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INDIA'S PATENT SYSTEM PLAYS BY WTO RULES AND SUPPORTS GLOBAL HEALTH

PEOPLE ACROSS THE DEVELOPING WORLD DEPEND ON INDIA FOR ACCESS TO AFFORDABLE GENERIC MEDICINES. RECENTLY, SOME PHARMACEUTICAL INDUSTRY GROUPS HAVE CRITICIZED INDIA'S PATENT RULES AND PRACTICES. BUT INDIA'S PRACTICE COMPLIES WITH THE WORLD TRADE ORGANIZATION'S AGREEMENT ON TRADE-RELATED INTELLECTUAL PROPERTY RIGHTS (WTO'S TRIPS). RECENT COURT CASES AND ADMINISTRATIVE ACTIONS IN INDIA HAVE STRUCK AN APPROPRIATE BALANCE BETWEEN PROTECTING THE RIGHTS OF PATENT HOLDERS AND THOSE OF THE PUBLIC, AND ARE CRITICALLY IMPORTANT TO ADVANCING GLOBAL HEALTH.

1. India's patent rules comply with WTO standards.

India's Supreme Court recently determined that a Novartis patent application, for a derivative of a known substance treating cancer, does not qualify as an invention. This has led to some speculation that India treats efficacy as a fourth patentability criteria; it does not.

Under WTO rules, countries are free to define what qualifies as an invention (patentable subject matter), subject to three basic requirements for standards of patentability (novelty, industrial application and inventive step).[1] Like the U.S., India excludes certain categories of subject matter from patentability.

For example, In India, combinations and derivatives of known substances are "considered to be the same substance," and therefore do not qualify as inventions, "unless they differ significantly in properties with regard to efficacy."[2] While this standard is most relevant to chemical and pharmaceutical inventions--and, as the Supreme Court noted, may indeed have been inspired by a concern for "evergreening" of chemical and pharmaceutical compounds--it applies uniformly to all known substances.[3] This is in full compliance with WTO rules.[4]

2. Compulsory licensing promotes access to medicines and health, including in the context of non-communicable diseases.

Compulsory licensing allows governments to authorize generic competition with patented medicines in exchange for royalty payments to patent holders. It is a flexibility included in WTO rules. Generic competition has consistently proven the most effective way to reduce the price of medicines, and ensure prices continue to fall with time.

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.

India set a royalty rate of six percent when it licensed Bayer's patent on sorafenib (Nexavar), a treatment for kidney and liver cancer. This royalty rate is relatively high by industry standards.[5]

[1] The U.S. uses the concepts of utility and non-obviousness, respectively, which can be analogous in some cases.
[2] India Patents Act of 1970, Section 3(d).
[3] Section 3(d) follows Section 3(c), which codifies the natural law doctrine recognized in the U.S. (which excludes abstract ideas, natural laws and products of nature from patentable subject matter). Section 3(d) of the Indian Patents Act excludes known substances from patent-eligible subject matter.
[4] In fact, it was not until 1995 that the U.S. Federal Circuit ruled in *In re Brana* that utility for a pharmaceutical invention does not depend on FDA approval; and it was not until 2006 that the Federal Circuit ruled in *Amgen Inc. v. Hoechst Marion Roussel, Inc.* that therapeutic utility does not depend on demonstrated effects on living humans.
[5] James Love, World Health Organization & United Nations Development Program, "Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies," WHO/TCM/2005., 34, http://keionline.org/sites/default/files/who_undp_2005_royalty_guidelines.pdf.

3. India has the right to issue compulsory licenses on grounds of its choosing.

According to the WTO, "Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."[6] There are no WTO rules which limit compulsory licensing to HIV, epidemics or emergencies, and no rules which prevent India from issuing licenses to address high prices.[7] According to the WTO, the TRIPS Agreement "should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."[8] U.S. courts issue compulsory licenses to remedy anti-competitive practices, and U.S. agencies have broad authority to make government use of patents.

4. Public and charitable institutions have contributed significantly to the research and development (R&D) of new cancer drugs, including Glivec.

Together, the taxpayer-supported National Institutes of Health (NIH) are the world's largest funder of biomedical research (roughly $30 billion annually). NIH has contributed significantly to the invention of many cancer drugs, including Glivec, the subject of the Novartis litigation in India.

The research leading up to STI-571, Glivec's active chemical ingredient, was supported in large part through public funding.[9] The National Cancer Institute at NIH provided 50% of the funding for this work compared to the 10% contributed by Novartis. Despite the significant public funding supporting Glivec's R&D, its price--which skyrocketed from $30,000 per year to $92,000 per year even though Novartis's former CEO explained that the original price was sufficient to recoup R&D costs and yield a sustainable profit[10]--has kept it out of reach of many patients.

In 2013, more than 100 physicians with expertise in chronic myeloid leukemia (the condition treated by Glivec)--including the lead scientific researcher in the development of STI-571, Dr. Brian Druker, published an editorial denouncing these exorbitant prices.[11]

5. Stringent patent laws have not been shown to create more American jobs.

Last year's report by the U.S. Patent and Trademark Office (USPTO) and Department of Commerce finding that IP-intensive industries account for 18.8% 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."[12] 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.[13]

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[6] Doha Declaration on the TRIPS Agreement and Public Health, Paragraph 5(b).
[7] The WTO's Frequently Asked Questions page refers to the idea of an emergency requirement as a "common misunderstanding," http://www.wto.org/english/tratop_e/TRIPs_e/public_health_faq_e.htm.
[8] Doha Declaration at para. 4
[9] James Love, "R&D Costs for Glivec," *Knowledge Ecology International* (Apr. 3, 2013), http://www.keionline.org/node/1697.
[10] D. Vasella, "Magic Cancer Bullet-How a Tiny Orange Pill is Rewriting Medical History," 178-181 (2003).
[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.
[12] 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.
[13] *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.