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Public Citizen Comments to the United States International Trade Commission

Re: Investigation No. 332-543, Trade, Investment, and Industrial Policies in India: Effects on the U.S. Economy

Public Citizen submits the following comments in response to the request by the United States International Trade Commission (USITC) for written submissions from the public to inform the Commission's report to Congress regarding investigation No. 332-543, *Trade, Investment, and Industrial Policies in India: Effects on the U.S. Economy*.

Public Citizen is a nonprofit consumer advocacy organization based in Washington, D.C. Our areas of focus include government transparency, global trade, health care and access to medicines, among others. Public Citizen's Global Access to Medicines Program works with partners worldwide to improve health outcomes through use of pharmaceutical cost-lowering measures. We provide technical assistance to public agencies in many countries regarding their responsibilities and rights to promote public health under patent and trade rules.

Medicine Access and Innovation in Relation to the Commission's Investigation

Generic competition is the most effective way to reduce pharmaceutical prices and ensure that prices continue to fall over time. Monopoly pricing, in the case of many diseases, has led to a morally repugnant status quo in which many people die for lack of access to existing medicines. Unfortunately, patent holders frequently believe (rightly or wrongly) that they stand to make the

greatest profits selling at very high prices to the few rather than at affordable prices to the many. This is certainly the case for industry pricing of the several cancer medicines at issue in India. In developing countries, including India and countries which rely on affordable Indian generics, these pricing practices lead to preventable suffering and death.

HIV/AIDS is a striking example. In the year 2000, basic AIDS drugs cost around $15,000 per person, per year. Very few people in developing countries were able to access these drugs. An HIV-positive diagnosis was effectively a death sentence for most people worldwide. Global debates regarding patent rules, not unlike the issue before the Commission today, consumed the World Trade Organization and gave rise to mass social movements in South Africa and Thailand. Treatment advocates changed the course of history, and generic competition out of India proved it was possible to treat AIDS for a dollar a day. Now, the same drugs are available for less than $100 per year. This competition has facilitated a treatment revolution that has saved ten million lives so far.

Many cancer medicines approved recently by the Food and Drug Administration cost more than $100,000. This drives personal bankruptcies in the United States. In developing countries, many public programs, including insurance and hospitals, will not be able to afford these treatments, and patients simply will not receive them. It will take manufacturing competition, again, to save the lives of people living with many different cancers across the global south. India is the world's leading supplier of affordable generic medicines, and has a critical health role to play in the global rollout of cancer-fighting "biosimilars."

Public policy everywhere must create an environment supportive of both access and innovation. Pharmaceutical innovation today is a product of both public and private investments. For example, taken together, the U.S. National Institutes of Health (NIH) are the leading funder of

biomedical research, at about $31 billion annually. Public investments catalyzed the development of the first HIV drugs, and the U.S. Government holds rights in a number of cancer drugs today due to its role in funding their invention. India, for its part, is a supporter of a Global Research and Development Treaty that could substantially increase and improve pharmaceutical innovation investments while improving access.

The 2013 India Supreme Court decision concerning whether Novartis was entitled to a patent for a new form of the chronic myeloid leukemia drug imatinib[1] is a good example. Imatinib (active ingredient STI-571) was invented by Dr. Brian Druker at Oregon Health and Science University.[2] The National Cancer Institute at NIH provided 50% of early funding compared to the 10% contributed by Novartis. Novartis, foundations and NIH each contributed to the drug's development. Using generous estimates, Novartis' risk-adjusted spending on imatinib was less than $100 million. In 2012 alone, Glivec -- the Novartis brand for its imatinib -- made $4.6 billion worldwide.[3]

This worked out well for Novartis, but what about patients? Novartis began marketing Glivec at about $36,000 in many countries around the world. It later *raised* the price to about $92,000. In 2013, more than 100 physicians with expertise in chronic myeloid leukemia including Brian Druker published an editorial denouncing these exorbitant prices.[4]

