Should All Drugs Be Patentable?: A Comparative Perspective

Cynthia M. Ho*

ABSTRACT

Although there has been substantial discussion of the proper scope of patentable subject matter in recent years, drugs have been overlooked. This Article begins to address that gap with a comparative perspective. In particular, this Article considers what is permissible under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), as well as how India and Canada have utilized TRIPS flexibilities in different ways to properly reward developers of valuable new drugs, while also considering the social harm of higher prices beyond an initial patent term on drugs.

This Article brings valuable insight into this area at a critical time. Many have noted that the industry is in a crisis because, despite exponentially increasing expenditures, the number of new drugs produced has been stagnant. Moreover, a predominant number of the slim pipeline features drugs that are not highly innovative. At the same time, the industry and some academics are seeking to increase protection of drugs in the United States and beyond, which could further exacerbate existing problems.

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* Clifford E. Vickrey Research Professor and Director of the Intellectual Property Program, Loyola University Chicago School of Law. The author thanks Professors Sean Seymour, Daniel Gervais, and the entire staff of the VANDERBILT JOURNAL OF ENTERTAINMENT & TECHNOLOGY LAW for their invitation to participate in the symposium that gave rise to the opportunity to write this Article. The author also thanks research assistants Jean Liu, Lindsay Shake, and Guthrie Weinschenck for their excellent help with this Article.

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I. INTRODUCTION

Should all drugs be patentable? In the United States, the typical response of many patent-owning companies, scholars, and policy makers is that all drugs meeting existing patent standards should not only be awarded a patent, but also that increased protection will necessarily promote more drug development.1


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However, other countries take a more cautious approach. As will be discussed, the different approaches seem to mirror different cultural concerns about the importance of promoting public health, including access to affordable medicine.

Although some countries may believe that patents on drugs unduly compromise the ability to promote access to low-cost drugs, most countries do not have the freedom to completely deny patents on all drugs in a world where most countries are members of the World Trade Organization, which requires its members to provide patents pursuant to the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). An important question, however, is the amount of flexibility that nations have in framing patentability requirements to promote their preferred balance of innovation versus health policy. Specifically, important current issues include what type of innovation the current industry produces, as well as whether countries should agree to higher patent standards than TRIPS requires, as repeatedly requested by the pharmaceutical and biotechnology industries.

In recent years, companies are increasingly seeking and obtaining a series of patents on different aspects of a drug, with each patent having a later expiration date to effectively result in a longer period of market exclusivity. Critics call this “evergreening,” in that the patent term appears “evergreen,” even if the commercial exclusivity is technically achieved through different patents. However, companies that engage in this practice consider this to be appropriate “lifecycle management” of their products. As most consumers know, patented drugs cost more than generic versions of faster access to low-cost generic drugs have suggested that the United States follow other countries in taking a more restrictive approach to patentability of drugs, these views are definitely in the minority of scholars as well as policy makers. E.g., Tahir Amin & Aaron S. Kesselheim, Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended for Decades, 31 HEALTH AFF. 2286, 2292 (2012) (suggesting that increased standards of patentability would be the “most effective method to counteract inappropriate extensions of market exclusivity” and mentioning India law in particular).

2. See infra note 22.

3. See infra Part II.C.


5. See infra Part II.C.
initially patented drugs. Accordingly, if companies obtain more patents on drugs, costs may increase.

A number of countries have expressed concern about this development, with some tailoring their patent laws to attempt to ensure that patent incentives better promote more socially beneficial innovation. In particular, some countries have excluded certain types of drugs from the scope of patentable subject matter or have raised patentability standards on drugs. Countries that are modifying, or contemplating modifying, their patent laws to restrict what drugs can be patented are addressing a phenomena that has been well documented: pharmaceutical companies are obtaining patents on drugs of limited therapeutic significance that promote their profits at a substantial social cost.

While there is global concern about questionable patent practices of pharmaceutical companies, there is also substantial discussion and debate concerning patentable subject matter in the United States. In recent years, there have been several decisions by the US Supreme Court concerning the scope of patentable subject matter. These cases indicate unrest concerning a traditionally broad scope of patentable subject matter in the United States. Of particular note is that some things long considered patentable, such as isolated genes, were recently challenged and, despite concerns that this would...

6. E.g., infra Part III (discussing India and Canada); see also EUROPEAN COMM’N, PHARMACEUTICAL SECTOR INQUIRY FINAL REPORT at 453 (July 8, 2009) [hereinafter EC PHARMACEUTICAL REPORT]; IP AUSTL., AUSTL. GOVT., PHARMACEUTICAL PATENTS REVIEW: BACKGROUND AND SUGGESTED ISSUES PAPER 15 (2012).

7. See Domenico Motola et al., An Update on the First Decade of the European Centralized Procedure: How Many Innovative Drugs?, 62 BRIT. J. CLINICAL PHARMACOLOGY 610, 610 (2006) (concluding that less than a third of drugs were important therapeutic innovations based on an algorithm); Johan C.F. van Luijn et al., Superior Efficacy of New Medicines?, 66 EUR. J. CLINICAL PHARMACOLOGY 445, 445 (2010) (finding only 10 percent of new drugs introduced between 1999 and 2005 to be clinically superior over existing medicine); Agnes I. Vitry et al., Assessment of the Therapeutic Value of New Medicines Marketed in Australia, J. PHARMACEUTICAL POLY & PRACT. 4–5 (2013) (assessing the therapeutic value of medicines in Australia and finding similar results as the Motola study). In 2014, the Food and Drug Administration (FDA) approved a record number of new drugs, including some important therapies. E.g., Bernard Munos, 2014 New Drug Approvals Hit 18-Year High, FORBES (Jan. 2, 2015, 1:40 PM), http://www.forbes.com/sites/bernardmunos/2015/01/02/the-fda-approvals-of-2014/; John Jenkins, CDER Approved Many Innovative Drugs, FDA VOICE (Jan. 14, 2015), http://blogs.fda.gov/fdavoice/index.php/2015/01/cder-approved-many-innovative-drugs-in-2014/. However, it is unclear whether this is an anomaly; moreover, existing patent laws in some countries may nonetheless still encourage companies to spend more time developing drugs of less therapeutic significance.


upend settled expectations, the US Supreme Court did modify existing law. Interestingly, while the United States has recently considered whether genes and software should be patentable subject matter, there is virtually no discussion concerning drugs. There are, of course, some differences in that drug patents are not considered to negatively impact researchers as much as patents on genes and software—one gene patent can stifle an entire area of research, and in software, a thicket of patents may preclude not only research, but also product development. However, for patients who can ill afford a patented drug, the policy implications loom large.


11. *Myriad*, 113 S. Ct. at 2119. Arguably, the decision does not substantially modify the commercial marketplace by denying patents only on some types of genes, but the fact that there was a challenge in the first instance to seemingly settled law for decades is nonetheless significant. In addition, since that decision, the Australian Supreme Court has come to a different conclusion concerning patentability of genes. *D’Arcy v. Myriad Genetics, Inc.* [2014] FCACF 115 paras. 195, 207 (upholding validity of Myriad’s patent over isolated gene sequences and expressly rejecting the approach of the US Supreme Court).


Even if drug patents may not have the same negative implications on research as genes and software, reconsidering whether there is a sound policy for extending a broad scope of patentable subject matter or other aspects of patentability for drugs is timely and appropriate. In addition to self-interested companies, some scholars have recently argued for more expansive protection of drugs. The arguments are often couched as necessary to promote pharmaceutical innovation because, despite exponential increases in the amount of money spent on research and development, there has been no corollary increase in new drugs; rather, innovation has generally been stagnant for years. These arguments also come at a time when the patents on many “blockbuster” drugs, each of which generates over $1 billion in sales, are expiring. Thus, the drug industry may be


particularly motivated to seek more protection either by maximizing benefits from existing laws or by modifying laws to obtain more protection. These arguments may sway policy makers; indeed, legislators have enacted regulatory protection for some types of drugs that are considered by the industry to provide protection of equal importance to patents for commercial products. In addition, Congress just issued a legislative discussion document that proposes even more regulatory protection to promote innovation. These arguments are likely to be particularly relevant in the near future as drug companies, as well as some scholars, note that profits are eroding due to competition from generic companies, stricter and more expensive regulatory requirements, product liability suits for injuries resulting from the products of generic companies, and allegedly increased costs of drug development.


19. E.g., Henry Grabowski et al., Recent Trends in Brand Name and Generic Drug Competition, J. MED. ECON. 1 (2013) (increased erosion of sales due to generic competition); Victor Schwartz et al., Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects, 81 FORDHAM L. REV. 1835 (2013) (increased costs from products liability suits against generic products); Neeraj Sood, The Effect of Regulation on Pharmaceutical Revenue: Experience in Nineteen Countries, 10 HEALTH AFF. 136 (2009) (regulatory requirements reduce revenues); Cost to Develop and Win Marketing Approval for a New Drug is $2.6 Billion, TUFTS CENTER STUDY DRUG DEV. (Nov. 18, 2014), http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study (suggesting increased regulatory costs). Although the latest estimate of cost development allegedly showing costs has doubled over the past decade, some have been critical of the study and noted that it likely suffers from similar flaws in earlier estimates. E.g., Aaron Carroll, $2.6 Billion to Develop a Drug? New Estimate Makes Questionable Assumptions, N.Y. TIMES (Nov. 18, 2014),
This Article aims to illustrate that the dominant US approach need not be the only approach and that, at a minimum, different approaches to the patentability of drugs are in fact permissible under international law and do have policy justifications. Since this Article is part of a symposium on patentable subject matter, this Article, of course, addresses whether some drugs can be excluded from the scope of patentable subject matter. However, because patentable subject matter is only one policy lever to address perceived problems with pharmaceutical patents, this Article does not restrict its focus to this single issue. Most importantly, this Article aims to show that not only developing countries, but also developed countries may approach the patent eligibility of drugs differently and that these approaches are in fact permissible under international law.

This Article proceeds in three parts. After this Introduction, Part II provides some fundamental background to drug development and marketing, including the role of patent protection. Part II also highlights problems that have been noted with the existing model of drug development, as well as how companies have used patent laws in conjunction with other mechanisms in questionable ways. Part III then provides a comparative perspective on how India and Canada have modified their patent laws to limit patents on drugs when doing so seems necessary to best promote the balance between innovation and access to affordable medicine. Part IV then evaluates the extent to which the Indian and Canadian patent provisions are permissible under TRIPS. This Part begins with an introduction to TRIPS and how it should be interpreted, before explaining why the approaches of both countries are in fact permissible, contrary to what some have suggested. This Part concludes by considering policy implications of these unusual laws, as well as possible additional related avenues for exploration.

II. BACKGROUND

To best understand the unique patent approaches in India and Canada and whether they are good policy, it is important to first


20. This is especially true because sometimes it is unclear whether a given law is limiting the scope of patentable subject matter, or instead, suggesting a heightened novelty or nonobviousness standard. See infra Part III.A (discussing India).

21. See infra Part IV.
address some fundamentals. Accordingly, this Part explains the basics of patent law and policy as well as how they intersect with drug development and marketing. The final section of this Part addresses a concern of some countries and commentators that multinational pharmaceutical companies are manipulating existing laws in a way that fails to promote drug innovation, while impeding access to affordable drugs.

A. Patent Law and Policy—Domestic and International

A patent is a legal document granted by a specific country to an inventor that provides the commercially valuable ability to exclude others from the patented invention within the boundaries of the patent-granting country. There is no patent right unless and until a nation decides to grant a patent in response to a patent application that meets domestic patentability requirements.

Traditionally, patents have involved a balance of competing policy interests. Since patents generally result in a cost increase for the patented item, granting a patent is only a reasonable policy if there is a countervailing social policy that is promoted. The earliest patents were granted to promote technology transfer; a patent was granted to inventors willing to move to the patent-granting territory to not only use their invention there, but also teach others how to use it. Today, patents are predominantly considered a way to promote domestic innovation, even though technology transfer is sometimes mentioned. Although patents may arguably promote technology


24. E.g., Christopher May & Susan K. Sell, Intellectual Property Rights: A Critical History 53 (2006). This technology transfer principle was so important that an early international agreement acknowledged that patent rights could be forfeited without proper use of the patent in the country: this was later softened by permitting patent owners to keep patents, but mandate a compulsory license if the owner was not utilizing the patent within the country. E.g., Paris Convention for the Protection of Industrial Property art. 5A, July 14, 1967, 21 U.S.T. 1583; 828 U.N.T.S. 303.

transfer for developing countries, most commentators consider patents to be predominantly a way to promote domestic innovation.

