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Reconsidering the U.S. Patent System: Lessons from Generics

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NOTE

Reconsidering the U.S. Patent System: Lessons from Generics

ABSTRACT

Scholars and pharmaceutical industry representatives consider the United States a worldwide leader in pharmaceutical innovation. However, the recent expansion of the international generics market has threatened the strength of the U.S. pharmaceutical industry. The pressure has led to the U.S. market's overreliance on a patentability standard that blocks generics competition without contributing substantially to the state of the art. This Note contrasts the U.S. nonobviousness standard and patent linkage regime with those of generics giants India and Israel and considers the effects of these policies on the relevant national and international generics industries. This Note proposes that the United States revise its current approach to patent protection of pharmaceuticals by adopting a heightened nonobviousness standard and lengthening the available patent-term-restoration period through modifications to the linkage regime. Only by balancing these two legal mechanisms will the United States maintain its status as the international leader in blockbuster pharmaceuticals.

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I. INTRODUCTION

Many people criticize brand-name drug manufacturers in the U.S. pharmaceutical industry for monopolizing drug therapies, thereby limiting global access to life-saving drugs.¹ The United States encourages high-risk research and development in the industry by ensuring strong intellectual property protection of pharmaceutical technologies domestically through (1) a relatively low standard of nonobviousness for patentability, and (2) the ability to extend the life of a patent beyond the standard term.² These pro-patent tools are intended to reduce the inherent risks associated with costly drug development, motivating U.S. manufacturers to continue advancing

1. See MICHELE BOLDRIN & DAVID K. LEVINE, AGAINST INTELLECTUAL MONOPOLY 241–43, 252 (2008), for a discussion and criticism of how the U.S. pharmaceutical industry has come under attack.

2. See discussion *infra* Parts II.A, III.A, IV.A (outlining the nonobviousness standard and patent linkage regime in the United States and how they influence the pharmaceutical industry).

in the field.³ Indeed, the United States has evolved into a pharmaceutical giant, with its manufacturers today producing brand-name drugs and technology available in the international marketplace.⁴ Meanwhile, patient populations in less wealthy countries often cannot afford to pay the prices necessary to support the costs of developing pioneer pharmaceutical therapies.⁵ Thus, many believe that the U.S. nonobviousness standard⁶ and patent-term-extension program need readjustment.⁷

In 1995, members of the World Trade Organization (WTO) signed the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which sets forth standardized measures for securing and enforcing patent protection.⁸ The agreement seeks to promote international trade while recognizing the “special needs” of developing countries.⁹ Among other considerations, TRIPS requires that a patentable invention be new, involve an “inventive step,” and be “capable of industrial application.”¹⁰ More controversially, the agreement allows developing countries to impose compulsory licenses on pharmaceutical patents, thereby giving these countries a means to provide medication to citizens that are unable to afford brand-name

3. See discussion *infra* Part IV.A.

4. See, e.g., STUART O. SCHWEITZER, PHARMACEUTICAL ECONOMICS AND POLICY 21–23 (2d ed. 2007) (describing how the United States has been the world’s leading innovator in internationally accepted drugs for the past twenty years).

5. See BOLDRIN & LEVINE, *supra* note 1, at 243 (discussing how patent holders can price drugs so that only the wealthy can afford them).

6. E.g., Yi-Chen Su, *What About Know-How: Heightened Obviousness and Lowered Disclosure Is Not a Panacea to the American Patent System for Biotechnology Medication and Pharmaceutical Inventions in the Post-KSR ERA*, 14 MARQ. INTEL. PROP. L. REV. 321, 323–26 (2010) (criticizing the industry-specific approach to nonobviousness as it is applied by the courts).

7. See BOLDRIN & LEVINE, *supra* note 1, at 212–15 (referencing the Hatch-Waxman Act and detailing the public resentment directed toward the U.S. pharmaceutical industry as a result of perceived monopolization of drug therapies). Patent-term extension, also referred to as patent-term restoration, enables pharmaceutical developers to extend the patent term on pioneer drugs. See *infra* note 93 and accompanying text.

8. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS].

9. *Id.* The preamble sets forth the WTO’s “[d]esir[e] to reduce distortions and impediments to international trade” while “[r]ecognizing also the special needs of the least-developed country Members.” *Id.* (emphasis omitted).

10. *Id.* at 311. The agreement defines “inventive step” and “capable of industrial application” as synonymous with the U.S. terms “non-obvious” and “useful.” *Id.* at 311 n.5. Members may exclude from patentability inventions that are necessary to maintain public order and morality, such as for protection of human life or health. *Id.* at 311. TRIPS does not further define the meaning of “inventive step,” but instead leaves the determination to the member countries. *Id.* at 311 n.5.

medications.¹¹ A later WTO agreement extended this policy, allowing compulsory licensees to supply drugs to foreign markets.¹²

Despite widespread adoption of TRIPS, there remains great variation among countries' patent policies. On one end, the United States, by supporting "follow-on" patents and evergreening practices, has allowed pharmaceutical giants to effectively extend their monopolies on brand-name drugs.¹³ Furthermore, the country has implemented a linkage regime that requires burgeoning generics manufacturers to enter into high-cost litigation proceedings in order to move their product to market.¹⁴ As generics manufacturers gain an increasing presence in the international marketplace, U.S. pharmaceutical companies have relied on these pro-patent tools to shift focus away from research and development toward merely maintaining a status quo and protecting existing technologies against follow-on patents brought by a competitor.¹⁵ However, this system is not self-sustaining and ultimately requires a shift back toward a steady output of blockbuster products.

Other countries, however, do not necessarily endorse follow-on patents and patent linkage regimes. For example, India has firmly rejected a patent linkage regime,¹⁶ and the country recently upset U.S. pharmaceutical company Bayer when it issued its first compulsory license.¹⁷ And despite Israel's implementation of a patent

11. See *id.* at 313–14 (stipulating that a developed country must grant a nonexclusive license when either (1) the person applying for the license first attempted to negotiate a voluntary license, or (2) there is a national emergency).

12. See Decision of the General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, ¶ 2, WT/L/540 (Aug. 30, 2003), available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (extending the TRIPS license obligations waiver to exports under certain conditions).

13. Follow-on patents claim derivative technologies that provide only minor innovative changes. Ron A. Bouchard et al., *Structure-Function Analysis of Global Pharmaceutical Linkage Regulations*, 12 MINN. J. L. SCI. & TECH. 391, 416 (2011). Such technologies typically preserve the gist of the primary patent by retaining the same active ingredient and general delivery technique while varying factors such as dosage, inactive ingredients, and carrier. *Id.* The strategy of filing follow-on patents is known as "evergreening" and results in an effectively perpetual extension of a monopoly on the pioneer patent, as each patent term is strategically staggered. See generally JOHN R. THOMAS, PATENT "EVERGREENING": ISSUES IN INNOVATION AND COMPETITION 4 (2009), available at http://ipmall.info/hosted_resources/crs/R40917_091113.pdf (summarizing the criticisms of the U.S. patent system and its tendency to support follow-on patents).

14. See Bouchard et al., *supra* note 13, at 398–99 (discussing interaction between the U.S. linkage regime and litigation).

15. See *infra* Part III.A for a discussion of the U.S. pharmaceutical industry's shift toward follow-on technologies.

16. See *infra* Part III.B for a discussion of India's High Court decision in *Bayer Corp. v. Union of India*.

17. See *infra* notes 131–35 and accompanying text.

linkage regime, its patent-term restoration is inadequate.¹⁸ The variation in patent systems creates tension between countries and frustrates the purpose of the TRIPS agreement.

This Note compares and contrasts the patent policies of the United States, India, and Israel in the context of the pharmaceutical industry and proposes a combination of policies that together should ensure the continued development and availability of pharmaceutical products. Part II investigates the nonobviousness patentability requirement or its equivalent in each of the three countries. Part III explores whether each country has implemented a patent linkage regime and analyzes the effects of such implementation or lack thereof. Part IV determines (1) the effect of each country's policies on its domestic generics industry and (2) each policy's effects on the international pharmaceutical trade. Finally, Part V proposes that the United States should implement a heightened standard for overcoming the nonobviousness bar while expanding the duration of patent-term extension offered to pioneer pharmaceutical technologies through the patent linkage regime.

II. THE IMPACT OF NONOBVIOUSNESS ON PATENT VALIDITY

In order for an inventor to obtain patent protection on an invention in any country, the inventor must first overcome the hurdle known alternatively as nonobviousness, inventive step, or inventive level. Under the TRIPS agreement, member countries have the flexibility to define "inventive step."¹⁹ Thus, the standard for interpreting whether an invention is obvious varies from country to country. For example, in the United States, § 103 of the American Patent Act instructs that an invention is nonobvious when, taken as a whole, it would not be obvious to a "person having ordinary skill in the art" (PHOSITA) at the time of invention.²⁰ While the current U.S. patent system applies its nonobviousness requirement relatively loosely, allowing applicants to protect trivial distinctions between

18. See Malini Aisola, *PhRMA Pushes for Data Exclusivity in 2010 Special 201 Comments*, KNOWLEDGE ECOLOGY INT'L (Mar. 1, 2010, 4:11 PM), <http://keionline.org/node/789> (describing the limitations of Israel's extended exclusivity terms).

19. See TRIPS, *supra* note 8, at 311 n.5 (explaining the term "inventive step" can be deemed equivalent to words such as "non-obvious" and "useful").

