines* got it better than the US Supreme Court in *KSR*.[53] The *Guidelines* provide that if a claimed invention "is merely an aggregation or juxtaposition of certain known products or processes, each functioning in its routine way, and the overall technical effect is just the sum of the technical effects of each part without any functional interaction between the combined technical features, that is, the claimed invention is just a mere aggregation of features, then the invention by combination does not involve an inventive step" but if the "combined technical features functionally support each other and produce a new technical effect, or in other words, if the technical effect after combination is greater than

47. SIPO GUIDELINES FOR EXAMINATION ¶ 3.2 (2010), *available at* http://www.gechengip.com/information/content2010_en.htm. The Guidelines provide several illustrations of technical motivation.

48. *Id.*

49. Deming Liu, *Now the Wolf Has Indeed Come! Perspective on the Patent Protection of Biotechnology Inventions in China*, 53 AM. J. COMP. L. 207, 232–33 (2005).

50. SIPO GUIDELINES, *supra* note 47 ¶ 4.3.

51. Latest Developments in Trial of Patent Cases Before the Beijing Higher People's Court in 2009, China Patents & Trademarks (2009) [hereinafter Latest Developments in Patent Trial].

52. SIPO GUIDELINES, *supra* note 47 ¶¶ 4.1–4.6.3.

53. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).

the sum of the technical effects of the individual features, then such combination has prominent substantive features and represents notable progress, and thus the invention involves an inventive step."[54]

The *Guidelines* list other factors to be considered in the examination of inventive step, namely: solving a long-felt but unsolved technical problem, overcoming a technical prejudice, producing unexpected technical effect, and achieving commercial success. When any of these secondary factors are present, the examiner is instructed not to make a "rash determination" of the absence of an inventive step.[55] Finally, the *Guidelines* instruct examiners—in a way that US experts may not find altogether surprising—to "note" the following points in the examination of the inventive-step criterion: generally avoid considering how an invention is accomplished even if by accident; avoid ex post facto analysis and the influence of subjectivity; do not overemphasize any unexpected technical effect; and finally, direct the analysis to the technical solutions as defined in the claims but considering the technical solution as a whole, rather than the individual technical features.[56]

SIPO assesses inventiveness differently for invention patents and utility model patents: whereas inventiveness for inventions requires "prominent substantive features" and "notable progress" over the state of the art at the filing date, utility model patents require only "substantive features" and "progress."[57] In fact, utility models are not examined as to substance, so "a large number of inventions-creations that are not inventive enough" are filed as utility model patent applications.[58] Judges have more discretion with utility model patents in determining the scope of prior art to reference.[59]

With respect to chemical inventions (including genes), if the claimed invention has a similar structure to any known compound, then in order to show inventiveness, it must be shown that the claimed invention has an "unexpected use or effect."[60] With respect to computer software, the Examination Guidelines require that

54. SIPO GUIDELINES, *supra* note 47, ¶ 4.2. The USPTO also uses this rationale based on *KSR*, 550 U.S. at 398.

55. SIPO GUIDELINES, *supra* note 47, ¶ 5.

56. *Id.* ¶¶ 6–6.4. This is also similar to the US approach.

57. Raymond M. Gabriel, *The Patent Revolution: Proposed Reforms in Chinese Intellectual Property Law, Policy, and Practice Are the Latest Step to Bolster Patent Protection in China*, 9 ASIAN-PAC. L. & POL'Y J. 323, 334 (2008).

58. Meng Fanxin, *Application of Equivalent Doctrine in Utility Model Patent Infringement Lawsuit*, 2006 CHINA PATENTS & TRADEMARKS 15.

59. Li Yonghong, *How to Define the Height of Inventiveness of Utility Model?*, 2008 CHINA PATENTS & TRADEMARKS 26–28.

60. *See id.*; *see also* Liu Xuqiang, *On the Inventiveness of Compounds Structurally Similar to Known Compounds*, 1997 CHINA PATENTS & TRADEMARKS 32–35 (discussing how SIPO assesses inventiveness of homologues, isomers, and analogues).

a computer-related invention "is intended to solve a technical problem, uses a technical means and is capable of producing a technical result" to meet the inventiveness requirement.[61] This is similar to the European approach to evaluating non-obviousness of software inventions, though "technical contribution" is better defined in the EPO jurisprudence.[62]

The case of *Schneider v. PRB and Chint* is an example of how the judiciary evaluates the inventiveness of a claimed invention. In that matter, the Beijing Higher People's Court concluded that in determining inventiveness of patents in the field of electricity, account should be taken not only of the connection of the circuit, but also the working state of the circuit. Differences in technical conception and technical solution resulting from a different working state generally produced an effect different from the prior art. The court determined that one skilled in the art would know that the value tested at one point in one of the references cited was the induction electric signal resulting from the change in the magnetic conductivity of the electromagnetic coil, after cutting off the supply of field current through the electromagnetic coil; and the tested value at another point was the change in the voltage at the artificial median point of the electric line output end at the disconnection of the contacts. By contrast, the patent in suit tested the field current going through the electromagnetic coil. This difference showed that the two technical solutions were in a different working state. In other words, the patent in suit, which was directed at resolving the technical problem of testing the dissipation loss of the switch, did so in a way quite different from the cited reference 1 and afforded a technical solution of different technical conception. It achieved a technical effect better than the prior art, and hence the Beijing Higher People's Court concluded it possessed inventiveness.[63]

China's inventive-step standard has been described as higher than the corresponding US and EPO standards.[64] For example, compared with the EPO approach, in China the problem, solution, *and effect* are interpreted in combination. [65] By contrast, the EPO, has adopted a problem-and-solution approach that focuses on the nearest prior art concerning the problem solved, identifies the solution disclosed in the application, considers whether the solution fits the

61. Li Yonghong, *Patent Protection for Software from the Perspective of EC Proposal for a Directive*, 2003 CHINA PATENTS & TRADEMARKS 26–30.

