Indian Pharmaceutical Industry Challenges

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Organisation of Pharmaceutical Producers of India
Prelude

OPPI acknowledges the challenges India faces in extending healthcare access to its large and growing population. Our members are concerned about patients’ access to medicines and are committed to working with the Government of India to provide sustainable access to medicines and healthcare overall. This includes making significant investments in the research and development of new medicines that will address significant unmet healthcare needs in Indian patients. Sustainable solutions to India’s healthcare concerns should be found through programs that prioritize healthcare financing, infrastructure, availability, human resource needs, and environmental and societal factors to achieve the goal of widespread access.

We remain concerned, however, about public policy issues that affect our member companies, as well as the broader healthcare industry in India. These policies are not likely to expand access and, in most cases, may even limit the availability of innovative medicines produced by both domestically owned companies and OPPI member companies because they create an environment that does not recognize the value of innovation. Further, there have been a number of negative policies that create market access barriers, including proposed further implementation of price controls, high import duties, and non-transparent clinical trials regulations. We welcome the opportunity to work with the Indian Government in designing an equitable approach and implementing a system that is appropriate to India and balances the need to support innovation while enhancing access.

Key Issues of Concern:

- **Patent protection**: India’s legal and regulatory systems pose procedural and substantive barriers at every step of the process, ranging from the impermissible hurdles to patentability posed by Section 3(d) of the India’s patents act, to the threat of compulsory licensing on specious grounds, to pre-grant and post-grant opposition proceedings. Since early 2012, at least fifteen products have had their patent rights undermined in India. In addition, the Government of India is considering issuance of compulsory licenses (CLs) through a Ministry of Health Committee on the grounds of national emergency; extreme urgency, and public non-commercial use.

- **Lack of regulatory data protection**: The Indian Regulatory Authority relies on test data submitted by originators to another country when granting marketing approval to follow-on pharmaceutical products. This indirect reliance results in unfair commercial use prohibited by the World Trade Organization (WTO)Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and discourages the development of new medicines that could meet unmet medical needs.
• **Government price controls:** The Department of Pharmaceuticals (DoP) has proposed an international reference pricing scheme with a purchasing power parity adjustment for government procured patented medicines and those patented medicines provided through health insurance. This proposal would create an unviable government pricing framework and business environment for medicines whose price levels in India are already low in comparison to other countries. The Drug Price Control Order (DPCO) 2013 includes a provision discriminating against foreign products by exempting only indigenous research and development.

• **Clinical trials:** New clinical trials were halted after the Indian Ministry of Health and Family Welfare adopted rules that require broader compensation for participants who claim to have been injured due to a clinical trial. Most recently, the Drug Controller General of India (DCGI) ordered that, in addition to obtaining written informed consent, audio-visual recording of the consent of each subject is mandatory in a clinical trial and effective immediately. Such uncertainty in the regulatory process for clinical trials threatens the overall clinical research environment in India, as well as the availability of new treatments and vaccines for Indian patents.

The compounding effect of the policies and practices summarized above is to “deny adequate and effective intellectual property rights” and to “deny fair and equitable market access” to the IP-intensive, research-based biopharmaceutical industry.

Moreover, despite the business community’s sustained work to raise concerns about the impact of these policies on the innovative biopharmaceutical industry’s products, research, and intellectual capital, the Indian Government has been unwilling to engage on these issues and make progress toward a reasonable solution. For example, India has been listed on the U.S. Trade Representative Special 301 Priority Watch List – requiring increased bilateral attention – *every year* since the first Special 301 Report in 1989 (except for three years when India was designated as a Priority Foreign Country). The U.S. Chamber of Commerce’s Global Intellectual Property Center placed India last out of 25 countries included in its 2014 International IP Index, well behind Ukraine, which was designated as a Priority Foreign Country in USTR’s 2013 Special 301 Report.¹ Yet India continues to embrace these damaging policies, especially its IP rules, by publicly highlighting them as models for other emerging economies while touting the flourishing Indian generic medicines industry and other industries that have benefited from India’s industrial policies.

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Intellectual Property Protections

Narrow Standards for Patentability

TRIPS requires that an invention which is new, involves an inventive step, and is capable of industrial application, be entitled to patent protection. Section 3(d) of the Indian Patents Act as amended by the Patents (Amendment) Act 2005 adds an impermissible hurdle to this by adding a fourth substantive criteria of “enhanced efficacy” to the TRIPS requirements. Moreover, this additional hurdle appears to be applied only to pharmaceuticals. Under this provision, salts, esters, ethers, polymorphs, and other derivatives of known substances are presumed to be the same substance as the original chemical and thus not patentable, unless it can be shown that they differ significantly in properties with regard to efficacy.

