

The Success of, and Response to, India's Law against Patent Layering

Rajarshi Banerjee. J.D. Candidate, Harvard Law School, 2014

I.	INTRODUCTION	2
II.	THE DEBATE OVER PATENT LAYERING	5
A.	<i>An Introduction to Patent Layering</i>	5
B.	<i>Arguments for and against Patent Layering</i>	6
III.	THE GLOBAL PATENT PROTECTION LANDSCAPE	9
A.	<i>The Emergence of TRIPS</i>	9
B.	<i>Patent Protection under the International Investment Regime</i>	12
C.	<i>Patent Protection under Other Agreements that Implicate Intellectual Property</i>	15
D.	<i>Most-Favored-Nation Provisions in TRIPS and International Investment Agreements (IIAs)</i>	16
IV.	THE CHALLENGE OF LIMITING PATENT LAYERING AMIDST THE GLOBAL PATENT PROTECTION LANDSCAPE	16
V.	THE SUCCESS OF INDIA'S LAW AGAINST PATENT LAYERING	17
A.	<i>An Introduction to India's Law against Patent Layering</i>	18
B.	<i>How India's Law Interacts with the Global Patent Protection Landscape</i>	21
1.	Section 3(d) is TRIPS-compatible	21
2.	Section 3(d) does not conflict with protections available under most IIAs	23
VI.	THE GLOBAL RESPONSE TO INDIA'S LAW AGAINST PATENT LAYERING	26
A.	<i>Post-Section 3(d) Anti-Layering Laws in Other Countries</i>	27
1.	The Philippines	27
2.	Argentina	28
B.	<i>Pro-Patent Evergreening Provisions in Post-Section 3(d) Preferential Trade Agreements</i>	29
C.	<i>The Pro-Patent Layering Provision in a Draft of the Trans-Pacific Partnership Agreement</i>	31
VII.	CONCLUSION	33

I. INTRODUCTION

A unique drug patentability standard that began as a last-minute addition to an Indian legislation is slowly spreading through the developing world, drawing plaudits from global health advocates and generic drug companies and stiff challenges from pharmaceutical innovators and their home countries. India's patentability standard severely restricts the practice of patent layering by drug manufacturers, yet complies with international intellectual property agreements, making it an effective instrument in the hands of countries that seek to limit pharmaceutical patents.

The global response to India's standard ranges from its adoption in Asia and Latin America to recent, unnoticed efforts by the United States to stem its spread by inserting specific obligations in what will soon be the world's largest trade agreement. Drug manufacturers, poor patients in the developing world, and—just as crucially—the future of global patent protection all have a stake in this ongoing tug-of-war over what was only recently an obscure, peculiar patentability standard.

Patent layering is a deeply contentious practice.¹ Popular among pharmaceutical innovators, it involves patenting multiple aspects of, or incremental improvements to, a single drug, so that the last patent expires well after the first.² To proponents of patent layering, it offers a commercial incentive for the research and

¹ I use the term “patent layering” here to distinguish it from other “patent evergreening”—or market-exclusivity-extending—strategies. The term “patent layering” has seen use in the legal literature. See Christine S. Paine, *Brand-Name Drug Manufacturers Risk Antitrust Violations By Slowing Generic Production Through Patent Layering*, 33 SETON HALL L. REV. 479, 506 (2003). The terms “patent layering” and “patent evergreening” may sometimes be used interchangeably. See Michael Enzo Furrow, *Pharmaceutical Patent Life-Cycle Management After KSR v. Teleflex*, 63 FOOD & DRUG L.J. 275 (2008). However, there are a number of evergreening strategies that do not involve applying for more than a single patent. See, e.g., Julia Rosenthal, *Hatch-Waxman Use or Abuse? Collusive Settlements Between Brand-Name and Generic Drug Manufacturers*, 17 BERKELEY TECH. L.J. 317, 319 (2002) (regarding a patent evergreening practice that takes advantage of a thirty month stay of ANDA approval in the United States).

² See 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 AFFAIRS 2286, 2286–87 (2012).

development of new, innovative drugs.³ To critics, it is a reward for non-innovation, one that affects public health by impeding the introduction of low-cost, generic drugs to a market. In low-income countries, critics argue, patent layering can deny patients access to what may be affordable, life-saving treatments.⁴

For much of the twentieth century, patent layering was a non-issue in low-income countries and in states with thriving generic drug industries; patent laws in these countries simply prohibited all pharmaceutical product patents.⁵ This is no longer the case. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement, which came into force in 1995, requires all one hundred and fifty-nine⁶ members of the World Trade Organization (WTO) to grant pharmaceutical product patents,⁷ and a web of agreements that implicate intellectual property, including over three thousand international investment agreements (IIAs), protects foreign drug manufacturers from the expropriation of these patents.⁸ Given this global patent protection landscape, countries that wish to restrict patent layering are often limited in the options that they can pursue.

Amidst this landscape, India's unique law against patent layering stands as a successful model for countries that wish to restrict the practice in a legal environment that makes it increasingly difficult to do so. This note argues that

³ See WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., RL30756, PATENT LAW AND ITS APPLICATION TO THE PHARMACEUTICAL INDUSTRY: AN EXAMINATION OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984 ("THE HATCH-WAXMAN ACT") (2005), available at

<http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/rl3075601102005.pdf>

⁴ See Greg Martin, et al., *Balancing Intellectual Monopoly Privileges and the Need for Essential Medicines*, GLOBALIZATION AND HEALTH (June 12, 2007), available at <http://www.globalizationandhealth.com/content/3/1/4>

⁵ See Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, 3 TUL. J. TECH. & INTELL. PROP. 1, 2 (2001); ROBERT P. MERGES & JOHN F. DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 186–87 (4th ed. 2007).

⁶ WORLD TRADE ORG., MEMBERS AND OBSERVERS, available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited April 9, 2013).

⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

⁸ UNCTAD, WORLD INV. REPORT 2010: INVESTING IN A LOW-CARBON ECONOMY (July 22, 2010), UNCTAD/WIR/2010, 81, available at www.unctad.org/en/docs/wir2010ch3_en.pdf (last visited Nov. 1, 2012).

India's law complies with TRIPS, and, unlike several alternative means of curbing patent layering, also complies with the obligations that most IIAs impose on states.

This note also takes stock of the global response to India's law, focusing on the patent laws of other countries, and on several post-TRIPS preferential trade agreements that implicate patent law. The note ends by highlighting two emerging trends: developing countries that wish to curb patent layering are taking note of India's law, and at least two countries—the Philippines and Argentina—have adopted similar provisions.⁹ Meanwhile, the United States and the European Union, which are home to major pharmaceutical innovators, continue to push for greater global patent protection through preferential trade agreements with other countries.¹⁰ A leaked draft of one agreement currently under negotiation—the Trans-Pacific Partnership (TPP) agreement¹¹—includes a provision that explicitly requires signatories to allow *exactly* what the Indian law prohibits, down to the choice of words.¹² This reveals that supporters of patent layering aim to shape the global patent protection landscape in a manner that curbs the spread of India's anti-patent layering law.

The law in question—Section 3(d) of the India Patents (Amendment) Act of 2005¹³—has achieved global notoriety following the Swiss pharmaceutical giant Novartis' unsuccessful and heavily-publicized challenge of it in India's courts.¹⁴ In the wake of Novartis' legal battle, a small set of scholars has defended Section 3(d), arguing that the law is TRIPS-compatible.¹⁵ Their analyses are incomplete—

⁹ See *infra* Part VI.

¹⁰ See *infra* Part VI.

¹¹ See *Trans-Pacific Partnership (TPP)*, OFFICE OF THE U.S. TRADE REP., available at <http://www.ustr.gov/tpp> (last visited Nov. 4, 2012).

¹² *The Complete Feb 10, 2011 text of the US proposal for the TPP IPR chapter*, KNOWLEDGE ECOLOGY INT'L, available at <http://keionline.org/node/1091> (last visited Nov. 5, 2012).

¹³ The Patents (Amendment) Act, 2005, Act No. 15 of 2005, available at http://ipindia.nic.in/ipr/patent/patent_2005.pdf (emphasis added) [hereinafter PAA 2005].

¹⁴ See Gardiner Harris & Katie Thomas, *Low Cost Drugs in Poor Countries Get a Lift in Indian Court*, N.Y. TIMES (Apr. 1, 2013), available at <http://www.nytimes.com/2013/04/02/business/global/top-court-in-india-rejects-novartis-drug-patent.html?partner%3Drss%26emc%3Drss>.

¹⁵ See generally Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act 2005*, 1 INDIAN J.L. & TECH. 15, 24 (2005), available at <http://ssrn.com/abstract=764066>; Dwijen Rangnekar, *No Pills for Poor People? Understanding the Disembowelment of India's Patent Regime*, 41 ECON. & POL. WEEKLY 409 (2006); Shamnad Basheer & Prashant Reddy, *Ducking*

a defense of Section 3(d) should discuss its interaction with other agreements that implicate intellectual property, as TRIPS forms only a part of the global patent protection landscape. Their analyses are also India-centric, as they do not consider the implications of other countries adopting the Indian law. By discussing Section 3(d)'s interaction with IIAs, and highlighting its impact on the global patent protection landscape, this note aims to both supplement and further the legal scholarship surrounding the law.

Part II of this note introduces the debate over patent layering. Part III follows with an introduction to the global patent protection landscape. Part IV briefly calls attention to the challenge of limiting patent layering amidst this landscape, before Part V demonstrates how Section 3(d) successfully meets this challenge. Part VI then discusses the global response to Section 3(d).