62. *Id.*

63. Latest Developments in Patent Trial, *supra* note 51; *see* Beijing Higher People's Court's Administrative Judgment No. Gaoxingzhongzi 225/2009; Beijing No.1 Intermediate People's Court's Administrative Judgment No. Yizhongxingchuzi 1156/2008.

64. *See* Li & Li, *supra* note 42, at 136.

65. *See id.* at 137; X.D. ZHANG, SUBSTANTIAL CONDITION OF PATENTABILITY (2002).

problem identified in the prior art, and then decides whether a person skilled in the art would find it obvious.[66]

B. India

The Indian Patents (Amendment) Act of 2005 made significant changes to the Indian Patent Act of 1970, including the introduction of product patents in the pharmaceutical field but also an exclusion in Section 3(d) of patents for "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance".[67] This followed a debate over what should be patentable in India, and took place against a backdrop of significant concerns about healthcare costs and other public health ramifications.[68] The government is trying to balance the emerging research-based industry in biotechnology and those using traditional (e.g., Ayurvedic) principles to develop new treatments, while providing access to antiretroviral and other patented drugs to the public[69] For example, India was not obligated to extend patents to pharmaceuticals until 2005, but the requirement that so-called "mailbox" applications should receive "exclusive marketing rights" was implemented by providing up to five years (or until the issuance or rejection of the patent application) a limited right to exclusively market the drug or medicine in question.[70]

The 2005 amendment to the Patents Act defines an "inventive" step to mean "a feature of an invention that involves technical advance as compared to the

66. *See* AMANDA WARREN-JONES, PATENTING rDNA: HUMAN AND ANIMAL BIOTECHNOLOGY IN THE UNITED KINGDOM AND EUROPE (2001). A factor not taken into consideration is the amount of effort expended to reach the solution if the work to achieve the solution was otherwise straightforward. *See* Unilever, EPO Technical Board of Appeal, T 939/92 (OJ EPO 1996, 309).

67. *See* India Patents Act, No. 39 of 1970, *as amended by* Patents (Amendment) Act, No. 15 of 2005, INDIA CODE (2005) [hereinafter India Patent Act]. In 1999, the Indian Parliament passed the Patents (Amendment) Act of 1999, made retroactive to January 1, 1995, to comply with the WTO decision that required a statutory provision for the mailbox/exclusive marketing rights provided for in TRIPS Article 70.9. For a more complete history, see Peter Drahos, *supra* note 17, at 81–84; Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act 2005*, 1 INDIAN J. L. & TECH. 22 (2005).

68. *See* Grace, *supra* note 42.

69. *See* Padmashree Gehl Sampath, *India's Product Patent Protection Regime: Less or More of "Pills for the Poor"?*, 9 J. WORLD INT. PROP. 694, 703–10 (2006).

70. Patents Act, 1970, § 24B. The extra transitional period (until January 2005) is contained in TRIPS Article 65.4. The mailbox system is provided in Article 70.9. On those provisions, see GERVAIS, *supra* note 6, at 545–46. On the Indian application, see Brook K. Baker, *India's 2005 Patent Act: Death by Patent of Universal Access to Second and Future-Generation ARVS?*, GLOBAL AIDSLINK (Sept./Oct. 2005), *available at* http://lists.essential.org/pipermail/ip-health/2005-September/008301.html.

existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art."[71] This "non-obviousness–plus" standard, a departure from India's former precedents, has been criticized as being a "'vague and arbitrary' definition that fails to 'reflect the distilled stock of knowledge' on what nonobviousness means."[72] The "technical advance" criterion, for example, "invites qualitative comparisons with the prior art but is devoid of any requirement that such comparisons be made from the perspective of a person of ordinary skill in the art at the time of application filing."[73] As for the "economic significance" requirement, it is unclear whether this is analogous to the US "commercial success" secondary consideration or simply redundant with the utility requirement.[74]

Section 3(d) of the Patents Act as amended, which excludes "derivatives of a known substance" from patentability unless the claimed invention "differ[s] significantly in properties with regard to efficacy," seems to be aimed at "preventing frivolous patents that are only trivial modifications of existing inventions."[75] This provision was the subject of the recent Novartis litigation. The Patent Office refused to grant Novartis a patent for Gleevec (imatinib mesylate).[76] The Patent Office reasoned that "because imatinib mesylate was a salt form of the free base imatinib, and Novartis claimed all pharmaceutical salt forms of imatinib" in earlier patents in the United States and elsewhere, the Indian patent therefore lacked novelty and inventiveness.[77] Further, the Patent Office held that, although the Novartis invention "had a 30% increase in bioavailability (the percentage of the drug absorbed into the bloodstream) as compared with imatinib," this was insufficient to meet the "enhanced efficacy" requirement of Section 3(d).[78] Finally, the Patent Office noted that the discovery of imatinib mesylate was obvious because "once the free base was disclosed in the 1993 Patent, it would have been 'obvious

71. GERVAIS, *supra* note 6, at 545–46.

72. *Id.*

73. *Id; see also* Vijay Yalamanchili, *State of India's TRIPS-Compliant Patent Regime*, 26 BIOTECH. L. REP. 211, 217 (2007) ("'The Indian MPP suggests using the following question during examination: 'Would a non-inventive mind have thought of the alleged invention?'").

74. Mueller, *supra* note 22. Since many patent applications are filed well before the invention has achieved any commercial success, "strict imposition of the new 'economic significance' language is likely to prejudice independent inventors and small business entities." *Id.*

75. Linda L. Lee, *Trials and TRIPS-Ulations: Indian Patent Law and* Novartis Ag v. Union of India, 23 BERKELEY TECH. L.J. 281, 294–95 (2008).