20. 35 U.S.C. § 103(a) (2006). This statutory standard has not been substantially changed by the recent enactment of the Leahy-Smith America Invents Act. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3(c), 125 Stat. 284 (amending § 103 to reflect that under the first-inventor-to-file system, the filing date is the appropriate time frame for determining the skill and knowledge of a person having ordinary skill in the art). The minor provisions to nonobviousness will take effect on March 16, 2013, eighteen months after enactment. *Id.* at § 3(n).

technologies, India and Israel raise the bar so high that development of pharmaceutical products becomes impractical.

A. In the United States

In the United States, judges typically take an industry-specific approach and lower the bar for nonobviousness in the biotechnology and pharmaceutical fields.²¹ One explanation for this behavior is that courts may be actively relaxing the nonobviousness bar for pharmaceutical inventions in response to policy rationales. Bringing a drug to market is an extremely expensive endeavor,²² and pharmaceutical laboratories typically must demonstrate a reasonable likelihood of success in order to obtain research funding.²³ However, if likelihood of success correlates with obviousness, the drug may not be patentable. Thus, institutions investigating potential drug solutions find themselves in a catch twenty-two, where patent protection is only available in scenarios where they are incapable of obtaining research funding to develop the technology. By lowering the bar for the pharmaceutical sector, courts can promote the development of research into drug advancements, furthering the patent system's goal of promoting innovation.

The relaxed nonobviousness standard in the pharmaceutical field may also be due to the high failure rate and the high costs of drug development. In determining whether an invention is obvious, courts look at secondary considerations, such as "commercial success, long felt but unmet needs, [and] failure of others," that can shed light on whether the PHOSITA would consider the invention obvious.²⁴ These factors weigh in favor of patentability despite the existence of prior art that suggests development of the technology would be logical.²⁵ In

21. *E.g.*, Su, *supra* note 6, at 326. The National Institute of Food and Agriculture defines "biotechnology" generally as "the use of biology or biological processes to develop helpful products and services." *Biotechnology & Genomics*, U.S. DEPT. OF AGRIC. NAT'L INST. OF FOOD & AGRIC., http://www.csrees.usda.gov/nea/biotech/biotech_all.html (last updated Mar. 18, 2009).

22. For example, a 2010 study indicated that the cost of bringing a drug to market is in the range of \$1 billion. Ian Evans, *Follow-On Biologics: A New Play for Big Pharma*, 83 *YALE J. BIO. & MED.* 97, 98 (2010). This number has been increasing from the \$54 million cost in 1976. OLIVER GASSMANN, GERRIT REEPMEYER & MAXIMILIAN VON ZEDTWITZ, *LEADING PHARMACEUTICAL INNOVATION: TRENDS AND DRIVERS FOR GROWTH IN THE PHARMACEUTICAL INDUSTRY 2* (2d ed. 2008).

23. *See* Su, *supra* note 6, at 332 ("Because of the high costs of biotechnology and pharmaceutical research, a research proposal is unlikely to receive grants or any sort of financial support without the projection of a 'reasonable expectation of success.'").

24. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

25. The Manual of Patent Examining Procedure defines prior art as any patent-defeating reference. *See* MPEP § 2121 (8th ed. Rev. 7, Sept. 2008) (describing

the pharmaceutical industry, the amount of time, resources, and funding necessary to move a pharmaceutical technology through the pipeline will often lead to an inference of nonobviousness.²⁶ Thus, the U.S. patent system's consideration of market forces and research effort will naturally favor a finding of nonobviousness in the pharmaceutical context.

The Supreme Court has been reluctant to endorse any bright-line rules for nonobviousness and has paved the way for an industry-specific approach.²⁷ For example, in *KSR International Co. v. Teleflex Inc.*,²⁸ the Court rejected a strict application of a bright-line rule because “[r]igid preventative rules that deny factfinders recourse to common sense . . . are neither necessary under our case law nor consistent with it.”²⁹ Following *KSR*, the Court of Appeals for the Federal Circuit has instructed that “[e]ach case must be decided in its particular context, including the characteristics of the science or technology.”³⁰

Although some scholars argue that the U.S. nonobviousness standard is changing, it is unlikely that the Federal Circuit's 2009

how to determine whether a reference constitutes prior art). The statutory definition of prior art is laid out in 35 U.S.C. § 102 (2006).

In the United States, a pharmaceutical invention tends to satisfy the nonobviousness requirement even when prior art suggests that the invention is logical to try. Even if the combination of prior art references is logical, research in this field is high risk and involves a large degree of trial and error. See Su, *supra* note 6, at 328. Thus, there are still high research costs and uncertainty despite the existence of the foundational technology. *Id.* A 2010 study indicated that the cost of bringing a drug to market is in the range of \$1 billion. Evans, *supra* note 22. Additionally, recent forays into follow-on biologic technologies indicate that these derivative technologies, while costing only \$400 million–\$500 million to develop, can spend as long as ten years in the pipeline. *Id.* at 99.

26. In the foundational article that proposed the use of secondary considerations in determining obviousness, long-unresolved need was evidenced by a significant quantity and quality of research devoted to the solution of similar problems in the field. Richard L. Robbins, Note, *Subtests of “Nonobviousness”: A Technical Approach to Patent Validity*, 112 U. PA. L. REV. 1169, 1173–74 (1964). Additionally, a large capital investment would lead to the inference that a solution was not obvious. *Id.* at 1174. The article further suggested that an inference of long-felt demand may be established if “the time the defect persisted [was] at least . . . longer than the average time lapse proceeding the unpatented solutions of defects in the relevant art,” and that the significance of this time period will vary from industry to industry. *Id.* Taken together, the amount of time, resources, and funding required in pharmaceutical research should often lead to a finding of nonobviousness.

27. See *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421–22 (2007) and *In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006) for an illustration of the Court’s rejection of the Federal Circuit’s rigid application of the “teaching-suggestion-motivation” test in favor of a more flexible approach.

28. *KSR*, 550 U.S. 398.

29. *Id.* at 421–22.

30. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1352 (2008).

decision in *In re Kubin*³¹ will result in a heightened standard of obviousness throughout the pharmaceutical sector.³² In *In re Kubin*, the Federal Circuit upheld a Board of Patent Appeals and Interferences (BPAI) decision, finding the claim for a protein binding site to be obvious.³³ However, the case will likely not have a far-reaching impact outside of the narrow field of gene sequencing. The appellants failed to argue, and the court failed to consider, the difficulty of locating the range of DNA sequences encrypting the binding site.³⁴ Instead, the court held that the binding-site sequence was an inherent part of the full protein sequence.³⁵ The BPAI considered the conventional techniques practiced in the field of biotechnology in determining obviousness, but failed to properly analyze the obviousness of the claimed invention—the specific binding site.³⁶ Therefore, the *In re Kubin* decision arguably does not diverge from the Federal Circuit's practice of applying an industry-specific approach to obviousness.

In sum, pharmaceutical inventions in the United States must only pass a low hurdle for nonobviousness to be patentable. Courts in the United States will apply an industry-specific approach and determine that a pharmaceutical invention is nonobvious even if it is obvious to try.³⁷ The lax standard for nonobviousness is intended to incentivize innovation by increasing protection and minimizing risk to pharmaceutical companies. However, in reality, the standard enables pharmaceutical companies to merely patent trivial adaptations of existing drugs, distracting companies from focusing on the development of new products and the continued push of drugs through the pipeline.

31. *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009).

32. *See id.* at 1360 (“This court cannot . . . cling to formalistic rules for obviousness, customize its legal tests for specific scientific fields in ways that deem entire classes of prior art teachings irrelevant, or discount the significant abilities of artisans of ordinary skill in an advanced area of art.”).

33. *Id.* at 1352.

34. Significantly, the court failed to distinguish between decoding a particular useful sequence and the routine practice of decoding the entire protein sequence. *Id.* at 1356 (finding that the appellants merely used conventional methods to determine the entire nucleotide sequence of the protein without discussion of how that partial sequence was distinguished from the rest of the DNA code).

35. *Id.* at 1358.

36. Indeed, in Richard Robbins's foundational article that led to the Supreme Court's adoption of secondary considerations as tools for determining obviousness, Robbins acknowledged that a “proper assessment of the magnitude of the [problem sought to be resolved] . . . will be hampered if the necessary evidence is . . . too technical.” Robbins, *supra* note 26 at 1173. Here, the BPAI appeared to struggle with grasping the definition of the technology itself and consequently applied the prior art too broadly in making its obviousness determination. *See In re Kubin*, 561 F.3d at 1360–61.

37. *See supra* note 25 for a discussion of obvious-to-try jurisprudence.

B. In India

India has a relatively high standard for nonobviousness and applies the standard strictly toward pharmaceutical inventions.³⁸ India's emphasis on a significant innovative step indicates the country's reluctance to monopolize drug therapies.³⁹ Instead, the country's pharmaceutical market is built around the generics industry.⁴⁰ Although India's patent system prevents the extended monopoly of pharmaceutical products through evergreening, which benefits its consumers, its strict patentability requirements would be overly burdensome on a pharmaceutical industry focused on high-risk development of breakthrough drugs.

Prior to the TRIPS agreement, India did not provide patent protection for pharmaceutical products.⁴¹ Instead, India only protected the drug manufacturing process, and only for up to a seven-year term.⁴² India's first independent Patents Act sought to create a domestic pharmaceutical market and decrease the cost of medication.⁴³ Thus, the Patents Act turned away many foreign pharmaceutical companies and resulted in a larger market share for domestically owned companies.⁴⁴ India flourished at reverse-engineering drugs and selling them both domestically and in other developing countries that did not honor patent protection for pharmaceutical products.⁴⁵ However, once TRIPS became fully effective in India in 2005,⁴⁶ the country was obligated to honor patent protection of pharmaceutical compositions.⁴⁷

38. See The Patents (Amendment) Act, No. 15 of 2005, § 2(a)(1)(ja), INDIA CODE, vol. 18 (requiring either an advance in technology or some economic significance).