II. THE DEBATE OVER PATENT LAYERING

A. *An Introduction to Patent Layering*

Patents grant their holders a period of market exclusivity over a product or process.¹⁶ Pharmaceutical innovators in particular rely on this incentive, since their products may not be commercially viable in the absence of a period of market exclusivity. This is because drug development requires substantial upfront investment, but drugs themselves are often relatively straightforward to copy.¹⁷ Given the relationship between patent protection, market exclusivity, and commercial returns in the pharmaceutical industry, pharmaceutical innovators use

TRIPS in India: A Saga Involving Novartis and the Legality of Section 3(d), 20 NAT'L L. SCHOOL OF INDIA REV. 131, 148 (2008); Linda L. Lee, *Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India*, 23 BERKELEY TECH. L.J. 281, 290, 294 (2008); Aditya Kant, *Section 3(d): 'New' Indian Perspective*, 14 J. OF INTELL. PROP. RTS. 385 (2009). Cf. Susan Fyan, *Pharmaceutical Patent Protection and Section 3(d): A Comparative Look at India and the U.S.*, 15 VA. J. OF L. & TECH. 198 (2010) (criticizing Section 3(d) for being ambiguously drafted, without challenging the argument that the provision is TRIPS-compatible).

¹⁶ See David M. Gersten, *The Quest for Market Exclusivity in Biotechnology: Navigating the Patent Minefield*, 2 NEURORX 572, 572–73 (2005).

¹⁷ See Joseph A. DiMasi et al., *The price of innovation: new estimates of drug development costs*, 22 J. OF HEALTH ECON. 151, 151–53 (2003) (estimating out-of-pocket cost of developing new drug to be \$403 million in 2000).

a number of practices to extend the period of patent protection available to their products—these practices are collectively referred to as patent evergreening.¹⁸

One particularly popular form of patent evergreening—the practice known as patent layering—involves successively patenting multiple aspects of, or improvements to, the same drug. For example, a drug manufacturer may, having patented a drug, seek several patents to cover its active ingredient, its formulations, and its chemical intermediates, or may seek to patent incremental improvements to the drug.¹⁹

If the manufacturer obtains each of these patents a few years apart, it may be able to extend the period of market exclusivity that it has over a drug well past the expiration of its first product patent. The longer a drug manufacturer enjoys market exclusivity, the greater its commercial returns from a single drug.

B. Arguments for and against Patent Layering

Supporters of patent layering and other forms of patent evergreening point out that it rewards pharmaceutical innovation, and thus encourages drug manufacturers to make the significant investments necessary to develop new, innovative treatments.²⁰ Supporters of patent evergreening also note that pharmaceutical innovation is incremental in nature. A patent system that allows drug manufacturers to patent incremental innovations allows them to pursue ambitious research goals, safe in the knowledge that a series of patents will protect each step along the way.²¹

Critics of patent evergreening dismiss these arguments. First, they observe that increased patent protection for pharmaceutical innovators does not necessarily lead to greater innovation: there has been a decline in the development of new

¹⁸ See Janice M. Mueller & Donald S. Chisum, *Enabling Patent Law's Inherent Anticipation Doctrine*, 45 HOUSTON L. REV. 1101, 1101 (2008); Aaron S. Kesselheim, *Think Globally, Prescribe Locally: How Rational Pharmaceutical Policy in the U.S. Can Improve Global Access to Essential Medicines*, 34 AM. J.L. & MED. 125, 129 (2008).

¹⁹ See Amin & Kesselheim *supra* note 2.

²⁰ See SCHAT & THOMAS, *supra* note 3.

²¹ Albert I. Wertheimer and Thomas M. Santella, *Pharmacoevolution: the benefits of incremental innovation*, IPN WORKING PAPERS ON INTELL. PROP., INNOVATION AND HEALTH 3, available at <http://www.who.int/intellectualproperty/submissions/Pharmacoevolution.pdf> (last visited Nov. 4, 2012).

chemical entities for pharmaceutical use over the past decade, even as the TRIPS agreement has ensured an unprecedented level of international patent protection to branded drug manufacturers.²²

Second, critics note that most new chemical entities that are patented do not represent genuine therapeutic innovation, but instead present therapeutic effects similar to those produced by existing drugs; it is questionable if such “incremental innovations” necessarily lead to new therapeutic breakthroughs.²³

Third, critics point out that even if pharmaceutical innovation is resource-intensive, drug manufacturers have more than enough resources to pursue such innovation, regardless of whether patent evergreening is allowed. A recent study published in the *British Medical Journal* notes that branded drug manufacturers spend an average of 1.3% of their revenues on discovering new therapies (compared to 25% of revenues on marketing).²⁴ The study goes on to show that while the cost of pharmaceutical research has risen greatly over the past decade, drug company revenues have increased six times faster.²⁵ Thus, to critics of patent evergreening, the market exclusivity granted to a drug by a single patent is more than enough reward for pharmaceutical innovators.

The arguments against patent evergreening gain potency from evidence that evergreening practices may have negative implications for public health. By extending drug inventors’ market exclusivity, patent evergreening practices impede generic drug manufacturers from releasing reverse-engineered versions of branded drugs.²⁶ Generic drugs are cheaper than their branded equivalents, partly because their manufacturers need not invest in developing or marketing original

²² See Aaron S. Kesselheim & Jerry Avorn, *Using Patent Data to Assess the Value of Pharmaceutical Innovation*, 37 J.L. MED. & ETHICS 176, 176 (2009) (citing Justin Bloom, *FDA Approves 19 New U.S. Drugs, Fewest Since ‘83; Glaxo Leads*, BLOOMBERG.COM (Jan. 8, 2008), available at <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=a2MOCNVDHucs>).

²³ See, e.g., Bruce M. Psaty & Rita F. Redberg, *Evidence of Pharmaceutical Innovation and Therapeutic Enthusiasm*, 172 ARCHIVES OF INTERNAL MED. 683, 683 (2012).

²⁴ See Donald W. Light & Joel R. Lexchin, *Pharmaceutical research and development: what do we get for all that money?*, BRITISH MED. J. ONLINE (Aug. 7, 2012), available at <http://www.bmj.com/content/345/bmj.e4348?ijkey=Y1g4ZVUImlbtXOI&keytype=ref>.

²⁵ See *id.*

²⁶ See Paine, *supra* note 1, at 488.

drugs,²⁷ but also because the introduction of these drugs leads to price competition between various drug manufacturers.²⁸ Thus, a measure that impedes the introduction of generic drugs to a market will keep drug costs high for consumers, and thereby limit their access to what may sometimes be life-saving treatments. This effect is especially striking in low-income nations: in 2003, when the Swiss pharmaceutical giant Novartis gained market exclusivity in India for its leukemia drug Glivec, and was able to enjoin generic drug manufacturers from selling Glivec copies in the country, the cost of the drug went up tenfold.²⁹ In a country with little health insurance coverage and a per capita income below \$1,500,³⁰ Novartis set the annual price for Glivec at a staggering \$26,000.³¹

Countries may oppose patent evergreening for more than just drug accessibility concerns. Low- or middle-income countries that have thriving generic drug industries, such as India, China, and Brazil, might want to limit patent evergreening simply to enable local generic drug makers to release reverse-engineered copies of these products without fear of legal repercussion.

Within many major economies, both advocates for and critics of patent evergreening make their arguments known on the national stage.³²

Internationally, however, high-income countries with established branded drug manufacturers side with these manufacturers in favor of patent evergreening, while low-income countries—especially those with indigenous generic drug

²⁷ See Ranit Mishori, *Why are generic drugs cheaper than brand-name ones?*, WASH. POST (July 11, 2011), available at http://www.washingtonpost.com/national/health-science/why-are-generic-drugs-cheaper-than-brand-name-ones/2011/07/05/gIQAwZdL9H_story.html.

²⁸ Henry G. Grabowski and Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 27 *MANAGERIAL DECISION ECON.* 491, 491 (2007).

²⁹ Ganapati Murdur, *Indian Patients Go to Court Over Cancer Drug*, 329 *BRIT. MED. J.* 419, 419 (2004), available at <http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=15321889>.

³⁰ See WORLD DEV. INDICATORS DATABASE., WORLD BANK, available at <http://databank.worldbank.org/ddp/home.do?Step=12&id=4&CNO=2> (last visited Nov. 10, 2012).

³¹ See Janice M. Mueller, *Taking TRIPS to India—Novartis, Patent Law, and Access to Medicines*, 356 *NEW ENG. J. MED.* 541, 541 (2007).

³² The United States and European Union, home to most of the world's largest branded drug makers, are also home to some of the world's largest generic drug makers. See PHARMAINTELLECT, *Top 20 Generic Companies in the World*, <http://www.pharmaintellect.com/2011/04/ww-generic-drug-sales-in-2009-top-20.html> (last visited Nov. 10, 2012).

industries—and non-government organizations that work on drug accessibility issues side against patent evergreening practices.³³

Countries in favor of patent layering, such as the United States, have helped shape the present global patent protection landscape, which provides branded drug manufacturers unprecedented levels of patent protection, through bilateral and multilateral trade and investment agreements. Countries that operate in this landscape, but wish to limit patent layering, must craft anti-layering laws that comply with their obligations under these agreements, even as pro-patent layering countries push for new international agreements that more explicitly protect the practice.