76. *Id.*

77. *Id.*

78. *Id.*

for a person skilled in the art to prepare corresponding pharmaceutically acceptable salts.'"[79]

Novartis, which had obtained from the Madras High Court an interim order for Exclusive Marketing Rights while its patent application was under examination, filed two writ petitions after the rejection: an appeal to the rejection order and a challenge to the validity of Section 3(d) on the grounds of incompatibility with India's obligation under TRIPS. [80] Novartis also contended that the patentability standards were arbitrary and in violation of the Equal Protection provisions of the Indian Constitution.[81] In response, the government argued that examiners had used scientific tools to make a determination on efficacy and, in any event, that there were higher forums to appeal an examiner's decision.[82]

The Madras Court ruled that Section 3(d) was constitutional, noting that "ambiguity was intended by the Parliament in order to avoid fixing a specific formula to be applied in all situations.... The Court noted that the legislative body, who were not technical experts, intended to provide the Patent Controller with a high degree of discretion to deal with both present and future technologies on a case-by-case basis."[83] On the compatibility with TRIPS, the Court declared that it had no jurisdiction to entertain a challenge based on TRIPS, a view with which two noted commentators took exception.[84]

On the substance of the patent dispute, the Court referred the matter to the Intellectual Property Appellate Board (IPAB). On June 6, 2009, the IPAB of Chennai rejected the lawsuit against the decision of the Patent Office. The IPAB ruled that Novartis's patent application covering Gleevec was not patentable under the Patents Act, noting that Section 3(d) is a heightened inventive-step standard.

79. Johanna Sheehe, *Indian Patent Law: Walking the Line?*, 29 Nw. J. Int'l L. & Bus. 577, 586 (2009).

80. *See* Shamnad Basheer & T. Prashant Reddy, *The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5 SCRIPTed 232, 237 (2008), *available at* http://www.law.ed.ac.uk/ahrc/script-ed/vol5-2/basheer.asp.

81. Constitution of India, art. 14, *available at* http://www.indiacode.nic.in/coiweb/welcome.html (last visited Sept. 3, 2013)

82. *See* Susan Fyan, *Pharmaceutical Patent Protection and Section 3(D): A Comparative Look at India and the U.S.* (2010), 15 Va. J.L. & Tech 198.

83. *Id.* The argument that patent offices should have more power to adapt the patentability criteria to evolving innovation practices and technological developments is supported by a number of commentators. *See* Dan L. Burk & Mark A. Lemley, The Patent Crisis and How the Courts Can Solve It 95–109 (2009); Michael J. Burstein, *Rules for Patents*, 52 Wm. & Mary L. Rev. 1747 (2011).

84. *See* Shamnad Basheer & Prashant Reddy, *"Ducking" TRIPS in India: A Saga Involving Novartis and the Legality of Section 3(d)*, 20 Nat'l Law Sch. of India Rev. (2008), *available at* http://ssrn.com/abstract=1329201.

The IPAB also held that the efficacy referred to in Section 3(d) was therapeutic efficacy. Novartis's product may possess improved bioavailability, thermodynamic stability, improved flow properties, and lower hygroscopicity, but according to IPAB this did not amount to an increase in "therapeutic efficacy."[85]

As a consequence, "Section 3(d) as applied to date appears to exclude from patentability new salt forms as well as new polymorphic forms of previously known substances. Exclusion of such new forms seems to be without regard to any improvement in properties such as bioavailability or physical or chemical stability of the drug."[86] However, the requirement of enhanced efficacy means that although some evergreening is not possible, patents for drug versions with even incremental efficacy should be available.[87]

Interestingly, recent Federal Circuit opinions in the United States do not seem to be radically different in result, if not reasoning. Pfizer's patent for the besylate salt of the drug amlodipine was invalidated after the Federal Circuit determined that a skilled artisan would have been motivated to combine prior art references to achieve the claimed invention, and that it would have been obvious to one skilled in the art to try substitution of the besylate salt for the earlier maleate salt form that had created issues of sticky tablets.[88]

Then, in *Schering Corp. v. Geneva Pharms, Inc.*, the Federal Circuit invalidated a patent for an active metabolite of the allergy drug loratadine (Claritin), on the grounds that "a limitation or the entire invention is inherent and in the public domain if it is the 'natural result flowing from' the explicit disclosure of the prior art."[89] According to one commentator, "it is conceivable that the concept of anticipation through inherency could be applied to new salt and polymorphic forms as well."[90]

With respect to genetic inventions, "there is unlikely to be an inventive step in identifying from within a sequenced genome any new gene, even those without known homologues," for it is "obvious to trawl the genome for previously unidentified genes, and any skilled worker would have some expectation of

85. *Id.* at 134–35.

86. Fyan, *supra* note 82.

87. *See* Shamnad Basheer, Limiting the Scope of Pharmaceutical Patents and Micro-Organisms: A TRIPS Compatibility Review (2005). On the notion of evergreening, see *infra* note 121. The Indian Supreme Court affirmed that Gleevec is not patentable in India. Novartis AG v. Union of India, Nos. 2706–16 (S.C. Apr. 1, 2013) (India), *available at* http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212.