39. See discussion *infra* Part IV.B (recounting India's hesitation toward protecting pharmaceutical innovation throughout the course of the history of the country's patent system).

40. See discussion *infra* Part IV.B.

41. See Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 495 (2007) (describing the historical evolution of pharmaceutical patents in India).

42. *Id.* at 514.

43. See *id.* ("The eventual economic effect of the India Patents Act, 1970, was a dramatic increase in domestic generic drug manufacturing and a sharp decline in the price of medicines sold in India.")

44. *Id.* at 515.

45. *Id.* at 514–15.

46. *Id.* at 518–19 (discussing the "TRIPS-catalyzed transformation of India's patent laws").

47. India amended its patent statute to allow for the protection of a pharmaceutical substance. See The Patents (Amendment) Act, No. 17 of 1999, INDIA CODE, vol. 22 (enabling protection of an invention for a substance itself intended for use as medicine or drug).

India's Patents Act requires that, to satisfy the nonobvious standard, an invention be nonobvious and either involve the advance of technology or be economically significant.⁴⁸ However, the Patents Act does not specify the standard that should be used to determine whether technology is advanced or whether the invention is economically significant.⁴⁹ While scholars have criticized the definition as "vague and arbitrary,"⁵⁰ it appears that India has successfully implemented a high standard of nonobviousness that will enable judicial flexibility in protecting competition and driving down market costs.⁵¹

When India amended its patent law to comply with the TRIPS agreement, it also added a controversial provision intended to curtail evergreening of pharmaceutical patents.⁵² The provision, § 3(d), bars companies from patenting new forms of known substances unless the new form demonstrates a significant enhancement in efficacy.⁵³ In January 2006, the Patent Controller in Chennai used § 3(d) in refusing to grant pharmaceutical manufacturer Novartis a patent on its beta crystalline salt form of an existing anti-cancer drug.⁵⁴ Novartis argued that the more stable salt form could be absorbed more easily into the bloodstream, resulting in an increase in bioavailability of up to 30 percent.⁵⁵ The Assistant Controller saw the difference as "only" 30 percent and ruled that the free base form could

48. The Patents (Amendment) Act, No. 15 of 2005, § 2(a)(1)(ja), INDIA CODE, vol. 18. This definition departs from the prior Indian case law, which equated "inventive step" with "nonobviousness." See *Shyam v. Hindustan Metal Indus.*, (1978) 254 S.C.R. 757, 777 (India), available at <http://www.indiankanoon.org/doc/1905157>.

49. The Patents (Amendment) Act, No. 15 of 2005, § 2(a)(1)(ja).

50. Mueller, *supra* note 41, at 564 (quoting Manoj Pillai, *India: India's Patents Bill, 2005—Is It TRIPS Compliant?*, MONDAQ, (Mar. 31, 2005), <http://www.mondaq.com/article.asp?articleid=31717>).

51. See Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CAL. L. REV. 1571, 1593 (2009) (describing how India's subject-matter exclusions create a narrower standard for patentability and allow for a larger scope of competition in the marketplace).

52. See, e.g., *Novartis AG v. Union of India and Others, SLP (Civil) Nos. 20539-20549 of 2009*, LAWYERS COLLECTIVE, <http://www.lawyerscollective.org/access-to-medicine/atm-current-cases.html#more-174> (last visited Oct. 1, 2012) [hereinafter *Novartis AG*] (describing § 3(d) of the Patents Act as one of the safeguards against evergreening).

53. The Patents (Amendment) Act, No. 15 of 2005, § 3(d). The statute also lists several examples of substances that will be considered the same as a known substance: salts, esters, ethers, polymorphs, metabolites, pure forms, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives. *Id.*

54. *Novartis AG*, *supra* note 52.

55. See Shamnad Basheer & T. Prashant Reddy, *The "Efficacy" of Indian Patent Law: Ironing Out the Creases in Section 3(d)*, 5 SCRIPTED 232, 239-40 (2008) (detailing the court's rejection of Novartis's argument that its drug's pharmaceutical composition constituted "increased efficacy").

be used wherever the salt was used.⁵⁶ Novartis has challenged the ruling, arguing that § 3(d) of the 2005 Patents Act does not comply with TRIPS.⁵⁷ The Supreme Court of India's decision, due later this year, will determine the country's position on the patenting of new forms of already known drugs. Until then, it remains unclear what constitutes a significant enhancement in efficacy.

India's approach to obviousness can provide guidance for the United States as it attempts to address the decreasing production in its pharmaceutical sector. Although a large degree of judicial discretion would probably not work well in the U.S. pharmaceutical industry, where the high-risk nature of the industry gives companies reason to shy away from projects that may not win patent protection, a heightened standard that leaves some room for judicial discretion could be used to push the pharmaceutical sector back toward higher-risk research investments.

C. In Israel

Like India, Israel endorses a demanding nonobviousness requirement for patentability.⁵⁸ Israel's use of nonanalogous art as references for obviousness rejections stretches the bounds of what is considered obvious.⁵⁹ Consequently, pharmaceutical companies run the risk of developing a drug therapy that is genuinely innovative, but that still is denied patent protection by the court system. The uncertainty in Israel's nonobviousness standard would not support the U.S. pharmaceutical industry.

Israel's strict nonobviousness requirement is based in the country's status as a dominant producer of generics. Israel is home to Teva Pharmaceutical Industries, the world's largest generics company,⁶⁰ and its pharmaceutical exports constitute 3 percent of the country's gross domestic product.⁶¹ Israel also has a strong domestic pharmaceutical market. Israel pushed the development of the

56. *Id.* at 240.

57. *Id.* at 234.

58. See DAVID MENCHER, ASS'N INT'LE POUR LA PROT. DE LA PROP. INTELLECTUELLE [AIPPI], QUESTION Q217: THE PATENTABILITY CRITERION OF INVENTIVE STEP/NON-OBVIOUSNESS (2011), available at <https://www.aippi.org/download/committees/217/GR217israel.pdf> (articulating Israel's requirement for a significant contribution to the relevant art).

59. See *id.* at 3 (discussing Israel's policy of looking even to fields that are "remote from that of the invention").

60. *Teva—Top 10 Generic Drug Companies 2010*, FIERCEPHARMA (Aug. 10, 2010, 8:06 AM), <http://www.fiercepharma.com/special-reports/top-10-generic-drug-companies-2010/teva-top-10-generic-drug-companies-2010>.

61. *Israeli Pharmaceutical Market in Numbers*, LN PHARMA, http://lnpharma.com/Israeli_pharmaceutical_market/ (last visited Jan. 20, 2012).

generics pharmaceutical industry in order to provide healthcare to its citizens at the cheapest possible cost.⁶² Accordingly, the domestic industry is supported by “sick funds,” which provide medical insurance and hospital services for Israelis,⁶³ and constitute 70 percent of domestic pharmaceutical sales.⁶⁴

Section 5 of Israel’s Patent Act indicates that, to be eligible for patent protection, an inventor must achieve an inventive step that is not obvious to the PHOSITA at the time of filing.⁶⁵ Additionally, Appendix G of Israel’s Patent Office Guidelines for Examination indicates that an “inventive step” requires a “quantum” advancement over the prior art.⁶⁶ In 2011, the Israeli Supreme Court confirmed that an “inventive step” requires a significant contribution to the relevant art and possesses the “spark of invention.”⁶⁷ Therefore, like India, Israel requires an inventor to overcome a greater threshold than mere likelihood of success and mandates that a patentable invention contribute to the progress of science by providing a significant advancement to the technical field.

One unique aspect of Israeli patent law is the broad selection of relevant prior art for determining obviousness. Unlike in the United States, where prior art sources are limited to analogous prior art,⁶⁸ Israeli law only *prefers* prior art from related fields. Israeli case law allows a combination of “all relevant knowledge . . . which could be applied to the invention as claimed even from fields remote from that of the invention.”⁶⁹ Therefore, an inventor seeking patent protection must demonstrate a significant advancement that would not have been suggested by the combination of prior art even from remotely related fields. Thus, Israel’s nonobviousness standard is extremely difficult for an inventor to overcome.

While Israel does have a heightened nonobviousness standard, the country’s patent office does not place a large burden of proof on

62. *Id.*

63. See *Protecting Patents*, WORLDPHARMA, http://www.worldpharmaceuticals.net/articles/wpf006_098.htm (last visited Oct. 1, 2012) (explaining Israel’s “main domestic market” for pharmaceutical sales is its sick funds).

64. *Id.*

65. Patents Law, 5727–1967, 21 LSI 149, § 5 (1967) (Isr.), available at <http://www.wipo.int/wipolex/en/details.jsp?id=8199>.

66. ISRAEL PATENT OFFICE GUIDELINES FOR EXAMINATION, app. G ¶ 1 (Isr.), available at <http://www.justice.gov.il/MOJHeb/RashamHaptentim/Ptentim/Bhina/>, interpreted by MENCHER, *supra* note 58, at 1.