The patentability requirements can be seen as ensuring that patents fulfill their social policy goals. For example, courts have frequently considered patents to be a type of social contract—for the social “cost” of a patent in terms of the higher prices that result on patented inventions, the patentee must adequately disclose information concerning the patented invention, including how to make and use it, such that society will benefit from the invention. In other words, although an inventor could keep an invention secret, the reward of a patent is, in part, given to induce disclosure of information to society so that others can learn from and build upon that innovation. Because most inventions build upon prior inventions, encouraging inventors to share their knowledge can be socially valuable, even if there is a temporary cost of higher prices during the period of patent protection.

The social harm of higher prices on patented goods is mediated by both the patent term and patentability requirements. Patents are

26. See Rachel Diamant et al., Promoting Technology Transfer in Developing Countries: Lessons from Public-Private Partnerships in the Field of Pharmaceuticals, in THE STOCKHOLM NETWORK EXPERTS’ SERIES ON PHARMACEUTICAL IPRs 8 (2007). However, evidence indicates that technology transfer only happens for mid-level developing countries and not the poorest ones. See Bronwyn H. Hall & Christian Helmers, The Role of Patent Protection in (Clean/Green) Technology Transfer, 26 SANTA CLARA COMPUTER & HIGH TECH. L.J. 487, 521 (2010) (noting that stronger patents have little effect on technology transfer to the lowest income countries).


generally awarded a limited term of protection of less than twenty years in order to minimize the period during which consumers must pay patent-inflated prices.\textsuperscript{29} In addition, patentability requirements are intended to restrict the harm of higher prices to deserving inventions.

There are two basic types of requirements that patent applications must meet to persuade a national patent office that a patent is deserved. First, the invention must meet certain requirements; typically, the invention must be patentable subject matter and also be useful, new, and nonobvious.\textsuperscript{30} Second, even if the invention is patent-worthy, a patent may still be denied if the inventor fails to properly disclose important aspects of the invention that are considered part of the social bargain of the disclosure noted above.\textsuperscript{31} Both of the requirements on patentability and disclosure are intended to ensure that the social harm of higher prices is limited to situations where society would most benefit, justifying the burden of a patent.

A traditional feature of patents, similar to all types of intellectual property, is that they are territorially limited. Patents are awarded by individual nations and patent rights are generally only enforceable against infringements that occur within that nation. Moreover, a patent granted by one country does not guarantee that another country will grant a patent; this is a fundamental principle that has been consistently recognized in international agreements governing patent protection.\textsuperscript{32} This is consistent with the fact that patents are policy tools and that not all countries will necessarily agree on when the negative short-term costs of patents are considered worthwhile.

A fundamental patent requirement is that an invention be patentable subject matter. If an invention is not patentable subject matter, there is no need to consider whether it meets the technical requirements of being new, useful, or nonobvious, since failure to

\textsuperscript{29} The patent term in most countries is a function of how long patent offices take to examine the patent and calculated to end twenty years from the first filing, such that it is always shorter than twenty years. E.g., 35 U.S.C. § 154(a)(2) (2012) (noting that the term begins on the date the patent issues and ends twenty years from the date of the relevant patent application). Although this term may seem lengthy, it is far shorter than copyright terms that last seventy years beyond the life of the author or the potentially infinite terms available for trade secrets and trademarks. 17 U.S.C. § 302 (2012) (copyright term); Melvin F. Jager, 1979 Uniform Trade Secrets Act, in 3 TRADE SECRETS LAW, app. A1; 1 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 6:17.50 (4th ed. 1996) (noting that trademarks have a potentially unlimited duration).


\textsuperscript{32} E.g., Paris Convention for the Protection of Industrial Property, supra note 24, art. 4bis (granting of patent in one country does not impact whether another country must grant a patent).
satisfy one element of patentability will bar a patent. Like all other patentability requirements, the patentable subject matter standard is a policy decision. The doctrine of patentable subject matter may preclude things that are indeed new to society, yet deemed undeserving of patent protection. For example, most countries will not patent a newly discovered, yet naturally occurring, phenomena because although newly discovered, the person that discovered it did not create anything. Similarly, many countries—but not the United States—bar patents on inventions that would be contrary to morality.

One traditional exclusion from patentable subject matter for many countries was an exclusion of drug and drug components because the higher cost of patented drugs would limit access to affordable medicine. However, countries that barred patents on drugs often still permitted patents on the methods of making drugs. Permitting only methods, but not products—such as an active ingredient of a drug—to be patented, has important consequences. When the drug or active ingredient is itself patented, no one else can make the identical compound, such that a patent can enable the manufacturer to charge a premium. On the other hand, a patent on only the process of making the drug does not block others from developing different methods of making the same drug. Moreover, if there are multiple manufacturers of the identical drug, such competition effectively lowers prices.

Contrary to what the pharmaceutical industry often suggests, countries that provide patentability standards on drugs that are different from the United States are not all doing so simply because they fail to value innovation and intend to free-ride off of the United States.

33. 35 U.S.C. § 101. Of course, whether patentable subject matter is considered before other patent requirements is currently subject to scholarly debate. E.g., Mark A. Lemley et al., Life After Bilski, 63 STAN. L. REV. 1315, 1342 (2011) ("Indeed, we agree with a number of commentators that the right time to apply § 101 is as a backstop after all other validity doctrines have been exhausted.").

34. E.g., Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012) ("The Court has long held that . . . '[l]aws of nature, natural phenomena, and abstract ideas' are not patentable." (quoting Diamond v. Diehr, 450 U.S. 175, 185 (1981))). Of course, if the natural item is modified from its natural form, patent protection is possible. For example, one landmark patent case found that genetically modified bacteria designed to help clean oil spills were patentable, even though bacteria are naturally occurring. Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980).

35. E.g., TRIPS, supra note 22, art. 27(2); Convention on the Grant of European Patents art. 53(a), Oct. 5, 1973, 13 I.L.M. 268 (1974). In the United States, it is permissible to patent something for use in an illegal activity, such as gambling. See Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1366 (Fed. Cir. 1999). Not only is it not excluded from the scope of patentable subject matter, but the United States has also abandoned a prior doctrine that required an invention’s use to be a moral one. E.g., id. at 1366–67.
States. Rather, countries at all levels of development have barred patents on drugs because of the policy concern that patented drugs unduly impede access to affordable medicine. Some industrialized countries only began to patent drugs long after the United States did, and often as a result of outside forces; for example, Switzerland and Italy only did so in the late 1970s, due to external pressure. In addition, even countries that granted patents on drugs sometimes required that patent owners permit others to make the patented drug under a “compulsory license” to ensure that they would be available at affordable prices.

Today, over one hundred countries must provide patent protection for drugs, and not just methods of making drugs, as members of the World Trade Organization (WTO). This is because all WTO members must comply with TRIPS, the WTO side agreement that requires certain “minimum” standards of patent protection.

An important issue is that although most countries must now provide patents on drugs, there is not necessarily broad consensus that doing so is good social policy. The idea of including the first international substantive standards of patent protection was the brainchild of US companies, including the pharmaceutical industry.

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36. E.g., Dickerson v. Maurer, 108 F. 233 (E.D. Pa 1901) (rejecting claim that patent was invalid as not new, but never questioning that patent on new chemical product was patentable subject matter), aff’d, Maurer v. Dickerson, 113 F. 870 (3d Cir. 1902).


38. E.g., BOLDRIN & LEVINE, supra note 37, at 249 (noting that the 1907 English patent act introduced mandatory licenses for medicine). Canada also previously required drugs to be subject to compulsory licenses. See infra Part III.B (discussing Canada).


Including patent protection, and especially patents on drugs, was always a controversial issue that some countries, such as India, objected to. Before TRIPS was concluded, there were nearly fifty countries that did not provide patents on drugs. These countries likely agreed to patent standards because of non-patent issues, such as trade benefits for their exports under the WTO. Since the patentability standards were likely not a reflection of consensus on proper policy, it is perhaps not surprising that a major interpretive issue with TRIPS is the extent to which nations have flexibility in deciding what aspects of drugs are patentable, as will be further discussed in Part IV.

B. Drug Development and the Role of Patents

Most consumers are aware that there are two different types of prescription drugs—expensive brand name drugs versus cheaper generic drugs. The difference in cost between generic and brand name patented drugs is a function of patent law. Patented drugs can command a premium price because patents legally entitle their owner to exclude all others from making or selling the patented invention during the patent term.

Drug companies often point to development costs in justifying the high cost of patented drugs. To sell a drug, a company must provide substantial clinical data from both animals and humans to show that a new drug is safe and effective to a domestic regulatory agency, such as the Food and Drug Administration (FDA) in the United States. The difference in cost between generic and brand name patented drugs is a function of patent law. Patented drugs can command a premium price because patents legally entitle their owner to exclude all others from making or selling the patented invention during the patent term.

In some countries, the difference may be mediated in a variety of ways, such as imposing caps on what companies can charge or negotiating in bulk for deep discounts. However, because the United States does not do any of these on a large-scale basis, the United States accounts for nearly half of global sales. E.g., Cynthia M. Ho, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS 26 (2011) [hereinafter Ho, ACCESS TO MEDICINE].

35 U.S.C. § 271 (2012). Of course, although competition generally results in lower cost generic prices, recently the cost of some generic drugs has increased. See, e.g., Elizabeth Rosenthal, Rapid Price Increases of Some Generic Drugs Catch Users by Surprise, N.Y. TIMES (July 8, 2014), http://www.nytimes.com/2014/07/09/health/some-generic-drug-prices-are-soaring.html. This, however, is a notable exception that occurs only if competition lessens, whereas patented drugs are generally always expensive since, by definition, they are legally sold only by the patent owner—unless others are licensed. Id.
United States. However, even before the multi-year clinical testing can begin, it may take years to identify any promising chemical compounds in the lab. Most initially promising chemicals fail before animal testing begins and even many drugs tested in humans may fail to make it to the market because of problems with efficacy or safety. The industry suggests that only one in eight to ten thousand lab tested compounds eventually reaches the marketplace. Accordingly, companies assert that the sale of commercial products must also cover the expense of investigating the many compounds that fail to reach the marketplace.

In contrast, a generic drug has an abbreviated path to market for a small fraction of the time and cost. The time and expenses for generic companies are substantially abbreviated not only because they do not need to invest in research, but also because regulatory agencies will generally grant approval for generic drugs based on an expedited procedure that requires a much more limited set of clinical data than required for new drugs. The proposed generic drug only needs to have testing that shows it is “bioequivalent” to the previously approved brand drug, allowing an agency to infer that the earlier clinical tests of safety and efficacy of the brand drug also apply to the generic. In addition, brand companies note that while they must incur marketing costs, generics do no marketing and simply copy commercially successful drugs, for which the brand companies have already created a market.