III. THE GLOBAL PATENT PROTECTION LANDSCAPE

A. *The Emergence of TRIPS*

Although multilateral treaties on patents have existed since the late nineteenth century,³⁴ for much of the twentieth century, countries that opposed pharmaceutical product patents simply disallowed such patents.³⁵ In the mid-1980s, as many as fifty countries prohibited pharmaceutical product patents; this list included a few developed countries, such as Spain and Portugal, but consisted primarily of large middle- and low-income nations, such as Brazil, India, Mexico and Egypt.³⁶ Around this time, industries across a variety of sectors in the United States claimed that they were suffering heavy losses because of the absence of adequate intellectual property protection in foreign markets. The U.S. International Trade Commission confirmed these claims, estimating that

³³ See Susan K. Sell, *TRIPS-Plus Free Trade Agreements and Access to Medicines*, 28 LIVERPOOL L. REV. 41, 41 (2007).

³⁴ See Paris Convention for the Protection of Industrial Property, July 14, 1967, 21 U.S.T. 1583, translated in G.H.C. BODENHAUSEN, GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY 17 (1968).

³⁵ See Correa, ROBERT P. MERGES & JOHN F. DUFFY, *supra* note 5.

³⁶ See Karin Timmermans & Togi Hutadjulu, THE TRIPS AGREEMENT AND PHARMACEUTICALS, REPORT OF AN ASEAN WORKSHOP ON THE TRIPS AGREEMENT AND ITS IMPACT ON PHARMACEUTICALS, WORLD HEALTH ORG. 11 (2000), available at <http://apps.who.int/medicinedocs/pdf/h1459e/h1459e.pdf>.

American firms were losing about \$50 billion a year from lack of overseas intellectual property protection.³⁷ This led American businesses to call upon their government to seek greater intellectual property protection in international trade agreements.³⁸

When the Uruguay Round of multinational trade negotiations began in 1986, the United States mounted a campaign that succeeded in adding “Trade-Related Aspects of Intellectual Property Rights,” or TRIPS, to the agenda.³⁹ Low-income countries were initially reluctant to join a binding intellectual property agreement—negotiators from these countries worried about drug accessibility issues, and saw no benefit in a global intellectual property regime that rewarded innovation that largely came from developed nations.⁴⁰ However, the promise of gains in other trade areas, coupled with practices such as the United States’ use of its domestic law to undertake trade retaliation against states with “unfair” intellectual property laws, eventually persuaded these countries to join such an agreement.⁴¹

On January 1, 1995, the Uruguay Round of negotiations ended with the establishment of the WTO, whose members were all required to sign on to the new, binding TRIPS agreement.⁴²

Section 5 of Part II of this agreement covers patents, and Articles 27 and 28, which form the core of this section, grant pharmaceutical innovators strong patent protections. Article 27 establishes a ceiling for patentability requirements, by requiring that patents be available “for any inventions . . . in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”⁴³ The article confirms that TRIPS requires all its signatories to allow pharmaceutical product patents. Article 28, which defines the rights conferred by a patent, prohibits third parties from “making, using, offering

³⁷ See Adronico O. Adede, *Origins and History of the TRIPS Negotiations*, in *TRADING IN KNOWLEDGE* 23, 24 (Graham Dutfield et al. eds., 2003).

³⁸ The American pharmaceutical industry was particularly instrumental in lobbying for greater intellectual property protections. *See id.*

³⁹ *See id.* at 25.

⁴⁰ *See id.* at 30–32.

⁴¹ *See id.*

⁴² *See* WORLD TRADE ORG., *Overview: The TRIPS Agreement*, http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Nov. 10, 2012).

⁴³ *See* TRIPS, *supra* note 7, art. 27.

for sale, selling or importing” a product that is patented without the consent of the patent holder.⁴⁴ It thus prevents generic drug manufacturers from infringing upon pharmaceutical product patents. Together, Articles 27 and 28 of TRIPS establish an international patent protection regime for pharmaceutical products. Over seventy countries signed on to TRIPS at the start of 1995, including Spain, Portugal, Brazil, India, Mexico and Egypt.⁴⁵ Today, with one hundred and fifty-nine TRIPS signatories, Articles 27 and 28 enjoy near-universal authority.⁴⁶ Signatories that violate these Articles, or any other part of the TRIPS agreement, can be brought before the WTO’s dispute resolution body, which may allow other signatories to impose retaliatory trade sanctions.⁴⁷

The patent protections granted by Articles 27 and 28, however, have their limits. First, Article 27 does not define the terms “new,” “inventive step,” and “industrial application.” TRIPS signatories are thus free to define these terms in a way that makes it difficult to obtain pharmaceutical product patents.⁴⁸ Second, Article 27 permits exclusions from patentability where necessary to protect *ordre public* or morality.⁴⁹ However, this exclusion cannot be made “merely because the exploitation is prohibited by [a state’s] law,” and it must be linked to a complete ban on the commercial exploitation of the excluded invention.⁵⁰ This is a very narrow limitation, since it allows TRIPS signatories to prohibit pharmaceutical product patents *only if* all pharmaceutical products in the country are produced and distributed non-commercially. Additionally, a signatory’s decision to use this exclusion is subject to a WTO panel’s scrutiny.⁵¹ Third, Article 31 of TRIPS limits the scope of Article 28 by allowing signatory governments to undertake compulsory licensing schemes for patents if they meet a set of conditions.⁵²

⁴⁴ *Id.* at art. 28.

⁴⁵ See WORLD TRADE ORG., MEMBERS AND OBSERVERS, *supra* note 6.

⁴⁶ See *id.*

⁴⁷ “[T]he Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) has been the most venerated aspect of the Uruguay Round Agreements.” Ruth Okediji, *TRIPS Dispute Settlement and the Sources of (International) Copyright Law Part II*, 49 J. OF COPYRIGHT SOC. OF THE U.S.A. 585, 595 (2001).

⁴⁸ See UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT, 359–61 (2005).

⁴⁹ See TRIPS, *supra* note 7, art. 27.

⁵⁰ *Id.*

⁵¹ Kevin J. Nowak, Note, *Staying within the Negotiated Framework: Abiding by the Non-Discrimination Clause in TRIPS Article 27*, 26 MICH. J. INT’L L. 899, 917 (2005).

⁵² See TRIPS, *supra* note 7, art. 31.

Compulsory licensing occurs when a government licenses, or permits a third party to license, a patent holder's exclusive right to use, manufacture, import or sell its patented invention, without the patent holder's consent.⁵³ Article 31 allows TRIPS signatories to license branded drug manufacturers' product patents to generic drug companies without the former's consent, for such reasons as poverty or high incidence of disease. However, signatories that undertake compulsory licensing are required to pay patent holders "adequate remuneration."⁵⁴

Although TRIPS has provided branded drug manufacturers with an unprecedented level of international patent protection, this protection comes with limits. The limits discussed above show that TRIPS signatories have several mechanisms at their disposal to restrict the market exclusivity available to drug manufacturers. Low-income TRIPS signatories are likely to employ these mechanisms: the WTO's 2001 Doha Declaration, proposed by a number of low-income countries, declares that the TRIPS agreement "can and should be interpreted and implemented in a manner supportive of WTO members' right . . . to promote access to medicines for all."⁵⁵

B. Patent Protection under the International Investment Regime

TRIPS constitutes only one aspect of the global patent protection landscape. For the past five decades, countries have been entering into bilateral and multilateral investment treaties. Today, there are over three thousand such international investment agreements (IIAs), and over one hundred and eighty countries have entered into at least one such agreement.⁵⁶ IIAs enshrine an assortment of standards for the treatment of foreign investors and their investments. They protect investments made by one party's investors from direct and indirect expropriation by another party, guarantee each party's investors fair and equitable

⁵³ WORLD TRADE ORG., *Glossary Term: Compulsory Licensing*, http://www.wto.org/english/thewto_e/glossary_e/compulsory_licensing_e.htm (last visited Apr. 14, 2013).

⁵⁴ TRIPS, *supra* note 7, art. 31.

⁵⁵ Doha Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/W/2 (Nov. 14, 2001), *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm [hereinafter "the Doha Declaration"].

⁵⁶ *See* UNCTAD, *supra* note 8. *See also Investment Instruments Online*, UNITED NATIONS CONFERENCE ON TRADE AND DEV., http://www.unctadxi.org/templates/DocSearch___779.aspx (last visited Nov. 5, 2012).

treatment, and protect foreign investors on the basis of most-favored-nation and national treatment principles.⁵⁷ Moreover, IIAs allow aggrieved foreign investors to directly settle their disputes with a host state through arbitration.⁵⁸

Given the ubiquity of IIAs, and the multinational nature of many pharmaceutical innovators, states that look to limit the patent protections available to pharmaceutical innovators ought to be aware of their obligations under these agreements. Most IIAs consider patents to be an investment, and protect the foreign investors that directly or indirectly own patents in a country from the expropriation of their intellectual property.⁵⁹ A state can therefore revoke a pharmaceutical innovator's patent, only to learn that a foreign investor with standing under an IIA owned that patent, and has decided to seek damages for the state's breach of its obligation not to expropriate foreign-owned investment.

