INDIA

PhRMA and its member companies remain concerned about the challenging policy environment in India. We support the Modi Administration’s efforts to create a world-class intellectual property (IP) environment in India, which can foster innovation, drive economic growth, and enhance India’s global competitiveness. While pharmaceutical innovators saw potentially positive signs and statements from the Indian Government in 2015, translating these positive statements into concrete progress and real results has remained a challenge. Despite initially identifying healthcare as a priority, the Indian Government has not increased investment in this critical area, leaving public healthcare spending at a very low level of approximately 1 percent of GDP. Negative policies remain and may limit Indian patient access to innovative medicines.

While important policy issues remain, on balance, we are encouraged by recent efforts to improve the Indian Patent Office’s (IPO) operations, as well as recent decisions by the IPO and Indian courts with respect to innovator pharmaceutical patent protection and enforcement. We hope the forthcoming National Intellectual Property Rights (IPR) Policy will reflect the Prime Minister’s desire to “work on [India’s] intellectual property rights guidelines to match global standards.” In addition to supporting the Government’s “Make in India” program goals of fostering innovation, facilitating investment, and protecting IP, a strong IPR Policy promoting consistent and predictable rules could accelerate the progress required to stimulate innovation, improve health and bring new medicines to market for Indian patients. Depending on the substance of the forthcoming National IPR Policy, it could be a catalyst for considering revising India’s position in the context of the Special 301 going forward.

The innovative biopharmaceutical industry greatly appreciates the efforts to address these concerns at the highest levels of the U.S. and Indian Governments. We welcome the opportunity to continue working with the U.S. and Indian Governments to improve access to medicines, and healthcare overall, by removing market access barriers and fostering legal and regulatory certainty for the protection of IP in India.

Key Issues of Concern:

- **Generally weak IP environment**: India’s legal and regulatory systems pose procedural and substantive barriers at every step of the patent process, ranging from the impermissible hurdles to patentability posed by Section 3(d) of India’s Patents Act to the narrow patentability standards applied in pre-grant and post-grant opposition proceedings. Not only is this a concern in the Indian market, but also in other emerging markets that may see India as a model to be emulated.

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80 See www.makeinindia.com.
Since early 2012, roughly twenty-five products have had their patent rights undermined in India. In 2015 alone, at least six products have faced issues due to the continued denial of applications under Section 3(d), infringement due to state-level marketing authorization for generic versions of on-patented drugs, and the threat of compulsory licenses (CLs), all of which demonstrate that there have been no concrete policy improvements in India.

- **Regulatory data protection failures:** The Indian Regulatory Authority relies on test data submitted by originators to seek approval in 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.

- **High tariffs and taxes on medicines:** Medicines in India 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 and assessments bring the effective import duty to approximately 20 percent. India collects more in taxes on pharmaceuticals than it spends on medicines.

- **Discriminatory and non-transparent market access policies:** A decision by an Inter-Ministerial Committee on a patented medicines pricing policy is still pending. The lack of transparency in the Committee process and the threat of an existing recommendation for strict price controls represent an effort to significantly reduce the benefits of patent protection, which will discriminate against importers and create an unviable government pricing framework and business environment for medicines in India. In addition, a provision under the Drug Price Control Order 2013 discriminates against foreign pharmaceutical companies by exempting new medicines developed through indigenous research from price controls.

- **Burdensome environment for clinical research:** While the Government is keen to reinvigorate clinical research in India, ambiguities continue to prevail in the Indian regulatory space. In particular, the ambiguities in the definition of “trial related injury”, a lack of appeals mechanism in decisions about causation, and criminal penalties for trial sponsors who deviate from clinical trials protocol continue to perpetuate a burdensome environment for clinical research and undermines the availability of new treatments and vaccines for Indian patents.

As noted above, the issues outlined in USTR's 2015 Special 301 Report remain significant areas of concern. In its 2015 report, USTR noted its expectation that “new

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81 Government of India Speed Post No. 31011/5/2009/Pl-II(pt), Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals, Subject: Inter-Ministerial Committee on Prices of Patented Drugs. New Delhi, Feb. 17, 2014.
channels for engagement created in the past year will bring about substantive and measurable improvements in India’s IPR regime” and that it would “monitor progress over the coming months .” Continued attention to IP and market access barriers in India has been a strong signal of the importance of these issues to the bilateral relationship and has been critical in preventing further deterioration of the innovation environment in that country. However, no meaningful action has been taken to address these barriers, and significant unpredictability in IP protection and enforcement remains.

For these reasons, PhRMA requests that India remain on the Priority Watch List in the 2016 Special 301 Report. Further, we urge USTR to provide an opportunity for a meaningful assessment of India’s IP regime through an Out-of-Cycle Review, so that the U.S. Government can evaluate progress on these important issues and dedicate the required bilateral attention necessary to translate India’s commitments into substantive and real policy change in the IP and market access barriers confronted by U.S. businesses in India.

