



## **COMMENTS ON THE FIRST DRAFT OF THE NATIONAL INTELLECTUAL PROPERTY POLICY**

Médecins Sans Frontières (MSF) welcomes the opportunity to provide comments on the first draft of the National Policy on Intellectual Property Rights (“draft policy”).

### **BACKGROUND**

**MSF’s expertise: Research and analysis on intellectual property (IP), access to medicines and innovation policy issues.**

Founded in 1971, MSF is an independent medical humanitarian organisation that operates in over 70 countries (including India and other countries in the region). We focus on providing medical care to populations in distress, regardless of race, religion, creed or political convictions. We are primarily recognised for our emergency responses to armed conflict, devastating natural disasters, and for our work against medical disasters like HIV/AIDS and Ebola.

A lesser-known aspect of our work is the care and treatment we provide to poor and marginalized people in developing countries suffering from diseases that are ignored by the rest of the world. MSF is the third largest philanthropic funder of neglected disease<sup>1</sup> research. We focus on stimulating research into new medicines and tools for neglected diseases such as drug-resistant tuberculosis, paediatric HIV/AIDS, sleeping sickness, kala-azar and Chagas disease.

Some of our advocacy and technical work on medical innovation, such as fixed-dose combinations of HIV medicines and anti-malarial drugs, paediatric formulations of HIV treatments, rapid diagnostic kits for diagnosis of malaria and empirical research on safer and more effective treatments for kala-azar, have benefited patients and public health in India.

---

<sup>1</sup> Diseases neglected by the market because of a lack of commercial interest despite of effective IP

In 1999, MSF was awarded the Nobel Peace Prize “in recognition of the organization's pioneering humanitarian work on several continents.” We accepted the Nobel Peace Prize with these words: “Today, a growing injustice confronts us. More than 90% of all death and suffering from infectious diseases occurs in the developing world. Some of the reasons that people die from diseases like HIV/AIDS, tuberculosis, sleeping sickness and other tropical diseases is that life-saving essential medicines are either too expensive, are not available because they are not seen as financially viable, or because there is virtually no new research and development for priority tropical diseases. This market failure is our next challenge.”

**Initiatives:** We acknowledged the crisis on access and innovation. MSF made use of the nobel Prize money to create the Campaign for Access to Essential Medicines and became a founding member of Drugs for Neglected Diseases initiative (DNDi), a product development partnership (PDP), a non-profit R&D organisation developing new treatments for neglected diseases.

**Policy development:** Our work on innovation has convinced us that while we wanted to advocate for new medicines and tools, we also needed to engage actively in the development of policies at the international level, especially in countries like India, that will impact R&D funding and access in the future.

MSF challenged the high costs of existing drugs—such as those to treat HIV/AIDS—and worked to support the introduction of generic competition in South Africa and other countries that were seriously affected by the AIDS epidemic in the late 1990s.

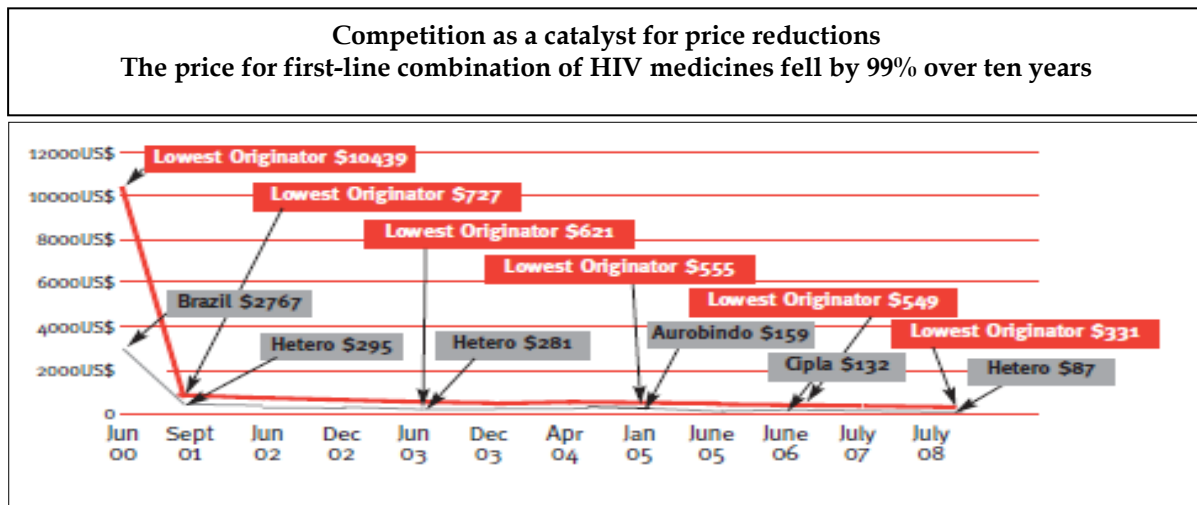
**Results:** MSF treated its first patients with antiretroviral therapy (ART) in 2000. At that time, the epidemic had already killed 16 million people, while 33.6 million people were living with HIV/AIDS worldwide, the majority in poor countries.