IIAs also protect foreign investors from the indirect expropriation of their patents. Indirect expropriation refers to instances when an investor still holds legal title to its investment, but is substantially deprived of the use of, or benefits from, the investment as a result of state action.⁶⁰ A state that issues a compulsory license for a foreign-owned patent, rather than revoking the patent, might find itself in breach of an obligation not to indirectly expropriate foreign investment. There is little certainty regarding what amounts to indirect expropriation, and where the difference lies between non-compensable, legitimate state regulation and compensable indirect expropriation.⁶¹ Despite these uncertainties, one commentator notes that a pharmaceutical innovator whose patent is subject to a compulsory license in a foreign country may be able to seek relief for indirect expropriation under an available IIA, if (1) the terms of the license, and the level of compensation provided, are such that the drug manufacturer can claim "substantial deprivation" of its patent; (2) the compulsory license goes against the

⁵⁷ See Jeswald W. Salacuse & Nicholas P. Sullivan, *Do BITs Really Work: An Evaluation of Bilateral Investment Treaties and Their Grand Bargain*, 46 HARV. INT'L L.J. 67, 82–86 (2005).

⁵⁸ See *id.*

⁵⁹ See Carlos M. Correa, *Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses*, 26 MICH. J. INT'L L. 331, 337 (2004); Christopher Gibson, *A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation*, 25 AM. U. INT'L L. REV. 357, 358–60 (2010).

⁶⁰ See RUDOLF DOLZER & CHRISTOPH SCHREUER, *PRINCIPLES OF INTERNATIONAL INVESTMENT LAW* 92–93 (2008).

⁶¹ See *id.* at 93 ("What was and remains contentious is the drawing of the line between non-compensable regulatory and other governmental activity and measures amounting to indirect, compensable expropriation.").

“legitimate or reasonable expectations” of the manufacturer; and (3) elements such as bad faith or discrimination influence the compulsory license.⁶²

IAs become less useful to pharmaceutical innovators when a state *denies* a drug manufacturer a patent, instead of granting but then revoking a patent. In these cases, there is a question as to whether an invention that has not received a patent is an investment protected by an IA. A few IAs suggest that *patentable* inventions may be considered investments: the bilateral investment treaty between the United States and Jamaica, for example, includes “patentable inventions” in its definition of investment,⁶³ while the Canada-Argentina bilateral investment treaty speaks of “rights with respect to” patents.⁶⁴ However, many—if not most—IAs include intellectual property rights in their list of investments only insofar as these rights are *recognized* by the government hosting the investment. This implies that inventions that have been denied patents are often excluded from protection under IAs.⁶⁵

That said, a state that denies a pharmaceutical innovator a patent in an opaque, inconsistent or arbitrary manner might be in breach of its obligation to subject foreign investors to fair and equitable treatment (FET) under an IA.⁶⁶ The FET standard is broad, and its meaning is grounded in the specific facts and the specific treaty language of a particular case.⁶⁷ Generally, it may be viewed as a guarantee by a host state to treat foreign investors in a transparent, consistent, and

⁶² Gibson, *supra* note 59, at 385–94. I take issue with the fourth factor in Gibson’s test, which calls for the patent subject to compulsory licensing to constitute an integral part of the manufacturer’s foreign investment. This factor is based on a mistaken assumption of what constitutes an investment. Under most IAs, a patent *itself* is an investment. Therefore, in compulsory licensing cases a patentee need not show that its patent is an integral part of any other investment.

⁶³ Treaty Between the United States of America and Jamaica Concerning the Reciprocal Encouragement and Protection of Investment, U.S.-Jam., art. 1, Feb. 4, 1994, S. TREATY DOC. NO. 103-135, *available at* http://tcc.export.gov/Trade_Agreements/All_Trade_Agreements/exp_005434.asp [hereinafter U.S.-Jamaica BIT].

⁶⁴ Agreement between the Government of Canada and the Government of the Republic of Argentina for the Promotion and Protection of Investments, Can.-Arg., art. 1, Nov. 5, 1991, *available at* <http://www.treaty-accord.gc.ca/text-texte.aspx?id=101514>.

⁶⁵ See Carlos M. Correa, BILATERAL INVESTMENT AGREEMENTS: AGENTS OF NEW GLOBAL STANDARDS FOR THE PROTECTION OF INTELLECTUAL PROPERTY RIGHTS?, *GRAIN* 9 (Aug. 3, 2004), *available at* <http://www.grain.org/article/entries/125-bilateral-investment-agreements-agents-of-new-global-standards-for-the-protection-of-intellectual-property-rights#twoone>.

⁶⁶ See DOLZER & SCHREUER, *supra* note 60, at 119 (defining the FET standard).

⁶⁷ See *id.* at 128.

even-handed manner, so as not to affect the basic expectations of a foreign investor when it makes an investment.⁶⁸ Several arbitral tribunals have reasoned that not all opaque, or inconsistent state acts violate FET—for an act to violate FET it must be grossly unfair, in a manner that “shocks . . . a sense of judicial propriety.”⁶⁹

One can conceive of certain circumstances under which a pharmaceutical innovator, subject to foreign state actions that limit its market exclusivity over a drug, may be able to claim a violation of FET. For example, an ambiguous patentability standard, arbitrarily and selectively applied in order to deny a manufacturer a patent, might constitute an FET violation, as might an arbitrary, uncompensated patent revocation. However the specific circumstances surrounding these cases, and the definition of FET in the available IIA, will ultimately determine if these state actions constitute FET violations.

C. Patent Protection under Other Agreements that Implicate Intellectual Property

Beyond IIAs, there is a less extensive web of agreements that both implicate intellectual property, and give foreign investors the ability to arbitrate against states that violate their treaty obligations. Many of these agreements are comprehensive preferential trade agreements, which encompass everything from investment and trade to environmental regulation and intellectual property.⁷⁰ Since there is little consistency between the intellectual property commitments found in preferential trade agreements, and since as of this writing India has not yet signed a preferential trade agreement that implicates intellectual property,⁷¹

⁶⁸ See *id.* at 133–34.

⁶⁹ *Elettronica Sicula SpA (ELSI) (U.S. v. It.)*, Judgment 1989 I.C.J. Rep. 1989 15, ¶ 128 (July 20). See also *Waste Management, Inc. v. United Mex. States*, ICSID Case No. ARB(AF)/00/3, Final Award, ¶ 98 (June 26, 2003), 42 ILM 811 (2003) (stating that “a manifest failure of natural justice in judicial proceedings or a complete lack of transparency and candour in an administrative process” would amount to a violation of FET).

⁷⁰ See *infra* Part VI (noting several preferential trade agreements).

⁷¹ See *Trade Agreements*, DEPT. OF COMMERCE, GOVT. OF INDIA, http://commerce.nic.in/trade/international_ta.asp?id=2&trade=i (last visited Apr. 5, 2013) (listing India’s trade agreements). Cf. *Patralekha Chatterjee, Leaked IP Chapter of India-EU FTA Shows TRIPS-Plus Pitfalls For India, Expert Says*, IP WATCH (Mar. 12, 2013), <http://www.ip-watch.org/2013/03/12/leaked-ip-chapter-of-india-eu-fta-shows-trips-plus-pitfalls-for-india-expert-says/> (noting that India will soon conclude a preferential trade agreement with the European Union that will implicate intellectual property).

this note does not discuss the Indian anti-patent layering law’s interaction with these agreements until Part VI, which highlights that a draft of the Trans-Pacific Partnership agreement, currently under negotiation, prohibits signatories from adopting laws that resemble the Indian law.

D. *Most-Favored-Nation Provisions in TRIPS and International Investment Agreements (IIAs)*

TRIPS, IIAs and preferential trade agreements do not operate in a vacuum—the protections that they provide pharmaceutical innovators may often be linked to other, more favorable protections. Article 4 of TRIPS states that with regard to intellectual property protection “any advantage, favour, privilege or immunity granted by a [WTO] Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members,” with certain limited exemptions.⁷² Most IIAs possess similar “most-favored-nation” clauses, which guarantee that investments protected by the treaties will receive treatment at least as favorable as the treatment the host country grants to investments from any third state.⁷³ These most-favored-nation provisions link together a country’s intellectual property-related commitments to other countries: a country that commits to pro-patent evergreening measures in a treaty with the United States, for example, will have to extend these measures to drug manufacturers from other TRIPS signatories, and from other countries with which it has signed IIAs.

IV. THE CHALLENGE OF LIMITING PATENT LAYERING AMIDST THE GLOBAL PATENT PROTECTION LANDSCAPE

The global patent protection landscape makes it difficult for countries that wish to restrict patent layering from doing so. Today, most countries are TRIPS signatories, and therefore must grant pharmaceutical product patents. TRIPS signatories must also grant patents to all new products that demonstrate an

⁷² TRIPS, *supra* note 7, art. 4.

⁷³ See DOLZER & SCHREUER, *supra* note 60, at 186. However, a foreign investor is unlikely to be able to use the most-favored-nation clause in a BIT to invoke a patent protection found in a trade or intellectual property agreement. See Andreas R. Ziegler, *Most-Favoured-Nation (MFN) Treatment*, in STANDARDS OF INV. PROTECTION 59, 64 (August Reinisch, ed., 2008).

“inventive step” and are capable of “industrial application.”⁷⁴ This limits the ability of signatory states to impose additional patentability requirements on pharmaceutical products.

Countries that are subject to these limitations and grant patents for several aspects of a single drug—or grant patents for incremental improvements to a drug—will have difficulty retroactively addressing such cases of patent layering. If a country tries to revoke these “layered” patents, it is possible that the pharmaceutical innovator affected will be a foreign investor with a direct expropriation claim under an available IIA. If a country non-voluntarily licenses these patents simply in order to limit a drug manufacturer’s market exclusivity over the patented drug, it may both run afoul of TRIPS and face indirect expropriation claims by the manufacturer under an IIA; and, regardless of whether these compulsory licenses are justified, the country issuing them will have to “adequately remunerate” the affected drug manufacturer.⁷⁵ In either of these situations, the country might face violation-of-FET claims under IIAs. Moreover, foreign drug manufacturers can take advantage of most-favored-nation clauses in TRIPS, IIAs, and other agreements that implicate intellectual property to secure the most favorable patent protections that the host country has committed to on the international stage.

