MSF Comments on the 'Final Draft of the National Intellectual Property Right Policy' submitted by the IP Think Tank to the Department of Industrial Policy & Promotion, Ministry of Commerce, India

Médecins Sans Frontières (MSF) offers comments on the final draft of the National Policy on Intellectual Property Rights (IPR) submitted by the IPR Think Tank[1] to the Government of India.[2]These comments have been prepared based on leaked text available from Knowledge Ecology International.[3]

The IPR Think Tank submitted the final draft of the National IPR Policy to the Department of Industrial Policy & Promotion (DIPP) in April 2015. The policy will go for cabinet approval in the next month, after incorporating comments from various concerned government departments.

Although the policy includes some important improvements, it also includes some areas for concern. As the final version of the draft will be submitted for cabinet approval without seeking further public comments, MSF is worried that many of the concerns that MSF and others are raising on the final draft of the IP Think Tank will not be considered. This could prove detrimental to access to affordable generics and the introduction of new innovation models that are well aligned to India's public health needs.

Positive changes in the final draft of the National IPR Policy

MSF welcomes the positive changes made in the final draft of the National IPR Policy, taking in consideration the comments received on the previous draft from concerned stakeholders. We would specifically like to highlight the following additions made in the revised version that align with measures that protect public health.

1. **Rejection of patent linkage.** The policy reaffirms India's use of flexibilities available under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the Doha Declaration. It also recommends that India avoid the introduction of TRIPS-plus measures. Recently, the Ministry of Health discussed the possibility of introducing TRIPS-plus provisions such as patent linkage, which would require India's drug regulatory authority Central Drugs Standard Control Organization (CDSCO), charged with determining medical products' quality, to also enforce all product and process patents on pharmaceutical products on behalf of pharmaceutical corporations. This would include enforcing weak or undeserved ever-greening claims (monopolies on minor improvements of medicines), even if they are challenged and the patents are subsequently revoked. It would also require CDSCO to refrain from approving a product until after any infringement lawsuits are settled. The draft National IPR Policy provides clear guidance to the Indian Health Ministry to reject patent linkage in any form.

2. **Avoidance of TRIPS-plus measures in trade**. The draft policy recommends that *"In future negotiations in international forums and with other countries, India shall continue to give precedence to its national development priorities whilst adhering to its international commitments and avoiding TRIPS plus provisions"* (p. 2). This policy guidance is critical for India's IP negotiators, since TRIPS-plus measures are a long-standing demand of US and EU pharmaceutical companies, and are likely to be part of the bilateral talks with US officials as well as future free trade agreement negotiations, including the ongoing Regional Comprehensive Economic Partnership (RCEP) Agreement talks, negotiations with European Free Trade Association area (EFTA), which is led by Switzerland, and ultimately any future FTA between India and the US.

3. **Exclusion of medical products in utility models**. The policy limits opportunities for patent ever-greening through utility models. The policy now clearly excludes pharmaceuticals, biological material or substances from any future law proposed on utility models, which is a very positive step. This would curb possibilities for ever-greening by pharmaceutical companies.

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[1] The IPR Think Tank was convened in November 2014 by Department of Industrial Policy & Promotion, Ministry of Commerce, Government of India, to draft a National IPR Policy for India.
[2]See Annex for additional background on the National IPR Policy drafting process and the IPR Think Tank.
[3]KEI. Final draft, India National IPR Policy, by IP Think Tank constituted by DIPP, Ministry of Commerce and Industry.2015 October 14. Available from: http://keionline.org/node/2340.

4. **Rejection of data exclusivity**. The final policy has reiterated the government's position that protection of undisclosed information is an important area of study for future policy development, but has clearly expressed that this would not extend to 'data exclusivity' pursuant to objective 3.6.3. This is a critical recommendation of the draft policy and in line with what the government has stated publicly. At the height of the EU-India FTA negotiations, Indian negotiators from the Ministry of Commerce rejected data exclusivity as being "well beyond" international trade obligations. In doing so, the government clearly established its position on the issue and offered public assurance that India will continue to ensure that the high-quality generic drugs it produces are accessible to all countries.

5. **Addressing abuses of IP rights.** The policy notes that licensing practices or conditions that may constitute an abuse of IP rights or have an adverse effect on competition will be addressed through appropriate measures. This recommendation is welcome, as patent-holding companies may not work their patents that cover new drugs. Alternatively they may abuse their dominant position by charging exorbitant prices for new, patented drugs, and/or attach problematic conditions to voluntary licenses on new drugs that they issue to a few generic companies. In this context a number of voluntary licenses between multinational pharmaceutical companies and generic companies, covering primarily HIV and hepatitis C medicines, need to be examined not just in the context of domestic needs but also for conditions that limit the potential of Indian generic manufacturers to expand supply of active pharmaceutical ingredient (API) and finished formulations to middle-income countries. The policy also proposes further examination of the inter-relationship of intellectual property with competition law.

Concerning recommendations on IP enforcement

Despite the positive developments, the final draft policy continues to make some recommendations that could impede access to affordable medicines. MSF comments are given below on areas concerning pharmaceuticals and access to medicines.