By importing cheaper generic drugs into South Africa, “we could be sued for patent infringement,” acknowledged Toby Kasper, a spokesman for MSF. However, noting that the Brazilian imports cost about half the price of the same medicines made by Western pharmaceutical companies, he added, “We are not going to stand for a situation where we would be able to treat twice as many patients as we could by using only patented drugs. As medical professionals, it is our obligation to put the lives of our patients first.”

From 2001 to 2004, we participated in the clinical trial (ANRS 1274), which proved the safety and efficacy of the Indian generic manufacturer Cipla’s first triple fixed-dose combination HIV treatment, triomune, and put to rest concerns regarding the quality and efficacy of HIV medicines produced in India. We called for WHO to assess the quality of Indian generic medicines that helped dramatically improve the procurement and scale of treatment in developing countries. WHO continues this work today through the WHO pre-qualification system.

Since then, the price of first-line HIV treatment (antiretrovirals, or ARVs) has fallen by roughly 99 percent over the last decade and a half: from over US\$10,000 per person per year

in 2000 to less than \$150 per person per year today. This was possible due to massive price reductions triggered by generic competition in India. The dramatic price drop has been instrumental in helping scale up HIV/AIDS treatment to more than 13 million people in developing countries today.



Source: *Untangling the Web of Antiretroviral Price Reductions*, MSF

India has now become an important manufacturer and supplier of quality generic medicines to millions of people around the world. MSF is highly dependent on the availability of affordable, quality-assured medicines to provide medical care, as are many of the health ministries with whom we work. In fact, we call India the “pharmacy of the developing world.”

**Challenges:** It is important to note that the introduction of pharmaceutical product patenting in India’s Patent Act in 2005, to comply with India’s international obligations as a member of the World Trade Organization (WTO), raised serious concerns at the time. However, in the last decade, India has established a balanced policy on intellectual property laws that impact pharmaceuticals. While India does grant patent monopolies to a number of new pharmaceutical products, it is trying to strike a balance between providing IP protection and having the legal flexibility to protect the right to health. It does so in at least four ways: first, the Indian Patent Office (IPO) applies strict patentability criteria; second, when deemed necessary in the interest of public health, the Indian government grants compulsory licenses; third, Indian courts maintain a balanced approach to IP enforcement; and fourth, Indian trade negotiators reject any IP proposals in free trade agreement (FTA) negotiations that go beyond the requirements of the WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). All four approaches are public health ‘safeguards’ enshrined in the TRIPS Agreement as legal flexibilities.

Recent pressure from multinational pharmaceutical companies backed by US officials, and the review of India’s position by the IP Think Tank, has raised uncertainty. Will India remain an affordable source of quality medicines under this new policy framework? Will India continue to be the “pharmacy of the developing world”? Can the new IP policy ensure access to medicines for all – in India and beyond?

**Conclusion:** Our experience shows that competition is the most effective way to achieve reliable price reductions and sustainable, affordable prices. IP can and should be managed in a way that fosters competition and does not impede innovation to improve access to medicines and medical tools.