**Intellectual Property Protection**

Following Prime Minister Modi’s visit to the United States in September 2014, India announced it would constitute an IPR Think Tank to draft a national policy on IP policy and advise the government on best IP practices to be followed in trademark offices, patent offices and other government offices in order to create an efficient and transparent system of functioning.\(^82\) India’s Draft National IP Policy, published for stakeholder comments in December 2014,\(^83\) recognized the tremendous economic and socio-cultural benefits that a strong IP regime could bring to India through economic growth, employment, and a vibrant R&D environment, but fell short of putting forward any meaningful improvements to patent protection and enforcement for medicines. The final policy, which is under deliberations within the relevant government ministries, is expected to put forward important administrative and procedural improvements, but do little to improve the business environment for the biopharmaceutical sector.

**Restrictive Patentability Criteria**

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 patentability 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

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same substance as the original chemical entity and thus not patentable, unless it can be shown that they differ significantly in properties with regard to efficacy.

Additional substantive 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 provided by TRIPS Article 27. The additional patentability hurdle imposed by section 3(d) was recently reinforced by the Pharmaceutical Patent Examination Guidelines issued in October 2014. Rule 122E of the Drugs and Cosmetics Rules states that a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier. The Drugs and Cosmetics Act goes on to specify that “Where an application under this Rule is for the manufacture of drug formulations falling under the purview of new drug as defined in rule 122-E, such application shall also be accompanied with approval, in writing in favor of the applicant, from the licensing authority.” Thus, to obtain a manufacturing license for a new drug, the Central Drug Regulatory must provide written approval. In the case of drugs which do not meet the definition of a new drug, an “Application for grant and renewal of license to manufacture for sale or distribution of drugs shall be made to the licensing authority appointed by the State Government.” See Ministry of Health and Family Welfare, “The Drugs and Cosmetics Rules, 1945 (As amended up to the 30th June 2005)”, available at http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf (last visited Feb. 5, 2016).

Weak Patent Enforcement

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 protection 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, which often results in irreparable harm to the patent holder. 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 notification or resolution of patent disputes prior to marketing of third party products. Such mechanisms are needed to prevent the marketing of patent-infringing products and resolve disputes in a timely manner. In recent examples, the patent holder waited two and a half years before the Court provided injunctive relief. In another example, the patent holder waited seven years before receiving a Court decision upholding its patent. The Court, however, neglected to grant an injunction because the patent is set to expire in early 2016. The pending Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Bill, 2015, provides for the creation of commercial divisions and commercial appellate divisions in high courts, and commercial courts at the district level to assist in addressing disputes in a timely manner. Additionally, the draft National IPR Policy proposes to establish specialized patent benches at the High Court level and designate an IP court at the district level. While this is a promising development, these courts will require a significant amount of technical expertise and commitment of resources to be properly implemented.

Compulsory Licensing

The Indian Government appears to have taken a more measured and cautious approach in responding to recent CL cases, including the denial of two CLs this year. We are encouraged by this trend. However, the grounds for issuing a CL under the provisions are broad, vague and appear to include criteria that are not clearly related to legitimate health emergencies. The Ministry of Health (MOH) continues to make recommendations to impose CLs on certain anti-cancer medicines under the special provisions of Section 92 of India’s Patents Act, which would make it even more difficult for patent owners to defend their patents. Moreover, Indian pharmaceutical companies continue to use Section 84 of the Patent Act as a commercial tool under the guise of better access to medicines, rather than a measure of last resort. The ongoing threat of CLs perpetuates the unreliable environment for patent protection in India.

The research-based pharmaceutical industry believes that the findings on the working requirements in the CL decision for a patented anti-cancer medicine in March 2012 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. The Bombay High Court further interpreted the working requirement to specify that satisfaction of the working requirement “would need to be decided on a case to case basis” and that “the patent holder would nevertheless have to satisfy the authorities under the Act as to why the patented invention was not being manufactured in India.”\(^\text{90}\) The Indian Supreme Court refused to hear the appeal arising out of the Bombay High Court judgment thereby perpetuating the ambiguity of the CL criterion and terms of use.

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.\(^\text{91}\) These are misunderstandings and do not justify widespread use of compulsory licensing.

At a minimum, India should ensure that CLs are exercised with extreme caution and as a measure of last resort. India should also clarify that importation satisfies the “working” requirement, pursuant to TRIPS Article 27.1.