Given the limitations imposed by the global patent protection landscape, countries that choose to restrict patent layering—either because they are low-income countries or simply because they wish to protect their generic drug industries—must be careful to craft anti-layering provisions that comply with TRIPS, as well as all relevant IIAs. Section 3(d) of the India Patents (Amendment) Act of 2005⁷⁶ can serve as a model for such countries—this provision is likely TRIPS-compliant, and, as this note argues, it steers clear of the protections that most IIAs grant foreign branded drug manufacturers.

V. THE SUCCESS OF INDIA’S LAW AGAINST PATENT LAYERING

⁷⁴ TRIPS, *supra* note 7, art. 27.

⁷⁵ TRIPS, *supra* note 7, art. 31.

⁷⁶ PAA 2005, *supra* note 13, § 3(d).

A. *An Introduction to India's Law against Patent Layering*

Shortly after India gained independence from Britain in 1947, the country's first government decided to replace the colonial-era patent system with one that "was more conducive to national interests."⁷⁷ This eventually resulted in the India Patents Act of 1970 (the "Patents Act").⁷⁸ The Patents Act, like other contemporary patent laws in low-income countries, prohibited the patentability of pharmaceutical products.⁷⁹ The prohibition was a deliberate policy choice; it allowed domestic drug manufacturers to produce versions of existing branded drugs without fear of legal retribution, and it gave Indians access to lower-cost versions of branded drugs.⁸⁰ Over the next few decades, the Indian generic drug manufacturing industry grew dramatically on the back of the Patents Act. Today, India is the world's third-largest producer of drugs by volume.⁸¹ By prohibiting patents for pharmaceutical products, the Patents Act stood in sharp contrast to contemporary patent laws in high-income nations, and these differences gained prominence when India joined the negotiations that eventually led to the establishment of the WTO. Throughout the GATT (later the WTO) negotiations that began in the late 1980s, India strongly opposed uniform, transnational intellectual property laws. Nonetheless, a declining economy in the 1980s persuaded India to become a founding member of the WTO in 1994; and as a WTO member, India reluctantly agreed to comply with TRIPS.⁸² Accordingly, the country's parliament amended the Patents Act in 2005 (the "2005 Amendment")—taking advantage of a ten-year transition period that TRIPS offered to low-income countries⁸³—and began granting pharmaceutical product patents.

⁷⁷ Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 511 (2006).

⁷⁸ The Patents Act, No. 39 of 1970, INDIA CODE, available at http://www.wipo.int/wipolex/en/text.jsp?file_id=128092.

⁷⁹ *Id.* § 5.

⁸⁰ See Lee, *supra* note 15, at 291.

⁸¹ Vikas Bajaj & Andrew Pollack, *India's Supreme Court to Hear Dispute on Drug Patents*, N.Y. TIMES (Mar. 6, 2012), available at http://www.nytimes.com/2012/03/07/business/global/indias-supreme-court-to-hear-long-simmering-dispute-on-drug-patents.html?pagewanted=all&_r=0.

⁸² Mueller, *supra* note 77, at 517–18.

⁸³ See TRIPS, *supra* note 83, art. 65.

The series of drafts that preceded the final version of the 2005 Amendment reflect Indian lawmakers' concern about granting pharmaceutical product patents and their wish to limit the availability of such patents.⁸⁴ These concerns gave rise to Section 3(d) of the 2005 Amendment, which prohibits patents for:

The mere discovery of a new form of a known substance which *does not result in the enhancement of the known efficacy of that substance* or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.⁸⁵

An explanation accompanies Section 3(d):

Explanation—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.⁸⁶

Section 3(d) prohibits patents for new forms or derivatives of known substances that do not result in the enhancement of the known efficacy of that substance. This “enhanced efficacy” standard, which had “no parallel anywhere else in the world” when it was crafted,⁸⁷ was drafted by a retired justice of India’s Supreme Court, and added to the draft of the 2005 Amendment with little explanation only days before it was debated in parliament.⁸⁸ According to one commentator, Indian parliamentarians welcomed the standard, but were unsure of what it meant and what its ramifications would be as they debated and enacted the 2005 Amendment.⁸⁹

⁸⁴ See Prashant Reddy, *Pages from History: The Mysterious Legislative History of Section 3(d)*, SPICY IP (Nov. 9, 2011),

<http://spicyipindia.blogspot.com/search?q=mysterious+legislative+history>.

⁸⁵ PAA 2005, *supra* note 13, § 3(d) (emphasis added).

⁸⁶ *Id.*

⁸⁷ See Shammad Basheer & Prashant Reddy, *The “Efficacy” of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5 SCRIPTED 232, 234 (2008), available at <http://www.law.ed.ac.uk/ahrc/script-ed/vol5-2/basheer.pdf>.

⁸⁸ See Reddy, *supra* note 88.

⁸⁹ See *id.*

Not long after its enactment, Section 3(d) came under attack. In 2006, India's Madras Patent Office denied the Swiss pharmaceutical giant Novartis a patent for the beta crystalline salt form of a compound called imatinib mesylate, the key ingredient in Novartis' anti-leukemia drug Glivec.⁹⁰ The patent office based its decision largely on the grounds that the beta crystalline form was a salt of a "known substance"—imatinib mesylate—that failed to demonstrate "enhanced efficacy" over its parent compound, and therefore failed to meet the patentability requirement set forth in Section 3(d).⁹¹

Novartis appealed the patent office's decision to India's newly-formed Intellectual Property Appellate Board (IPAB), and challenged the constitutionality and TRIPS-compatibility of Section 3(d) before the Madras High Court.⁹² The latter court issued its opinion first.⁹³ It found Section 3(d) to be valid under the Indian constitution,⁹⁴ held that it lacked jurisdiction over the TRIPS issue,⁹⁵ and declared that "enhanced efficacy" in Section 3(d) meant "enhanced therapeutic efficacy."⁹⁶ Employing the Madras High Court's definition of enhanced efficacy, IPAB held that imatinib mesylate, though novel and inventive, failed to demonstrate enhanced efficacy over imatinib.⁹⁷ Novartis appealed these decisions to India's Supreme Court, and lost.⁹⁸ The Supreme Court upheld the Madras High Court's "enhanced therapeutic efficacy" standard, and agreed with the IPAB's ruling that Novartis had not met this standard.⁹⁹ The Supreme Court further held that the "enhanced efficacy" standard complied with TRIPS, given that agreement's flexibility.¹⁰⁰

⁹⁰ See Shammad Basheer, *First Mailbox Opposition (Gleevec) Decided in India*, SPICY IP (Mar. 11, 2007), <http://spicyipindia.blogspot.com/search?q=First+Mailbox+Opposition+%28Gleevec%29+Decided+in+India>. Glivec is marketed in the United States under the name Gleevec.

⁹¹ See *id.*

⁹² See Lee, *supra* note 15, at 299.

⁹³ *Novartis AG v. Union of India and Ors.*, 2007 A.I.R. 24759 (Madras H.C.).

⁹⁴ See *id.* ¶ 16.

⁹⁵ See *id.* ¶ 8.

⁹⁶ *Id.* ¶ 13.

⁹⁷ *Novartis AG v. Union of India and Ors.*, Intellectual Property Appellate Board, Judgment, June 26, 2009, available at <http://www.ipab.tn.nic.in/Orders/100-2009.htm>.

⁹⁸ *Novartis AG v. Union of India and Ors.*, Supreme Court of India, Judgment, Apr. 1, 2013 [hereinafter *Novartis Judgment*], available at <http://supremecourtindia.nic.in/outtoday/patent.pdf>.

⁹⁹ *Id.* ¶ 189.

¹⁰⁰ *Id.* ¶¶ 65–67.

Novartis' case has drawn the world's attention to Section 3(d): critics of patent layering have hailed the Indian Supreme Court's decision to uphold the law,¹⁰¹ while supporters of the practice, especially pharmaceutical innovators like Novartis, have decried the judgment, arguing that it will hurt India's innovation and investment climate.¹⁰² Nuanced observers have noted that the decision discourages the least useful instances of patent layering, while still preserving an incentive for incremental innovation.¹⁰³

B. How India's Law Interacts with the Global Patent Protection Landscape

Novartis' unsuccessful challenge of Section 3(d) has sparked considerable global interest in the anti-layering provision.¹⁰⁴ However, for the Section to be a model provision for countries that wish to prohibit patent layering, it must be TRIPS-compatible, and it must not give foreign drug manufacturers grounds to claim relief under the expropriation or FET guarantees in an available IIA. Section 3(d) arguably fulfills both criteria.

1. Section 3(d) is TRIPS-compatible

The Novartis case has focused attention on the issue of Section 3(d)'s compatibility with TRIPS. A number of scholars who have analyzed the issue agree that the Section does not violate the agreement.¹⁰⁵

¹⁰¹ See, e.g., DOCTORS WITHOUT BORDERS, *Indian Supreme Court Decision on Novartis Case a Victory for Access to Medicines in Developing Countries* (Apr. 1, 2013), available at <http://www.doctorswithoutborders.org/press/release.cfm?id=6707&cat=press-release>; Soutik Biswas, *Novartis India Case: Campaigners Hail Patent Rejection*, BBC NEWS (Apr. 1, 2013), <http://www.bbc.co.uk/news/business-21992724>.