## **COMMENTS ON THE DRAFT POLICY**

The draft policy touches on many aspects of IP. MSF is providing comments on the following six areas that concern pharmaceuticals and access to medicines:

- I. Perspective on IP, innovation and access to medicines
- II. Over-emphasis on IP enforcement, criminalisation and failure to qualify “counterfeit”
- III. Exclusion of Pharmaceuticals from proposed Utility Models legislation
- IV. Disclosure of international non-proprietary name (INN) for ensuring transparency in IP system
- V. Article 39.3 of TRIPS - pharmaceutical test data
- VI. Think Tank observations on TRIPS and TRIPS plus provisions

### **I. Perspective on IP, innovation and access to medicines**

#### *IP protections pose a barrier to innovation and access to medicines*

The draft policy adopts a one-size-fits-all model and fails to recognise the crisis in the IP-driven model of biomedical innovation. In its vision, mission and objectives<sup>2</sup>, the draft policy repeatedly emphasises intellectual property monopolies as the key driver of innovation. However, such claims have been refuted by experts at the World Health Organization and by numerous other studies that have repeatedly found IP to be a barrier not only to access to affordable medicines, but also to innovation for medicines desperately needed for diseases that disproportionately affect people in developing countries. The draft policy thus fails to take into account the international perspective on the key debates and developments in this area.

Relying on patent monopolies to encourage research and development (R&D) and innovation is fundamentally flawed for two reasons. It assumes that R&D should be

---

<sup>2</sup> **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)

predominantly driven by commercial rewards, rather than public health priorities. This steers research towards areas that are the most profitable, leaving fundamental medical needs – particularly those that disproportionately affect developing countries like neglected tropical diseases or tuberculosis – unaddressed. Moreover, patent monopolies result in unaffordable prices for new medicines for treating both communicable and non-communicable diseases, which are often priced out of reach in developing countries, and are increasingly becoming unaffordable in wealthy countries as well. In April 2013, 100 cancer physicians raised the alarm about the high prices being charged in the US for new cancer drugs. They stated that the unsustainably high prices harm patients. As we have seen in HIV/AIDS, high medicine prices are an issue of life and death for millions of people in developing countries.

MSF's operations force us to bear witness to the failures of the current IP-driven model of biomedical innovation to deliver effective, appropriate and affordable medical tools that we desperately need for patients in developing countries. Previously treatable diseases are becoming difficult to cure due to antibiotic resistance, whilst effective treatments for Ebola and other neglected diseases, such as tuberculosis, are yet to be developed. Thus, in MSF's experience, neglected diseases are those for which diagnosis and treatment options are inadequate or do not exist and for which intellectual property is insufficient incentive to attract R&D. WHO has a list of seventeen such neglected tropical diseases and in addition there is drug resistant tuberculosis and snake bite.

Between 2000 and 2011 (Pedrique et al. 2013), barely 3.8 percent of approved drugs were indicated for tropical diseases, tuberculosis and other neglected infections, even though these diseases represent 10.5 percent of the global disease burden. Of these 29 drugs, only 4 were new chemical entities (NCEs). The future is equally troubling: scarcely 1.4 percent of a total of nearly 150,000 registered clinical trials were focused on neglected diseases, with very few of these trials for new chemical entities.

A review of 42 studies assessing innovation in drug development (Kesselheim et al. 2013) established that despite the rising costs of R&D and the consistently high revenues earned by pharmaceutical manufacturers, transformative pharmaceutical innovation is rare.

Increased levels of IP have done nothing to address, for example, the looming global health crisis caused by antibiotic resistance. While the US had approved 30 new antibiotics between 1983-1992, since 2003 (in the post-TRIPS era), it has approved only seven new antibiotics. Notably, despite economist Jim O'Neill's report (published in December 2014), which concluded that drug-resistant infections would cause ten million extra deaths a year globally, with economic costs up to \$100 trillion by 2050, fewer than five of the 50 largest pharmaceutical companies have active antibiotic development programs.

These findings support calls from the World Health Organization and experts to change the way medical research and development (R&D) is conducted, in order to address the needs of developing countries.