**Regulatory Data Protection Failures**

Contrary to its TRIPS Article 39.3 obligation, India fails to ensure that there is no unfair commercial use of the regulatory data submitted by another party in securing marketing approval in a third country. Rather, when a pharmaceutical product has been previously approved by a Regulatory Authority in another country, India requires only limited clinical data (in some cases involving as few as 16 Indian patients). This is in lieu of requiring submission of the entire dossier for review by India’s Regulatory Authority. Moreover, in some instances when an applicant seeks approval for a drug that has already been approved abroad, Indian authorities waive the requirement to submit even this data.\(^\text{92}\) In those circumstances, any subsequent approval of the drug in India is based entirely on the prior approval of the drug in a third country.

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. Approval by the Indian regulatory authorities based on third-

\(^{90}\) *Bayer v. Union of India*, Writ Petition No. 1323 of 2013.

\(^{91}\) See, e.g., http://thehill.com/blogs/congress-blog/campaign/316883-india-honors--not-dishonors--patent-laws (last visited Feb. 5, 2016). 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.

country approvals amounts to indirect reliance on the clinical trial and other test data that underlie the third-country approvals. This indirect reliance results in unfair commercial use prohibited by TRIPS Article 39.3.

Administrative Burdens

Section 8 of the Patents Act sets forth overly burdensome requirements that effectively target foreign patent applicants in a discriminatory manner since foreign applicants are more likely to have filed patent applications for the same invention in other jurisdictions. 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 mainly impact foreign patent applicants – those most likely to have patent applications pending in other jurisdictions. Further, Section 8 was enacted in 1970 when the information was only available from the applicant; much of the information sought is now publicly available on patent office websites in most major countries. For example, through the Global Dossier Initiative of five major patent offices (the U.S. Patent and Trademark Office, the European Patent Office, the State Intellectual Property Office of China, the Japanese Patent Office, and the Korean Intellectual Property Office), the current file histories from each of these offices are accessible at one website. Thus, accurate information about counterpart foreign applications is easily available to the Indian Patent Office Examiners.

Additionally, recent requests pursuant to Section 8(2) for the translation of foreign search and/or examination reports are not only unduly burdensome but costly as well. In practice, attorneys routinely receive informal translations of foreign search and/or examination reports intermingled with local attorney advice and counsel (information subject to attorney-client privilege). Moreover, translations of the search and/or examination reports may not yet be available at the time of the Section 8(2) request.

Moreover, the remedy for failure to comply with Sections 8(1) and 8(2) is extreme compared 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 (although a recent court decision indicates some flexibility for mere clerical errors). 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.\(^{93}\)

Market Access Barriers

High Tariffs and Taxes on Medicines

PhRMA member companies operating in India 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 and assessments are imposed that bring the effective import duty total to approximately 20 percent. In fact, India collects more in taxes on pharmaceuticals than it spends on medicines. Broad analysis indicates total annual Government expenditure on drugs in India around $1.15B\textsuperscript{94} in comparison to the $1.22B\textsuperscript{95} it receives in taxation of pharmaceuticals. 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.

Discriminatory and Non-Transparent Market Access Policies

PhRMA’s members are concerned about the general lack of access to healthcare in India. The Indian government circulated a draft National Health Policy\textsuperscript{96} early in 2015 that called for greater access to healthcare for low-income patients. 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.\textsuperscript{97} Still, government spending on healthcare remains at 1 percent of GDP, one of the lowest levels of expenditure in the world.\textsuperscript{98} In the absence of increased resources and reform, high out-of-pocket spending on healthcare and pressure on the cost of medicines persist. 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.\textsuperscript{99} Still, 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.\textsuperscript{100}

\textsuperscript{94} High Level Expert Group (HLEG) report on Universal Healthcare Coverage for India 2011, Instituted by Planning Commission of India.

\textsuperscript{95} 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.


\textsuperscript{100} Analysis based on IMS MIDAS Data.
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, poor access to physicians, and inadequate healthcare facilities.\(^{101}\) For example, medicines and vaccines which are offered free of charge often do not reach the patients who need these medicines.\(^{102}\) A recent study by IMS on “Analyzing the Impact of Price Controls on Access to Medicines” found that price controls are neither an effective nor a sustainable strategy for improving access to medicines. The study further found that the primary beneficiaries of price controls have been high-income patients, rather than the intended low-income population.\(^{103}\) 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.\(^{104}\)

The Department of Pharmaceuticals (DoP) Committee on Price Negotiation for Patented Drugs released a report in February 2013 which recommended an international reference pricing scheme with a purchasing power parity adjustment for government procured patented medicines, and those patented medicines provided through health insurance. The Committee also considered whether the price negotiation of a patented medicine should be linked with its marketing approval. In 2014, an Inter-Ministerial Committee was constituted to suggest a methodology to be applied to pricing of patented medicines before their marketing in India.\(^{105}\) While the Committee has met several times in recent months, the decision on a patented medicines pricing policy is still pending. PhRMA members are highly concerned that the lack of transparency in to the Committee process and the threat of the existing recommendation represent an effort to significantly reduce the benefits of patent protection, which will de facto discriminate against importers, and will create an unviable government pricing framework and business environment for innovative pharmaceutical companies.