¹⁰² See, e.g., Ranjit Shahani, *Supreme Court's Glivec Ruling Will Ruin Innovation, Says Ranjit Shahani, Novartis India MD*, THE ECONOMIC TIMES (Apr. 2, 2013), available at http://articles.economictimes.indiatimes.com/2013-04-02/news/38218340_1_glivec-pharma-industry-novartis; Press Trust of India, *Supreme Court Order on Novartis Will Impact Investment in India: USIBC*, NDTV PROFIT (Apr. 3, 2013), <http://profit.ndtv.com/news/industries/article-supreme-court-order-on-novartis-will-impact-investment-in-india-usibc-320379>.

¹⁰³ See, e.g., Editorial, *India's Novartis Decision*, N.Y. TIMES (Apr. 4, 2013), available at http://www.nytimes.com/2013/04/05/opinion/the-supreme-court-in-india-clarifies-law-in-novartis-decision.html?_r=0.

¹⁰⁴ See *supra* notes 101–103.

¹⁰⁵ See *supra* note 15.

Article 27 of TRIPS stipulates that patents be available “for any inventions . . . in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”¹⁰⁶ Article 27 thus obliges signatories to grant product and process patents in all fields of technology and sets up three criteria—novelty, inventive step, and industrial applicability—for patentability. However, TRIPS does not define “novelty,” “inventive step,” or “industrial applicability.” TRIPS signatories therefore have some discretion over how to define the patentability criteria in a manner that suits their national interests.¹⁰⁷

Section 3(d) may be considered to be an alternative definition of the “inventive step” patentability requirement in Article 27. Viewed this way, it is by no means the only provision in the world to deny patents to insubstantial derivatives of known substances. In American patent law, an invention may not be patentable if it is obvious to an ordinary person skilled in the relevant art, in light of prior inventions and references. Employing this “non-obviousness” requirement, in 2007 the Federal Circuit invalidated a patent for a drug molecule because it was a salt form of a known substance, and because the salt itself had previously been employed for a similar purpose in another drug molecule.¹⁰⁸

Section 3(d) may also be viewed as derived from the “industrial applicability” requirement in Article 27. It is possible to argue that a derivative of an existing substance has little industrial applicability if it fails to demonstrate “enhanced efficacy” over the substance.¹⁰⁹

Thus, Section 3(d) is arguably TRIPS-compatible. If, in its decision in the Novartis case, India’s Supreme Court had interpreted Section 3(d)’s “enhanced efficacy” requirement in a manner that effectively denied patents to all derivatives of known substances, then Section 3(d) would likely have run afoul of Article

¹⁰⁶ TRIPS, *supra* note 7, art. 27(1).

¹⁰⁷ *See id.*

¹⁰⁸ *See* Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1364 (Fed. Cir. 2007).

¹⁰⁹ FEROUZ ALI KHADER, THE LAW OF PATENTS: WITH A SPECIAL FOCUS ON PHARMACEUTICALS IN INDIA 65 (2007).

27.¹¹⁰ However, the Court did not adopt such a broad interpretation of “enhanced efficacy” in its holding.¹¹¹

2. Section 3(d) does not conflict with protections available under most IIAs
 - a. *Section 3(d) does not give rise to direct expropriation claims under most IIAs*

The “enhanced efficacy” standard in Section 3(d) is a patentability requirement—products that fail to meet this standard are denied patents. Therefore, under most IIAs, a foreign branded drug manufacturer denied a patent under this standard will be unable to show that it has an intellectual property “investment” that was “expropriated” by the act of patent denial.¹¹²

Thus, for countries that wish to restrict patent layering, Section 3(d)’s patentability requirement is preferable to another anti-layering measure: patent revocation. Countries that grant patents to a foreign drug manufacturer for several aspects of a single drug only to *then revoke* these “layered” patents risk facing direct expropriation claims, since most IIAs recognize patents as investment.¹¹³

- b. *Section 3(d) does not give rise to indirect expropriation claims under IIAs*

Whereas acts such as compulsory licensing might give rise to indirect expropriation claims, a pharmaceutical innovator that is denied patent protection in a foreign state will find it difficult to argue that patent denial amounts to indirect expropriation.

According to the test suggested earlier in this note, compulsory licensing might amount to indirect expropriation. A patent is an investment; and compulsory licensing is a “substantial deprivation” of that investment. This substantial deprivation might amount to indirect expropriation if the compulsory license goes

¹¹⁰ See Basheer & Reddy, *supra* note 15, at 148 (“[C]are must be taken to ensure that [Section 3(d)] is not interpreted in a manner that no pharmaceutical derivative or incremental innovation is ever patentable; else the provision runs the risk of falling foul of TRIPS.”).

¹¹¹ See *Novartis Judgment*, *supra* note 98, ¶191.

¹¹² See Correa, Gibson, *supra* note 59.

¹¹³ See *id.*

against the “legitimate or reasonable expectations” of the manufacturer; and elements such as bad faith or discrimination influence either act.¹¹⁴

Under this test, it is unlikely that patent denial under Section 3(d) will give rise to indirect expropriation claims under IIAs. This is because in patent denial cases, unlike in compulsory licensing cases, a foreign pharmaceutical innovator has no patent to claim as an investment. Consequently, it must argue that patent denial amounts to indirect expropriation of its overall investment or business. This is difficult to do: patent denial might force a pharmaceutical innovator to lower its drug prices to compete with generic competitors, and this in turn might affect the value of its business in a country, but this loss in value is highly unlikely to meet the “substantial deprivation” standard set by arbitral tribunals. The NAFTA tribunal in *Pope & Talbot v. Canada* held that a foreign investor is substantially deprived of its overall investment if its host state (1) controls its investment, (2) directs the day-to-day operations of its investment, (3) interferes with management or the payment of dividends, or (4) takes any of the proceeds of company sales.¹¹⁵ Several subsequent tribunals have adopted this definition, thus indicating its influence in international investment law, despite the lack of any doctrine of binding precedent in the field.¹¹⁶ Under the *Pope & Talbot* standard, patent denial does not amount to substantial deprivation of an overall investment: it does not lead to state control or management of a foreign pharmaceutical innovator, and even though it affects the sales of drugs, it does not take *the proceeds* of any sale.

Given that it is unlikely to substantially deprive a pharmaceutical innovator of its overall investment, patent denial under Section 3(d) is highly unlikely to give rise

¹¹⁴ *See id.*

¹¹⁵ *See Pope & Talbot v. Canada*, UNCITRAL, Interim Award, 34 (June 26, 2000), available at <http://italaw.com/sites/default/files/case-documents/ita0674.pdf>.

¹¹⁶ *See e.g.*, *CMS Gas Transmission v. Argentina*, ICSID Case No. ARB/01/8, Award, ¶ 263 (May 12, 2005), available at https://icsid.worldbank.org/ICSID/FrontServlet?requestType=CasesRH&actionVal=showDoc&docId=DC504_En&caseId=C4; *PSEG Global Inc. and Konya Ilgin Elektrik Üretim ve Ticaret Sirketi v. Republic of Turkey*, ICSID Case No. ARB/02/5, Award, ¶ 278 (Jan. 19, 2007), available at <http://italaw.com/documents/PSEGGlobal-Turkey-Award.pdf>. *See also Metalclad Corp. v. United Mexican States*, ICSID Case No. ARB(AF)/97/1, Award, ¶ 108 (Aug. 30, 2000) (regarding the persuasive power of previous tribunal decisions, despite there being no doctrine of binding precedent in international investment law).

to indirect expropriation claims under IIAs. It is more likely that compulsory licensing, an alternative anti-layering measure, will give rise to such claims.

c. Section 3(d) does not appear to violate the Fair and Equitable Treatment Requirement under most IIAs

There is uncertainty regarding the meaning of fair and equitable treatment (FET) in the international investment regime, and there is significant variation among FET clauses in different IIAs.¹¹⁷ Nonetheless, arbitral tribunals have noted that state acts and regulations should be given deference, and presumed not to be violations of FET, unless they are so grossly unfair as to offend a sense of “judicial propriety.”¹¹⁸

The Indian Supreme Court’s judgment against Novartis made the meaning of Section 3(d)’s “enhanced efficacy” standard clear to pharmaceutical innovators. All patent applicants in the country can be expected to know of the standard and its clear—if controversial—policy objective: to restrict patent layering. Therefore, patent denial under Section 3(d) is unlikely to be so grossly unfair as to offend a sense of judicial propriety.

The NAFTA tribunal in *Mondev v. United States* would support this conclusion.¹¹⁹ Although there is no doctrine of binding precedent in international investment law, as noted above, arbitral tribunals often give weight to interpretations of investment treaty standards in prior arbitration decisions.¹²⁰ The tribunal in *Mondev* agreed with the Canadian claimant that a Massachusetts law granting unincorporated government bodies immunity from tort suits was potentially unfair and could be subject to criticism.¹²¹ Nevertheless, it concluded that the law did not violate the FET standard found in NAFTA, since it was known to the claimant when it invested in Massachusetts, and since the policy

¹¹⁷ See DOLZER & SCHREUER *supra* note 66.

¹¹⁸ See Elettronica Sicula SpA, *supra* note 69.

¹¹⁹ See *Mondev Int’l Ltd. v. United States of America*, ICSID Case No. ARB(AF)/99/2, Award (Oct. 11, 2002), available at <http://www.state.gov/documents/organization/14442.pdf>.