Additional requirements for patentability beyond that the invention be new, involve an inventive step and capable of industrial application, are inconsistent with the TRIPS Agreement. Article 27 of the TRIPS Agreement provides a non-extendable list of the types of subject matter that can be excluded from patent coverage, and this list does not include “new forms of known substances lacking enhanced efficacy,” as excluded by Section 3(d) of the Indian law. Therefore, Section 3(d) is inconsistent with the framework provided by the TRIPS Agreement. Moreover, Section 3(d) represents an additional hurdle for patents on inventions specifically relating to chemical compounds and, therefore, the Indian law is in conflict with the non-discrimination principle also provided by TRIPS Article 27. From a policy perspective, Section 3(d) undermines incentives for innovation by preventing patentability for improvements which do not relate to efficacy, for example an invention relating to the improved safety of a product.

Other examples of the overly narrow standards for patentability in India are the recent patent revocations using “hindsight” analysis made during post-grant oppositions and pre-grant oppositions citing a lack of inventiveness concluding that the patent applications are based on “old science” or failed to demonstrate an inventive step.

Compulsory Licenses on Patented Pharmaceutical Products

The Government has set up a Committee under the Ministry of Health and Family Welfare (MoH Committee), which has been tasked with examining the medicines under patent which are required for various diseases such as HIV/AIDS, cancer, diabetes, Hepatitis C, TB, and MDR TB and which they assert are not affordable on account of the price barriers created by patents. The Government Committee is proceeding under the special provisions of Section 92 and Section 66 of India’s Patents Act for grant of CLs, which would make it even more difficult for patent owners to defend their
patents. In fact, it is reported that the Government of India is considering whether to issue CLs under Section 92 on approximately 20 patented medicines across a wide range of therapeutic areas. None of the grounds have been justified and the Government has not given any of the patentees a chance to be heard.

On March 9, 2012, India issued the first-ever CL for an anti-cancer patented pharmaceutical product. The research-based pharmaceutical industry is concerned that the findings in the CL decision on the working requirements contravene India’s obligations under the TRIPS Agreement (as well as the General Agreement on Tariffs and Trade and the WTO Agreement on Trade-related Investment Measures), which prohibit WTO members from discriminating based on whether products are imported or locally produced. Moreover, India’s use of CLs in these circumstances distorts provisions that were intended to be used in limited circumstances into tools of industrial policy. We further believe that resort to CLs is not a sustainable or effective way to address healthcare needs. Voluntary arrangements independently undertaken by our member companies can better ensure that current and future patients have access to innovative medicines. Statements from the Government incorrectly imply that CLs are widely used by other governments, both developed and developing. These are misunderstandings and do not justify widespread use of compulsory licensing.

At a minimum, India should ensure that the CL provisions comply with TRIPS. India should also clarify that importation satisfies the “working” requirement, pursuant to TRIPS Article 27.1.

Unnecessarily Burdensome Patent Application Requirements

Section 8 of the Patents Act, as interpreted by recent jurisprudence, sets forth overly burdensome requirements that effectively target foreign patent applicants in a discriminatory manner. Section 8(1) requires patent applicants to notify the Controller and “keep the Controller informed in writing” of the “detailed particulars” of patent applications for the “same or substantially the same invention” filed outside of India. Section 8(2) requires a patent applicant in India to furnish details to the Indian Controller about the processing of those same foreign patent applications if that information is requested. These additional patent application processing requirements have been interpreted in a manner that creates heightened and unduly burdensome patent application procedures that target foreign patent applicants – those most likely to have patent applications pending in other jurisdictions.