I visited the primary cancer hospital in Quito, Ecuador several years ago, when Glivec's price was still $36,000. Even at that price, hospital staff informed me that they could not afford Glivec, and, due to patents and Novartis 'aggressive monopoly stance, the hospital had no option but to

[1] Novartis AG v. Union of India and others, Civil appeal 2706-2716 of 2013. Supreme Court of India.
[2] James Love, "R&D Costs for Glivec," Knowledge Ecology International (Apr. 3, 2013), http://www.keionline.org/node/1697.
[3] Jamie Love. R&D cost for Gleevec. see at: http://keionline.org/node/1697
[4] 11 Camille Abboud et al, "The Price of Drugs for Chronic Myeloid Leukemia (CML); A Reflection of the Unsustainable Prices of Cancer Drugs: From the Perspective of a Large Group of CML Experts," Blood, published online before print, Apr. 25, 2013, doi: 10.1182/blood-2013-03-490003.

forego offering life-saving treatment to its chronic myeloid leukemia patients. Many of those individuals are most likely dead by now.

India declined to grant a patent for a *derivative* of the original drug. (In the pharmaceutical space, many patents are absolute barriers to competition.) The decision was taken according to uniformly-applied technical standards permitted by the World Trade Organization. For this decision, lobbyists for the patent-based pharmaceutical industry have criticized India as being anti-innovation and a trade outlier.

This status quo, where companies enjoy monopolies over lifesaving medicines, even when public funding has helped develop a drug, and prices are far beyond the ability of individuals or health programs to pay, clearly demands some remedy, or at the very least, safeguards to help save lives. Compulsory licensing and standards for obtaining patents (including what qualifies as patent-eligible subject matter as well as patentability criteria) are two such safeguards. They are flexibilities preserved under World Trade Organization rules, and they are absolutely essential to protecting public health within a system that facilitates medicine monopolies.

Questions Before the Commission

The August 2, 2013 letter from Senators Baucus and Hatch and Representatives Camp and Levin requests that the Commission "conduct an investigation … regarding Indian industrial policies that discriminate against U.S. imports and investment for the sake of supporting Indian domestic industries, and the effect that those barriers have on the U.S. economy and U.S. jobs." The letter asserts that India "has applied its patent law in a discriminatory manner, particularly against innovative U.S. pharmaceutical companies, so as to advantage its domestic industries."

The letter suggests that “The overview will take a historic view, but focus on the period since 2003. It will include examples of changes in tariff and nontariff measures, including measures related to the protection of intellectual property rights.” The letter also states, “In preparing its report, we do not expect the Commission to make findings regarding the legal merits of any Indian laws or policies.”

Brief Considerations Regarding the Questions and Scope of Inquiry

Discrimination

Investigating the proposition that India has applied its patent law in a discriminatory manner requires a standard. Indian patent rules or practices cannot be considered discriminatory merely because private actors dislike some outcomes. What standard, or what types of evidence, may apply? If it were the case that India has denied certain patent rights merely because the applicants are American or otherwise foreign, such practices would satisfy our conventional understanding of discrimination, and perhaps serve for purposes of the investigation. But this is not the case. Instead, India has patent rules and practices which serve various public interests. In some cases, these may deny market exclusivity by authorizing competition or deny patent protection because the application does not satisfy the substantive requirements.

It is difficult and perhaps impossible in this context to assert discrimination without reference to the rules. Patent and trade law provide standards for what types of actions may constitute discrimination, and which serve legitimate public policy objectives. The latter include, among others, preventing patent abuse, preserving the public domain and protecting public health.

India is a member of the WTO, and party to its Agreement on Trade-Related Aspects of

Intellectual Property RIghts (TRIPS). India is therefore subject to the same international standards with regard to patents and discrimination as the United States and all other WTO members. TRIPS compliance would seem the logical, indeed the only logical, standard to which India can be held. The WTO rules exist in part precisely to govern questions of discrimination. Attempting to assert discrimination in the field of patents outside of this legal framework undermines this established international rule of law.