67. See generally MENCHER, *supra* note 58, for a summary of the Israeli Supreme Court’s landmark decisions.

68. MPEP § 2141.01(a) (8th ed. Rev. 6, Sept. 2007). However, a reference in a different field of art may be considered analogous if, “because of the matter with which it deals, [it] logically would have commended itself to an inventor’s attention.” *Id.*

69. MENCHER, *supra* note 58, at 3 (quoting Israeli Supreme Court case *Akerstein v. Alumim*).

the applicant to demonstrate significant improvement over the art. In a recent dispute, the Israeli Patent Office determined that, as long as the applicant made a convincing argument that the inventive step requirement had been satisfied, the burden is on the challenger to show lack of inventive step.⁷⁰ If an invention is sufficiently enabled and demonstrates some inventive step and utility, there is no requirement that the applicant provide extensive documentation backing the inventive step.⁷¹

Although Israel's heightened obviousness standard has the potential to encourage pharmaceutical companies to invest in pioneer products rather than be content with follow-on patents, it is likely insufficient to singlehandedly foster such innovation. Israel's practice of incorporating nonanalogous art, if adopted by the United States, would push U.S. pharmaceutical companies to seek only follow-on patents because the risk of developing sufficiently innovative new drugs would be economically infeasible to shoulder. Israel's obviousness standard is too biased toward the generics market and would not support the continued development of blockbuster drugs in the United States.

III. THE CHOICE TO ADOPT LINKAGE REGULATION AND ITS IMPACT ON THE GENERICS INDUSTRY

A pharmaceutical manufacturer that obtains a monopoly on a drug passes the high costs of research and commercialization on to the consumer.⁷² Consumers that are unwilling or incapable of paying for brand-name medication must wait until the patent expires before generics are introduced to the market.⁷³ Thus, countries must balance incentivizing pharmaceutical innovation with bringing

70. See Michael Factor, *Is a Patent Applicant Obligated To Make Clinical Trials Available To Prove the Efficacy and Non-Obviousness of an Invention?*, THE IP FACTOR (May 30, 2012, 10:23 PM), <http://blog.ipfactor.co.il/2012/05/30/is-a-patent-applicant-obliged-to-make-clinical-trials-available-to-prove-the-efficiency-and-non-obviousness-of-an-invention/> (explaining the "onus" is on the opposer if the "application is sufficiently enabled and convincing to show inventive step and utility").

71. See *id.* ("[T]he applicant is only responsible to make publications available to examiners during prosecution, not clinical trials, if the application is sufficiently enabled and convincing to show inventive step and utility" . . .).

72. See BOLDRIN & LEVINE, *supra* note 1, at 244 (discussing how manufacturers will pass the cost of research and development on to consumers in the form of increased prices).

73. Manufacturers that have complete control over pricing can price a drug so that only the wealthy can afford it. See *id.* at 243 (describing how manufacturers can create pricing tiers).

cheaper generics options to the market.⁷⁴ The United States was the first country to adopt a patent linkage regime intended both to reward pioneer pharmaceutical companies and to facilitate the entry of generics into the marketplace.⁷⁵ Many countries have since followed suit, intending to better negotiate terms of trade agreements known as “TRIPS-Plus” provisions.⁷⁶

Patent linkage is defined as “the practice of linking the granting of . . . any regulatory approval for a generic medicinal product to the status of a patent for the originator reference product.”⁷⁷ Under this practice, intellectual property rights are linked to regulatory rights, which include the rights to exclusivity periods attached to drug-approval data.⁷⁸ Generics manufacturers cannot receive regulatory approval or marketing authorization for a developing medicinal product that is still protected by a patent.⁷⁹ Thus, the benefit of the patent linkage regime is that it enables research and development into the generics market. However, by linking development to the status of the pioneer patent, the regime also restricts the ability of generics manufacturers and often results in potentially long and costly litigation before market approval is granted.⁸⁰

The power of linkage regimes expands when the marketing of a drug can be “linked” to multiple patents.⁸¹ Linkage regimes enable a pioneer company to register a list of any patents that might be relevant to the marketing of a particular pharmaceutical compound.⁸² For a generics manufacturer to overcome claims of infringement when seeking regulatory approval, the manufacturer must

74. By reducing drug prices, treatment can be made available to a larger population. However, there is still a need to reduce risk in drug development in order to encourage manufacturers to advance the field so that new treatments can continue to be developed. See *supra* note 26 for a discussion of the risks involved in development of a new drug.

75. Bouchard et al., *supra* note 13, at 396–97.

76. *Id.*

77. Mabel Tsui, *Access to Medicine and the Dangers of Patent Linkage: Lessons from Bayer Corp. v. Union of India*, 18(3) J. LAW & MED. 577, 582 (2011) (quoting EUROPEAN COMM’N, EUROPEAN COMMISSION PHARMACEUTICAL SECTOR INQUIRY: FINAL REPORT pt. 1, at 130 (2009), available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf).

78. Ron A. Bouchard et al., *The Pas de Deux of Pharmaceutical Regulation and Innovation: Who’s Leading Whom?*, 24 BERKELEY TECH. L.J. 1461, 1475 (2009).

79. EUROPEAN COMM’N, *supra*, note 77, at 130.

80. See Bouchard et al., *supra* note 13, at 392, 394–95 (“Linkage regulations tie generic drug availability to existing drug patents by connecting approval to the resolution of patent validity or infringement. This can result in long and costly litigation, the costs of which are ultimately borne by consumers.”).

81. See Bouchard et al., *supra* note 78, at 395–96 (discussing the linkage regime and generic drugs).

82. *Id.* at 394–95.

demonstrate that each patent listed in the register is invalid.⁸³ Thus, a company's ability to list many patents on a register imposes a significant burden on the generics manufacturer. This results in the delayed release of generics into the market as the manufacturers wait for the patents to expire before initiating the regulatory approval process.

A. In the United States

The United States attempts to strike a balance between consumer and industry through the implementation of a patent linkage regime. However, the regime's patent-term-extension mechanism frustrates the pharmaceutical market's problem with evergreening because patent holders can further extend their monopolies based on trivial distinctions between drugs.

When the United States passed the Hatch–Waxman Act, it became the first country to adopt a linkage regime.⁸⁴ The Hatch–Waxman Act balances the twin goals of strengthened patent protection and facilitated generics market entry. The Act achieves both these goals by providing a facilitated method of patent enforcement complemented by a mechanism for generics to enter the market with reduced regulatory costs.⁸⁵

The initial implementation of the Hatch–Waxman Act led to increased policing of pharmaceutical patents because patent owners were no longer solely responsible for detecting infringing activity. To obtain marketing approval, generics hopefuls now had to disclose existing patents related to the proposed generic and explain why the applicant's activity did not infringe these patents.⁸⁶ This initial cooperation between the regulatory body and patent owners in policing patents benefited the pioneer pharmaceutical companies while indirectly passing the cost to the consumer through litigation

83. *Id.*

84. *See id.* at 1477 (describing how Canada modeled its linkage regime after the Hatch–Waxman Act, which was the only existing linkage regime at the time).

85. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, tit. 1 (1984). An incentive to enter the market is important. The typical research and development process takes up to seventeen years and involves four general stages: one to two years of preliminary research for identifying the target and synthesizing the active substance; two to four years for early-stage screening and preclinical trials; six to seven years for clinical trials; and two to four years for registration with the relevant health authorities and product launch. GASSMANN, REEPMEYER & VON ZEDTWITZ, *supra* note 22, at 62–65.

86. *See* W. Edward Bailey, A. Joy Arnold & Thomas D. Lyford, *Recent Hatch-Waxman Reform: Balancing Innovation, Competition, and Affordability*, BUILDING IP VALUE, http://www.buildingipvalue.com/05_NA/107_110.htm (last visited Oct. 1, 2012) (describing the certifications that generic manufacturers must now make in order to seek approval).

and, as a result, increased the cost of generics. The Hatch–Waxman Act’s goal of bringing generics to market, however, was not initially realized.

Amendments to the Hatch–Waxman Act have provided increased protection for generics manufacturers. In the Bolar provision, Congress stated that generics manufacturers may engage in otherwise infringing activity that is necessary for regulatory approval.⁸⁷ The broader safe harbor provision allows generics manufacturers to practice the protected patent in an ordinarily infringing manner if it is for purposes of investigating new treatments and the research could reasonably lead to a regulatory submission.⁸⁸ Consequently, the safe harbor is not limited to follow-on and generics applications.⁸⁹ The Bolar and safe harbor provisions are intended to encourage research and development of both new and generic drugs.⁹⁰ Without these provisions, the monopoly on a brand-name drug would effectively be extended because the holder of an expired patent would be granted an additional two- to three-year lead time before any generics became ready for market.⁹¹

Even with these provisions, however, the protective mechanisms available to safeguard the generics industry appear to be secondary to protective mechanisms for patent holders. The safe harbor and Bolar provisions were added by Congress only in response to case law where generics manufacturers were found to be infringing patents simply by preparing for the release of the generic product upon the expiration of the patent.⁹² Additionally, preliminary interpretations of the Hatch–Waxman Act by the Federal Circuit interpreted the scope of the Act broadly, favoring an interpretation that benefits exiting patent holders. Another aspect of the Hatch–Waxman Act that favors patent holders is a provision that provides for a form of patent-term extension for pioneer drugs known as patent-term restoration, which allows a pharmaceutical company to extend the term of its patent for

87. See 35 U.S.C. § 271(e)(1) (2006) (“[I]t shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under federal law which regulates the manufacture, use, or sale of drugs . . .”).

88. Bouchard et al., *supra* note 13, at 415.

89. *Id.* at 414.

90. *Id.* at 411–12.

91. *Id.* at 415.