88. Pfizer, Inc. v. Apotex, Inc., 480 F. 3d 1348, 1361–68 (Fed. Cir. 2007).

89. Schering Corp. v. Geneva Pharms, Inc., 339 F.3d 1373, 1379–80 (Fed. Cir. 2003).

90. Fyan, *supra* note 82.

success."[91] In *Genentech,* the court noted that a genetic invention was obvious if "'the materials in question were lying in the road and ready for a research worker to use,'" even if the skilled man faced a number of obstacles in proceeding to his goal. However, if overcoming these obstacles required "'a spark of imagination…beyond the imagination properly attributable to him as a man skilled in the art' then there may be some element of inventive step."[92]

II. Utility/Industrial Applicability

Thomas Jefferson is said to have devised the utility requirement in the 1793 Patent Act of the United States.[93] A high threshold of utility might be defined, based on the plain meaning of the words, as requiring evidence that the claimed invention accomplishes a socially desirable goal. Industrial applicability seems a stricter notion. The evidence required here might be that the invention can in fact be used in at least one "industry." Due in part to a perception that the Patent Office is ill-equipped to gauge actual utility of an invention, the current US standard is extremely low: basically an invention is useful if it "does something."[94] Yet, as the US Supreme Court noted in the famous case of *Brenner v. Manson,* "[T]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility."[95]

In Europe, the industrial applicability criterion is applied liberally and "industry" in that context is basically any economic activity.[96] In keeping with TRIPS,

91. COMPTROLLER GEN. OF PATENTS DESIGNS & TRADEMARKS, REPORT OF THE TECHNICAL EXPERT GROUP ON PATENT LAW ISSUES (2006), *available at* http://ipindia.nic.in/ipr/patent/mashelkar_committee_report.doc.

92. *Id.*

93. "Although the Patent Act was amended, revised or codified some 50 times between 1790 and 1950, Congress steered clear of a statutory set of requirements other than the bare novelty and utility tests reformulated in Jefferson's draft of the 1793 Patent Act." Graham v. John Deere Co., 383 U.S. 1, 10 (1966) (citing THOMAS JEFFERSON, V WRITINGS 47 (Paul Leicester Ford ed., 1895)); *see also* JEFFREY H. MATSUURA, JEFFERSON VS. THE PATENT TROLLS: A POPULIST VISION OF INTELLECTUAL PROPERTY RIGHTS 37–38, 41 (2008).

94. The US Manual of Patent Examining Procedure (MPEP) (last revised July 2010) states that "[i]f the applicant has asserted that the claimed invention is *useful for any particular practical purpose* (i.e., it has a 'specific and substantial utility') and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility." USPTO, MPEP, § 2107(II)(B)(1) (8th ed., 2001, as amended) (emphasis added), *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep-2100.pdf. It all seems to boil down to a somewhat credible assertion by the applicant.

95. 383 U.S. 519, 534–35 (1966).

96. In the words of Justice Hitchin of the English High Court: "All manufacturing, extracting and processing activities of enterprises that were carried out continuously, independently

all that is required is *potential* applicability.[97] However, there are limits. First, the exploitation of a patent on human biological materials might violate the morality provision.[98] Second, inventions destined to be used in private (e.g., a contraceptive method) would not be "industrially" applicable. In the case of DNA sequences, industrial applicability can have a significant impact. The English Court of Appeals recently noted that "just describing the existence of a protein and its structure is not enough. Nor is it enough to describe the function at a high level of generality—e.g., that the compound must have a significant function biologically and so it (or its antibodies) may be usable to treat some sort of disease. You have to say what it is for with more particularity."[99] Interestingly, the court signaled that it was in a better position to make a determination of industrial applicability, which in that case required a fact-intensive inquiry that a patent office was ill-equipped to perform, mostly relying instead on the applicant's assertions.[100] The UK Supreme Court reversed, noting that plausibility of a claimed use, or an "educated guess," could suffice, adding that otherwise there might be a "chilling effect on investment in bioscience."[101]

A. China

"Practical applicability," deemed the equivalent of "utility,"[102] means that the invention "can be made or used and can produce effective results."[103] This requires that the invention be repeatable and not be contrary to established natural law and, not unlike the US standard, not be negative or harmful.[104] An invention must

and for commercial gain." Eli Lilly and Company v Human Genome Sciences Inc. [2008] EWHC 1903, conf. by [2010] EWCA Civ 33 (Eng. C.A.), *rev'd,* [2011] UKSC 51. Article 57 of the EPC, *supra* note 37, extends industry to "any kind of industry, including agriculture." *See also* Aurora Plomer, *Towards Systematic Legal Conflict: Article 6(2)(c) of the EU Directive on Biotechnological Inventions, in* EMBRYONIC STEM CELL PATENTS: EUROPEAN LAW & ETHICS 189 (Aurora Plomer & Paul Torremans eds., 2009); Chiron Corp. v. Murex Diagnostics Ltd. [1996] R.P.C. 535, 607.

97. TRIPS Article 27.1 says "*capable* of industrial application." TRIPS Agreement, *supra* note 1, art. 27.1; *see also* Plomer, *supra* note 96, at 190.

98. EPC, *supra* note 37, art. 53(a); *see also* Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 98/44/EC, art. 6 & pmbl. ¶ 37, 1998 O.J. (L 213), 13.

99. Human Genome Scis. v. Eli Lilly, [2008] EWHC 1903, ¶ 64.

100. *Id.*

101. *Id.* ¶¶ 122, 145, 171.

102. Louis S. Sorell, *Comparative Analysis of Selected Aspects of Patent Law in China and the United States,* 2002 PAC. RIM LAW & POL'Y J. 319, 326 (2002).

103. China Patent Act, *supra* note 44, art. 22.

104. *See* Gabriel, *supra* note 57; *see also* Yahong Li, *Imitation to Innovation in China: The Role of Patents in Biotechnology and Pharmaceutical Industry* 132 (2010); Zhang Xiaodu,

generally meet the needs of society, which inventions that pollute the environment, seriously waste energy or other resources, or injure human health would not.