45. See FTC, To Promote Innovation, supra note 1, ch. 3, at 6.
46. Salomeh Keyhani et al., Are Development Times for Pharmaceuticals Increasing or Decreasing?, 25 HEALTH AFF. 461, 463 (2007) (reporting an average of five years of clinical testing, with a range of 1.4 to 14.6 years).
47. See FTC, To Promote Innovation, supra note 1, ch. 3, at 6–7.
48. PHRMA 2014 Submission, supra note 1, at 16.
49. E.g., INT’L FED’N PHARM. MFRS. & ASS’NS, ENCOURAGEMENT OF NEW CLINICAL DRUG DEVELOPMENT: THE ROLE OF DATA EXCLUSIVITY 6–7 (2000) (estimating $1 million); Henry G. Grabowski et al., Entry and Competition in Generic Biologics, 28 MANAGERIAL & DECISION ECON. 439, 443 (2007) (estimating in the low end of a $2 million to $200 million scale). In contrast, estimates for the cost of a new drug are substantially higher. E.g., Joseph A. DiMasi & Henry G. Grabowski, The Cost of Biopharmaceutical R&D: Is Biotech Different, 28 MANAGERIAL & DECISION ECON. 469, 477 (2007) (finding over $500 million in out-of-pocket costs); see also Tufts Center for the Study of Drug Development, supra note 19 (press release alleging current out-of-pocket costs of over $1,300 million according to a currently unpublished study). The differential may sometimes appear greater because the industry has repeatedly represented the “average” cost of all drugs to be an inflated figure that only represents the most expensive minority of drugs that are developed. See Ho, supra note 1, at 456–57 (explaining cost “schema”).
52. E.g., FTC, To Promote Innovation, supra note 1, at 9.
It is widely recognized that the pharmaceutical industry is unique among most industries in that patents are considered essential. Whereas issues such as first-mover advantage are more important in other industries, patents are critical to the success of a pharmaceutical company.\textsuperscript{53} In addition, patented drugs are also different from most patented products in that they are expensive and time-consuming to develop, but easy to copy.\textsuperscript{54}

Because a patent permits a company to legally exclude all others from making or selling the identical drug,\textsuperscript{55} pharmaceutical companies mostly rely on patents to protect their investment in new drugs and to maintain a competitive advantage.\textsuperscript{56} Of course, competitors may sell a drug that aims to treat the same condition; however, the ability to exclude others from making the identical patented drug generally permits the patent-owning company to sell its drug at a substantial premium. This is true even when there are two or more drugs that treat the same condition in the same way; each drug is usually priced at a substantial premium in contrast to a generic drug.\textsuperscript{57} In other words, even when a new drug is only an incremental innovation with no therapeutic benefit over existing drugs, it may still cost just as much as similar drugs. There is generally no substantial reduction in price unless and until there are multiple generic drugs on the market.\textsuperscript{58} Moreover, the premium cost


\textsuperscript{54} E.g., Adam B. Jaffe & Josh Lerner, \textit{Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It 42–43 (2004) (noting that, unlike a business that builds a new factory, a pharmaceutical business is building an intangible asset that is easier to steal).}


\textsuperscript{56} See, e.g., Nat'l Research Council, \textit{supra} note 12, at 35–36.


\textsuperscript{58} See, e.g., Richard G. Frank, \textit{The Ongoing Regulation of Generic Drugs, 357 New Eng. J. Med 1993, 1995 (2007) (indicating that average price drops to 94 percent of original with}
of a patented drug has been increasing—whereas a patented drug was roughly twice the cost of generics in 1990, by 2008, the differential had doubled, such that branded drugs may cost roughly four times the cost of a generic.59

Although consumers may view drugs as either expensive patented drugs or cheap generics, from a developmental cost perspective, newly patented drugs are far from identical. In particular, while pharmaceutical companies tend to suggest that every drug has a long and expensive pathway to the commercial market, this is, in fact, only true for a minority of new drugs that are “new molecular entities.” The new molecules take longer to develop but are more likely to result in treatments that are dramatically different. For example, the new Hepatitis C drug sold as Sovaldi is a new molecular entity and, for the first time ever, offers a cure to the disease. However, most new drugs are incremental modifications of previously developed drugs; drugs sold as “new” may be incremental modifications of existing drugs such as a different dosage or a different form of administration.60 Although an incremental modification may be of some clinical benefit, these are notably easier and less expensive to develop;61 one estimate suggests that the cost of development is only a quarter of the cost of the most expensive drugs (based on new molecular entities).

When patent law realities are combined with regulatory realities and rational business decisions, all considerations point towards a focus on incremental drugs.62 First, patent laws provide the
same term of protection for all drugs without regard to whether the drug is an important clinical breakthrough or an incremental drug of little therapeutic importance. In addition, some types of incremental innovations may also be able to rely on earlier clinical data to obtain regulatory approval for sale and thus substantially limit the usual time and cost to develop a truly new drug. Accordingly, a rational profit-maximizing company would logically seek to focus on incremental inventions. In fact, that is the case. During the 1990s more than half of applications for “new” drugs were incremental innovations that utilized known active ingredients. In addition, studies of pharmaceutical innovation in the United States, Australia, and Europe all found most new drugs were incremental innovations and that only between 10 and 30 percent of drugs were more therapeutically valuable than existing drugs.

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63. See 35 U.S.C. § 154 (2012) (providing patent term for all inventions). In addition, although the term may be extended in some cases, including for drugs, there is no adjustment of patent terms based on the importance or value of the invention. See generally 35 U.S.C. § 156 (2012) (providing patent term extension). In addition, simply providing a shorter patent term for less innovative drugs may not be possible because of international obligations that require a minimum patent term for all inventions. TRIPS, supra note 22, art. 33.


65. This does not mean that incremental innovations have no value; however, this class of inventions is more likely to have issues, as discussed in the next section.


68. See sources cited supra note 7.
C. Current Concerns with Drug Patents

This Section focuses on a few dominant recent strategies used by companies to maintain market exclusivity of drugs, such as “secondary (later issued) patents,” as a backdrop for the discussion of Indian and Canadian laws that seem to address these issues. Companies use a number of strategies to maximize potential revenue in each country with somewhat different patent and regulatory laws. Given the focus of this Article on evaluating different patent approaches by these companies, this Section aims to highlight some patent issues.

1. Secondary (And Sometimes Sequential) Patents

Although companies have traditionally protected their drugs with a single patent on the active ingredient, in recent years, companies have obtained “secondary” patents on different aspects of a single commercial drug after obtaining an initial patent on the active ingredient. Secondary patents may cover peripheral features such as a tablet coating, an intermediate product that naturally results after ingesting the drug, or methods of use; it could also include a different dosage or delivery route.

This practice can be considered a creative way to address the problem of shorter patent terms for drug patents as compared to other patented products; whereas most patents have an average patent term...
of about seventeen years, the “effective” patent term of drugs is often only eleven to twelve years. Technically, all patents have the same basic patent term, but because the owner of a patented drug cannot sell the drug until regulatory approval has been granted showing it is safe and effective, which generally occurs after the patent is issued, the effective term for patents is shorter than for most other products.

Secondary patents can help provide longer terms of commercial exclusivity when they are filed and issued sequentially, as is common practice. In particular, if each sequential patent has a later expiration date and no generic manufacturer can make the drug without infringing at least one patent, that will prolong the period of exclusivity in the marketplace. Accordingly, some refer to this patent strategy as “evergreening” because, although different aspects of the drug are patented, patent protection seems “evergreen.” Although some suggest this term is derogatory or incorrect, the term is widely used by scholars and policymakers.


74. This is true, even though a number of countries grant an extension of patent term for drug patents in recognition of this phenomena. See, e.g., 35 U.S.C. § 156(a)(4) (2012); Australia Patents Act of 1990, (Cth) ch 6, pt 3, s 77; Patent Act, Act. No. 950 Dec. 31, 1961, art. 89 (S. Kor.) (as amended); Patent Act, Act. No. 121 of 1959, art. 67(2) (Japan) (technically supplementary protection certificates). In addition, Canada may be considering this. E.g., Noel Courage, Canadian Patent Term Extension is Coming, LEXOLOGY (Oct. 18, 2013), http://www.lexology.com/library/detail.aspx?g=4a6646ab-db6d-4c8a-9832-41a5352e6732.

75. An excellent example of this phenomena in fact occurred at the symposium, where a federal judge suggested that those who complain about evergreening simply fail to understand patent fundamentals. This inadequate defense of evergreening is also common among patent owning pharmaceutical companies and those that seem to support their interests. See, e.g., GSK Public Policy Positions: Evergreening, GLAXOSMITHKLINE (Aug. 2011), http://www.gsk.com/media/280836/evergreening-policy.pdf; Scott Parker & Kevin Mooney, Is ‘Evergreening’ a Cause for Concern? A Legal Perspective, 13 J. COM. BIOTECHNOLOGY 235, 238–39 (2007); European Fed’n Pharm. Indus. & Ass’n, The Degree to Which Patenting, and in Particular Secondary Patenting, Protect Pharmaceutical Products During their Lifecycle is Often Misconstrued, EFPIA (Nov. 28, 2012), http://www.efpia.eu/blog/971/The-degree-to-which-patenting-and-in-particular-secondary-patenting-protect-pharmaceutical-products-during-their-lifecycle-is-often-
One classic example of the effective use of secondary patents is with the heartburn treatment sold as Prilosec. The patent on the active ingredient expired in 2001. However, the manufacturer obtained additional patents to help delay generic entry, including a patent on an internal coating that helped ensure that the drug would resist stomach acid. Although generic companies ultimately prevailed, the litigation resulted in an extra fourteen months of exclusivity for Prilosec, which resulted in more profits to the manufacturer, as well as continued financial costs to consumers.

Another example of the effective use of subsequent patent filings exists with regard to the blockbuster antidepressant sold as Paxil. The first patent on the active ingredient was filed in the 1970s. Subsequent patents were obtained on this drug, with the last patent expiring in 2019, sixteen years after the first patent expired. Due to a successful challenge by a generic competitor, generic approval and entry occurred in 2003. However, if that had not occurred, the patent owner would have essentially had a full additional term of sixteen years of protection. In addition, even though a generic option was available, many patients were still switched to the newer patented version that provided an extended release.

A more current example of the use of secondary patents is related to Eli Lilly’s lung cancer drug sold as Alimta. Although this
drug may not be as well known to consumers as Prilosec, it generates well over $2 million in annual sales and is expected to generate $3.5 billion by 2016. The patent on the initial compound is set to expire in 2017. However, Eli Lilly filed and obtained a second patent on the method of using the compound together with vitamins that does not expire until 2022 which will delay generic entry.

The number of secondary patents covering individual drugs has increased over the last three decades. In addition, companies are more likely to obtain these patents on blockbuster drugs, each of which, by definition, has over a billion dollars in sales. This seems logical given that the industry generally relies predominantly on such drugs for the majority of its profits.

Companies seem aware that secondary patents are often vulnerable to challenges of invalidity. Nonetheless, because each patent is presumed valid in most countries, even if one patent is deemed invalid, a drug is more easily protected from generic competition if protected by multiple secondary patents instead of a single patent on the active ingredient.


87. E.g., C. Scott Hemphill & Bhaven N. Sampat, When Do Generics Challenge Drug Patents?, 8 EMPIRICAL LEGAL STUD. 613, 615 (2011); EC PHARMACEUTICAL REPORT, supra note 6, at 188.

88. E.g., Hemphill & Sampat, Evergreening, supra note 73, at 328.


90. EC PHARMACEUTICAL REPORT, supra note 6, at 192 (noting companies admitting a strategy to have patents which “might not be ‘rock solid’” rather than no patent).

2. Follow-On Patents in Combination with Active Marketing

In addition, companies may develop and patent “follow-on” inventions, such as slightly different versions of existing drugs, to maintain market share after the patent term of the original drug expires. These variations may be mirror image versions of the prior active ingredient, slower release formulas, or combinations of existing drugs. These “newer” variations are viewed by patent owning companies as legitimate innovations, whereas critics often view the practice as another type of evergreening.

Although incremental innovation is common in all industries, what happens in the pharmaceutical industry is likely unique. The practice of patenting follow-on drugs often occurs in combination with substantial, and usually successful, marketing to consumers and doctors to “switch” to a newly patented drug. The follow-on drug typically launches towards the end of the patent life of the original drug, before a generic of the original drug is available. In addition, the company will often either reduce the price of the new drug or even remove the old drug from the market to promote a switch to the new drug. Importantly, whatever mechanism a company uses, it aims to persuade doctors and consumers to switch to the newer drug with a new patent life before a low-cost generic version of the original enters the market, because once a generic enters the market, it is more difficult to convince patients to switch to a more expensive follow-on product. However, even if a lower cost generic is able to enter the market, doctors and consumers may not switch to a lower cost generic drug once they have started using another drug.

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92. E.g., THOMAS, supra note 4.
93. EC PHARMACEUTICAL REPORT, supra note 6, at 351, 362.
94. E.g., id. at 356.
95. E.g., id. at 351, 360–61, 364–65 (noting that this was a problem with at least nine products); see also David Balto, Removing Obstacles to Generic Drug Competition: A Critical Priority for Health Care Reform, CENTER FOR AMERICAN PROGRESS (June 2009), available at http://www.dcantrustlaw.com/assets/content/documents/CAP/Removing%20Obstacles%20to%20Generic%20Drug%20Competition.pdf (noting alternative strategy of increasing the price of the drug whose patent is about to expire to encourage switching to the newer version that one company successfully used to encourage patients to switch from Provigil to more newly patented Nuvigil). The European Commission has since modified its laws so that withdrawal of a reference product will not bar entry of a generic version. Commission Directive 2001/83, art. 10(1), 2001 O.J. (L. 311) (EC).
97. EC PHARMACEUTICAL REPORT, supra note 6, at 360.
company, “Once the patient is switched to a [follow-on] product the physician does not have to, cannot and will not switch him to a generic, and what is more important: the pharmacist cannot substitute!!”