92. See Christopher Garrison, *Exceptions to Patent Rights in Developing Countries*, UNCTAD-ICTSD, 14 (Aug. 2006), http://www.unctad.org/en/docs/iteipc200612_en.pdf (discussing how Congress created the Bolar provision after Roche successfully sued Bolar Pharmaceuticals Co. for carrying out testing necessary to prepare its regulatory dossier).

up to five years to compensate for lost time during the investigational new drug period and the new drug application review period.⁹³

Thus, despite the Act's goal of encouraging early investigation into new generic products, studies have indicated that the introduction of generics to the market has slowed, resulting in an increased cost to the consumer.⁹⁴ Furthermore, pharmaceutical companies have increasingly participated in a race to file follow-on patents rather than spending time and money investigating pioneer drugs.⁹⁵ As a result, innovation suffers and extended monopolies are weighted over public health concerns.

Again, it appears that U.S. policy makers have missed the mark in their attempt to encourage development of pioneer drugs. The relatively easy availability of follow-on patents has encouraged pharmaceutical companies to focus on protecting existing drugs rather than investing in the development of new drugs.⁹⁶ Likewise, the patent-term-extension option, while certainly an aid in mitigating risk, only compounds the protection of incremental steps in technical advancement and does not effectively encourage development of new drugs. The longer the patent-term-extension period, the greater the incentive to *only* innovate when the obviousness standard and patent-term extension are adjusted in tandem.

B. In India

India has battled the establishment of a patent linkage regime, which it believes would hamper its generics industry.⁹⁷ The country's High Court recently ruled against Bayer in a patent-infringement suit, finding that India's Drugs and Cosmetics Act could not be read

93. 35 U.S.C. § 156 (2006).

94. Ron A. Bouchard, *I'm Still Your Baby: Canada's Continuing Support of U.S. Linkage Regulations for Pharmaceuticals*, 15 MARQ. INTELL. PROP. L. REV. 71, 114 (2011); Bouchard et al., *supra* note 13, at 398-99.

95. Bouchard, *supra* note 94; Bouchard et al., *supra* note 13; Joseph A. DiMasi & Laura B. Faden, *Competitiveness in Follow-On Drug R&D: A Race or Imitation?*, 10 NATURE REVS. DRUG DISCOVERY 23 (2011).

96. See sources cited *supra* note 95.

97. There is a history of Indian case-law jurisprudence recognizing a human-rights policy for promoting the generics industry. Tsui, *supra* note 77, at 587. The High Court has indicated that "protection of one's life . . . [is] an obligation cast on the State to provide" and that "[t]he obligation includes improvement of public health as its primary duty." *Id.* at 586 (quoting *Punjab v. Bagga*, (1998) 4 S.C.C. 117 (India)). The court has also indicated that health includes "medical care and health facilities." *Id.* at 586 (citing *ESC Ltd. v. Bose*, (1992) 1 S.C.C. 441 (India)). Furthermore, the court has indicated that maximum resources should be devoted to preserving human life. *Id.* at 587 (citing *Mazdoorsamity v. West Bengal*, (1996) 4 S.C.C. 37 (India)).

together with its Patents Act to establish a de facto linkage regime.⁹⁸ Bayer argued that in reading the statutes together, the Indian government was also bound by the patent laws to respect Bayer's patent rights.⁹⁹ Under this theory, the government-affiliated Drug Controller General of India could not grant marketing approval to a generics manufacturer while the patent was still in force.¹⁰⁰ This reading would effectively impose an additional condition on the Drugs and Cosmetics Act, "linking" the marketing approval to the use of the patented claimed invention.¹⁰¹ However, the court held that marketing approval in and of itself does not constitute patent infringement, and that it would be nonsensical to allow development of research performed in preparation for approval but not the approval itself.¹⁰² The court determined that patent linkage is only a TRIPS-Plus construction that is not applicable to India, which is only bound to the parameters of TRIPS itself.¹⁰³ The court acknowledged the growing opinion in developed countries cautioning against the use of linkage.¹⁰⁴ Although India's opposition to patent linkage regimes may be optimal for a country focused on the development of its generics industry, such opposition would only discourage pharmaceutical companies from investing in high-risk ventures to develop pioneer patents. Without the benefit of patent-term extension and a regulatory body to police generics manufacturers, such research and development would be too risky.

C. In Israel

Israel, like the United States, is part of the global linkage-regime network. In 1998, Israel passed the Teva Act, which largely mirrors

98. See generally *Bayer Corp. v. Union of India*, (2009) WP(C) No. 7833/2008 (Delhi H.C.) (India), available at <http://lobis.nic.in/dhc/SRB/judgement/18-08-2009/SRB18082009MATC78332008.pdf>.

99. See Tsui, *supra* note 77, at 580 (outlining Bayer's argument for a collective reading of the Patents Act and the Drugs and Cosmetics Act).

100. See *id.* ("The effect of a collective reading meant that the patent 'has the same effect on the Government as on others.'").

101. See *id.* (describing how the reading together of the two provisions would result in a de facto linkage regime).

102. *Id.*

103. See Bouchard et al., *supra* note 13, at 418 ("The court based its decision in part based on the finding that patent linkage is a 'TRIPS-Plus' concept and that India had only signed on to TRIPS.").

104. See *id.* ("Earlier in the decision, Judge Muralindhar noted that there was a growing opinion in developed countries, including the European Union, that cautioned against linkage.").

the Hatch–Waxman Act.¹⁰⁵ The Teva Act enables generics pharmaceutical companies to perform research and development activities in furtherance of bringing generics to market while the controlling pioneer patent is still in force.¹⁰⁶ Additionally, the Teva Act includes a patent-term-restoration provision, enabling extensions of up to five years on the pioneer patent.¹⁰⁷ In effect, the legislation strikes a bargain between generics and brand-name drug makers, allowing generics manufacturers to perform research while extending the pioneer patent owner's monopoly.¹⁰⁸

Despite Israel's implementation of a patent linkage regime, its patent-term restoration is inadequate.¹⁰⁹ Under Israel's Patents Act and the Pharmacist Ordinance, patent-term-extension periods are linked to the earliest date of product approval in any country recognized by the legislation.¹¹⁰ Consequently, the patent-extension terms are, in effect, considerably shorter than the five years stated in the statute.¹¹¹ As a result, U.S. pharmaceutical companies are unable to obtain meaningful protection in Israel.¹¹² Israel's restricted use of patent-term extension gives Israel an unfair advantage when exporting its generics into the U.S. market.¹¹³

Although Israel utilizes a patent linkage regime, it is purposed for the advancement of the generics industry and not the protection of brand-name pharmaceutical companies. Because Israel's patent linkage regime provides inadequate patent-term restoration, it does not significantly promote the advancement of pioneer drugs.

105. Gene Kleinhendler & Renana Dolev-Harel, *IP Law Challenges in Israel: New Strategies for Emerging Technologies*, ASPATORE, July 2009, available at 2009 WL 2029094, at *3.

106. *Id.*

107. Yafit Avital, *Israel: Patent Term Extension Matters in Israel*, MONDAQ (Aug. 30, 2004), <http://www.mondaq.com/article.asp?articleid=28037>; Kleinhendler & Dolev-Harel, *supra* note 105.

108. See Kfir Luzzatto, *Pharmaceutical Patent Term Extension in Israel*, LUZZATTO & LUZZATTO 1 [http://www.luzzatto.com/articles/11.12.08\(12\).pdf](http://www.luzzatto.com/articles/11.12.08(12).pdf) (last visited Oct. 1, 2012) (discussing how the patent-term extension is a quid pro quo for generics research).

109. See Malini Aisola, *PhRMA Pushes for Data Exclusivity in 2010 Special 301 Comments*, KEI (Mar. 1, 2010, 6:11 PM), <http://keionline.org/node/789> (describing the limitations of Israel's extended exclusivity terms).

110. *Id.*

111. *Id.*

112. *Id.*

113. *Id.* (explaining how Israel's practices provide local generic companies with an unfair commercial advantage when exporting their generic products to the major markets in the United States and Europe).

IV. THE IMPACT OF PATENT POLICY ON THE GENERICS INDUSTRY

The differences in the patent policies of the United States, India, and Israel have a profound effect on the entrance of generics into each national market. While the United States' relatively relaxed nonobviousness requirement and its patent-term extension lead to a pro-industry outcome, India and Israel have developed more consumer-friendly industries by restricting a patent applicant's ability to protect developments that do not reach breakthrough status. The policy decisions made by these countries are gradually sculpting the landscape of the international pharmaceutical industry.

A. *In the United States*

In the United States, the lenient approach toward patentability and the introduction of the linkage regime have stifled entry of generics into the market and have led to the development of the world's most powerful brand pharmaceutical industry.¹¹⁴ By lowering the bar for nonobviousness, whether through the application of secondary considerations or through a direct, policy-driven exception for the pharmaceutical sector, the United States has become a unique source of follow-on patents.¹¹⁵ The strategy for filing follow-on patents, also known as evergreening, results in an effectively perpetual extension of a monopoly on the pioneer patent.

Follow-on patents are strategically used to stunt competition; such patents often are filed in anticipation of the release of generics into the market.¹¹⁶ The trend proves that brand-name pharmaceutical companies can abuse the system by lengthening their monopolies and prolonging dominance in the market.¹¹⁷ The pharmaceutical-specific, flexible approach to determining obviousness is intended to encourage research and innovation, but there is a risk that the standard is actually self-defeating.¹¹⁸ The practice of evergreening turns innovation into a race to secure even the most minor patents, even if a generics manufacturer is merely reserving a

114. See, e.g., SCHWEITZER, *supra* note 4 (labeling the United States as a world leader in the pharmaceutical industry).

115. See generally THOMAS, *supra* note 13 (describing the tendency for U.S. pharmaceutical companies to pursue follow-on patents).

116. See *id.* (describing how brand-name companies will often patent an over-the-counter formulation that can be brought to market before a generic formulation, thereby establishing brand recognition without pressure from competitors).