In short, where a case or practice is not *prima facie* discriminatory, then an assessment of discrimination requires some standard. *On what basis can the Commission identify discrimination if not under law?*

Economic Effect

How can the commission identify or measure economic effect or harm, if not according to some standard of legal rights and responsibilities?

The Commission has been asked to examine whether and to what degree American economic interests have been harmed by Indian intellectual property rules. Harm must be measured against some standard. Asserting economic harm where no legal right under any international rule has been deprived, once again, undermines those rules, and equally importantly, fundamentally misrepresents the nature of patent systems.

Specifically:

1) Patent applicants are not entitled to patents in every instance. Patent applications are evaluated according to technical criteria. Countries have freedom within WTO rules to define several of the relevant standards (see herein), in order to protect public interests in access,

innovation, competition and scientific progress.

2) Patent holders are not entitled to market exclusivity in every instance. Rather, patent holder rights are constrained by public rights, including the right of a government to license the patented technology in exchange for royalty payments to the patent holder.

A company that fails to secure a patent under the rules cannot claim profit *loss*, because this possible profit was always subject to its patent application *qualifying under these rules*. A patent applicant has no right to expected monopoly profits. How can the Commission assert an economic harm where no legitimate expectation of profit subsists?

Without a finding of some action in violation of a legal standard, some expectation guaranteed, for example, by World Trade Organization rules, it cannot be said that Indian policy or practice has inflicted economic harm, whether to profits or jobs. If the patent claimants' rights have not been infringed, if India has acted within the scope of its rights and obligations, then the policies cannot be said to have inflicted economic harm.

Measuring economic effect by comparing a current competitive product situation in India to a different scenario under which a patent holder exercised market exclusivity -- without asserting any misapplication by India of a legal rule -- would subvert the patent system. It would, in its vision, turn a system which advances the public interest by rewarding innovation and ensuring dissemination of knowledge and knowledge goods, according to rules and limits, into a system of absolute monopoly guarantees to those who claim them. This is not how patents work. How could the Commission claim to have reviewed Indian patent practice, if the review depends on a fundamental misconception of patent systems?

If the Commission, nevertheless, were to choose to identify economic effect in this manner, it would face a second difficult question: how to quantitatively measure that effect? Would the Commission claim the difference between potential profits under conditions of monopoly, charging at a profit-maximizing price, and profits (plus royalties) in a competitive situation? Would this calculation not discount the many people priced out of access to drugs under monopoly conditions?

Historic View

Pharmaceutical patent protection in India has actually intensified considerably during the period identified for the Commission's focus (since 2003). WTO rules required pharmaceutical patent protection in India beginning only in 2005. Since that time, the patent-holding industry has availed itself of patent protections, while the government has made relatively scarce use of the public rights and flexibilities to protect competition and health. India has denied several compulsory license applications, despite the obvious public health need to lower costs via much more robust pharmaceutical manufacturing competition in many disease areas. Compared to the recent industry intensification and projection of pharmaceutical monopoly power, India and other governments lag far behind in promoting corresponding health safeguards. In other words, in the critical interests of public health, India and other countries should be making far greater use of their rights under law, including compulsory licensing, than they are.

Patent Rules and American Jobs

TRIPS-plus patent laws have not been shown to create more American jobs. A 2012 report by the U.S. Patent and Trademark Office (USPTO) and Department of Commerce finding that IP-intensive industries account for 18.8 percent of U.S. jobs has been widely cited in support of

proposals to transform patent policies in the U.S. and abroad. However the report itself notes that, "The bulk of employment and value added correspond to the 60 trademark-intensive industries, which is a reflection of the nearly ubiquitous use of trademarks and logos in the marketplace."[5] Compared to the 2.5 million jobs annually attributed to the top job-supporting IP-intensive industry -- grocery stores -- the pharmaceutical industry accounts for only 291,300 jobs annually. Even so, the report, which has been widely criticized, offers no support for a causal connection between the IP-intensity of an industry and the creation of jobs in that industry, nor any consideration of the effects on job creation of varying levels of patent protection.[6]

India's TRIPS-Compliant Rules

Because it is very difficult to identify discrimination or economic effect without reference to the rules (*see above*), we believe at least some internal consideration of India's TRIPS-compliant rules is important to the Commission's inquiry. While the Commission has not been asked to make legal findings, it is relevant that India is providing the patent protections required of it under WTO. Since India is not *prima facie* discriminating against American firms, it is not clear what discrimination or economic harm the Commission could identify in the area of patents.