1. **Unclear definition of the term 'counterfeit'.** The final draft of the policy strongly opposes treating generic drugs as spurious or counterfeit, which is an important clarification, but the lack of a precise definition of what constitutes a 'counterfeit' will make this objective hard to achieve when 'counterfeit' is strongly embedded in IP enforcement measures pushed by other countries. These measures have manifested themselves in multiple insidious forms: as part of customs regulations (EC Council Regulation no. 1383/2003 and EC Council Regulation 608), international treaties (the Anti-Counterfeiting Trade Agreement) and FTAs, including proposed enforcement rules in the EU-India FTA talks set to resume in the near future and in the ongoing negotiations of RCEP agreement (proposed by Japan and South Korea in the negotiating text of the IP chapter). The EU is also completing deliberations and eventual approval (in the first quarter of 2016) of an additional set of border measures for trademarks that will provide even greater enforcement powers for customs officials within the EU. India must continue to challenge and reject IP enforcement measures in international and bilateral forums due to the threat it presents to the export and eventual use of generic medicines around the world.

2. **Unwarranted enforcement through establishment of a 'Task Force.'** The Think Tank recommends the creation of a 'Task Force' to enforce IP rights. The TRIPS Agreement does not create any obligation to create a taxpayer-funded 'Task Force' to enforce IP rights. IP rights are private rights. It is not the responsibility of governments to defend each right but rather to provide a predictable legal system to enforce such rights. At the same time, the government is responsible for curbing abuses resulting from IP monopolies and any dominant position in the market. Enforcement measures by the "Multi-Agency Taskforce" in the pharmaceutical sector on claims of trademark infringement or patent infringement are unwarranted as these claims can already be handled by the courts. Instead such measures will squeeze what little space remains for generic companies to continue to produce lifesaving medicines, and could undermine the role the judiciary plays in protecting the right to health, in particular balancing private IP rights with the public interest. Indian policy makers need to encourage and protect judicial discretion in the area of IP enforcement. A growing number of ex-parte injunctions against Indian suppliers of API and finished formulations could threaten access to affordable medicines domestically and also undermine export of generic medicines to other countries.

In a 2008 case (F. Hoffmann-La Roche Ltd. &Anr. v. Cipla Limited), an Indian court applied the test of whether patients would suffer irreparable hardship if a generic drug was blocked from the market and the court would in effect be stifling Article 21 (The Right to Life) of the Constitution of India (I.A 642/2008 IN CS (OS) 89/2008, Delhi High Court, Order dated March 19, 2008). However, since then that test has been discarded and the opposite trend is now apparent.

3. **Proposed unnecessary specialised IP courts.** Specialised IP courts are outside the purview of TRIPS obligations. The majority of IP disputes for pharmaceuticals in India today cover two categories. The first is the disputes brought by pharmaceutical companies concerning the rejection or grant of a patent on a particular drug. These disputes are usually between a pharmaceutical company and IP offices. When determining whether to grant a patent, patent offices exercise a quasi-judicial function, which requires another avenue of appeal. For this India already has a specialized administrative tribunal that exclusively hears appeals. The Indian Intellectual Property Appellate Board (IPAB) was set up to hear appeals against decisions of the Patent Controller. It must include at least one judicial member and one technical member. IPAB's jurisdiction is limited to appeals arising out of patent office decisions and revocations, but it cannot adjudicate upon infringement issues. Infringement suits can be filed before district courts or before the High Courts. It is this category of disputes –namely patent holding pharmaceutical companies regularly alleging infringement of a patent and seeking injunctions against generic producers –that such drug companies would like to see moved to specialised IP courts as such companies believe that decisions on enforcement of their patents will be faster and more favorable.

   Thus, the recommendation to set up dedicated IP courts must be approached with caution by policymakers in India. Judicial impartiality may be at risk due to the likelihood that only a few judges and lawyers will specialize in IP, thereby potentially biasing the judicial system as judges consistently interact with a limited group of lawyers and petitioners. Judges that could be captured by narrowly focused professional groups is more likely. Specialised IP courts can lead to judicial isolation with judges losing sight of how patents fit into the larger fabric of society, resulting in the over-emphasis of the importance of IP. In addition, extreme specialization can narrow a judge's view and could undermine the critical role the judiciary can play in the future to protect the constitutional right to life, and in particular establishing a balance between the enforcement of private IP rights with the public interest to access more affordable medicines due to direct competition. The TRIPS Agreement does not obligate its signatories to establish separate IPR courts.

Failure to consider theevidence for new biomedical innovation policies

The draft policy's vision, mission and objectives[4] repeatedly emphasise IP monopolies as the key driver of innovation. However, in the context of access to medicines, such claims have been refuted by experts at the World Health Organization (WHO) and through numerous other studies. These experts have found IP to be a barrier not only for access to affordable medicines, but also to innovation for new medicines desperately needed for diseases that disproportionately affect people in developing countries.