The manufacturer of Prilosec also engaged in this strategy to protect its profits by marketing Nexium, which is a variation of the compound sold as Prilosec. Manufacturer AstraZeneca had strong motivation to do so; in 2000 alone, Prilosec earned an estimated $6 billion and was the world’s best selling pharmaceutical in 2001. Given the pending expiration of the Prilosec patent, it initiated the “Shark Fin Project” to develop a way to protect its market share.

The company also conducted a number of tests to compare 20 mg of Prilosec against 40 mg of what would be marketed as Nexium, to establish that the newer drug was “better.” Even with this uneven playing field, not all the study results showed superiority of the newer drug. However, AstraZeneca only published the somewhat positive test results: improvement of 90 percent versus 87 percent. The FDA approved Nexium in February 2001, six months prior to the earliest possible generic entry.

AstraZeneca was highly successful in prompting most consumers to switch from Prilosec to Nexium. In addition to massive advertisement concerning the “improved” drug (based on the selective publication of the stronger dose of Nexium), the company discounted Nexium slightly below the cost of Prilosec, provided free samples to doctors, and provided discounts to managed care plans and

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98. Id.
99. This is referred to by some as “chiral switching” since it involves replacing a mixture of two chemical mirror images of compounds (called a “racemic mixture) with just one half (a single enantiomer), which may be “purer” and thus more effective. E.g., Yoshitani et al., supra note 64, at 392.
101. Gorlin, supra note 79.
102. U.S. Patent No. 4,255,431 (filed Apr. 5, 1979); Gorlin, supra note 79, at 834 (noting expiration of patent on Oct. 5, 2001). The patent was then granted a six-month extension for completing pediatric studies, such that it did not expire until October 2001. E.g., Harris, supra note 77.
105. Id.
106. Harris, supra note 77.
hospitals.\textsuperscript{108} Nexium was introduced one month before Prilosec’s patent would expire,\textsuperscript{109} before any generic versions of Prilosec could enter the market. In addition, Prilosec was withdrawn from the prescription market and was only available over-the-counter.\textsuperscript{110} Since Nexium is technically a different compound than Prilosec, even if very similar, pharmacists could not automatically substitute generic Prilosec for prescriptions of Nexium, even when generic versions of Prilosec were available. Accordingly, even when generic Prilosec was available by prescription, sales were modest.\textsuperscript{111} Until Nexium recently became available as an over-the-counter medication, it was the most prescribed product in its class, despite the existence of other patented drugs in its class, as well as a substantially cheaper over-the-counter generic version of Prilosec that costs less than $2 per day.\textsuperscript{112}

The most extreme situation is where the follow-on patented drug of incremental improvement is the only option for patients because the original drug has been removed from the market. In such a case, advertising of the advantages of the new drug are not even necessary since consumers have no alternative. Importantly, when the generic is launched, unless doctors specifically prescribe the generic, there is no automatic substitution of the generic for the newly patented improvement because even though they are very similar, they are not identical. As recently noted by one CEO, once patients are switched to the newer version, “it’s very difficult for the generics then to reserve-commute back, . . . [t]hey don’t have the sales force, they don’t have the capabilities to do that.”\textsuperscript{113}

\begin{footnotes}
\item[108] E.g., Gorlin, supra note 79, at 848 (noting that the company secured agreements to have Nexium be the exclusive proton pump inhibitor used by the hospital in exchange for deep discounts, as well as agreements with insurance companies for favorable placement on their formularies).
\item[109] Gladwell, supra note 103, at 86.
\item[111] See Walgreen Co. v. Astrazeneca Pharms. L.P., 534 F. Supp. 2d 146, 149 (D.D.C. 2008) ("[I]f Nexium had not gone to market, the manufacturers of generic substitutes to prescription Prilosec would have far more than their current 30% of the market . . . ."); Gorlin, supra note 79, at 849 (noting that contrary to analyst predictions that generics of Prilosec could be 50 percent of the 2004 market, they were only 14 percent of prescriptions).
\item[112] E.g., Schondelmeyer, supra note 57, at 123.
\end{footnotes}
consumers may have no access at all to earlier versions that are cheaper. For example, Abbott successfully used this strategy of removing the older drug from market right before its patent expired several times to protect its sales of cholesterol-reducing drug Tricor from generic competition for nearly a decade.\textsuperscript{114} Most recently, Actavis publicly announced its intention to pursue a similar strategy of withdrawing its Namenda drug before patent expiry to prevent generic competition.\textsuperscript{115} Although such actions properly prompt antitrust disputes, the need for such actions may still result in a delay in generic competition.\textsuperscript{116}

Although drug companies often assert that complaints of evergreening are unjustified because patients can elect to purchase cheaper alternatives if they are not convinced the patented version is superior, these examples clearly illustrate this argument is not necessarily true. Also, drugs are sold in a unique market with noticeable information asymmetry. Patients do not have full knowledge or control of what prescription drugs they purchase. Doctors can better evaluate whether the cost of a new drug is justified, but studies show that doctors are often not cost-conscious.\textsuperscript{117} In addition, even if doctors were cost-conscious, they may not truly be able to evaluate whether a new drug is better because they are

\textsuperscript{114} E.g., Nicholas S. Downing et al., \textit{How Abbott’s Fenofibrate Franchise Avoided Generic Competition}, 122 ARCH. INTERNAL MED. 724 (2012); David Balto, supra note 95, at 15.


generally presented with company-sponsored studies of the “benefits” of a new drug. There are a number of cases where a drug initially promoted as an improvement by drug companies has later been found to not be an improvement, or even harmful, when independent studies were conducted. Moreover, both doctors and patients are susceptible to substantial advertising by companies; in fact, data indicates that they spend more on marketing than on researching and developing new drugs.

3. Additional Complications

One major issue with both secondary and follow-on patents is that they are often of questionable patentability. When generic competitors challenge these patents, courts find many invalid or not infringed—studies concerning the United States and the European Union found that generic companies win nearly three-quarters of cases. However, it can be difficult and expensive to challenge these

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118. For example, antihypertensives to treat high pressure known as ACE inhibitors quickly replaced older and cheaper treatments, but were found to not only not be significantly better, but, in fact worse in some respects nearly two decades after they were introduced when the National Institutes of Health (NIH) did an independent study. Ho, supra note 1, at 502. Similarly, hormone replacement therapy was initially widely adopted to address menopause, as well as to prevent heart disease, but was later revealed to actually increase the risk of heart disease after an independent study by the NIH. Id.


120. See, e.g., Marc-Andre Gagnon & Joel Lexchin, The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States, 5 PLOS MED. 29 (2008); Rachel Kornfield et al., Promotion of Prescription Drugs to Consumers and Providers, 2001–2010, 8 PLOS MED. 1 (2013); Novartis Set To Remain Top Spender As R&D Investment Dips, EVALUATE (June 18, 2012), http://www.evaluategroup.com/Universal/View.aspx?type=Story&id=302035&sectionID=&isEPVantage=yes (noting that the industry spent $135 billion on research in 2011, which is less than 20 percent of sales). The advertising expenses are particularly large in the United States where direct to consumer advertising is permissible. E.g., Keeping Watch Over Direct-to-Consumer Ads, U.S. FOOD & DRUG ADMIN. (May 10, 2010), http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107170.htm (noting that the United States is one of the only countries worldwide to allow direct to consumer advertising); see also 21 C.F.R. § 202 (2014) (authorizing advertisements).

121. See, e.g., FED. TRADE COM‘N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION 20 (2002) (finding that generic companies win in 73 percent of challenges, with 28 percent of patents found invalid, 35 percent of the cases finding lack of infringement, and 10 percent of cases abandoned by the patent owner before a judicial finding); EC PHARMACEUTICAL REPORT, supra note 6, at 224–26 (noting that generic companies won more than 60 percent of all cases, 71 percent of challenges they initiated, and 74 percent of cases involving secondary patents); see also W. “RP” Ragupathi, Pharmaceutical Patent Validity: An Empirical Study of the Recent Decisions of the U.S. Court of Appeals for the Federal Circuit (2008–2011), 18–19 (Fordham
patents. In addition, there may be other issues that interfere with incentives to challenge these patents. For example, in the United States, Congress actually attempted to ensure that the public not be burdened by invalid patents by providing a valuable commercial bounty to the first generic competitor that showed a drug patent was invalid or not infringed; the bounty is a six-month period during which other generic competitors could not sell their products. However, patent owning companies are eliminating the incentive to challenge patents by either paying generics not to challenge their patents, or introducing their own generic version. Although the US Supreme Court recently recognized that paying generics not to challenge may be an antitrust problem, it is currently unclear whether the practice will soon abate. In the meantime, without the incentive to challenge improperly issued patents, consumers and countries may face higher than necessary costs.

122. E.g., Maurice Ross, Leveling the Playing Field—The Role of Venture Capital in Hatch-Waxman Patent Litigation, 79 PAT. TRADEMARK & COPYRIGHT J. 730 (2010); see also Ravikant Bhardwaj et al., The Impact of Patent Linkage on Marketing of Generic Drugs, 18 J. INTELL. PROP. RIGHTS 316, 318 (2013) (noting that only large generic companies can afford to challenge validity of patents and the exclusivity provided for generics may not recover the cost of litigation); EUROPEAN GENERIC MEDS. ASS’N, PATENT-RELATED BARRIERS TO MARKET ENTRY FOR GENERIC MEDICINES IN THE EUROPEAN UNION 17–22 (Kristof Roox ed., 2008) (noting challenges to generic companies in litigation).


III. A COMPARATIVE PERSPECTIVE

This Section provides a comparative perspective of two countries that have different patent laws from the United States: India and Canada. These countries are at different stages of economic development, yet both have patent laws that aim to comply with international standards, while still promoting access to affordable drugs. As noted earlier, US patent laws are not focused on ensuring access to affordable medicine and have always permitted drugs to be patentable; although there are laws passed pursuant to the Hatch-Waxman Act of 1984 that promote faster approval of generic drugs, US patent laws have never been designed to promote access to affordable medicine as a primary goal. In contrast, India and Canada have a history of promoting lower cost generic drugs and although they were recently required to modify their patent laws to comply with international agreements, they have chosen divergent methods to do so. India’s patent provision is arguably a restriction on patentable subject matter, whereas Canada’s provision is a new interpretation of the utility requirement.

A. India

India is an example of a developing country that has taken maximum use of flexibilities under TRIPS to craft patent laws that accommodate its policy preferences. However, before addressing those current laws, the historical context of India’s patent laws is helpful to place current laws in proper context.

India first took steps to address the impact of patents on drugs in the mid-1900s. Before that time, India was under British rule and its patent laws reflected the UK patent laws, which did not exclude drugs from patentability. After India seceded from the UK in 1947, it appointed a committee to examine the implications of the patent act to see if it was in the national interest. The committee found that the patent act mostly benefited foreigners and did not promote Indian scientific research. The committee also recommended “compulsory licensing” of patents on drugs to ensure that such products would be

126. The first patent act in India was in 1856 and modeled on the British Patent Law Amendment Act of 1852, which provided patents on inventions that were new and useful. Katherine Connor Linton & Nicholas Corrado, U.S. Int’l. Trade Comm’n., A “Calibrated Approach”: Pharmaceutical FIDI and the Evolution of Indian Patent Law, J. OF INT’L COMMERCE AND ECON. 1, 3 (Aug. 2007); see also, e.g., NARAYANAN, INTELLECTUAL PROPERTY LAW 4 (2005).
128. See id. at 511–12.
available to the public at the cheapest price; this would require owners of these patents to accept licenses at government determined royalties, rather than charge their desired prices—hence, the name compulsory. 129

In 1957, a committee led by Justice Ayyangar again studied Indian patent law and found that it still failed to stimulate domestic invention and that it should be designed to minimize possible abuses of the patent system. 130 One suggested improvement was to exclude drugs from patentable subject matter to prevent detriments to public health that would occur due to the inevitable expense of patents on drugs. 131 In making this recommendation, the report noted that other countries had previously taken similar steps; Germany was the first to permit patents only on methods but not drug products, and other countries including Brazil, Japan, and Norway followed suit. 132 In fact, the report noted that the United States was the only country to not restrict patent protection at all for food or medicine. 133 Following this report, India enacted The Patents Act, 1970 (the “Indian Patent Act”), which repealed patents on drugs. 134 In addition, the Indian Patent Act reduced the patent term for patents on methods of making drugs from fourteen years to five years from the patent grant. 135 Further, expansive compulsory license provisions for patented processes of making medicine were included. 136 India’s patent laws are generally attributed with helping to promote a thriving and substantial generic drug industry 137 that currently supplies a

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129. See id. at 512–13.
131. Ayyangar, supra note 130, at 23.
132. Id. at 3, 24.
133. Id.
134. In particular, the Act prohibited patents on “substances intended for use, or capable of being used as food or medicine or drug.” Although it was possible to obtain a patent on a process of making a drug, only one such method could be patented. The Patents Act, No. 39 of 1970, A.I.R. Manual 450, ch. 2 §§3 5(a)–(b) (India).
135. Id. at ch. 6 §53(a)–(b).
136. See id. at §§ 84–87.
137. Mueller, supra note 127, at 514–15 (noting dramatic increase in domestic generic drug manufacturing that also reduced the cost of drugs); Rajesh Kochhar, Indian Pharmaceutical Industry: Policies, Achievements and Challenges, 106 CURRENT SCI. 1345 (2014) (explaining India’s pharmaceutical industry “success story”). Of course, lack of patent protection on drugs alone is not enough to create a thriving generic industry. India was able to succeed because it had the technical capacity to develop such an industry, whereas some other countries that had similar laws did not. See CHAUDHURI, supra note 41, at 59 (noting that the pharmaceutical industry was underdeveloped in countries such as Iran, Iraq, Uruguay, and Vietnam because they lacked technological and entrepreneurial capacity to take advantage of the patent laws).
substantial number of drugs and drug components worldwide, especially to the developing world, such that it is considered the “pharmacy of the developing world.”