The TRIPS Agreement

The WTO's TRIPS agreement reserves to signatory nations certain sovereign rights and flexibilities. TRIPS allows for diversity in the methods of implementing its provisions. Members are not obliged to adopt standards that are more extensive or onerous than the TRIPS

[5] Economics and Statistics Administration & USPTO, Intellectual Property and the U.S. Economy: Industries in Focus (2012), http://www.uspto.gov/news/publications/IP_Report_March_2012.pdf.
[6] See, e.g., James Love, "The USPTO/DOC's liberal and misleading definition of IP-Intensive industries is designed to influence policy debates," Knowledge Ecology International (June 6, 2012), http://www.keionline.org/node/1432.

Agreement. TRIPS leaves countries room to adopt national policies that favor public interests, competition, encouragement of foreign direct investment (FDI), technology transfer and stimulation of local innovation.

The 'objectives' introduced by TRIPS Article 7, as well as the 'principles' within Article 8 accommodate factors that are necessary for the interpretation and implementation of the rights and obligations under the Agreement. These provisions are as effective as the other provisions of the TRIPS Agreement which indicate its object and purpose.

The objectives of Article 7 are detailed with an explicit reference to "the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge."

Article 8.1 notes that "Members may … adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development."

At the 2001 WTO Doha Ministerial Conference, WTO Members, including the United States, unanimously agreed upon a Declaration on the TRIPS Agreement and Public Health[7]. The Doha Declaration states:

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public

[7] Adopted November 14, 2001, and *available at*: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

health and, in particular, to promote access to medicines for all[8].

The flexibilities in TRIPS enable governments to mitigate, by enacting appropriate legislation and regulations, the negative impact that intellectual property rules may have on the realization of the right to health.

Patent-Eligible Subject Matter and Patentability Criteria

TRIPS Article 27.1 provides:

Subject to the provisions of paragraphs 2 and 3 [exclusions from patentability]*, patents shall be available for any inventions…* [emphasis added]

TRIPS does not define the term "invention." One crucial TRIPS flexibility is the ability of a WTO Member to determine for itself what constitutes an invention.

The United States excludes various subject matters from the definition of invention. For example, the U.S. Supreme Court recently ruled that isolated DNA is not an invention, and therefore not patent eligible[9].

If the subject of a patent claim is not an invention -- not patent-eligible -- then by definition it may not be patented, even if the subject matter claimed is otherwise new, involves an inventive step and is industrially applicable. Patent-eligible subject matter analysis is separate from, and precedes, analysis of whether a claimed invention satisfies these patentability criteria.

[8] Doha Declaration, Paragraph 4.
[9] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (U.S. 2013).

Article 27.1 does not provide definitions for 'novelty,' 'inventive step,' or 'capable of industrial application.' According to Article 1.1, WTO Members may determine substantive requirements in accordance with their own local systems and practices. The Members are free to define these three patentability criteria.

Patent Eligible Subject Matter in India (Novartis Litigation)

Recent criticisms of Indian patent rules tend to take the Patent Act's Article 3(d) as an impermissible fourth patentability criteria. (See, for example, the recent Novartis litigation.) This is not how the Indian law is structured. 3(d) falls under Chapter II of the Act, "Inventions Not Patentable," and Article 3, "What Are Not Inventions." Before patentability criteria are applied, India asks whether the subject matter of a patent qualifies as an invention, per its Article 27 right to define the term (see "Antecedents," above).[10]

3(d) could permissibly prohibit any new form of a known substance. Instead, India allows new forms to be patent eligible where they "result in the enhancement of the known efficacy of that [known] substance."[11] Patent applicants have an opportunity overcome the presumption.