In recent years, the Government of India has played a key role in advancing efforts to address this at the WHO. This includes a recent monetary contribution by India to advance new models of research and development (R&D) to promote innovation and access, and the submission of two demonstration projects to develop diagnostics and medicines for key public health priorities. The draft policy thus fails to take into account these key debates and discussions occurring internationally, in which India is already involved, regarding new approaches to innovation.

1. **Failure to recognize public contributions to biomedical R&D.** The draft policy too narrowly focuses on patenting, ignoring the fact that public sector research institutions in India contribute in multiple ways:

[4]**Vision:**An India where Intellectual Property led growth in creativity and innovation is encouraged...; an India where intellectual property rights promote advancement in science and technology(p. 5).
Objectives: A nation-wide program of promotion will be launched with an aim to improve the awareness about the benefits of IPRs and their value to the rights-holders and the public. Such a program will build an atmosphere where creativity and innovation are encouraged in public and private sectors, R&D centers, industry and academia, leading to generation of protectable IP that can be commercialized(p. 6).

through publishing in journals, collaboration with other partners, technical support to the industry, and working with product development partnerships (PDPs) on neglected diseases. As patenting increases, it may reduce free access to knowledge and adversely affect the contributions made by these economic inputs. The final draft policy does not lay out clear standards and guidelines for policy makers to ensure that the fruits of publicly financed research and development are available, affordable and accessible to patients – in India and in other countries.

2. **Narrow focus on commercializing IP.** The policy also narrowly focuses on commercializing IP, without due attention to the complexities of ensuring access to publicly funded biomedical innovations. The policy as finalized by the IPR Think Tank should have more comprehensively captured the policy issues that define the increasing levels of publicly-financed R&D in India. In particular, the policy should consider recommendations to develop biomedical innovations that do not solely focus on commercializing IP, but that institute guidelines and safeguards that ensure such products are affordable and accessible. Currently, the US is dealing with access problems precisely created by this commercial approach. For example, the cancer drug, imatinib –developed with critical inputs from scientists and other resources at publicly-funded institutions in the US, exclusively licensed to Novartis and then patented several times over –comes at an exorbitant price of 100,000 USD per patient per year in the US. In addition, the delays and costs associated with negotiating access to patented technologies needed for biomedical innovation is another factor that needs close examination.

Promoting a better model of biomedical R&D

Promisingly, the final policy draft does specifically mention open source research such as the Open Source Drug Discovery (OSDD) project, a project of the Council for Scientific & Industrial Research (CSIR) for new inventions for prevention, diagnosis and treatment of life threatening and high burden diseases. OSDD has the potential to play an important role to develop new drug regimens for drug resistant TB in India, but has been unable to move forward due to a budgetary crisis.

In addition to resisting proposals to further entrench access-restricting IP protections, India should seek opportunities to further these open, collaborative research initiatives and other measures to de-link the costs of R&D from the high prices of medicines protected by IP monopolies. Doing so will allow India to better promote accessible, affordable pro-patient medical innovation *made in India* needed by patients and treatment providers around the world.

Annex: Background on the IPR Think Tank

The IPR Think Tank was convened in November 2014 by Department of Industrial Policy & Promotion, Ministry of Commerce, Government of India, to draft a national IPR Policy for India.[5]

A particular area of concern for health groups is IP policy making that impacts the pharmaceutical sector, as India is a key global supplier of affordable generic versions of drugs that otherwise would be out of reach for public health programmes, treatment providers and millions of people.

In November 2014, a letter to India's newly constituted IPR Think Tank signed by patient groups, public interest organisations, treatment providers and academia worldwide, raised critical issues around the IP system in India.[6] In the context of heightened US pressure on India's government, and in particular on India's Department of Industrial Policy and Promotion (DIPP), the letter signatories opposed any re-opening of the discussion on patentability criteria, interpretation of Indian patent law, or the introduction of TRIPS-plus standards. Re-opening this discussion could provide multinational pharmaceutical companies and the US Trade Representative an opportunity to take forward their agenda to undermine generic competition from India and public health safeguards in India's patent law. It would also undermine India's negotiating position in various bilateral and international forums."

The first draft of the National IPR Policy was released in December 2014.[7]In February 2015 MSF presented critical comments – written and oral – to the IPR Think Tank on the draft National IPR Policy, specifically on areas concerning IP, innovation and access to medicines.[8]

The IPR Think Tank submitted the final draft of the National IPR Policy to the Department of Industrial Policy & Promotion (DIPP) in April 2015. The policy will go for cabinet approval in the next month, after incorporating comments from various concerned government departments.

[5]See Public Notice. 2015 November 19. Available from:http://dipp.nic.in/English/News/publicNotice_13November2014.pdf.

[6]Global Sign-On Letter to India's new IPR Think Tank on IP and Access to Medicines. 30 Nov 2014. Available from: http://issuu.com/msf_access/docs/letter_global_ip_and_access_to_medi/1?e=3239302/10382422.

[7]Available from: http://dipp.nic.in/English/Schemes/Intellectual_Property_Rights/IPR_Policy_24December2014.pdf.

[8]Available from: http://www.msfaccess.org/content/india-msf-submission-ip-think-tank-committee-draft-ip-policy.