Here we see that even a standard expressed in the statute as a fairly high threshold (evidence of positive effects or results) has apparently been watered down to a not negative standard by the Patent Re-examination Board (PREB).[105] In the pharmaceutical field, human clinical trials are not required, as expectation of applicability to humans can be presumed from animal or other efficacy tests.[106]

Still, China's practical applicability requirement seems broader than the "industrial applicability" adopted by some other countries, allowing more inventions to qualify for patent protection.[107] For instance, in Europe, where "an invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture," an invention that could be manufactured, but not industrialized, would not pass the "industrial application" test; however, such an invention would meet China's utility requirement.[108] This broader standard is reflective of the role of economic development policies in the formation of Chinese patent law.[109]

In the case of pharmaceuticals, the invention must "produce positive effects," which implies effects that are stable and repeatable.[110] Traditional medicines that can only be made manually are not industrially applicable, nor are methods of medical treatment.[111]

B. India

An invention has "industrial applicability" in India if the product can be (1) made, (2) used in at least one field of activity, and (3) reproduced with the same characteristics as many times as necessary.[112] Usefulness depends not on whether the

Practical Applicability and Full Disclosure of Technical Solutions, 2002 CHINA PATENTS & TRADEMARKS 23–28.

105. *See* Decision 2758, June 18, 2002, international category A01N57/14; Li, *supra* note 104, at 132–33.

106. Li, *supra* note 104, at 133.

107. Kong Qingjiang, *The Political Economy of the Intellectual Property Regime-Building in China: Evidence from the Evolution of the Chinese Patent Regime*, 21 PAC. MCGEORGE GLOBAL BUS. & DEV. L.J. 111, 121 (2008).

108. Xuqiang, *supra* note 60.

109. Qingjiang, *supra* note 107.

110. *See* Li & Li, *supra* note 42, at 142.

111. *See id.* at 143.

112. Yalamanchili, *supra* note 73.

invention will have commercial success, but whether the invention "had utility at the date of filing and will actually have the effects the patentee professed."[113]

According to the Patent Office Manual, "industry" should be "understood in its broad sense (as it is in the EPO), which includes any useful and practical, as distinct from intellectual or aesthetic, activity. As such, it does not necessarily imply the use of a machine or the manufacture of a product and covers such thing as a process for dispersing fog or a process of converting energy from one form to another."[114] However, "vague and speculative indication of possible objectives that might or might not be achievable by carrying out further research with the tool as described is not sufficient for fulfillment of the requirement of industrial applicability" because "the purpose of granting a patent *is not to reserve an unexplored field of research* for an applicant."[115] The reader of the patent should not need to look for ways "to exploit it in industry by carrying out work in search for some practical application."[116]

Although the exclusion applies to inventions that defy the laws of nature (a typical example being a perpetual motion machine) or machines that cannot perform the function described in the application, in India it also excludes from the realm of patentability methods of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body and parts/pieces of the human or animal body to be used in transplants.[117]

India also excluded from patentability a number of potential inventions that might have fallen on the sword of utility. Article 3 of the Patent Act provides inter alia that the following shall not be patentable:

- An invention that is frivolous or that claims anything obvious, contrary to well-established natural laws. The notion of frivolity was interpreted as applying to an application for making in one piece, an article previously made in two or more pieces, noting that "mere usefulness" was insufficient.[118]

113. *Id.*

114. EUROPEAN PATENT OFFICE (EPO), GUIDELINES FOR EXAMINATION IN THE EUROPEAN PATENT OFFICE 5.1 (June 2012), *available at* http://www.epo.org/law-practice/legal-texts/guidelines.html.

115. Decision of the Boards of Appeal of the European Patent Office, Case T0870/04, ¶ 64 (May 11, 2005), *available at* http://www.epo.org/law-practice/case-law-appeals/pdf/t040870eu1.pdf.

116. *Id.* ¶ 19.

117. *Id.* ¶ 59. On inventions that cannot work as described and claimed, see Eastman Kodak Co. v Am. Photo Booths Inc., BLO/457/02. Such applications might also fail on the disclosure and enablement fronts.

118. Indian Vacuum Brake Co. Ltd. v. Laurd, AIR 1962, Cal 152.

A perpetual motion machine alleged to be giving output without any input is not patentable as it is contrary to natural law.

- An invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;[119]
- The mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or nonliving substances occurring in nature; and, as already discussed, the mere discovery of a new form of a known substance that does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine, or apparatus unless such known process results in a new product or employs at least one new reactant. [120] It has become common practice in the pharmaceutical industry to repackage a molecule (active ingredient) with known salts, metabolites etc., in some cases with little if any demonstrated advantage, to claim a new patent, one of the forms of "evergreening" (the prolongation of rent from otherwise out-of-patent branded medications) that has been criticized.[121] Pharmaceutical companies have argued that the cost of research requires protection beyond the twenty-year term on a new drug, much of which is not used to commercialize the drug because of regulatory approval processes.[122] This is an empirical matter that is beyond the scope of this chapter, but one on which different countries, at different stages of development and with different industrial setups and public health concerns, might examine from dissimilar perspectives.

119. India Patent Act, *supra* note 67, art. 3b.

120. *Id.* arts. 3c–d.

121. "Evergreening" techniques writ large include getting laws enacted requiring generic manufacturers to notify brand name competitors of their intention to enter the market and requiring government regulators not to give marketing approval for a generic medicine unless no contrary patent claims can be established (the Canadian system); getting a patent covering the capsule or gel of the drug, instead of its contents; threat of litigation; introducing once-a-day versions of a drug just before patent expiration to replace a three-times-a-day form or bringing a single isomer version of a drug that was previously marketed as a racemic isomer; asking doctors to attack generic products in academic journals; contractual agreements in which the generic manufacturer agrees not to enter the market in return for financial remuneration from the brand name manufacturer; and last but not least using data exclusivity forbidding generic companies from using the original safety and efficacy data for a period of time. *See* Thomas Faunce, Submission to the Department of Foreign Affairs and Trade Review of Export Policies and Programs 53–54 (May 2, 2008) (Austl.), *available at* www.dfat.gov.au/trade/export_review/submissions_received/TheAustralianNationalUniversityDrThomasFaunce.doc.