The Supreme Court of India utilized the patent eligibility test under Section 3(d) in its recent decision about the anti-cancer drug Glivec. Novartis' claim was required to demonstrate improvement over the known efficacy of imatinib mesylate in order to pass the subject matter

[10] *See,* Burcu Kilic & Luigi Palombi, "The Question of Patent Eligible Subject Matter and Evergreening Practices", http://infojustice.org/archives/30314#more-30314

[11] The following are not inventions within the meaning of this Act:

[11]"(d) 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.

[11]*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;"

eligibility threshold.[12] Both the Patent Office and the Supreme Court found that Novartis failed to fulfill its burden of proof in this respect.[13]

India's Section 3(d) complies with the TRIPS Agreement.

The procedure for substantive examination of a patent application starts with the determination of subject matter eligibility. Patent eligible subject matter is governed by the definition of 'invention' in domestic law and refers to the requirement that the subject matter for which a patent is sought be inherently suitable for patent protection. It is not sufficient for a patent applicant to satisfy the criteria of patentability; to be eligible to receive a patent, the subject matter must first pass the definition of invention threshold."

In the United States, patent eligible subject matter is governed by Section 101 of the Patent Act (as opposed to Sections 102 and 103, which cover the patentability requirements of novelty and non-obviousness) and, as further defined by the courts, excludes abstract ideas, laws of nature and natural phenomena.

The USPTO recently updated the guidelines for determining subject matter eligibility under 35 USC § 101. The guidelines implement the Supreme Court's recent decisions in *Association for Molecular Pathology v. Myriad Genetics*, *Inc.*, 133 S. Ct. 2107 (2013) and *Mayo Collaborative Services v. Prometheus Laboratories*, *Inc.*, 132 S. Ct. 1289 (2012).

The Guidelines take the position that "a product claim reciting something that initially appears to be a natural product" is directed to patent eligible subject matter only if the claimed product "is

[12] Ibid
[13] Novartis AG v. Union of India and others, Civil appeal 2706-2716 of 2013. Supreme Court of India.

determined to be non-naturally occurring and markedly different in structure from naturally occurring products."[14] In other words, derivatives of natural products may not be patent eligible subject matter unless they are markedly different from natural products.

The European Patent Convention provides a non-exhaustive list of things which are not regarded as inventions, based on various policy rationales.[15] The invention requirement is "essentially separate and independent of other patentability requirements."[16]

Similarly, India's Patents Act 1970 at Section 3 contains a non-exhaustive list of things that shall not be regarded as inventions. Section 3 provides a gateway to patent derivatives of known substances with improvements in efficacy and in the meantime excludes derivatives of substances without any significant difference in properties with regard to efficacy from patentable subject matter. It thus seeks to prevent extension of the patent term by minimal or insubstantial changes to a substance, known as evergreening. The invention threshold is critically important to ensuring that patents benefit society.

Compulsory Licences: India May Issue Licenses on Grounds of its Choosing

The WTO's Doha Declaration states:

Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.[17]

[14] *Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena,* & *Natural Products, available at http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf*
[15] See, Article 52.2 of the European Patent Convention
[16] (T_0154/04 (DUNS LICENSING ASSOCIATES/Estimating Sales Activity), [2007] EPOR 38, [5]
[17] Doha Declaration, Paragraph 5(b).

Too many cancer drugs on the market today are priced vastly beyond the ability of most people and many health programs to pay. This problem is especially grave in developing countries, including India as well as the many countries which rely on generic or biosimilar medicines sourced from India. Compulsory licensing can help bring the cost of life-extending and life-saving cancer treatments under control, combating artificially high monopoly prices and still contributing meaningfully to research and development.

Since the TRIPS agreement India has issued one compulsory license and rejected several applications. In 2012 India granted a compulsory license to Natco Pharma Ltd for sorafenib, a cancer medicine patented by Bayer (and marketed at a very high price as Nexavar). India has deferred license requests since. For example, in 2013 the patent Controller rejected a license application for Bristol Myers-Squibb's Dasatinib and denied a Ministry of Health application for a license on Roche's patented breast cancer drug Herceptin. India should make more frequent use of compulsory licensing to promote public health.