In 1994, India became a member of the WTO. As noted earlier, WTO members must comply with TRIPS, including its patent provisions. However, as a country that did not provide patents on drug products prior to the conclusion of TRIPS, India was permitted a ten-year period, until 2005, to do so. Although other countries that did not provide patents on drugs were also permitted to do so, India is the only country that took advantage of this provision.

India was in a unique position before amending its law to permit patents on drugs, as opposed to only processes for making drugs and drug compounds. Although historically, other countries had laws similar to India, not only was India the last developing country in the WTO to amend its laws (not considering least developed countries that are not yet required to do so), but India was also a major manufacturer and exporter of generic drugs to the rest of the world. This was well recognized by organizations and policy makers that aimed to ensure that India would exercise the maximum amount of flexibility under TRIPS when required to finally provide patents on drugs in 2005. For example, the World Health Organization wrote to

138. See, e.g., DEPT. OF PHARM., MINISTRY OF CHEMS. & FERTILIZERS, INDIAN PHARMACEUTICAL INDUSTRY: WORLD QUALITY MEDICINES AT REASONABLE PRICE 1, available at http://pharmaceuticals.gov.in/aboutus.pdf (noting that India ranks fourth in the world in terms of generic production and exports worldwide, including to the United States, Western Europe, and Japan); Ajoy Bera & Ashish Mukherjee, The Importance of Generic Drugs in India, 2 INT’L J. PHARM., CHEM. & BIOLOGICAL SCI. 575, 578 (2012) (noting that India ranks third in the world in terms of manufacturing drug products by volume); Vikas Bajaj & Andrew Pollack, India’s Supreme Court to Hear Dispute on Drug Patents, N.Y. TIMES (Mar. 6, 2012), http://www.nytimes.com/2012/03/07/business/global/indias-supreme-court-to-hear-long-simmering-dispute-on-drug-patents.html (noting that India is the third largest drug producer by volume and exports more generic drugs than any other country).

139. UNICEF recognizes India as the largest supplier of generics for essential medicines that it distributes to developing countries. UNICEF, 2012 SUPPLY ANNUAL REPORT: SUPPLY CHAINS FOR CHILDREN 37 (2012), available at http://www.unicef.org/supply/files/UNICEF_Supply_Annual_Report_2012_web.pdf; see also Bajaj & Pollack, supra note 138 (noting that India has been the largest provider of generic drugs to poor countries).

140. This is especially the case because India supplies over 80 percent of HIV medications. Brenda Waning et al., A Lifeline to Treatment: The Role of IndianGeneric Manufacturers in Supplying Antiretroviral Medicines to Developing Countries, 13 J. INT’L AIDS SOCY. 35 (2010); MÉDECINS SANS FRONTIÈRES, UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS 6 (2014), available at http://www.msfaccess.org/sites/default/files/MSF_UTW_17th_Edition_4_b.pdf; see also Simon Reid-Henry & Hans Lofgran, Pharmaceutical Companies Putting Health of Worlds Poor at Risk, THE GUARDIAN (July 26, 2012, 2:00 PM), http://www.theguardian.com/global-development/poverty-matters/2012/jul/26/pharmaceutical-companies-health-worlds-poor-risk (stating that the label “pharmacy of the developing world” is not surprising given the vast number of exports).

141. TRIPS, supra note 22, art. 65 § 4.
the Indian Minister of Health and Family Welfare to express concern about the future supply of generic antiretrovirals.\textsuperscript{142} Similarly, the Joint United Nations Programme on HIV/AIDS (UNAIDS) wrote to India to note concern about Indian proposals that “threaten to undermine India’s leadership” in terms of making it more difficult to provide generic drugs to other countries.\textsuperscript{143} Against this backdrop, India held hearings and ultimately amended its patent laws to comply with TRIPS while also aiming to minimize evergreening. India also amended its patent laws to include a robust system of oppositions both before and after patent issuance to help ensure patent validity.\textsuperscript{144}

1. Section 3(d)

Section 3(d) of the Indian Patent Act was introduced in 2005 to permit some incremental innovations in the pharmaceutical arena to be patented, but not innovations that do not substantially add social value with respect to improved “efficacy.” In addition, this provision bars new uses of already known substances. In particular, Section 3(d) excludes from the scope of inventions “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 or the mere discovery of any property or new use for a known substance . . . .”\textsuperscript{145} In addition, this same section includes an explanation to clarify that known substances include variations that companies have been known to patent, such as metabolites and isomers.\textsuperscript{146} All of these variations are common to the practice of evergreening that India intended to restrict as having a weak policy basis for granting without improved efficacy. Although the standard clearly tied patentability of similar substances to enhanced “efficacy,” that term is not defined in the patent act itself.

The term “efficacy” is now understood to be therapeutic or clinical efficacy, following extensive litigation by patent owner Novartis in an attempt to obtain a patent on its cancer drug Gleevec after previously patenting a similar compound in most other countries.\textsuperscript{147} The Indian Supreme Court recently held that “efficacy” in this context depends on “the function, utility or the purpose of the

\textsuperscript{142} Novartis v. Union of India, (2013), 6 S.C.C. 1, para. 76 (India).
\textsuperscript{143} Id. at 45.
\textsuperscript{144} E.g., The Patents (Amendment) Act, No. 15 of 2005, INDIA CODE (2005) § 25.1–25.2.
\textsuperscript{145} Id. § 3(d).
\textsuperscript{146} Id.
\textsuperscript{147} Novartis v. Union of India, (2013), 6 S.C.C 1, 90 (India). Novartis could not previously obtain an India patent on Gleevec when it obtained patents in the United States and other countries because India did not provide patents on drugs at the time and was not required to. Id.
product,” such that for a drug that claims to cure a disease, “efficacy can only be ‘therapeutic efficacy.’” In addition, the Court noted that this must be judged narrowly given the explanatory note to Section 3(d), such that “not all advantageous or beneficial properties are relevant, but only such properties that directly relate to . . . therapeutic efficacy.” The Court did not resolve whether increased “bioavailability,” which refers to the amount of a drug in the bloodstream, constitutes therapeutic efficacy. Novartis’ sole claim to improved efficacy was that the invention in question resulted in an improvement of 30 percent bioavailability. The Court noted that the parties disagreed on whether bioavailability alone constitutes efficacy and ultimately did not reach this issue because Novartis did not establish adequate evidence of this in the patent application itself.

B. Canada

Canada is an interesting example of an industrialized country with a historically very different approach to drug patents than that of the United States. Until Canada signed the North American Free Trade Agreement (NAFTA) with the United States, which came into force in 1994, there were two notable differences relating to drug patents. First, Canada only permitted processes of making drugs to be patented and not drugs themselves. Moreover, even for these processes, Canada required that they be subject to a “compulsory license,” which means that the patent owner would need to permit someone else to make and use the patented invention and receive only a government determined royalty that is most likely far less than what the patent owner would prefer to charge.


150. Id. at para. 189.

151. See Patent Act Amendments, S.C. 1987, c. 41 (Bill C-22) (Can). However, this was intended originally to cease effect in four years. Patent Act (1987) s. 39 (1.1) (Can).

152. E.g., Patent Act, S.C. 1923, c. 23, s. 17; see Cameron’s Patent & Trade Secrets Law, Chapter 9, Canadian Drug Patent Laws and Regulations 9.2.2(b) (noting that prior to Bill C-22, only methods of making drugs and not drugs themselves were patentable), available at http://www.jurisdiction.com/patweb09.pdf.

Canada's compulsory license law was intended to ensure that products were made available to the public at the lowest possible price while giving the inventor due reward for the research leading to the invention.\textsuperscript{154} Of course, as recent global controversies in Thailand and India indicate, patent owners generally do not consider any compulsory license to provide due reward.\textsuperscript{155} Nonetheless, this was Canada’s approach and until NAFTA, over a thousand applications for compulsory licenses were made and the majority were granted.\textsuperscript{156}

Although Canada modified its patent laws after NAFTA, it also took another step in an attempt to prevent patents on drugs from barring access to affordable medicine. In particular, Canada created the Patented Medicines Prices Review Board (PMPRB) that introduced price controls on patented medicines with the goal of ensuring affordable health care costs. The PMPRB is mandated to ensure that prices for new and existing patented medicines are not “excessive.”\textsuperscript{157}

1. Promise Doctrine

Canada has not changed its patent act since signing NAFTA, but since 2005, its courts have been applying a judicial interpretation to the utility requirement that has resulted in the invalidation of

\textsuperscript{154} Patent Act, s. 41(3) (Can).


roughly a dozen pharmaceutical patents. In particular, if a patent or patent application “promises” a certain result, such as fewer side effects, evidence of that promise, such as data establishing fewer side effects, must be disclosed or “soundly predicted” in the patent to satisfy utility pursuant to the “promise doctrine.” If there is no promise, only a scintilla of utility is required.

Although the promise doctrine has been criticized as without basis, the policy articulated by the Canadian Supreme Court is grounded in basic patent policy. In 2002, it suggested that rigorous disclosure was especially important for pharmaceutical patents to prevent a “shot-gun approach” to patent applications that would have serious costs on the public. Although Canada’s interpretation of what is “useful” is different than the interpretations of other countries, countries widely recognize that a patent should only be granted when the inventor has provided enough to justify the social contract of a patent.

The promise doctrine has been criticized not only by patent-owning pharmaceutical companies, but also by the United States on a number of grounds. Some key criticisms are that it is inconsistent with TRIPS, inconsistent with the practices of other countries, discriminates against pharmaceuticals, is ambiguous and thus leads to uncertainty and undermines patent incentives, and that it is unfair to apply the doctrine retroactively to issued patents. The next Part of this Article will explain why Canada’s law is in fact consistent with TRIPS. However, the other criticisms will be


addressed here to establish that even beyond being consistent with TRIPS, these criticisms are unwarranted.

The first contention that Canada’s promise doctrine is flawed because it is inconsistent with common practice of other countries is a red herring since there is currently no requirement for all countries to have uniform patent laws. Although countries did attempt to create uniform patentability standards through a Substantive Patent Law Treaty, that effort failed. Accordingly, it should be clear that countries can continue a long tradition of tailoring patent laws to meet their own domestic policy interests, so long as they are consistent with the minimum requirements of TRIPS. Moreover, some scholars have noted that although Canada is the only country to apply the “promise doctrine” in interpreting whether an application or patent is useful, other countries effectively have similar requirements, demonstrating that Canada’s law is actually not an outlier.

Another common complaint is that the promise doctrine is discriminatory in that pharmaceutical patents are the ones primarily invalidated. However, the doctrine is not limited to pharmaceuticals. In fact, the Canadian Manual for Patent Practice uses a non-pharmaceutical example. In addition, it has been applied to at least one mechanical invention. Moreover, there are a number of facially neutral patent requirements that impact different types of inventions differently, further underscoring that differential impact does not necessarily mean that a patent standard is invalid.