In July 2014, the National Pharmaceutical Pricing Authority (NPPA), without prior notice to industry, issued 50 identical orders setting prices for 108 non-scheduled diabetes and cardiovascular medicines beyond the scope of the existing Drugs Prices

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\(^{105}\) Government of India Speed Post No. 31011/5/2009/PI-II(pt), Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals, Subject: Inter-Ministerial Committee on Prices of Patented Drugs. New Delhi, Feb. 17, 2014.
Control Order (DPCO), 2013, which sets ceiling prices for 348 essential medicines.\textsuperscript{106} The notifications fall under Paragraph 19, which authorizes the NPPA “in case of extraordinary circumstances, if it considers necessary so to do in public interest, [to] fix the ceiling price or retail price of any Drug for such period, as it may deem fit.”\textsuperscript{107} Subsequently, NPPA withdrew the underlying guidelines,\textsuperscript{108} but continued to pressure the industry to implement the prices fixed by the July 2014 orders. Transparency and predictability are paramount to a robust environment for business investment. These recent pricing decisions, as well as the broad authority granted to NPPA under this provision, do not respect the need for transparency, predictability, and trust in the decision-making process.

Finally, Paragraph 32 of the DPCO 2013 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 un-level playing field that favors local Indian companies and discriminates against foreign pharmaceutical companies.

PhRMA 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.

Burdensome Environment for Clinical Research

India has many of the components of an effective regulatory system, such as institutional capacity across central and state regulators and a robust technical framework. India also has several components to support a broader ecosystem for clinical research and drug development, such as the presence of a highly skilled workforce of qualified scientists, hundreds of medical colleges, and a large and diverse patient pool. Still, India faces the consequences of a burdensome and unpredictable


\textsuperscript{107} Drugs (Prices Control) Order, 2013. Published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section(ii) dated May 15, 2013.

regulatory environment as clinical trials move out of the country\textsuperscript{109} and new medicines face significant launch delays.\textsuperscript{110}

We welcome the fact that the MOH and the Central Drugs Standard Control Organization (CDSCO) have undertaken regulatory reform efforts with the goal of strengthening the regulatory regime and reinvigorating clinical research. However, inconsistencies and ambiguities continue to prevail in the Indian regulatory space resulting in lack of clarity and burdensome approval process for trial sponsors. In particular, the ambiguities in the definition of “trial related injury”, a lack of appeals mechanism in decisions about causation, and criminal penalties for trial sponsors who deviate from clinical trials protocol are particularly burdensome.

The current clinical trial injury compensation regulations—consisting of the January and February 2013 regulations and the December 2014 amendments thereto—are overly broad and lack a legally or scientifically sound process for determining causality of injury. In addition, there are no appeals of causation determinations made by the Ethics Committee, Expert Committee, and Licensing Authority, and no mandated opportunity for the clinical trial sponsor or investigator to introduce their own assessments of causation for those committees or the Licensing Authority to consider. As a result, there is great uncertainty relating to future costs and liabilities associated with conducting trials in India, resulting in many sponsors not sitting trials in India until these uncertainties have been resolved.\textsuperscript{111}

The proposed Drugs and Cosmetics (Amendment) Bill, 2015\textsuperscript{112} makes deviation from clinical trial protocol a criminally punishable conduct. By failing to distinguish between intentional violations of conditions, inadvertent mistakes, genuine misinterpretations of such conditions, or even scientifically valid reasons for deviating from protocol, the legislation fails to comprehend the complex requirements and conduct of clinical trials. 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.

Further, despite the July 3, 2014 CDSCO Office Order on waiver of local clinical trial requirements, the criteria established for waiver of local clinical trials limiting them to only cases of national emergency, extreme urgency, epidemics and for orphan drugs

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for rare diseases and drugs indicated for conditions/diseases for which there is no therapy are very restrictive.\textsuperscript{113} Clinical trials for life threatening conditions are often lengthy and complex, thus delaying their entry into the market. Under the current norms, all new drugs which have not been used in India have to undergo trials on a specified minimum number of patients to gain marketing approval from the Drug Controller General of India (DCGI). The DCGI has the ability to grant an exemption only if deemed to be in the “public interest” or if they fall under the criteria as per the CDSCO Office Order dated July 3, 2014. The current list of criteria for a waiver are very narrow, ambiguous and open to subjective interpretation thus limiting the ability for medicines treating serious or life-threatening disease to receive such a waiver. Greater clarity and predictability are needed for administrative procedures of drug registration applications and drug review standards and procedures.