117. See *id.* at 1 (noting that a common critique of evergreening is the extension of market exclusivity).

118. See discussion *supra* Part II.A (discussing the effect of the nonobviousness standard on pharmaceutical innovation).

place in line and not planning on using its own invention until an original blockbuster patent expires.

Scholarship has indicated that the U.S. pharmaceutical industry is suffering from “a lack of genuine innovation.”¹¹⁹ Patent overprotection has led brand-name companies to focus on maintaining patent protection of existing drugs rather than investing in new therapies.¹²⁰ However, this approach only works in the short term; long term stability and growth of the U.S. pharmaceutical industry requires the regular deployment of blockbuster drugs.¹²¹

Despite the need for new, innovative drugs in the United States, there was a 3.8 percent decrease in blockbuster sales from 2000 to 2008.¹²² Although the development of screening technologies has improved, only three out of every ten drugs that are brought to market actually generate enough revenue to meet or exceed the average cost of research and development.¹²³ Because the average gestational period for a drug is approximately thirteen years,¹²⁴ there is a narrow window of about eight years before the patent expires to recoup the cost of innovation.¹²⁵ Therefore, the structure of the U.S. patent law system is not currently optimized for inducing innovation. The pharmaceutical sector suffers from both too much and not enough protection, squelching incentive to seek out the truly blockbuster ideas necessary to keep the industry afloat.

B. In India

India has aggressively built its generics pharmaceutical market.¹²⁶ After barring the patentability of pharmaceutical products completely during the first thirty-five years of its patent system's existence,¹²⁷ India finally allowed these products to be patented when TRIPS came into full effect in 2005.¹²⁸ Since then, India has applied a

119. GASSMANN, REEPMAYER & VON ZEDTWITZ, *supra* note 22, at 51.

120. *Id.*

121. *Id.* at 52.

122. *Id.*

123. *Id.* at 56.

124. See *supra* note 85 for a discussion of the time frame for drug development.

125. Once launched, the drug will only be protected for the remaining duration of the twenty-year patent term. 35 U.S.C. § 154(a)(2) (2006) (defining the patent term). Assuming that the manufacturer files for the patent early in the research and development process, this will allow approximately eight years of exclusive sales.

126. See *supra* Parts II.B and III.B for a discussion of the evolution of India's patent system.

127. Mueller, *supra* note 41, at 512.

128. *Id.* at 518–19.

strict standard for obviousness determinations¹²⁹ while firmly rejecting a patent linkage regime.¹³⁰

The implementation of TRIPS and the availability of compulsory licenses following therefrom further bolstered India's generics market and continued India's battle against brand-name manufacturers.¹³¹ A March 2012 decision by the Controller General of Patents Designs and Trademarks (CGPDTM) marked the first time that a compulsory license was granted in India.¹³² Citing a provision of the Indian Patents Act that allows for compulsory licensing three years after the grant of a patent on a drug that is not available at affordable prices in India, the CGPDTM required Bayer to license one of its cancer drugs to an Indian company.¹³³ The CGPDTM found that only about 200 bottles of the tablets had been imported into the country since its 2006 release and that an estimated 23,000 citizens required the drug for life-saving treatment.¹³⁴ While Bayer had priced the drug at 280,000 rupees (\$5,600) for a month-long treatment, the terms of the compulsory license allowed the Indian company to sell the drug for 8,880 rupees (\$176) for the same treatment, supplying Bayer with a 6 percent royalty rate on net sales.¹³⁵ The decision is likely to create concern for brand-name pharmaceutical manufacturers who rely on patent protection to recoup development costs.

C. In Israel

Like India, Israel is home to several large-scale generics manufacturers.¹³⁶ Teva Pharmaceutical Industries, in addition to

129. The Patents (Amendment) Act, No. 15 of 2005, § 2(a)(1)(ja), INDIA CODE, vol. 18.

130. See *supra* Part III.B for a discussion of India's High Court decision in *Bayer Corp. v. Union of India*.

131. See *Natco Pharma Ltd. v. Bayer Corp.*, (2012) C.I.A. No. 1 of 2011 55 (India), available at http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf (granting a compulsory license to a generics manufacturer to market and produce Nexavar).

132. *Id.*; Vikas Bajaj & Andrew Pollack, *India Orders Bayer to License a Patented Drug*, N.Y. TIMES, Mar. 12, 2012, at B2.

133. *Natco Pharma Ltd.*, C.I.A. No. 1 of 2011 at 60. A compulsory license establishes an involuntary contract between an unwilling seller and a willing buyer. The contract is imposed and enforced by the governing body. Under the current Indian Patents Act, such a license can only be imposed after the drug has been patented for three years. The Patents Act, No. 39 of 1970, § 84(1), INDIA CODE.

134. *Natco Pharma Ltd.*, C.I.A. No. 1 of 2011 at 13–14.

135. *Id.* at 15, 60–61; Bajaj & Pollack, *supra* note 132 (“Legal specialists and patient advocates said it could open the door to a flood of other compulsory licenses in India and possibly in other developing countries, creating a new supply of cheap generic drugs.”).

136. Karen S. Ginsbury, *Israel Generics Drug Manufacturers and the Market*, 2003 BUSINESS BRIEFING: PHARMAGENERICS 61, 61 (discussing Israeli generic manufacturers, including Teva, Taro, and Agis).

being the world's largest generics manufacturer,¹³⁷ is also one of the top twenty pharmaceutical companies overall¹³⁸ and recently merged with both generics¹³⁹ and brand drug companies.¹⁴⁰ Israel's generics pharmaceutical market reportedly was valued at \$7 billion in 2010.¹⁴¹ Israel's exports to the United States constitute 75 percent of its total pharmaceutical exports.¹⁴²

Israel's focus on dominating the worldwide generics market requires a substantial commitment to research and development.¹⁴³ A generics company must devote resources toward development in order to compete on price and be the first to market.¹⁴⁴ By entering the marketplace first, a company assures itself a large market share and customer loyalty.¹⁴⁵ Brand companies, on the other hand, do not participate in the same race to the market as generics, but instead rely on monopolies and increased prices to recover their development costs. Thus, although both brand and generics manufacturers invest substantially in research and development, one has the goal of developing blockbuster drugs while the other focuses on pushing late-comers out of the market. Brand companies rely on the patent system while generics companies rely primarily on supply and demand.

The development of the large generics markets in countries like India and Israel has begun to shift the worldwide pharmaceuticals market in favor of generics.¹⁴⁶ Fewer blockbuster drugs are moving through the pipeline.¹⁴⁷ And as the costs of research and development

137. *Id.*

138. *Teva Pharmaceutical Industries—Jerusalem*, BIOJERUSALEM, http://www.biojerusalem.org.il/database_company.asp?ID=76 (last visited Oct. 1, 2012).

139. Natasha Singer, *Teva To Acquire Top German Generics Maker for \$5 Billion*, N.Y. TIMES, Mar. 18, 2010, at B2 (RatioPharm); *Teva Completes \$934m Taiyo Acquisition*, GLOBES (July 14, 2011, 9:40 AM), <http://www.globes.co.il/serveen/globes/docview.asp?did=1000664169&fid=1725> (Taiyo Pharmaceutical Industry Co.).

140. Chris V. Nicholson, *Teva To Buy Cephalon for \$6.8 Billion*, N.Y. TIMES, May 3, 2011, at B4 (Cephalon); *Teva Buys Drug Rival, Barr, for \$7.46 Billion*, N.Y. TIMES (July 19, 2008), <http://www.nytimes.com/2008/07/19/business/19teva.html> (Barr Pharmaceuticals).

141. *Israeli Pharmaceutical Market in Numbers*, *supra* note 61.

142. *Id.*

143. See Ginsbury, *supra* note 136, at 64 (discussing how an emphasis on research and development (R&D) is necessary to be competitive on price and first to market).

144. See *id.* (stating that a company must be able to be the first to market and provide competitive pricing to remain competitive in the generics industry).

145. See *id.* (discussing how being first to market "ensures a large initial share of the market that is subsequently relatively easy to maintain and has the possibility to increase").

146. See, e.g., Hitesh Gajaria, *India To Be Amongst Top Three Generic Makers in the World*, EXPRESS PHARMA (Jan. 16–31, 2008), <http://www.expresspharmaonline.com/20080131/indianpharmain202008.shtml> (discussing how India's generics market is expected to grow due to economic prosperity).

147. See *id.* (discussing the "increasing spread of generics").

increase while countries cut their healthcare budgets, many countries feel even greater pressure to shift toward the use of generics.¹⁴⁸ As a result of this worldwide trend toward generics, the U.S. brand pharmaceutical industry, already the worldwide brand industry leader, will only increase its dominance.¹⁴⁹

V. PROPOSED ALTERATIONS TO THE U.S. PATENT SYSTEM

The U.S. patent and regulatory system should be revamped with a heightened nonobviousness standard and assurance that the resulting meritorious patents receive extended protection through the patent linkage regime. Public healthcare can only thrive by ensuring both the continued development *and* availability of pharmaceutical products, which requires concurrent reformation of the nonobviousness patentability standard and the Hatch–Waxman regulatory mechanism.

The patent system promotes technical innovation by balancing two competing interests: the inventor's interest in a monopoly and the public's interest in disclosure and the right to practice. If the system is functioning properly, the inventor receives just enough of a monopoly to be motivated to disclose his invention. The monopoly should also encourage the inventor to pursue the invention in the first place by investing substantial time and money in research. This second motivation, which primarily drives the patent system to "promote the progress of science and useful arts,"¹⁵⁰ can vary dramatically from one technical field to the next.¹⁵¹ The more one must invest in research, the greater the risk and the greater the necessary reward.¹⁵²

The U.S. patent system has recognized the disparity in motivational factors across the sciences by allowing flexibility in its

148. See *id.* (describing how the pharmaceutical industry is facing pressure due to "declining R&D productivity on the back of steeply rising drug discovery and development costs, as well as increasing sales and marketing expenses").