166. E.g., Burk & Lemley, supra note 1.
Although some have characterized the doctrine as being inconsistent with the research and development timeline since a patent application may be filed before clinical data is available, those concerns are overstated. First, the promise doctrine can be met without clinical data if there is a “sound prediction.” Moreover, patents invalidated on this ground are generally secondary patents that claim an improvement over an original, often broader patent. These secondary patents are filed later, often after the product is commercially successful and has already benefited from an initial patent term. Thus, Canada applies the promise doctrine to prevent additional patents for inventions that were already protected by an earlier patent and could be considered evergreening. In other countries, a patent might be denied on other grounds, such as obviousness.

The criticism of the promise doctrine as ambiguous is a stronger one, but many patentability doctrines are ambiguous. For example, courts have for years struggled to clearly articulate and apply when an invention is obvious, as well as when a pharmaceutical invention meets requirements of written description or enablement. Considering that the promise doctrine has only recently been applied and common law doctrine is meant to evolve, some ambiguity should be expected. Indeed, even in the less than ten years that Canadian courts have been applying the doctrine, there is arguably a trend towards greater clarity. For example, whereas initially courts were inconsistent in terms of where they found a promise—whether in the claims or the specification—and what they would consider to be a promise, recent decisions have more narrowly construed what constitutes a promise.167

There is arguably a separate criticism that the doctrine is flawed as unpredictable and thus leads to uncertainty for pharmaceutical companies that rely on patents. However, this criticism is a generic criticism that has been raised concerning a large number of patent law doctrines.168 In addition, even outside the area of pharmaceuticals, there are other patent issues that are unpredictable, such as claim construction. Further, there is inherently some level of unpredictability with patents that are


168. See generally Holman, supra note 14.
presumed valid when issued, but always subject to invalidation. Although some have noted that the doctrine is unpredictable because different courts may come to different conclusions concerning the same patent, that is no different than other patent doctrines.

The utility doctrine is obviously a patent requirement distinct from patentable subject matter, which was the primary focus of this symposium. However, Canada’s approach is nonetheless an important example of a different approach that a nation can take to comply with international obligations under TRIPS to address the same phenomena of secondary patents that India addressed more directly by excluding certain compounds from patentability. The first Canadian Supreme Court case to apply this doctrine did so in the context of an invention on a new use of a known compound—the use of AZT to treat HIV/AIDS.169 In other words, this is a situation that might have been barred by India’s Section 3(d) statute, which prohibits not only new variations without increased efficacy, but new uses.

IV. WHAT APPROACH(ES) ARE BOTH PERMISSIBLE AND DESIRABLE

This Part evaluates whether the approaches of India and Canada noted in Part III are permissible under international law, as well as whether they should be followed by other countries. This is important not only because India and Canada have been criticized for failing to comply with international law, but also because other countries have either copied these laws, or are contemplating doing so. This Part begins with an explanation of the fundamental patentability requirements for most countries, pursuant to TRIPS. It then explains why India and Canada’s laws are both permissible under TRIPS. This Part concludes by noting that although India and Canada can be commended for attempting to address recognized problems with pharmaceutical patents, there are still practical problems with their approaches that suggest other countries should not adopt them wholesale. Other approaches for countries desirous of balancing patent rights and public health are outlined as an alternative to consider.

A. TRIPS

This Section explains the requirements of TRIPS—the most important international agreement to consider in assessing what approaches are permissible because it provides the first ever

international requirements on substantive standards of patent protection and does so for the majority of countries.\textsuperscript{170} Although TRIPS is a landmark agreement, it only requires “minimum,” but not uniform, standards.\textsuperscript{171} To best understand what TRIPS requires, this Section will first explain how TRIPS should be appropriately interpreted using rules that apply to all international agreements.

1. Interpretive Framework for TRIPS

To properly assess what TRIPS requires, as well as whether countries are complying with those requirements, it is important to use the appropriate interpretive framework. According to Article 64 of TRIPS, it is to be interpreted pursuant to WTO rules; the rules governing interpretation of the WTO are elaborated in the Understanding on Rules and Procedures Governing the Settlement of Disputes, which specifies that “customary rules of interpretation of public international law” apply.\textsuperscript{172} The customary rules of interpretation are understood to refer to the principles expressed under the Vienna Convention on the Law of Treaties, which states that a treaty shall be interpreted in good faith, with “ordinary meaning” to be given to the text of a treaty.\textsuperscript{173} In other words, the final text, rather than what individual parties desired but did not succeed in getting in the final text, is important. Secondary material, such as negotiating history, is only considered to confirm an interpretation achieved by the traditional method of interpretation, or if the usual interpretation leads to an interpretation that is ambiguous or reaches an absurd result.\textsuperscript{174} Importantly, this approach to secondary materials is different than the approach taken by predecessor panels to the WTO that interpreted the General Agreement on Trade and Tariffs (GATT).\textsuperscript{175} In addition, even when negotiating history is considered, it is based on actual documents and

\textsuperscript{170} Members and Observers, WORLD TRADE ORG. (Mar. 2, 2013), http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm. There are subsequent agreements that establish higher standards, referred to as “TRIPS-plus” agreements. \textit{E.g.}, HO, ACCESS TO MEDICINE, supra note 43, at 225–28. To the extent that these agreements bar suggestions requiring more than TRIPS, some of the noted suggestions may be impermissible.

\textsuperscript{171} TRIPS, supra note 22, art. 1.1; HO, ACCESS TO MEDICINE, supra note 43, at 57.

\textsuperscript{172} TRIPS, supra note 22, art. 64; Understanding on Rules and Procedures Governing the Settlement of Disputes art. 3.2, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401 [hereinafter DSU].


\textsuperscript{174} \textit{Id.}, art. 32.

\textsuperscript{175} \textit{E.g.}, HIROKO YAMANE, INTERPRETING TRIPS: GLOBALISATION OF INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO MEDICINES 191 (2011).
cannot be based on the intent of one party. Along similar lines, if language was proposed but not adopted, that should be interpreted as meaning that it was rejected.

The Vienna Convention states that the ordinary meaning of treaty terms should be viewed in appropriate “context,” as well as in light of the object and purpose of the agreement. Accordinly, a fundamental issue to understanding what any specific TRIPS article requires involves identifying and understanding the appropriate context, as well as the object and purpose of the agreement. There are three parts of TRIPS that provide appropriate context—the preamble, and Articles 7 and 8. The Vienna Convention expressly considers the treaty preamble to be part of the context. In addition, Articles 7 and 8 provide the object and purpose of TRIPS; indeed, they are entitled “objectives” and “principles.”

The preamble, as well as Articles 7 and 8, all point to a need to consider patents not only from the perspective of the rights holder, but also with respect to other social interests. The preamble of TRIPS recognizes not just a need for standards concerning intellectual property rights, such as patents, but also that there are domestic public policy objectives. Similarly, Article 7 states that intellectual property rights “should contribute to the promotion of technological innovation . . . to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare . . . .” Article 7 thus seems to expressly note that patent standards are not intended to solely benefit patent owners, but should benefit society as a whole. Moreover, Article 8 expressly notes public health as an important issue. In particular, Article 8 states that members may “adopt measures necessary to protect public health,” so long as those measures are consistent with TRIPS. Accordingly, the preamble, as well as Articles 7 and 8, all underscore that patent standards are not intended to solely benefit patent owners, but should benefit society as a whole; in addition, Article 8

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176. Vienna Convention, supra note 173, art. 31.1.
177. TRIPS, supra note 22, pmbl. (“Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives . . . .”).
178. Id. art. 7.
180. TRIPS, supra note 22, art. 8.
specifically emphasizes public health as a social issue to be considered.\footnote{181}{UNCTAD-ICTSD, supra note 179.}

Another pertinent context to examining any provision of TRIPS is Article 1 of the agreement. This Article lays out the “minimum standards” approach of TRIPS. It specifies that although nations may provide more protection than required, they are free to decide how to implement TRIPS.\footnote{182}{TRIPS, supra note 22.} In other words, TRIPS contemplates diversity among member state laws, rather than uniform laws.\footnote{183}{Although members have flexibility, they should still expect that if their laws are challenged, a WTO panel will evaluate whether the national laws in fact meet the standards and will not give complete deference. \textit{E.g.}, Appellate Body Report, \textit{India—Patent Protection for Pharmaceutical and Agricultural Chemical Products}, ¶¶ 64–66, WT/DS50/AB/R (Dec. 19, 1997); see also UNCTAD-ICTSD, supra note 179, at 28.}

In addition to the context in TRIPS, the Vienna Convention states that proper interpretation also includes consideration of any subsequent agreement between the parties regarding the interpretation of the treaty.\footnote{184}{Vienna Convention, supra note 173, art. 31(3)(a).} This is important because there is a 2001 Doha Public Health Declaration that addresses the topic of drug patents.\footnote{185}{Doha Public Health Declaration, supra note 179.} Although a few argue that this Declaration is a mere political statement of no interpretive weight,\footnote{186}{See U.S. Gov’t Accountability Office, GAO-07-1198, \textit{Intellectual Property—U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification} 3 (2007) (noting that the United States considers the Doha Declaration to be a political statement that does not modify TRIPS); \textit{PhRMA: WTO Doha Declaration Reaffirms Value of Intellectual Property Protection}, PR NEWswire (Nov. 14, 2001), http://www.prnewswire.com/news-releases/phrma-wto-doha-declaration-reaffirms-value-of-intellectual-property-protection-74263327.html (stressing that the Declaration was a “political statement”); Press Release, Office of the U.S. Trade Rep., \textit{USTR Zoellick Says World Has Chosen Path of Hope, Openness, Development and Growth} (Nov. 14, 2001), available at http://www.ustr.gov/archive/Document_Library/Press_Releases/2001/November/USTR_Zoellick_Says_World_Has_Chosen_Path_of_Hope_Openness_Development_Growth.html (referring to USTR remarks on Doha Public Health Declaration as a “political signal”).} scholars generally consider the Declaration to be a subsequent agreement.\footnote{187}{See, \textit{e.g.}, Carlos Correa, World Health Org. [WHO], \textit{Implications of the Doha Declaration on TRIPS Agreement and Public Health}, at 2 (June 2002), available at http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf; Denis Borges Barbosa, \textit{Slouching Towards Development in International Intellectual Property}, 2007 Mich. St. L. Rev. 71, 1131–32 (2007) (viewing the Doha Public Health Declaration as not only a subsequent agreement, but one that establishes the right to health as an important right not to be trumped by provisions of TRIPS in a call for a broader interpretation of evolving international norms); Steve Charnovitz, \textit{The Legal Status of the Doha Declarations}, 5 J. Int’l Econ. L. 207, 211 (2002) (evaluating both the Public Health Declaration and the Ministerial Declaration and concluding that while their legal category is ambiguous, they could be considered subsequent agreements by the parties); Susy Frankel, \textit{WTO Application of “The Customary Rules of Interpretation of Public International Law” to Intellectual Property}, 46 Va. J. Int’l L. 365, 400–01 (2006) (using the Doha Health Declaration as an example of a subsequent agreement between the parties, although also...}
The Doha Declaration provides interpretive guidance on specific provisions of TRIPS, as well as insight into the importance of public health in interpreting TRIPS. In particular, the Declaration states, “We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health,” and affirms that TRIPS “can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.”

This statement could be construed as further elaborating on the Article 8 principle concerning the relevance of public health. In addition, the Declaration goes beyond Article 8 in adding more detail concerning public health issues with respect to patents on drugs. In particular, it states, “We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.”

Importantly, this quote not only underscores that patent protection is considered important to incentivize the development of new medicine, but that patent protection may increase costs of drugs.

The Declaration further confirms that in applying customary rules of interpretation of international law, which as noted earlier is what the Vienna Convention applies to, “each provision of the TRIPS Agreement shall be read in light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.”