The TRIPS Agreement allows countries to grant compulsory licenses on grounds of their choosing. Section 84 of India's patent law is somewhat narrower, providing three separate grounds for compulsory licensing, any one of which suffices to warrant a license: reasonable requirements of the public, price, and failure to work a patent in India. The sorafenib license is very important to public health. It makes use of each of the three grounds, but reviews of the license have emphasized health interests and price. Even if the availability of working failure (which could in some cases relate to local manufacturing) as a license grounds were objectionable as a matter of policy or law, India's other grounds -- price and the reasonable requirements of the public, including health -- are precisely the point of the WTO's Doha Declaration and compulsory licensing in the public interest. The sorafenib license does not depend on local working. It is valid and TRIPS-compliant on any of several theories, leaving little

room for criticism.

Recently the Delhi High Court issued an order[18] that Natco cannot export sorafenib under the compulsory license, a decision which limits the commercial market available to Natco, showing that India's compulsory licensing regime is not in place to serve domestic commercial interests, but rather to meet public health needs.

Working Failure is a Permitted Grounds for Licensing Under TRIPS

Does the availability of working failure as grounds for a compulsory license in Indian law nevertheless merit criticism? No. During the TRIPS negotiations, U.S.-proposed language to prohibit local working requirements was soundly rejected by the other negotiating countries. Article 31 provides no limits on grounds for compulsory licensing -- except with particular regard to semiconductors. If the drafters listed a specific limit on grounds for semiconductors, they could have also prohibited working failure grounds. They did not. *Expresio unius est exclusion alterius:* express inclusion of one thing (the semiconductor limit) implies exclusion of others (no prohibition of local working grounds). This is a standard canon of statutory interpretation. Further, TRIPS favors technology transfer (Article 7).

Compulsory Licensing Does Not Diminish Patent Rights

Article 27 of TRIPS provides that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention ... and whether products are imported or locally produced." It is important to note, however, that a compulsory license does not diminish patent

[18] Bayer Corporation v. Union of India. The High Court of Dehli. Order W.P.(C) 1971/2014 of March 26, 2016. see at: http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=63590&yr=2014

rights. Local working is not a requirement for obtaining, or even maintaining, a patent in India, but rather failure to work a patent is grounds for government authorization of others to use the patented technology in exchange for payments of royalties to the patent holder.

Governments grant patents and, similarly, retain the sovereign authority to determine under what circumstances a patent should be licensed or publicly used to promote public interests. The right of the state to license third parties or make use of a patented invention is reserved in the grant of the patent – it is part and parcel of the patent right. Patent holders are not guaranteed that the state will not make use of a patent or otherwise license it. Rather, the rights of patent holders in case of compulsory license include procedural protections (right of appeal and in some cases prior negotiation) and adequate remuneration (except where a license remedies anti-competitive practices). Notably, the sorafenib license affords a seven percent royalty to Bayer, which is high by industry averages.

Licenses are issued with enumerated conditions, and the patent holder retains the patent and its rights. Bayer may continue to compete in the Indian market.

Pharmaceutical Pricing

Critics of India have also claimed its National Pharmaceutical Pricing Policy 2012 discriminates against foreign industry. On June 27, 2013, Ms. Linda Menghetti Dempsey (Vice President of International Economic Affairs, National Association of Manufacturers) said the following with regard to the Indian government's new National Pharmaceutical Pricing Policy 2012:

"India imposes price caps on hundreds of medications. However, those caps do not apply to drugs Indian researchers develop."

However, the new pharmaceutical pricing policy, which replaces the Drugs (Price Control) Order 1995, establishes a price ceiling formula to be applied to *generic* drugs included in the National List of Essential Medicines, regardless of where they were developed (although the vast majority are *locally* manufactured). Other generic medicines are not subject to the price ceiling formula, but are limited to price increases of 10% per year (§4(xiv)).