149. In 2010, the worldwide generics market was valued at \$124 billion. *India To Dominate World Generic Market*, INDIAN EXPRESS (Dec. 1, 2010, 2:36 PM), <http://www.indianexpress.com/news/india-to-dominate-world-generic-market/718642/>.

150. U.S. CONST. art. 1, § 8, cl. 8.

151. See JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 96 (2008) ("Patent values vary considerably across different technologies . . .").

152. See GASSMANN, REEPMAYER & VON ZEDTWITZ, *supra* note 22, at 10 (discussing the high risk in pharmaceutical development due to abandonment of research projects from safety and efficacy concerns rather than merely financial concerns).

nonobviousness requirement¹⁵³ and instituting the patent linkage system in the pharmaceutical context.¹⁵⁴ Trends toward weaker follow-on patents, however, suggest that the current pro-patent system will stifle rather than promote development in the sciences.¹⁵⁵ U.S. patents might not be as valuable as one would expect because the patent holder has to contend with any unexpected litigation arising from patent disputes.¹⁵⁶ Nonetheless, the U.S. pro-patent system has proved to be effective in producing blockbuster drugs thus far.¹⁵⁷

Blockbuster drugs typically are successful because they contain clearly defined claims that are broad in scope and easy to police, therefore making it difficult for competitors to engineer around the pharmaceutical compound.¹⁵⁸ In reality, however, few brand companies are able to turn a profit due to the long gestational period for drugs.¹⁵⁹ Therefore, once profits are realized, it is tempting and increasingly common for companies to reinvest in research to develop follow-on or spin-off drugs.¹⁶⁰

The U.S. pharmaceutical market has been largely successful in applying a blockbuster business model and is the international leader in drug innovation.¹⁶¹ However, the U.S. industry's aggressive enforcement of patent protection is often construed negatively because the public equates the pharmaceutical industry with other

153. See discussion *supra* Part IIA (describing how courts have recognized the disparity between technical fields through policy rationales and secondary considerations).

154. See discussion *supra* Part IIIA (describing the twin goals of the patent linkage system in the United States).

155. See ADAM B. JAFFE & JOSH LERNER, *INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT* 102–07 (2008) (discussing how the “pro-patent” orientation of U.S. jurisprudence might be due to the creation of the specialized Court of Appeals for the Federal Circuit).

156. See BESSEN & MEURER, *supra* note 151 (discussing how a badly functioning property system imposes costs arising from unanticipated disputes).

157. The high risk and unique nature of the R&D involved in pharmaceutical development has resulted in American pharmaceuticals accounting for two-thirds of the worldwide patent value. *Id.* at 109. Furthermore, over half of the worldwide patent value is held by large pharmaceutical companies who rely on high-stakes, blockbuster drugs. See GASSMANN, REEPMEYER & VON ZEDTWITZ, *supra* note 22, at 4–10 (describing how large pharmaceutical companies rely on blockbusters to recoup losses from their high-risk ventures).

158. See Sean B. Seymore, *Rethinking Novelty in Patent Law*, 60 DUKE L.J. 919, 926–28 (2011) (discussing how chemical and pharmaceutical patents are broad in scope and “often depict discrete molecular structures, [where] the boundaries are clearly defined and thus easier to police”).

159. See SCHWEITZER, *supra* note 4, at 51 (describing how few firms generate revenue due to the risks of R&D).

160. *Id.*

161. *Id.* at 21–23.

manufacturing industries and fails to consider the pharmaceutical industry's unique research and development requirements.¹⁶² The high-risk nature of the industry suggests that perhaps there are significant and legitimate policy reasons for relaxing the nonobviousness standard in the pharmaceutical context.

On the other hand, the pharmaceutical market has decreased in competitiveness as the worldwide market has become more concentrated.¹⁶³ As companies merge and top-selling drugs are clustered among fewer and fewer firms, the market narrows.¹⁶⁴ Additionally, as all countries come into adherence with the TRIPS agreement, larger generics producers, such as India, are legitimized and no longer considered to be "outlaws" that profit from counterfeit production.¹⁶⁵ Thus, the international community faces a serious question: should the patent system be tightened to the detriment and perhaps collapse of an established U.S. pharmaceutical market in order to prevent further monopolization of an already narrowing international market?

A. Heightening the Nonobviousness Standard

The nonobviousness standard applied by the courts should not be loosened with respect to the pharmaceutical field, but instead should become a uniform approach across the entire spectrum of inventions. The standard in fact already takes account of the need for flexibility from field to field, as it is judged with respect to a person having ordinary skill *in the art*. Anything looser than this approach to nonobviousness would increase the number of patents granted. Granting more patents would be an issue because patents are difficult to contest in court due to a court's presumption that all patents are valid.¹⁶⁶ The heightened nonobviousness standard also should include a burden-shifting mechanism that requires the applicant to demonstrate not that the result was merely unpredictable, but that there was no suggestion of success. This standard, when applied in conjunction with a revised patent-term-extension regime, should strengthen the integrity of the patent system by ensuring that patent protection is restricted to legitimate innovation.

162. See, e.g., *id.* at 21–22 (recounting how senators during the Kefauver hearings would frequently refer to pricing practices of the pharmaceutical industry while ignoring R&D activities).

163. *Id.* at 24.

164. *Id.*

165. *Id.*

166. 35 U.S.C. § 282 (2006) (mandating that an issued patent shall be presumed valid).

In determining whether a combination of prior art elements would have been obvious, a court must determine whether a PHOSITA would find a reasonable expectation of success in combining the elements.¹⁶⁷ In *Pfizer, Inc. v. Apotex, Inc.*,¹⁶⁸ the Federal Circuit held that a pharmaceutical compound stabilized with besylate salt was obvious with regard to prior art references that discussed the use of the salt as a stabilizer for unrelated drugs.¹⁶⁹ The court disregarded the fact that the active ingredients were used to treat unrelated illnesses and instead held that it was enough that the prior art suggested the use of the salt generally as an agent for stabilizing, solubilizing, and improving the bioavailability of an active ingredient.¹⁷⁰ The court was not persuaded by Pfizer's argument that stabilizers can have varying and unpredictable effects when combined with different active ingredients.¹⁷¹

In coming to its conclusion, the court articulated that a combination is considered obvious so long as there is a reasonable probability of success, even if there is some degree of unpredictability in the art.¹⁷² The court refused to hold that unpredictability should lead to patentability, reasoning that any such rule would allow the separate patenting of each combination of an active ingredient and a stabilizer merely because the properties of each stabilizer would have to be verified through testing.¹⁷³ In this case, there was a "reasonable probability" of success in combining the drug with one of fifty-three possible salts listed in the prior art, even if the results for each salt could not be predicted, because common knowledge and the nature of the problem itself would suggest the combination.¹⁷⁴ However, the court did recognize that there must be motivation to do more than "merely . . . try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave . . . no direction as to which of many possible choices is likely to be

167. [T]he burden falls on the challenger of the patent to show by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.

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

168. *Id.*

169. *Id.* at 1361–64 (holding that there was motivation to combine the stabilizer with the active ingredient based on the characteristics of the stabilizer generally).

170. *Id.* at 1363.

171. *Id.* at 1364.

172. *Id.*

173. *Id.*

174. *Id.* at 1362, 1366.

successful.”¹⁷⁵ A “reasonable probability” test as implemented in *Apotex* should effectively heighten the nonobviousness standard and go a long way toward halting the evergreening process.

Apotex's holding that the Pfizer patent was invalid due to obviousness suggests that the Federal Circuit has begun to shift away from its pro-patent stance in pharmaceutical innovation. Pfizer's efforts to optimize drug delivery through the development of an appropriate stabilizer and other nonactive ingredients required a significant amount of research. And as Pfizer indicated, the resulting efficacy of each combination of active and nonactive ingredient was largely unpredictable. However, the Federal Circuit appears to be raising the threshold for what is considered nonobvious, clearly articulating that demonstrating unpredictability is not enough; an inventor must demonstrate that the prior art, including common knowledge and the nature of the problem, gave *no* indication of a probability of success.¹⁷⁶ Although a court still presumes that the patent is valid, the heightened standard enables a challenging party to more easily assert that there was a reasonable probability of success in combining the prior art.

The Federal Circuit's new approach to nonobviousness in the pharmaceutical context approaches the Indian Patents Act's definition of inventive step. Under the Patents Act, an inventive step is accomplished if the invention (1) is not obvious to a PHOSITA, and (2) either has economic significance or involves technical advances.¹⁷⁷ Thus, under this statute, unpredictability is insufficient to demonstrate an inventive step.¹⁷⁸ Instead, an invention should reveal a combination of prior art elements that previously had no suggestion of success. Where there had been no indication of probability of success, any success that results would contribute to the

175. *Id.* at 1365 (emphasis added) (quoting *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006)) (internal quotation marks omitted).