In other words, the Doha Declaration expressly confirms the analysis above that TRIPS Articles 7 and 8, that are titled “objectives” and “principles,” guide how each provision of TRIPS, including the patentability provisions, should be interpreted. This is also consistent with an earlier WTO panel ruling that stated that these provisions were relevant.
There is, of course, an important question of how broadly to interpret the Doha Declaration provision that TRIPS requirements should be read in a way not only promote public health generally, but also to promote access to medicines for all. One way to ensure low-cost drugs is to bar patents on any drugs, since patents permit their owner to charge a premium. However, that would completely nullify the fundamental requirement of TRIPS that nations must grant patents on “inventions” without discrimination as to “subject matter,” because there must be some drugs that would be inventions and barring all of them would clearly discriminate based on subject matter. Thus, barring all drugs is not a possible interpretation. At the other end of the interpretive spectrum, some might suggest that all aspects of the Declaration should be limited to the situation noted in the first paragraph of the Declaration, which refers to public health problems of developing countries and especially those resulting from epidemics. However, if that were true, it would negate TRIPS Articles 7 and 8, which recognize the need to balance patent rights against other public policy objectives. The most appropriate interpretation seems to be that the Declaration recognizes that public policy, expressly noted in TRIPS, includes the impact of patents on the cost of drugs and further supports the idea that nations should be given some leeway in their interpretation of TRIPS.

The fact that the Doha Declaration focuses expressly on pharmaceuticals and their impact on drug prices also lends further support to the fact that nations may be permitted to differentiate without violating the discrimination requirement. In particular, the very existence of the Declaration, in addition to the earlier WTO panel decision that first articulated the differentiation concept, suggests that members recognize that the area of pharmaceutical patents and their impact on public health is an issue deserving of special attention. In addition, member states do have laws that differentiate based on pharmaceuticals that have never been challenged. For example, a number of nations provide additional patent terms on drugs to compensate for the period of patent protection that is essentially

194. Id. ¶ 1.
195. Although there are aspects of these articles that talk about development, they are not limited solely to developing countries in the process of development. In particular, Article 8 notes that member states can adopt TRIPS-consistent laws to promote public health without qualification of development status, and it separately states that members may adopt measures to promote public interest in sectors of “vital socioeconomic and development.” TRIPS, supra note 22, art. 8. Moreover, TRIPS Article 7 refers to the need to balance the interests of producers and users of technology “in a manner conducive to social and economic welfare,” without any reference that this should apply only to countries of a particular development status. Id. art. 7.
ineffective while the patented drug is under regulatory review. In addition, different standards of patentability for drugs, as well as slightly different compulsory license rules for drugs, exist without formal WTO challenge, even if sometimes criticized.

2. TRIPS Requirements

The crux of patent requirements at issue appear in TRIPS Article 27, which states, “[P]atents 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... [P]atents shall be available... without discrimination as to... the field of technology.” This provision does two things. First, it establishes criteria for patentability that are basically the standards that have been used in industrialized countries, such as the United States, Japan, and EU member states.

Second, TRIPS does not define critical requirements, such as what constitutes a “new” invention, or even the more fundamental question of what constitutes an “invention.” As previously noted, TRIPS is intended to provide minimum, but not uniform standards. The lack of definition of terms such as what is a “new” invention, accordingly, gives nations flexibility to define these terms on their own when there is no international consensus. This is supported by

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196. See supra note 74 (indicating patent term extensions in the United States, Australia, South Korea and Japan to account for time lost to regulatory approval).
197. India has a different law on patentability of drugs. The Patents Act, No. 39 of 1970, A.I.R. MANUAL 450, §3(d) (India). In addition, French patent law has a different compulsory license provision on pharmaceutical products. Loi 92-597 du 1992, CODE DE LA PROPRIÉTÉ INTELLECTUELLE, July 1, 1992, arts. 613–16 (Fr.).
198. TRIPS, supra note 22, art. 27. There are some types of subject matter explicitly excluded as methods of treatment: plants and animals and essentially biological processes, as well as inventions. Id. art. 27(3). In addition, there is a broader exception to permit exclusion from patentability of inventions when their commercial exploitation would interfere with ordre public or morality. Id. art. 27(2).
199. Although these terms are not identical to US patentability standards, a footnote to TRIPS clarifies that the terms “inventive step” and “industrial application” are intended to be synonymous with the US terms “nonobvious” and “useful.” See TRIPS, supra note 22, at art. 27 n.5.
pharmaceutical guidelines issued by the World Health Organization in conjunction with a UN body that deals with development issues; the guidelines recommend taking advantage of this flexibility to consider certain subject matter not inventive, such as new forms of existing pharmaceutical products.\textsuperscript{201} History also supports this approach. Historically, some states have not patented new forms or properties of known inventions, such that it is reasonable for states to continue to do so under TRIPS, or only do so under qualified conditions, such as enhanced efficacy.\textsuperscript{202} This is particularly true because the WTO dispute settlement process to address alleged violations of WTO agreements, including TRIPS, prohibits panels from creating new law, such that they cannot resolve deliberate textual ambiguities that are designed to reflect the compromises and balances reached by negotiating parties.\textsuperscript{203}

There is a fundamental question of what constitutes an “invention” because only inventions must be subject to the stated criteria. Some might suggest that any subject matter that meets the other patentability criteria of being new and nonobvious would suffice. However, if that were true, the word “invention” would not be necessary, such that the inclusion of the term “invention” must have some separate meaning under standard tools of treaty interpretation. This would also be consistent with prior national practice before TRIPS, pursuant to which nations had different standards of what constituted patentable subject matter. For example, there were differences in whether genes and computer software were considered patentable. Similarly, some, but not all, countries permitted patents on methods of use of known products.

Countries cannot bar an entire category of inventions, such as drug products, because that would discriminate based on a field of technology.\textsuperscript{204} However, since the conclusion of TRIPS, there is a dispute over what constitutes discrimination concerning a field of

\textsuperscript{201} Correa, Guidelines, supra note 200, at 3–4, 6–7, 9–11 (suggesting exclusion of similar compounds, including different formulations of the same active ingredient, or slight modifications of the active ingredient, such as salts and polymorphs).

\textsuperscript{202} Id. at 6–7.

\textsuperscript{203} DSU, supra note 172, art. 3(2) (can not “add to or diminish” covered agreements); WORLD TRADE ORGANIZATION, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 355 (1999) (prohibiting adding rights and obligations); see also Report of the Panel, supra note 192, ¶ 7.26 (warning against interpretations that “would be equivalent to a renegotiation of the basic balance of the Agreement”); Correa, supra note 200, at 273.

\textsuperscript{204} TRIPS, supra note 22, art. 27; see also Ho, ACCESS TO MEDICINE, supra note 43, at 63.
technology besides the outright denial of patents on an entire class of inventions. One WTO panel report made an important distinction between “improper discrimination” versus “legitimate differentiation”; the panel stated that TRIPS “does not prohibit bona fide exceptions to deal with problems that exist only in certain product areas.” The panel did not provide a general rule regarding what would be a bona fide purpose and its finding is technically not binding on other panels. Nonetheless, WTO panels generally consider prior decisions to be persuasive authority and noted intellectual property scholars have praised the distinction between discrimination and differentiation.

B. Is India’s Section 3(d) Law Consistent with TRIPS?

A key question is whether India’s Section 3(d) provision is consistent with TRIPS. Although a number of commentators, including the powerful lobbying group for companies that sell patented drugs, Pharmaceutical Research and Manufacturers of America (PhRMA), have suggested that this provision violates TRIPS, it is notable that no country has thus far formally challenged India since the provision was adopted in 2005. Nonetheless, it may be useful to consider criticisms of this provision and whether such criticisms are appropriate in light of a proper interpretation of TRIPS.

PhRMA claims that India’s Section 3(d) law violates TRIPS for two different reasons. First, PhRMA asserts that India has added “a fourth substantive criteria of ‘enhanced efficacy.’” PhRMA also claims that because Section 3(d) only applies to pharmaceuticals, it violates the nondiscrimination principle in TRIPS Article 27.

Similarly, Roy Waldron, Chief IP Counsel of Pfizer, testified before Congress in 2013 that India has “systematically failed to interpret and apply its intellectual property laws in a manner consistent with global standards.”

205. Report of the Panel, supra note 192, ¶¶ 7.92, 7.94.
208. PhRMA 2014 SUBMISSION, supra note 1, at 26; PhRMA 2015 SUBMISSION, supra note 207, at 49.
Contrary to PhRMA’s contentions, there are several possible reasons why the Section 3(d) law may be permissible under TRIPS Article 27. First, Section 3(d) could be considered to help clarify what is not an eligible “invention” under TRIPS, rather than a fourth requirement. Second, Section 3(d) could be considered to simply provide a new interpretation of “novelty” or “inventive step.” In addition, as will be explained, in neither of these situations is India’s action inconsistent with the nondiscrimination principle, since India is legitimately differentiating, rather than discriminating.

India’s Section 3(d) law can be considered a permissible limitation on what is an “invention” under TRIPS. As noted earlier, although TRIPS requires that an “invention” be patented, it does not define what constitutes an “invention,” thus giving member states discretion to define this themselves. Moreover, India’s Section 3(d) provision is actually Part (d) of Section 3 of the Indian Patent Act; Section 3 of the Indian Patent Act is entitled, “What are not inventions.” The fifteen items listed in Section 3 include things that are traditionally considered not patentable inventions in many countries, such as discovery of scientific principles and methods of medical treatment; thus Section 3(d) seems to be an interpretation of what is not a patentable invention.211

India’s Section 3(d) provision can alternatively be considered TRIPS consistent as a permissible interpretation of the “novelty” or “inventive step” requirements of TRIPS that are similarly undefined. In particular, Section 3(d) could be interpreted as providing a new definition of what pharmaceutical inventions would be considered new or as having an inventive step. For example, Section 3(d)’s bar of a new use for a known compound from the scope of patentable inventions could be considered an interpretation of the novelty requirement. Similarly, the requirement under Section 3(d) that similar compounds are not patentable unless they show improved efficacy could be interpreted as a new type of inventive step standard, in that what is similar to existing pharmaceutical inventions is considered not inventive unless it shows improved efficacy. Indeed, Indian courts have made this suggestion. For example, the Intellectual Property Appellate Board stated that this provision “is nothing but a requirement of higher standard of inventive step” in an

211. See The Patents Act, No. 39 of 1970, A.I.R. Manual 450, § 3 (India). In addition, some other exceptions may not be common to US patent law, but are common to other countries, such as bars to inventions on methods of treatment, as well as inventions contrary to morality. Compare id. § 3(b) (contrary to morality), with Convention on the Grant of European Patents art. 53(a), Oct. 5, 1973, 13 I.L.M. 268 (1974) (contrary to morality), and id. § 3(d) (methods of treatment), with Convention on the Grant of European Patents art. 53(c) (methods of treatment).
opinion that focused on the application of Section 3(d) to Novartis’s rejected patent application on cancer drug Gleevec.\footnote{Novartis v. Union of India, (2013) 6 S.C.C 1, ¶ 17 (India) (citing Appellee Board decision).}

India’s Section 3(d) provision is also consistent with the TRIPS requirement of nondiscrimination in granting of patents, although the analysis is more complex. It is true that Section 3(d) only refers to pharmaceuticals since the example lists compounds that only exist in the pharmaceutical industry. However, as noted earlier, countries are permitted to have rules that differentiate between different subject matter for problems that are unique to a particular field. Understanding why India’s Section 3(d) provision should be considered permissible requires an evaluation of the previously noted WTO panel decision that distinguished permissible differentiation versus impermissible discrimination, as well as the Doha Public Health Declaration.

The prior WTO panel found that a Canadian law that provided an exception from patent infringement for generic companies to make limited amounts of a patented drug during a patent term was appropriately “limited,” and thus consistent with a TRIPS provision permitting limited exceptions to usual patent rights.\footnote{Report of the Panel, supra note 192, ¶ 7.99.} Importantly, the panel noted that although the exception from patent infringement only applied to drug companies, the TRIPS requirement barring discrimination against a field of technology “does not prohibit bona fide exceptions to deal with problems that exist only in certain product areas.”\footnote{Id. ¶ 7.92.} In particular, because patented drugs are one of the few patented products to need regulatory approval to be sold, if a generic version of the patented drug had to wait until after patent expiry to start the regulatory approval process, the owner of the patented version would actually get an undue extension of their patent term. Given the unique problem of this industry, the fact that the exception only seemed to apply to pharmaceuticals was considered appropriate differentiation, rather than discrimination. Similarly, India’s Section 3(d) provision is addressing the evergreening phenomena that only seems to occur in the pharmaceutical arena.\footnote{See The Patents Act, No. 39 of 1970, A.I.R. MANUAL 450, § 3(d) (India). On the other hand, the prior WTO case is somewhat different in that the Canadian law at issue was neutral on its face in discussing use of a patented product for development and submission of information for any law that regulates sale of a product, such that it did not explicitly apply only to pharmaceuticals. Report of the Panel, supra note 192, ¶¶ 7.95–7.96. However, the Indian law could still be considered neutral on its face in that it talks about “known substances” without specifying the field of pharmaceuticals. However, the “explanation” in the law does talk about substances that would seem to primarily appear in the pharmaceutical arena such as salts and}
In addition, it is important to note that the prior WTO panel decision preceded the Doha Public Health Declaration that now establishes the importance of considering public health implications in interpreting TRIPS patent provisions. As noted earlier, the Declaration states that the Agreement “can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.”