¹²⁰ See *Metalclad*, *supra* note 116, ¶ 108.

¹²¹ See *Mondev*, *supra* note 119, ¶ 148.

implications of the law meant that the scope of its application was best left “for competent organs of the State to decide.”¹²²

It is possible that certain alternative anti-layering measures, such as patent revocation or compulsory licensing without adequate compensation, can violate FET guarantees in IIAs. According to one comprehensive definition of FET, found in the arbitral tribunal’s decision in *Tecmed v. Mexico*, foreign investors expect states not to revoke pre-existing decisions upon which they have relied or deprive investors of their investment without adequate compensation.¹²³ Arbitrary violations of such expectations may therefore amount to violations of FET. Thus, countries that adopt retroactive anti-layering measures open themselves up to violation-of-FET claims under available IIAs, especially if they fail to adequately compensate the affected foreign branded drug manufacturers.

Patent denial under Section 3(d) does not give rise to the same issues: Section 3(d) is a law known to foreign investors—as opposed to being an arbitrary measure—and patent denial under this law neither reverses a prior decision nor takes away an existing investment. Thus, if a branded drug manufacturer is denied a patent under this standard, and receives no remuneration, the standard should still be in compliance with FET guarantees in IIAs.

VI. THE GLOBAL RESPONSE TO INDIA’S LAW AGAINST PATENT LAYERING

Section 3(d) is an effective provision against patent layering, one that is both TRIPS-compatible and unlikely to implicate the protections available to foreign investors under most IIAs. For countries that wish to restrict patent layering, Section 3(d) is preferable to retroactive anti-layering measures such as patent revocation or compulsory licensing: these measures require governments to adequately compensate the affected branded drug manufacturers, and may expose

¹²² *Id.* ¶ 154.

¹²³ See *Tecnicas Medioambientales Tecmed S.A. v. United Mexican States*, ICSID Case No. ARB(AF)/00/2, Award, ¶ 154 (May 29, 2003), *available at* https://icsid.worldbank.org/ICSID/FrontServlet?requestType=CasesRH&actionVal=showDoc&docId=DC602_En&caseId=C186.

countries to a whole host of claims by foreign branded drug manufacturers under available IIAs.

It is unsurprising then that Section 3(d) has attracted attention outside India. Two trends become apparent when one takes stock of the global response to the law. First, certain countries that wish to restrict patent layering are following India's lead and adopting similar laws and regulations. In the years since India adopted Section 3(d), the Philippines and Argentina have introduced their own anti-layering laws and regulations. At the same time, countries that support patent layering, such as the United States, are employing preferential trade agreements to curb the spread of such laws. A leaked draft of one such agreement currently under negotiation—the Trans-Pacific Partnership agreement (TPP)—requires signatories to reject Section 3(d)'s “enhanced efficacy” standard. If the final text of the TPP retains this provision, it will not only preclude signatories from across four continents from adopting Section 3(d)-like laws, but might help push pro-patent layering norms on the global stage.

A. *Post-Section 3(d) Anti-Layering Laws in Other Countries*

1. The Philippines

In 1997, two years after the Philippines became a signatory to TRIPS, the country's Congress enacted a law, known as R.A. 8293, that prescribed a common, TRIPS-compliant intellectual property code.¹²⁴ In 2008, Congress amended Section 22 of this act, which lists non-patentable inventions, by inserting the following text:

[I]n the case of drugs and medicines, the mere discovery of a new form or new property of a known substance *which does not result in the enhancement of the known efficacy of that substance*, or the mere discovery of any new property or new use for a known substance, or the mere use of a known process [is non-

¹²⁴ An Act Prescribing the Intellectual Property Code and Establishing the Intellectual Property Office, Providing for its Powers and Functions, and for Other Purposes, Rep. Act. No. 8293 (June 6, 1997) (Phil.), *available at* http://www.lawphil.net/statutes/repacts/ra1997/ra_8293_1997.html [hereinafter R.A. 8293].

patentable] unless such known process results in a new product that employs at least one new reactant.¹²⁵

The amended Section 22 incorporates Section 3(d)—including its choice of words—into the patent law of the Philippines. Officials in the Philippines adopted Section 22 in an effort to increase access to drugs in the low-income country of ninety-five million, where drug prices continue to be five to thirty times higher than in India.¹²⁶ Indian generic drug manufacturers, together with non-profits working on drug accessibility issues, were quick to praise the 2008 amendment that incorporated the language of Section 3(d).¹²⁷

2. Argentina

In May 2012, Argentina's Ministry of Industry, Ministry of Health, and its National Institute for Industrial Property published three joint resolutions that restricted the patentability of derivatives of pharmaceutical products.¹²⁸ Among other things, the joint resolutions declare that the new salts of known active ingredients, and the derivatives of known substances, are no longer patentable.¹²⁹ The resolution, which entered into force upon its promulgation, is applicable to all pending and future patent applications.¹³⁰

Argentina's joint resolutions have largely the same effect as Section 3(d): they preclude branded drug manufacturers from patenting different aspects of the same drug, effectively preventing patent layering. In fact, Argentina's resolutions

¹²⁵ R.A. 8293, as Amended by an Act Providing for Cheaper and Quality Medicines, Amending for the Purpose Republic Act No. 8293 or the Intellectual Property Code, Republic Act No. 6675 or the Generics Act of 1988, and Republic Act No. 5021 or the Pharmacy Law, and for Other Purposes, Rep. Act. 9502, § 22 (June 6, 2008) (Phil.), *available at* http://www.jpo.go.jp/shiryuu_e/s_sonota_e/fips_e/pdf/philippines_e/e_tizai.pdf (emphasis added). *Compare id. with* PAA 2005, *supra* note 13, § 3(d)

¹²⁶ *See* Rupali Mukherjee, *Indian Pharma May Export to Philippines*, TIMES OF INDIA (May 5, 2008), *available at* http://articles.timesofindia.indiatimes.com/2008-05-05/india-business/27783865_1_generic-versions-patent-law-essential-medicines; Oscar F. Picazo, *Medicines Still beyond Reach of Many*, PHILIPPINES DAILY INQUIRER (July 21, 2012), *available at* <http://opinion.inquirer.net/33107/medicines-still-beyond-reach-of-many>.

¹²⁷ *See* Mukherjee, *supra* note 126.

¹²⁸ Res. Nos. 118/2012, 546/2012, 107/2012, May 8, 2012 (Arg.), *available at* http://www.moellerip.com/index.php?PN=news_detail&FX=0&EX=1&DX=139 (English tr.).

¹²⁹ *See Non-Patentable Subject Matter According to the New Guidelines of the Argentine PTO*, MUELLER IP (May 2012), http://www.e-moeller.com/index.php?PN=news_detail&FX=1&EX=1&DX=138.

¹³⁰ *See id.*

impose a more stringent patentability requirement than Section 3(d), since they deny patents to derivatives of known pharmaceutical products *even* if they demonstrate enhanced efficacy. If Novartis were to apply for an Argentine patent for the beta crystalline form of imatinib mesylate today, it would almost certainly be denied a patent on the grounds that the product is a new salt form of the known active ingredient imatinib.

Indian lawyers and commentators have noted Argentina's joint resolutions and its similarities to Section 3(d).¹³¹ One commentator sees Argentina's measure as a sign that the "3(d) wave is spreading to other developing countries."¹³² That said, because it denies patents to all derivatives of known pharmaceutical products, without any regard to efficacy, the Argentine resolution seems more likely than Section 3(d) to run afoul of Article 27 of TRIPS.¹³³

B. Pro-Patent Evergreening Provisions in Post-Section 3(d) Preferential Trade Agreements

Just as certain countries might want to adopt Section 3(d)-like anti-layering laws, countries with established pharmaceutical innovators, which support patent evergreening practices on the international stage, might want to prevent these states from adopting such laws. Since TRIPS came into force in 1995, the United States and the European Union—home to eight of the world's ten largest branded drug manufacturers¹³⁴—have signed about two dozen free trade agreements with countries around the world.¹³⁵ Critics of patent evergreening have called these

¹³¹ See, e.g., Shouvik K. Guha, *Argentina Goes the 3(d) Way: Creases of Worry for the Pharmaceutical Patent Applicants?*, SPICY IP (May 23, 2012), <http://spicyipindia.blogspot.com/2012/05/argentina-goes-3d-way-creases-of-worry.html>; V. Lakshmikumaran, *Intellectual Property and Public Health: Regional Perspectives—India*, LAKSHMI KUMARAN & SRIDHARAN, ATTORNEYS, 6, <http://www.unescap.org/tid/projects/trips2012-lakshmi2.pdf> (last visited Nov. 15, 2012).

¹³² Guha, *supra* note 131.

¹³³ See Basheer & Reddy, *supra* note 15.

¹³⁴ *Factbox — The 20 Largest Pharmaceutical Companies*, REUTERS (Mar. 26, 2010), <http://www.reuters.com/article/2010/03/26/pharmaceutical-mergers-idUSN2612865020100326>.