176. In effect, the nonobviousness test proposed in *Apotex* appears to be a hybrid of the nonobviousness requirement and a heightened utility requirement. Section 101 of the U.S. Code allows patent protection of a “new and *useful* process, machine, manufacture, or composition of matter, or any new and *useful* improvement thereof.” 35 U.S.C. § 101 (2006) (emphasis added). This has been interpreted to mean that the invention must have a “concrete, specific, and real-world use,” which is not a difficult requirement to meet. Francesco De Prospero, *The Utility Requirement: When Undeclared Policy Choices and Epistemological Barriers Derail the System*, UNIV. OF PA. LAW SCH. (Dec. 6, 2011, 3:29 PM), <http://www.law.upenn.edu/blogs/polk/patents/archives/2011/12/the-utility-req.html>. Rather than simply requiring some definable, practicable use, the court in *Apotex* read into the nonobviousness standard a requirement for some sort of *beneficial* use. That is, the proposed invention must contribute toward the advancement of the art more than merely adding to it, even if the success of the invention was unpredictable.

177. The Patents (Amendment) Act, No. 15, § 2(a)(1)(ja), INDIA CODE, vol. 18.

178. *Id.*

advancement of technology rather than merely being a nonobvious contribution to the state of the art. The Federal Circuit's shift in the *Apotex* decision toward the Indian Patents Act's definition of inventive step is clear proof that the Federal Circuit has drifted away from its traditional nonobviousness standard.

The United States should embrace the *Apotex* holding as the new standard for nonobviousness and further adopt a burden-shifting test upon review. If the challenging party can illustrate that the combination of prior art suggested some probability of success, the burden will shift to the patent holder to prove that the probability of success was not reasonable. The patent holder must prove that the prior art gave no indication of any probability of success.

Here, whether there was any indication of a probability of success should still be determined from the point of view of the PHOSITA, with *art* in this case referencing pharmaceutical technology. The results of adopting this test are that a manufacturer could realize the particular frustrations of optimizing a drug depending on the use of different nonactive ingredients, but an inventor could not evade obviousness simply by pointing to the unpredictability of the combination or by suggesting that the nonactive ingredient was in a different pharmaceutical context, so long as it was applied in *some* pharmaceutical context. Although this proposal heightens the nonobviousness standard through the "reasonable probability of success" test, the potential combinations of prior art should still be restricted to those that fall within an analogous field. Accordingly, Israel's catch-all approach of looking to even remote fields for prior art should not be followed.

This heightened nonobviousness standard would prevent patent owners from evergreening their existing patents by obtaining follow-on patents with therapeutically insignificant contributions to the state of the art. There would still be a limit to the risk involved in pharmaceutical research and development through the general nonobviousness PHOSITA standard; however, the patent owner should now have to focus on continuing to innovate rather than simply blocking generic drugs from entering the market. Ultimately, this will spur genuine innovation and lift the industry out of its current complacent position. After all, the purpose of the patent system is to reward individual innovation while ensuring the continued advancement of the technical field. The goals of the patent system are only truly realized if the scientific community has incentive to continue developing the field. At the same time, the

increased standard should lead to the greater distribution and affordability of drugs in the marketplace.¹⁷⁹

B. *Holding on to Patent-Term Restoration*

Despite the promise provided by a heightened nonobviousness standard, a restriction on patentability alone would likely cause substantial harm to the U.S. pharmaceutical sector. Alone, such a standard would strip the U.S. market of a significant portion of its intellectual property protection and open the door to foreign generics competition, driving down prices to a point where U.S. manufacturers cannot compete. And if U.S. companies are unable to quickly recoup their losses by releasing new blockbuster drugs, a heightened standard might ultimately lead to the suppression of innovation. Therefore, the heightened nonobviousness standard should be implemented in conjunction with a powerful patent-term-extension program. The coupling of these two tools would weed out patents that hamper the industry and instead “promote the progress of science.”¹⁸⁰

Although a patent linkage regime and a corresponding patent-term-extension program are critical to support an innovation-driven pharmaceutical industry, particularly one that is restricted by the increased scrutiny of a strict nonobviousness standard, the United States should not follow in the footsteps of Israel.¹⁸¹ Although Israel has both a patent linkage regime and patent-term-restoration program, both programs are lopsided in favor of generics manufacturers.¹⁸² While Israeli pharmaceutical manufacturers are given a safe harbor to execute experimentation for the development of generics, pioneer patent holders are left with a shadow of a version of the extension program currently in place in the United States.¹⁸³ Such a model might work for a country that is primarily invested in the generics industry, but the model is inadequate to support the tremendous risk of pioneering discovery. If anything, the United States might be better off with a patent-term-extension policy that provides an even lengthier extension than that already in place in order to balance the competing interests of a heightened nonobviousness bar.

179. See discussion *supra* Part III (describing the relationship between distribution and pricing).

180. U.S. CONST. art. I, § 8, cl. 8.

181. India lacks a patent linkage regime entirely and thus is also not an appropriate model for the United States. See discussion *supra* Part III.B (detailing India's conscious decision to not adopt a linkage regime).

182. See *supra* Part III.C for a discussion of Israel's patent linkage regime.

183. See *supra* Part III for discussions of both the U.S. and Israeli patent linkage regimes.

Scholars criticize the current U.S. patent linkage regime because of the debilitating effect of patent-term restoration on the pursuit of novel drugs.¹⁸⁴ However, such criticism is unwarranted. An assessment of the business strategies of U.S. pharmaceutical companies reveals that the most successful companies focus their resources on the development of blockbuster drugs in order to retain their share of the market and recover the costs of research and development.¹⁸⁵ Follow-on patents, while certainly a recognizable portion of a typical company's intellectual property, can just as easily be obtained by generics manufacturers engaged in research protected by the Hatch–Waxman Act.¹⁸⁶ Therefore, implementation of a patent linkage regime is unlikely to result in an increased number of follow-on patents.

Furthermore, the potential innovation-inhibiting effects of patent-term restoration are mitigated by the heightened standard for nonobviousness. Under the proposed burden-shifting standard, fewer patents for follow-on “inventions” should be granted. Further, empirical studies suggest a nexus between public health policy and patent policy, illustrating the importance of a patent linkage regime in the United States.¹⁸⁷ Congress has determined that the extension of patent terms for pharmaceutical technologies is necessary to promote innovation in the field.¹⁸⁸ Thus, just as a limited monopoly is warranted in exchange for the disclosure of protected work, an extended term is necessary to encourage continued investment in research and development in a field where such investment comes with very high risk.¹⁸⁹

Conversely, linking regulatory rights to weak patents is detrimental to the patent system because it blocks generics from entering the market without adding the benefit of greater innovation. Instead, the patent owner is awarded for relatively insubstantial contributions to the field. An ideal policy for avoiding this situation

184. See Bouchard, *supra* note 94, at 114 (“[T]he production of new and innovative drugs declined over the last decade . . .”); Bouchard et al., *supra* note 13, at 427 (discussing how firms have focused on producing as many follow-on patents as possible through internal competition);

185. See GASSMANN, REEPMAYER & VON ZEDTWITZ, *supra* note 22, at 4–10 (describing how large pharmaceutical companies rely on blockbusters to recoup losses from their high risk ventures).

186. Bouchard et al., *supra* note 78, at 1467; see also Bouchard et al., *supra* note 13, at 415 (suggesting that the safe-harbor provision protects generics manufacturers against infringement while working up their regulatory submissions).

187. See Bouchard et al., *supra* note 78, at 1510 (speculating that there is a “strong legal and functional nexus between public health policy and patent policy”).

188. See *supra* note 93 and accompanying text (discussing the Hatch–Waxman Act’s provision for patent-term restoration).

189. See *id.* (discussing how there is increased social value in the exchange of increased up-front investment for a greater reward).

would not be to limit or eliminate the patent linkage system, but instead to simply restrict patentability of weaker patents. Under such a system, pioneer firms would still be motivated to continue their search for blockbuster drugs with the understanding that they would receive an extended monopoly that prohibits generics companies from marketing similar products.

With the two policies operating in tandem, more drugs would be available for release into the generics market, but companies that made substantial investments in research and development would be rewarded for their efforts with the prolonged protection of their blockbuster drugs. Without these measures, companies are not motivated to engage in high-risk research. Thus, a system that embraces a heightened nonobviousness standard similar to that of India's and Israel's inventive step requirements, while also maintaining a patent linkage system, would best achieve the goals of promoting the success of a worldwide pharmaceutical market.

VI. CONCLUSION

Both India and Israel have developed their generics pharmaceutical market in an effort to better serve their poor populations. The availability of generics allows for greater access to medication and necessary healthcare in countries where the majority of the population would not be able to afford brand pharmaceuticals. On the other hand, the United States is a wealthy country with a history of promoting the arts and sciences. Part of what enables the United States to retain its wealthy status is its ability to excel in technical advancements. However, the U.S. pharmaceutical market has lessons to learn from the Indian and Israeli markets.

The United States should modify its current approach to patent protection of pharmaceuticals. The solution proposed by this Note provides for a stricter nonobviousness standard for determining patentability—one that requires more than merely *some* change away from the prior art, even if unexpected. However, raising the nonobviousness bar alone would only result in damage to the pharmaceutical industry, which would not be able to profit quickly enough from its narrowed pool of patents to recoup costs incurred during research and development. Therefore, this Note also proposes even greater protection through the patent-term-restoration program established under Hatch–Waxman.

By limiting patentability of weaker pharmaceutical patents while simultaneously strengthening protection for those patents that contribute more substantially to advancing the state of the art, the proposed changes would best further the goals of pharmaceutical innovation. The proposed policy would shift the volume of patents in favor of those with a true spark of invention while remaining

sensitive to the risk-mitigating needs of the industry. As a result, the United States would maintain a stronghold in the pharmaceutical sector, and consumers and generics manufacturers would benefit from the increased availability of low-cost drugs resulting from incremental changes to the original patents. Only by maintaining a balance between these two patent policies can the U.S. pharmaceutical market resume its renowned development of blockbuster drugs.

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