Moreover, the remedy for failure to comply with Sections 8(1) and 8(2) is extreme compared

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2 See https://www.indianembassy.org/prdetail2164/note-on-indiaandrsquo%3Bs-intellectual-property-regime and http://thehill.com/blogs/congress-blog/campaign/316883-india-honors--not-dishonors--patent-laws. These allegations of wide-spread use of CLs in the U.S. and the premise that CLs can resolve access problems in India have been refuted by OPPI and PhRMA.
to other countries with similar (but less onerous) administrative requirements. In India, the failure to disclose under Section 8 can be treated as a strict liability offense that by itself can invalidate a patent. This is in contrast to a requirement that the failure to disclose be material and/or intentional as in the U.S. or Israel. Thus, India’s disclosure requirement and remedy are each more burdensome as compared to other jurisdictions, thereby creating a barrier to patentability that has an unfairly greater effect on foreign patent applicants, and, in some instances resulted in India revoking patents on the grounds of non-compliance with this particular provision.³

Patent Enforcement and Regulatory Approval

Indian law permits state drug regulatory authorities to grant marketing approval for a generic version of a medicine four years after the original product was first approved. State regulatory authorities are not required to verify or consider the remaining term of the patent on the original product. Therefore, an infringer can obtain marketing authorization from the government for a generic version of an on-patent drug, forcing the patent holder to seek redress in India’s court system. India should close this regulatory loophole in order to provide effective patent protection and enforcement for pharmaceutical patent holders.

Moreover, India does not provide mechanisms for resolution of patent disputes prior to marketing approval of third party products. Such mechanisms are needed to prevent the marketing of patent infringing products. There is a pending bill in the Indian Parliament that would establish fast-track IP Courts and assist in addressing disputes.

Lack of Regulatory Data Protection

TRIPS Article 39.3 requires India to provide protection for certain pharmaceutical test and other data, but India has not yet done so. India conditions the approval of pharmaceutical products on the prior approval by a Regulatory Authority in another country rather than requiring submission of the entire dossier for review by its Regulatory Authority. An applicant in India needs only to prove that the drug has been approved and marketed in another country and submit confirmatory test and other data from clinical studies on a very few (in some cases as few as 16) Indian patients.

By linking approval in other countries that require the submission of confidential test and other data to its own drug approval process, India, in effect, uses those countries as its agents. Thus, India relies on test data submitted by originators to another country. This indirect reliance results in unfair commercial use prohibited by TRIPS Article 39.3.

Market Access Barriers

Government Price Controls

OPPI members are concerned about the general lack of access to health care in India. For a country of over one billion with significant healthcare issues, the Indian Government spends only 1.2% of GDP on healthcare. India has an insufficient numbers of qualified healthcare personnel, inadequate and poorly equipped healthcare facilities, and most importantly lacks a comprehensive system of healthcare financing which would pool financial risk through insurance and help to share the cost burdens. However, India has thousands of manufacturers of pharmaceuticals who operate in a very competitive environment, and as a result, India has some of the lowest prices of medicines in the world. Despite decades of government price controls in India, the objective of which has been to improve access to medicines, essential medicines are still not easily accessible; for example, essential medicines may only be available at government pharmacies 20 percent of the time.

Expansion of price controls to a larger range of medicines will not substantially improve access to medicines in India because lack of access is more a function of insufficient healthcare financing systems and inadequate healthcare facilities. For example, medicines and vaccines which are offered free of charge often do not reach the patients who need these medicines. Further, a considerable body of evidence demonstrates that price controls contribute to lower investment in pharmaceutical research and development, ultimately harming patients who are in need of improved therapies.

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6 Analysis based on IMS MIDAS Data.
The Department of Pharmaceuticals (DoP) Committee on Price Negotiation for Patented Drugs released a report in February 2013 which recommends an international reference pricing scheme with a purchasing power parity adjustment for government procured patented medicines, those patented medicines provided through health insurance. The Committee is also considering whether the price negotiation of a patented medicine should be linked with its marketing approval. OPPI members are highly concerned that this proposal represents an effort to significantly reduce the benefits of patent protection, will discriminate against importers of patented drug products, and will create an unviable government pricing framework and business environment.

In May 2013, the DoP notified and NPPA began implementing the Drug Price Control Order (DPCO) 2013, which sets ceiling prices for 348 essential medicines by taking the simple average of all drugs with a market share of 1% or more. OPPI advocated for a market-based policy, rather than a cost-based policy, in order to balance the need for affordability and industry competitiveness. The DPCO has faced ongoing challenges by NGOs before the Supreme Court, which has been monitoring the Government’s progress through public interest litigation, as well as questions about accuracy of ceiling price calculations. Finally, the DPCO 2013 also includes Section 32 that exempts from the pricing formula, for a period of five years, new medicines developed through indigenous research and development that obtain a product patent, are produced through a new process, or involve a new delivery system. This section creates an unlevel playing field that favours local Indian companies and discriminates against foreign pharmaceutical companies.