122. *See* Robert Chalmers, *Evergreen or Deciduous? Australian Trends in Relation to the "Evergreening" of Patents*, 30 MELB. U. L. REV. 29, 32 (2006).

- A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;[123]
- The mere arrangement or rearrangement or duplication of known devices each functioning independently of one another in a known way.[124]

It seems fair to say that India has decided not to rely only, or even mainly, on patentability criteria to exclude from patentability matter that it considers unpatentable. The best example is Article 3(d) of the Patent Act, which has been described as "crude, but constitutional."[125] It may be, however, that the definitional flexibility resulting from the undefined nature of the three main patentability criteria in TRIPS Article 27 would be the hook to justify the compatibility of the measure with TRIPS, in keeping with Article 1.1. Another option is to look at Article 30 as an exception, but Article 30 seems designed to provide exceptions to patent rights, not subject matter.

III. Lessons

As an early expert on US patent law, Willard Phillips noted that deciding what kinds of subjects should be covered by patents is a very difficult task.[126] Additionally, patentability rules—like most rules—can rapidly become obsolete because by definition patent law will encounter subject matter not before seen.[127]

Are general standards better than more specific ones? The debate about the flexibility of patentability standards enunciated in TRIPS, namely inventive step and industrial applicability, which may be "deemed to be synonymous" with non-obviousness and utility, respectively, is linked to the debate about rules versus standards. At the very least, echoes of that debate reverberate here, as well.[128]

Although the demands of global industries, especially pharmaceutical companies, to have as much uniformly high protection as possible, and to allow as many forms of evergreening as possible, are understandable, a world in which patent offices may be said to apply a strict patentability rule simply is not upon us.[129]

123. India Patent Act, *supra* note 67, art. 3e.

124. *Id.* art. 3f

125. Basheer & Reddy, *supra* note 80, at 265.

126. WILLARD PHILLIPS, THE LAW OF PATENTS FOR INVENTION 76 (1873).

127. *See* THOMAS WEBSTER, THE LAW AND PRACTICE OF LETTERS PATENT FOR INVENTIONS 9 (1841).

128. TRIPS Agreement, *supra* note 1, art. 27.1; *see* Ruth Okediji, *Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement*, 17 EMORY INT'L L. REV. 819, 902–03 (2003).

129. *See* Dianne Nicol, *Strong Patent Rights, Weak Standards and Innovation in Biomedicine*, *in* INTELLECTUAL PROPERTY POLICY REFORM 55–56 (Christopher Arup & William van Caenegem eds., 2009).

Patent offices, at least those that examine incoming applications, and the courts that review their decisions, must retain a degree of flexibility.

Echoes of the "rules versus standards" debate can be heard in the demands of TRIPS-plus advocates to cabin any flexibility in *refusing* patents for non-obviousness (for example parents on new forms of known substances) or lack of utility (for example because the application discloses no known treatment, as in many genetic sequence patents). One might say a rule is then superimposed on a standard to limit the field of application of that standard. This is problematic according to the traditional distinction because it is assumed to have a temporal component. A rule does not differ from a standard simply because of the specificity of the command, but also because it typically provides content ex ante, whereas a standard is used to consider conduct ex post.[130]

TRIPS demanders typically assert that patents are necessary to empower market forces to create incentives for innovation.[131] However, this does not make a case for a uniform standard across industries and technologies, because each may have its own market structure, thus requiring flexible standards.[132] Moreover, even if a good degree of predictability seems a priori desirable, one should distinguish the predictability of the notice function (e.g., the scope of the property rights claimed) from the application of the patentability criteria.[133] Greater ex ante predictability of the scope of a patent (essentially, rules concerning the construction of claims) allows easier and more efficient private ordering, legal advice, etc. However, strict patentability *rules* may not take account of changes and variations in a technological field and differences among technological fields.[134] Indeed, decisions about patentable subject matter are often informed by policy judgments about the desirability of patents in a given area.[135] Here, a standard often may seem fairer because it allows the decision-maker to factor in relevant circumstances, but it may also involve greater transaction and evidentiary costs.

130. *See* Louis Kaplow, *Rules versus Standards, An Economic Analysis*, 42 DUKE L.J. 557, 559 (1992).

131. *See* JOEL MOYKR, THE GIFTS OF ATHENA: HISTORICAL ORIGINS OF THE KNOWLEDGE ECONOMY 76 (2002).

132. *See* BURK & LEMLEY, *supra* note 83, at 95.

133. *See* Craig A. Nard, *Legal Forms and the Common Law of Patents*, 90 B.U. L. REV. 51, 80 (2010).

134. *See id.* at 99 ("[T]he judge, in the Hayekian sense, is more closely tethered to industry customs and norms, and this is more likely to develop doctrine that reflects the parties' and the relevant industry's expectations.")

135. *See* John F. Duffy, *Rules and Standards on the Forefront of Patentability*, 51 WM. & MARY L. REV. 609, 617 (2009–10) (discussing Justice Breyer's opinion in Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124 (2006)).

Leaders in some industries believe that greater harmony in defining what is patentable will lead to more uniform global markets, reduced transaction costs, and more possibilities for rent extraction from more countries. They might refute the access to medicine concerns, for example, by stating that getting the patent is only a first step, and that measures to allow access by poorer patients can be taken as a second step, and that indeed taking that step (e.g., providing low-cost or free drugs) will be easier if patent rents are paid by more affluent patients in the developing world.