¹³⁵ See *Free Trade Agreements*, OFFICE OF THE U.S. TRADE REP., <http://www.ustr.gov/trade-agreements/free-trade-agreements> (last visited Nov. 10, 2012); *Free Trade Agreements*, EUR. COMM., INT'L AFFAIRS, http://ec.europa.eu/enterprise/policies/international/facilitating-trade/free-trade/index_en.htm (last visited Nov. 10, 2012).

trade agreements “TRIPS-plus,” since they accord pharmaceutical innovators greater rights and protection than are available to them under TRIPS.¹³⁶ The TRIPS-plus agreements signed since Section 3(d)’s enactment in 2005 extend pharmaceutical innovators’ period of market exclusivity over their drugs in at least two ways. First, they allow drug manufacturers to extend the lifespan of their pharmaceutical product patents in a country, typically by five years, to make up for regulatory procedures that delay the patented drug’s entry into that country.¹³⁷ Second, these agreements prevent signatories from disclosing test data necessary for determining a new pharmaceutical product’s safety and efficacy for a period of a few years.¹³⁸ This means that countries that are parties to these agreements cannot disclose the test data submitted to them by pharmaceutical innovators to third parties for a certain number of years. During this time period, since generic drug companies are unable to access the safety and efficacy data submitted by branded drug manufacturers, they must conduct their own clinical trials and submit their own safety and efficacy data in order to gain approval for generic versions of existing drugs.¹³⁹ Since clinical trials are an expensive, time-consuming process, the prohibition on test data disclosure extends the period of market exclusivity available to pharmaceutical innovators.¹⁴⁰

Despite these market exclusivity-extending provisions, TRIPS-plus agreements, by and large, do not further broaden the patentability requirements found in TRIPS. The United States’ recent free trade agreements with Panama, Korea and Colombia, for example, reiterate the patentability standard in Article 27 of TRIPS, namely, that parties shall make patents available for “new” inventions that involve an “inventive step” and that are “capable of industrial application.”¹⁴¹ Parties to

¹³⁶ See, e.g., Mohammed El-Said, *The Road from TRIPS-Minus, to TRIPS, to TRIPS-Plus—Implications of IPRs for the Arab World*, 8 J. WORLD INTELL. PROP. 53, 53 (2005).

¹³⁷ See Francisco Rossi, *Free Trade Agreements and TRIPS-plus Measures*, 1 INT’L J. INTELL. PROP. MGMT. 150, 150 (2006); Carlos M. Correa, *Implications of Bilateral Free Trade Agreements on Access to Medicines*, 84 BULL. WORLD HEALTH ORG. 399, 400 (2006).

¹³⁸ See Correa, *supra* note 137.

¹³⁹ See Correa, *supra* note 137, at 400.

¹⁴⁰ See *id.*

¹⁴¹ United States-Panama Trade Promotion Agreement, U.S.-Pan., art. 15.9, June 28, 2007, available at <http://www.ustr.gov/trade-agreements/free-trade-agreements/panama-tpa/final-text>; Free Trade Agreement Between the United States of America and the Republic of Korea, Kor.-U.S., art. 18.8, June 30, 2007, available at <http://www.ustr.gov/trade-agreements/free-trade-agreements/korus-fta/final-text>; Free Trade Agreement Between the United States and Colombia,

these free trade agreements are given the option of viewing “inventive step” and “capable of industrial application” as being synonymous with the U.S. patent law terms “non-obvious” and “useful,” but they are not required to do so.¹⁴² Since this patentability standard gives countries considerable discretion in setting their patentability requirements, low-income parties to these free trade agreements, such as Panama and Colombia, can probably adopt Section 3(d)-like laws without breaching their obligations under these agreements.

The European Union’s recent free trade agreement with Peru and Colombia reflects the same patentability standard. Article 196 of that agreement states that no intellectual property-related provision in the agreement “will contradict or be detrimental to” the provisions of TRIPS; and the following article notes that parties may “make use of the exceptions and flexibilities” permitted by TRIPS, particularly to guarantee access to medicines.¹⁴³ Thus, Peru and Colombia can adopt Section 3(d)-like laws without violating their treaty obligations.

C. The Pro-Patent Layering Provision in a Draft of the Trans-Pacific Partnership Agreement

Given these recent TRIPS-plus agreements, one may assume that pro-patent evergreening countries have failed to notice, or chosen to ignore, Section 3(d)’s potential as a law that can limit pharmaceutical innovators’ market exclusivity over their drugs. However, the United States’ draft treaty for the on-going Trans-Pacific Partnership agreement (TPP) negotiations proves otherwise. TPP will be a multilateral trade agreement between the United States and several Pacific Rim countries, including low-income nations such as Vietnam and Peru.¹⁴⁴

U.S.-Colom., art. 16.9, Nov. 22, 2006, *available at* <http://www.ustr.gov/trade-agreements/free-trade-agreements/colombia-fta/final-text>.

¹⁴² *See supra* note 141.

¹⁴³ Trade Agreement between the European Union and its Member States, of the One Part, and Colombia and Peru, of the Other Part, E.U.-Colombia, Peru, art. 196, June 26, 2012, *available at* http://trade.ec.europa.eu/doclib/docs/2011/march/tradoc_147704.pdf.

¹⁴⁴ *See generally* OFFICE OF THE U.S. TRADE REP., *The United States in the Trans-Pacific Partnership*, <http://www.ustr.gov/about-us/press-office/fact-sheets/2011/november/united-states-trans-pacific-partnership> (last visited Apr. 11, 2013). As of April 12, 2013, the countries negotiating the TPP are Australia, Brunei, Canada, Chile, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States, and Vietnam, with Japan set to join. *See* Kaori Kaneko & Doug Palmer, *Japan, U.S. Agree on Tokyo Joining Trans-Pacific Trade Talks*, REUTERS (Apr. 12, 2013), <http://www.reuters.com/article/2013/04/12/us-trade-asiapacific-japan-idUSBRE93B09R20130412>.

Negotiations between the states began in 2010, and as of this writing, the seventeenth round of negotiations was scheduled to be held in Lima, Peru in May 2013.¹⁴⁵

In March 2011, before the sixth round of TPP negotiations were set to begin in Singapore, a website leaked the United States Trade Representative's draft of the treaty's intellectual property chapter.¹⁴⁶ The draft chapter, which likely reflects the United States' negotiating positions at the time, contains intellectual property protections different from those in TRIPS and in recent TRIPS-plus agreements. In particular, Article 8.1 of the draft chapter declares that "Patents shall be available for any new forms, uses, or methods of using a known product . . . even if such invention *does not result in the enhancement of the known efficacy* of that product."¹⁴⁷

In doing so, it explicitly requires TPP parties to allow *exactly* what Section 3(d) prohibits, down to the choice of words: patents for derivatives of an existing substance that do not "result in the enhancement of the known efficacy" of that substance.

If Article 8.1 enters the final text of the TPP, it might be the first treaty provision to explicitly prohibit countries from adopting Section 3(d)-like laws. Considering the most-favored-nation provisions in TRIPS and IIAs, the benefits of Article 8.1 will be available to branded drug manufacturers in the European Union and other entities or states that may have existing trade agreements and IIAs with TPP parties.

If it is incorporated into the TPP, there are several ways in which the anti-Section 3(d) norm expressed in Article 8.1 can spread to countries beyond those that are currently negotiating the agreement. Jean-Frédéric Morin lists at least four ways in which TRIPS-plus norms introduced in bilateral and regional trade agreements can become global norms.¹⁴⁸ First, countries that sign onto TRIPS-plus provisions might actively negotiate similar provisions in treaties with third countries.

¹⁴⁵ See OFFICE OF THE U.S. TRADE REP., *Trans-Pacific Partnership*, <http://www.ustr.gov/tpp> (last visited Apr. 11, 2013).

¹⁴⁶ See KNOWLEDGE ECOLOGY INT'L, *supra* note 12.

¹⁴⁷ *Id.* Compare this to the text of Section 3(d), *supra* Part V.B.

¹⁴⁸ See Jean-Frédéric Morin, *Multilateralizing TRIPs-Plus Agreements: Is the US Strategy a Failure?*, 12 J. WORLD INTELL. PROP. 175, 178–86 (2009).

Second, third countries might join existing treaties (such as the TPP) in order to take advantage of the overall trade benefits on offer. Third, countries that sign onto TRIPS-plus norms might form a strategic bloc in multilateral settings, and push other countries to adopt these norms. Finally, if enough countries around the world subscribe to certain TRIPS-plus norms, the World Trade Organization's dispute resolution body might employ these norms to interpret provisions in TRIPS.¹⁴⁹

Article 8.1's inclusion in the TPP may thus make it increasingly difficult for countries that wish to restrict patent layering from adopting Section 3(d). This will be an important victory for branded drug manufacturers and their home countries, as it will help keep the global patent protection landscape from tilting against their favor.

VII. CONCLUSION

This paper goes past the India-centric view that has dominated the literature on Section 3(d), and observes that the law is an effective instrument for countries that wish to restrict patent layering amidst a global patent protection landscape that makes it harder than ever to do so. The law's ability to steer clear of TRIPS and IIA obligations—the major components of the patent protection landscape—can lead to its widespread adoption beyond India. However, countries that might benefit from enacting Section 3(d)-like laws might soon find that they are unable to do so, as a new set of international trade agreements beginning with the TPP change the landscape in favor of increased protection for pharmaceutical innovators.

¹⁴⁹ Morin calls these the “Domino Effect,” the “Club Effect,” the “Coalition Effect,” and the “Interpretive Effect,” respectively. *See id.* at 178–186. Morin describes a fifth effect, the “Emulation Effect,” whereby countries embrace these norms in the belief that this will improve their ability to attract investment. *Id.* at 184. It seems unlikely to me that countries that wish to restrict patent layering will look upon states that have TRIPS-plus laws in such a manner.