OPPI members believe that competitive market conditions are the most efficient way of allocating resources and rewarding innovation; however, the research-based pharmaceutical industry recognizes the unique circumstances in India and is committed to engaging with the Government to discuss pragmatic public policy approaches that will enable the development of simple and transparent government pricing and reimbursement mechanisms that provide access to medicines, reward innovation, include the patient perspective, and encourage continued investment into unmet medical needs.

Foreign Direct Investment (FDI) in Pharmaceutical Sector

The Indian government recently decided that the current policy in brownfield and greenfield projects in the pharmaceutical sector will continue, subject to the additional condition that in all cases of FDI in brownfield pharmaceutical projects, non-compete clauses will not be permitted in any of the agreements. Per this policy, outright purchases of brownfield projects require prior approval from the Foreign Investment Promotion Board. The new restrictions on the use of non-compete clauses have the potential to significantly undermine FDI in brownfield investments, given that without such clauses a local company may sell its business to a foreign investor only to use its
knowledge, expertise and former goodwill (on which such sales are typically predicated) to immediately compete with the foreign investor. In short, these ongoing changes lead to an atmosphere of uncertainty for potential investors.

Clinical Trials

New clinical trials were halted after the Indian Ministry of Health and Family Welfare adopted rules that require broader compensation for participants who claim to have been injured due to a clinical trial. The tougher regulations, coming in response to public protests over reported deaths in clinical trials last year, have stopped or delayed a number of studies. The Indian government and Supreme Court had begun a process working with trial sponsors to modify the rules. The Court previously held that, rather than the Drug Controller, the Secretary of Health shall be accountable for the approval of all clinical trials related to Investigational New Drugs (IND), which had caused a significant decline in the number of approved trials. In response to public interest litigation, the Indian Supreme Court instituted a full moratorium on clinical trials, asking the Ministry of Health to justify its recent approvals and put forward an appropriate framework for approval of clinical trials. In November, the Drug Controller General of India (DCGI) ordered that, in addition to obtaining written informed consent, audio-visual recording of the consent of each subject is mandatory in a clinical trial and effective immediately. Such uncertainty in the regulatory process for clinical trials threatens the overall clinical research environment in India, as well as the availability of new treatments and vaccines for Indian patents.

Import Policies

Despite the stated intention by the Government to lower pharmaceutical duties, OPPI member companies face high effective import duties for active ingredients and finished products. Though the basic import duties for pharmaceutical products average about 10 percent, additional duties commensurate with the excise duty applicable on the same or similar product, even when there is no such product manufactured in India, as well as other assessments, bring the effective import duty to approximately 20 percent. In fact, India collects more in taxation on pharmaceuticals than it spends on medicines. Broad analysis for 2011 indicates total annual Government expenditure on drugs in India around $1.15B in comparison to the $1.22B it receives in taxation of pharmaceuticals.

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13 High Level Expert Group (HLEG) report on Universal Healthcare Coverage for India 2011, Instituted by
Moreover, excessive duties on the reagents and equipment imported for use in research and development and manufacture of biotech products make biotech operations difficult to sustain. Compared to the other Asian countries in similar stages of development, import duties in India are very high.

**Counterfeit Medicines**

India is a major channel for the export of counterfeits to consumers worldwide. In cases where counterfeit pharmaceutical products bear a deceptive mark, civil and criminal remedies are available under India’s trademark statute. However, the effectiveness of such remedies is undermined by judicial delays and, in criminal cases, extremely low rates of conviction.

Beyond these trademark-related deficiencies, weaknesses in India’s drug regulatory regime can contribute to the proliferation of counterfeit pharmaceuticals and their global export. Even though pharmaceutical counterfeiting is first and foremost a drug safety violation, India has yet to enact drug laws that expressly address all aspects of drug counterfeiting, or to provide the kind of remedies and enforcement resources necessary to combat this growing problem. In India, criminal liability appears to be conditioned upon proof of adulteration or harm. This burdensome evidentiary requirement not only precludes criminal prosecution of many counterfeiters, it fails to acknowledge the inherent dangers of any deceptively mislabeled drug.

Anti-counterfeiting enforcement is further undermined by poor interagency coordination and India’s failure to provide administrative remedies for drug safety violations.

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14 Includes domestic tax (VAT and excise duty) and import taxes; based on broad analysis of 2011 data representative at National level – state level data not investigated. Source: Indian Department of Pharmaceuticals Annual Report 2012, HLEG report on Universal Healthcare Coverage for India 2011.