This cuts both ways however. First as to the method: India has shown that it can use rules to remove the flexibility to *grant* a patent on, for example, new forms of known substances.[136] We see this in the ruling by the Madras High Court, which noted the considerable degree of (necessary) discretion left to examiners and the Patent Appeal Board. Second, on the normative underpinning, one might counter that granting a patent and then having to go through a possible compulsory license exercise imposes transaction costs on the state and causes delays. Empirically, those who take this position might point to the sharp drop in new molecules in the approval pipeline in spite of their having the highest level of protection for the industry.[137] That said, countries who take a position viewed as unfavorable by the "TRIPS- plus" demanders should expect repeated visits by European and US officials and possible threats of retaliatory action, which in itself is a transaction cost worth pondering.

Indeed, the Indian decision concerning Novartis's Gleevec seems informed by the belief that fewer patents should result in a stronger indigenous industry, particularly in the area of pharmaceuticals and chemicals.[138] Article 3(d) of the Patents Act, presented as requiring a higher threshold of inventiveness, is a policy implementation of that belief, as are provisions on compulsory licensing, the fairly wide experimental use exception, and the parallel import provisions contained in Indian law.

The policy issue at the core of the debate on pharmaceutical patents is optimal, cumulative innovation, which one may situate between banal incremental innovation and rare substantive departures from the prior art ("breakthroughs").[139] Although there are occasional major breakthroughs in biopharmaceutical research as in other areas, most patents are granted to follow-on innovators. Economists have been actively debating for several years the best way to allocate efficiency between original and follow-on

136. India Patent Act, *supra* note 67, art. 3d.

137. At least for antibacterial research. *See* David J. Payne, Michael N. Gwynn, David J. Holmes & David L. Pompliano, *Drugs for Bad Bugs: Confronting the Challenges of Antibacterial Discovery*, 6 NATURE REVS. DRUG DISCOVERY 39 (2007).

138. *See* Shamnad Basheer, *"Policy Style" Reasoning at the Indian Patent Office*, 3 INTELL. PROP. Q. 309 (2005).

139. *See* Correa, *supra* note 30, at 4.

inventors.[140] The risks at both ends of the policy spectrum—that is, extreme under- or overprotection—include a lack of incentive for innovation and patent thickets with anticommons effects (holdups), respectively.[141] There are several options between those extremes, including the application of compulsory licensing for dependent patent use and the application of competition law measures in cases of patent abuse.[142]

The binary nature of the debate is itself a significant part of the problem. As with TRIPS, the first two phases of which (namely first, an attempt to get as high a level of protection as possible followed by an attempt to resist TRIPS and lower protection) were both ill-advised as a single source for policy development.[143] Calibration is required here as in so many other fields of regulatory endeavor. The debate is not about getting as many proprietary rights to support privately funded (closed) innovation with high proprietary barriers versus making innovation available at the lowest cost. China, India, and other countries, including many ranked as industrialized, should experiment with other forms of innovation and adapt patentability standards accordingly. Open innovation, sharing of information, possibly allocating public funding among countries instead of competing as in the closed model may indeed lead to much more promising developments while giving private biopharmaceutical companies the leeway to continue to invent as they see fit. This broader approach may work better for orphan, tropical, or low-market diseases, as recognized by the World Health Organization.[144]

Patent pools and licensing will not solve all issues that open source innovators might face. A private party may patent a basic innovative step and prevent the exploitation of (more advanced) results funded by public and/or open source innovators. Although excesses in this sphere may be addressed in some cases by (typically complex) competition law measures, the scope of potential abuses may also be reduced by applying patenting standards and possibly exceptions to exclusive rights informed by the need to allow basic scientific progress. [145]

140. Nicol, *supra* note 129, at 69–70.

141. The evidence of anticommons effects exists but is reportedly counterbalanced by "prolific licensing activity." *See id.* at 71; *see also* Rebecca S. Eisenbeg, *Genomic Patents and Product Incentives, in* HUMAN DNA: LAW AND POLICY 373–74 (Bartha M. Knoppers, C.M. LaBerge & Marie Hirtle eds., 1997).

142. *See* UNAIDS, *supra* note 1.

143. *See* Gervais, *supra* note 18.

144. *See* WORLD HEALTH ORG. (WHO), THE PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY: GLOBAL STRATEGY AND PLAN OF ACTION (2009). Paragraphs 17 through 20 focus especially on essential medical research and development (R & D) relevant to diseases that disproportionately affect developing countries.

145. *See* Margo A. Bagley, *Academic Discourse and Proprietary Rights: Putting Patents in Their Proper Place*, 47 B.C. L. REV. 217, 223–24 (2006); Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 182–84 (1987).

Developing countries, in implementing patentability standards as part of a broader, systemic innovation strategy can and should avail themselves of opportunities that more industrialized countries, ensconced in strict constraints of private, market-based innovation, are unable to exploit. Public health is, one might suggest, about more than commerce but this is not my point.[146] Developing countries may have lower development costs for new drugs and can focus on orphan and tropical diseases that have a smaller market in industrialized countries. Current research focuses heavily on diseases not because they are serious or life-threatening but, rather, because they affect a significant number of potential buyers (patients). Some might see this as ideologically desirable or at least inevitable. Orphan-disease subsidies meant to correct this imbalance are not working well. [147] This notion points clearly to an advantage for lower-cost research environments, and the patent rents that those drugs could generate even in small markets in industrialized countries should be proportionally much more substantial if the drug was developed at a lower cost.

Beyond pharmaceuticals, the data concerning the benefits of patents are mixed in the aggregate. Bessen and Meurer report, for example, that "patents are neither the only nor even the most important means of encouraging innovation. On average, patents made a rather small contribution in this regard. Claims that the US patent system is responsible for current US technological leadership are exaggerated."[148] Still, a number of companies have benefited enormously from patents, and some would not exist but for the patent system. Proponents of strong patent protection can usually point to jobs created, etc. as a result of their patent-led growth, a good way to mollify policymakers, especially in hard economic times. However, it behooves those policymakers to consider the impact on their country's economy as a whole in making forward-looking policy, as opposed to anecdotal (but not necessarily insignificant, of course) examples in the rear-view mirror. Developing countries in particular might look at studies specific to

146. Though it is often made in this context. *See* Jeffrey D. Shelley, *Patent Pools for Orphan Diseases*, 18 ANNALS HEALTH L. ADVANCE DIRECTIVE 141, 149 (2009) ("[T]he social and economic benefits stemming from orphan disease research and development, and global access to related drugs, outweigh for-profit interests and is well worth the endeavor.").