The policy categorically excludes patented medicines from these price caps. Patented medicines exported from the U.S. to India are not subject to price ceilings imposed by the new policy. It is possible that patented medicines may, in the future, be subject to a system of reference pricing in accordance with the recommendations of the Committee on Price Negotiation for Patented Drugs (§4(xv)), which were recently open for public comments.[19] Because the Committee's report was issued six years after the Committee was formed, commentators remain quite uncertain whether the Indian government will adopt the Committee's recommendations.

The new policy also states that Indian drug manufacturers may request a five-year exemption from price controls for newly approved drugs developed with Indian investments and produced only in India (§4(xvi)). This temporary exemption exists within a legal framework in which the vast majority of price caps fall on Indian firms -- and exclusively on generic medicines manufacturers. Notably, BIO explicitly supported an exemption for medicines developed and exclusively introduced in India from the pricing policy in its public comment submission to the

[19] Section 4(xv) Patented Drugs: There is a separate Committee constituted by the Government order dated 1st February, 2007 for finalizing the pricing of Patented Drugs, and decisions on pricing of patented drugs would be taken based on the recommendations of the Committee.

Committee's report.[20]

A comprehensive consideration of India's rules affecting pharmaceuticals should acknowledge that India's new pricing policy primarily impacts generic medicines, as it explicitly excludes patented medicines from its pre-determined price controls. It is difficult to conceive of a way in which this policy on the whole could be construed as economically harming U.S. industry.

Data Protection

TRIPS Article 39 covers the "protection of undisclosed information", which relates broadly to what are generally known as trade secrets. It does not require "data exclusivity," which prevents regulators from relying on a pharmaceutical company's data to evaluate competing products. Instead, Article 39 only requires protection of undisclosed test data on new chemical entities, the collection of which involved considerable effort, against disclosure unless steps are taken to ensure that the data is protected against "unfair commercial use."

The U.S. sought a provision in TRIPS based on the The North American Free Trade Agreement (NAFTA) paragraph preventing regulators from relying on an originator's data for a reasonable period. This proposed provision was excised from the TRIPS Dunkel Draft in 1991 and never restored to the TRIPS Final Act of 1994. The refusal of TRIPS drafters to adopt the NAFTA provision is one of several factors demonstrating their intention to provide for data protection, not data exclusivity, in TRIPS.

India's rules meet the data protection requirements under Article 39.3 of TRIPS. The Drugs and

[20] "For medicines developed and introduced in India first (p. 32), BIO recommends that no price negotiation or controls be placed on these medicines by the Indian government whatsoever. This is to encourage, not discourage, the discovery of medicines primarily for the benefit of the Indian people. As noted before, placing limits on the returns of Indian biopharmaceutical companies will undoubtedly dissuade some investigators from pursuing promising discoveries" (pp.5-6).

Cosmetics Act of 1940 prohibits the disclosure of information received by an officer of the Drug Controllers' Office, except for the purpose of official business, where it is required by a court of law, or with the permission of an official superior where test data is required when considering marketing approval for a new drug. The Drugs and Cosmetics Act of 1940 does not prevent the Government from relying on the data presented by the first applicant to assess submissions by the second and subsequent applicants for similar products. It provides data protection rather than data exclusivity, and is TRIPS-compliant.

Conclusion

In conclusion, in its investigation, the Commission should strongly consider the comments above. If policies adopted by India are legally permissible under its international trade obligations, then they should not be considered barriers. The TRIPS Agreement gives broad discretion to Member countries in determining intellectual property policies, and, as clarified in the Doha Declaration, allows for wide use of flexibilities in developing these policies to promote public interests, including public health. Our analysis shows that Indian law falls well within the bounds of what is allowed under WTO rules, and therefore should not be considered discriminatory. In light of this, the Commission's report should not find these policies to be harming U.S. industrial interests. We thank the Commission for the opportunity to comment, and would welcome further engagement as it develops its report.

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