This statement indicates an understanding among WTO members that public health and access to affordable medicine are of concern in interpreting TRIPS. Moreover, the fact that the Declaration also explicitly recognizes the impact of patent protection on drug prices and the need to interpret all TRIPS provisions to consider public health, suggests that application of even the nondiscrimination clause be applied in a way that supports public health.

In other words, although it would be impermissible to bar patents on all drugs, the more narrowly tailored provision of Section 3(d) that aims to address a unique problem in pharmaceuticals, seems to be appropriate differentiation, and not discrimination. A number of other scholars support this interpretation.

C. Is Canada’s Promise Doctrine Permissible Under International Law?

Evaluating whether Canada’s unique promise doctrine is permissible under international law requires an evaluation of not only TRIPS, but also NAFTA. Whereas most countries are members of TRIPS, only the United States, Canada, and Mexico are members of NAFTA; however, the United States negotiated both agreements at roughly the same time, and sought similar provisions in each.

esters. Nonetheless, it may be helpful that the prior panel held that, even though a law that “in effect” only applied to pharmaceuticals, it does not indicate a discriminatory purpose. Id.


217. See id. ¶ 3 (“We recognize the concerns about [intellectual property’s] effects on prices”); id. ¶ 5(a) (noting each TRIPS provision should be read in light of its “objectives and principles”); see also TRIPS, supra note 22, art. 8 (titled “Principles”).

218. E.g., DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 358 (3d ed. 2008) (noting that because Doha focuses on pharmaceutical products, this further supports a WTO panel decision that bona fide differentiation is not discrimination); Amy Kapczynski, Harmonization and its Discontents: A Case Study of TRIPS Implementation in India’s Pharmaceutical Sector, 97 CALIF. L. REV. 1571, 1598 (2009) (“[E]xceptions to patentability adopted in order to protect public health might not be deemed to discriminate by field of technology, even if they have applications only to particular fields.”); Doha Public Health Declaration, supra note 39, ¶ 5.

One allegation is that Canada’s promise doctrine is inconsistent with the utility requirement under TRIPS as well as NAFTA. PhRMA has stated that the “heightened standard” of utility violates TRIPS because it “imposes onerous and unjustified patentability criteria,” narrowing the scope of inventions that receive patent protection.\(^{220}\) PhRMA alleges that “all [other] developed countries require only that an invention be ‘useful’ or ‘capable of industrial application,’” while ignoring the fact that proper interpretation of TRIPS permits Canada to define what is useful when this is not defined by TRIPS. Similarly, Eli Lilly, a multinational pharmaceutical company that is part of PhRMA, claims separately that Canada’s interpretation of the utility requirement “contradicts the standard” accepted by NAFTA parties.\(^{221}\)

The claims that Canada’s promise doctrine is impermissible under the utility requirement of TRIPS and NAFTA are without basis. Although these are separate agreements, they have the same requirement on utility—it is stated as a requirement for patents, but not defined.\(^{222}\) As noted earlier, undefined terms in minimum standard agreements such as TRIPS and NAFTA explicitly contemplate that countries may adopt different standards, including providing their own unique definitions of the undefined standards.\(^{223}\) Eli Lilly’s claim that Canada’s interpretation “contradicts” what was previously accepted by the parties is completely inconsistent with proper interpretation of international agreements, which focuses on the text of the agreement and not unsubstantiated claims of what the countries accepted. It is true that Canada previously had a different view of the utility requirement. However, no conventional tool of treaty interpretation requires that member states’ laws be read into the treaty provisions as part of the text.

Canada’s law is also accused of violating the TRIPS nondiscrimination requirement. PhRMA has alleged that the law “discriminates against innovative pharmaceutical companies.”\(^{224}\) Eli

\(^{220}\) PhRMA 2014 SUBMISSION, supra note 1, at 76; PhRMA 2015 SUBMISSION, supra note 207, at 81 (claiming heightened standard inconsistent with TRIPS).

\(^{221}\) Eli Lilly Notice of Arbitration, supra note 161; see also Eli Lilly & Co. v. Canada, Notice of Intent to Submit a Claim to Arbitration under NAFTA Chapter 11 (Nov. 7, 2012), available at http://www.italaw.com/sites/default/files/case-documents/italaw1172.pdf (seeking $100 million in damages after its patent on a drug to treat attention deficit disorder sold as Strattera).


\(^{223}\) See supra text accompanying notes 200–02.

\(^{224}\) PhRMA 2014 SUBMISSION, supra note 1, at 76.
Lilly has also made this claim. However, this claim is equally inappropriate with Canada’s patent laws as with India’s laws. So long as the domestic law is intended to deal with the evergreening phenomena that only happens in this industry, there is no improper discrimination, and rather, is solely an issue of appropriate differentiation.

**D. Evaluating Underlying Policies and Alternative Approaches**

Whereas the prior sections addressed what is permissible under TRIPS, this Section addresses what would be desirable as a matter of domestic policy, since patents are fundamentally tools to promote domestic policy. In particular, this Section notes that although the Indian and Canadian provisions are important to consider as first attempts at better tailoring patent law to promote desired innovation and better access to low-cost drugs, further experimentation with either variations of these provisions, or entirely different approaches altogether, is recommended.

A major issue with both patent provisions is that it may be difficult for companies to meet these standards given the practicalities of drug discovery, as well as patent law fundamentals. In particular, both laws—depending on interpretation—may require applicants to provide clinical data concerning a drug that does not yet exist. This is because patent applications are filed as soon as a chemical compound is discovered in a lab that seems like it may be promising for some type of drug, but long before any animal or even human tests are conducted to see if the compound in fact could be effective and safe as a drug. To obtain a patent, an application must be filed promptly to meet the fundamental requirement that it is “new,” such that waiting for clinical test results is not possible. Accordingly, pharmaceutical companies may have a basis for complaining that these standards may place them in a catch-22 situation.

Consequently, although some countries are eager to address evergreening and copy India’s Section 3(d) provision, that may not be the best approach. Although the fundamental tension between

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meeting the “new” requirement of patentability and not having relevant clinical data could potentially be mediated with modification of these laws or how they are applied,228 further consideration and experimentation with different approaches to address evergreening would be a better idea.229 This is especially true since the India and Canadian laws may have been adopted under less than ideal circumstances. India’s provision was crafted quickly to comply with a TRIPS deadline after an initial proposal was deemed to be likely not in compliance with TRIPS.230 Canada’s promise doctrine is even less likely to be well tailored to evergreening. Unlike India’s provision, Canada’s doctrine was not considered by a legislature; rather, it was simply announced by a court and subsequently followed by other courts.

There are also other avenues to address evergreening. For example, a more stringent nonobviousness standard could address evergreening. However, for countries like India that have understaffed patent offices and a substantial number of pharmaceutical patent applications, a bright-line exclusion from India’s patent law, but the law of Argentina that excludes similar compounds even if they have improved efficacy); PEDRO PARANAGUA ET AL., CTR. FOR STRATEGIC STUD. & DEBATES, BRAZIL’S PATENT REFORM: INNOVATION TOWARDS NATIONAL COMPETITIVENESS 114 (2013), available at http://infojustice.org/wp-content/uploads/2013/09/Brazilian_Patent_Reform.pdf (noting that Chile, Argentina, Uruguay, Paraguay, and Brazil have signed an agreement that acknowledges concerns about “proliferation of patent application on matters that do not properly constitute an invention” with “negative effects to access to medicines”); Divya Rajagopal, EU, Australia, Canada May Follow India’s Patent Law, ECON. TIMES (Apr. 4, 2013, 4:00 AM), http://articles.economictimes.indiatimes.com/2013-04-04/news/38278712_1_patent-act-patent-protection-patent-quality; Gireesh Chandra Prasad, Copycats Popping Patent Law Pill, ECON. TIMES (Aug. 13, 2007, 4:03 AM), http://articles.economictimes.indiatimes.com/2007-08-13/news/27677651_1_patent-law-section-3d-dg-shah (reporting that Maldives, Pakistan, Sri Lanka, Vietnam, Indonesia, Malaysia, and Bangladesh are reported to consider adopting provisions similar to India’s Section 3(d) proposal).

228. Canadian courts, for example, have recently taken a more narrow approach to applying the promise doctrine, which has resulted in drug patents being found valid. E.g., Teva Can. v. Novartis, [2013] F.C. 141, ¶¶ 164–65 (Can.) (finding a patent covering the cancer drug sold as Gleevec by Novartis to be consistent with the promise doctrine even without test data and noting that this doctrine is not intended to “give a crushing hammer to those who challenge patents”); Sanofi-Aventis v. Apotex Inc., [2013] F.C. 186 (Can.) (reversing trial court decision that had found Sanofi’s patent on the active ingredient of blockbuster drug sold as Plavix to fail the promise doctrine because the trial court improperly inferred a promise and holding that this doctrine is inapplicable unless the patent makes an explicit promise of a specific result).


230. E.g., Novartis v. Union of India, (2013) 6 S.C.C. 1, ¶ 76 (India). In addition, India’s provision is actually in part copied from an EU regulatory provision concerning when a proposed generic can rely on earlier clinical data, such that it may not be appropriately tailored to patentability standards. See Council Directive 2004/27/EC, art. 10(2)(b). 2004 J.O. (L 136) 36 (EC).
patentability could be considered more efficient and thus desirable.\(^{231}\)

Alternatively, a more robust examination of patentability can be easily enhanced without changing any patentability standards. For example, permitting third parties to challenge patents, and even patent applications, would help; indeed, India permits both types of challenges. Countries could also improve the validity of patents through additional governmental help outside the patent office; the regulatory agency that approves drugs for sale could do its own analysis of patentability in addition to the patent office.\(^{232}\)

Of course, there are those that would resist any of these approaches because of concern that they unduly hinder innovation by either reducing the patent term or entirely barring patentability of drugs. For example, the United States has criticized other countries that permit third parties to challenge patent applications as creating unnecessary delay in issuance of patents, and thus limiting patent terms that are generally calculated as a function of when the patent application was filed.\(^{233}\) In addition, the pharmaceutical industry would likely object to any changes to the patent system that would restrict what is patentable given the fact that they have sought more protection. Moreover, there are many who believe that the problem is not that the pharmaceutical industry is patenting too much, but rather, that it needs more protection. This Article alone is unlikely to sway any of those adherents, but hopefully it has at least highlighted that this view is not the only possible one.

V. CONCLUSION

Hopefully this Article has helped raise awareness not only about current problems with drug patents, but has also illustrated the existence of different approaches that are permissible under TRIPS. Given the long US history of granting patents on drugs as well as a recent history of favoring rights of patent owners over consumer access, the United States is unlikely to modify its laws to address the problems recognized by other countries. However, it would still be


\(^{232}\) This is in fact the approach of Brazil. CÓDIGO DE PROPRIEDADE INDUSTRIAL [C.P.I.] art. 229(C) (Braz.) (requiring consent of Brazilian regulatory authority to granting of drug patents); see also PARANAGUÁ ET AL., supra note 227 (recommending that the Brazilian regulatory authorities responsible for approving drugs for sale, ANVISA, continue to help ensure valid patents, with some small modifications for improvement); Tahir Amin et al., Expert Review of Drug Patent Applications: Improving Health in the Developing World, 28 HEALTH AFF. 948, 954 (2009) (noting Brazil requires a review by government public health experts before a patent is granted).

\(^{233}\) 2014 SPECIAL 301 REP., supra note 161, at 40.
beneficial to recognize that there is a problem and to avoid exacerbating it. In particular, it is most desirable to resist the entreaties to increase protection for drugs. In addition, recognizing that there is a problem could result in less US pressure on other countries to modify laws that are in fact permissible and can be justified as proper policy for those countries.