147. *See, e.g.*, the Orphan Drug Act, 21 U.S.C.A. §§ 360aa–ee (2007); European Union Regulation on Orphan Medicinal Products, Regulation (EC) No. 141/2000, OJ L18, 22/1/2000; Therapeutic Goods Regulations, 1997, Part 3B (Austl.). Most commentators agree that, although those measures were helpful, much more is needed. Suggestions include more public research, patent pools, and biobanking. *See* Dan Phair, *Orphan Drug Programs, Public-Private Partnerships and Current Efforts to Develop Treatments for Diseases Of Poverty*, 4 J. HEALTH & BIOMED. L. 193 (2008); Shelley, *supra* note 146; Brian Su, *Developing Biobanking Policy with an Oliver Twist: Addressing the Needs of Orphan and Neglected Diseases*, 66 LA. L. REV. 771 (2006).

148. JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE 118 (2008).

their situation in crafting a patent policy most likely to develop their economy and local innovative potential.

India wants to leverage the fact that it has highly trained researchers but much lower costs than US and European laboratories.[149] Seen in this light, there is no reason not to support significant increases in the use of the patent system, "a rent extraction machine, which, used correctly, allows domestic firms to dominate foreign markets."[150] Yet winning the global innovation game by imposing lower patentability standards is a risky endeavor, at least temporarily: more patents likely will be granted to foreign applicants thus imposing additional rents and licensing constraints on Indian researchers and users.[151]

If a country decides not to invest in substantive patent examination, it has a number of options. One is to grant all patents applied for, and let courts debate their validity in case of infringement. Another is to have the applications examined by a foreign patent office. In that latter scenario, a country would have the option of going to a major industrialized Office (e.g., EPO, JPO, USPTO) or to the office of a developing countries with kindred views on development. In either case, however, the matter of whether a patent is valid and infringed will appear before courts sooner in later. Developing countries should be training judges and members of the local bar, providing them with interpretive tools and at least an overview of the underlying policy issues. Courts should adopt rules allowing themselves to appoint a neutral expert if necessary, as is the case in a number of European systems.[152]

A developing country might well decide to adopt fairly high standards, so as to exclude inventions that have no clear usefulness or that seem such a small incremental step that they could be considered "obvious." Yet, the patent system was not designed only for pioneer inventions, those major technological breakthroughs capable of transforming an industry or indeed establishing a new one; the obviousness and utility criteria are more typically filters that apply to "close calls." If the standard is too high, local inventors might be discouraged. Efforts in China and India to develop indigenous standards should be welcomed by policymakers in the developing world as they are likely to broaden the palette of options available to them in that regard.

Patent policy might be used to exclude subject matter, such as "pure" software or business methods for example. That may be made partially dependent on

149. *See* Drahos, *supra* note 17, at 90–91.

150. *Id.* at 91.

151. Drahos reports that the 1250 in-house R & D institutions in India had collectively filed only 743 applications, a much lower number than their counterparts in China. *Id.*

152. Strict rules are also required to ensure the neutrality of the expert.

industrial applicability for example, but may also be excluded at the subject matter level. Excluding software is a good example of a risk worth calculating: in many developing countries, access to computers and an abundance of bright programmers may lead to a rapidly emerging industry, one that is much less costly to establish than, say, a biotechnological research industry.[153] To make appropriate policy, one should consider the evidence of the impact of patents on the software industry. This should include consulting with, and providing information to, students in engineering and computer science schools and in small and medium businesses. Still, obviousness and utility will apply directly to genetic and many pharmaceutical reformulation patents, and those decisions may have considerable welfare and trade impacts and should thus be properly calibrated. More important perhaps, if a country wishes to develop its innovation potential, much more than calibrated patentability standards are required. Inventors must understand the patent system and have access to the necessary assistance to use it. In particular applicants who wish to obtain protection in foreign markets often need venture-type funding to finance a Patent Cooperation Treaty (PCT) process. At an even more fundamental level, education systems must reflect the value of inventiveness and creativity and provide the intellectual toolkits to enable citizens to innovate effectively. Patents can be barriers for many inventors because the threshold of inventiveness and especially novelty is usually judged in light of worldwide prior art. This means that local inventors must be global innovators.

Conclusion

In this chapter, I situated the "semantic" flexibilities following from the use of undefined terms in the TRIPS Agreement in the broader context of other forms of policy space available to WTO members in their effort to implement TRIPS and calibrate such implementation to maximize innovation outcomes while trying to minimize welfare and transition costs. I then considered two specific undefined terms, non-obviousness/inventive step and utility/industrial applicability, and how those definitions may be implemented in national law to embody domestic policies specific to a country's priorities. Such national design flexibility in applying these international standards may produce significantly different outcomes and better align patent law to the innovation goals with which it is often associated without compromising interests in making public goods readily accessible. Definitional flexibility, as seen in India and

153. *See* Robert E. Thomas & Larry A. DiMatteo, *Harmonizing the International Law of Business Method and Software Patents: Following Europe's Lead*, 16 TEX. INTELL. PROP. L.J. 1, 37 (2007).

China, allows for policy experimentation in supporting research in new fields of scientific inquiry, providing adequate levels of incentives for those industries that depend more heavily on patents and, ultimately, in assuring that the patent system produces net gains that are meaningful in the specific context of each country.