By entering into intergovernmental negotiations, member countries of the WHO, along with multiple experts over the years, have issued reports and recommendations to guide biomedical R&D relevant to the health needs of developing countries.

In 2006, a report by the WHO-convened Commission on Intellectual Property, Innovation, and Public Health (CIPHI) made an important observation on biomedical R&D relevant to the health needs of developing countries: "...For diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to the market." The CIPHI Report, in fact, goes on to add that increasing levels of IP protection will not reverse the neglect of R&D: "there is no evidence that the implementation of the TRIPS agreement in developing countries will significantly boost R&D in pharmaceuticals on Type II, and particularly Type III diseases. Insufficient market incentives are the decisive factor." The report called on the WHO to take the lead and address issues where IP acts as a barrier to innovation and access to medicines.

In the following years, an Intergovernmental Working Group on Public Health, Innovation and Intellectual Property was formally established and charged with creating a framework to secure sustainable R&D for the diseases that disproportionately affect developing countries.

The outcome was the WHO Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, which included an expert from the Indian Ministry of Health, and made critical recommendations:

1. *Establish an evidence-based, inclusive process that sets the priorities for medical R&D.*
2. *The current R&D for neglected diseases is largely reliant on philanthropy and the largesse of a few donor countries. The WHO experts' report recommends that all countries should commit to spend at least 0.01% of GDP on government-funded R&D devoted to meeting the health needs to product development. The report also recommends a number of direct and indirect taxation proposals - including the introduction of a financial transaction tax with a proportion dedicated to health R&D - to raise required funds.*
3. *The WHO experts recommend that "R&D should focus on the development of health technologies for Type II and Type III diseases as well as the specific needs of developing countries related to Type I diseases. Type I diseases are incident in both rich and poor countries, with large numbers of vulnerable populations in each. Type II diseases are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries. Type III diseases are those that are overwhelmingly or exclusively incident in developing countries.*
4. *To fund all phases of R&D, in particular utilizing open approaches to R&D and prize funds as well as the costs of late-stage development, including clinical trials;*

5. *The WHO experts recommend that R&D outcomes be considered as public goods, freely available for further research and production.*

***Exclusive Licensing of public research to private industry without safeguards can impede development of access to medicines***

In its recommendations that endorse the patenting of public funded research, the draft policy<sup>3</sup> bears a strong similarity to the US Bayh-Dole model.

Developing countries are increasingly adopting the US model, which encourages commercialization of publicly-funded research through exclusive licensing to industry. However, as this approach is strongly linked to market incentives and material benefits, it typically fails for diseases that predominantly affect poor patients in developing countries like India.

This attempt to imitate US legislation fails to take into account that recipients of government funding in the US often pursue patents and agreements with industry that are not aligned to

---

<sup>3</sup> **Objective 1: IP Awareness & Promotion**

1.3.2 Engaging public funded research organizations and the private sector to create campaigns highlighting the process of IPR creation and the value generated there from. (p. 7)

**Objective 2: Creation of IP**

India has one of the largest pools of scientific and technological talent in the world. In several sectors they have created considerable technological output without commensurate IP generation. This talent pool is spread over R&D institutions, large, medium and small enterprises, universities and technical institutes. It is necessary to come up with targeted programs to encourage them to generate IPRs and utilize them in developing new technologies, products and solutions particularly in areas of national priority. (p. 9)

2.14 Encourage and incentivize IP generation and utilization among students at all levels, use awareness programs and educational materials to inculcate an appreciation for the value of IP. (p. 11)

2.3 Focus on improving IP output of national research laboratories, universities, technology institutions and other researchers by encouraging and facilitating the protection of intellectual property created by them. (p. 10)

2.6 Establish and strengthen IP facilitation centers as nodal points especially in industrial and innovation university clusters. (p. 10)

**Objective 3: Legal and Legislative Framework**

3.2 to strengthen IP and innovation eco-system for example IP created from public funded research. (p. 12)

**Objective 5: Commercialisation of IP**

5.1 Establish an IP Promotion & Development Council (IPDC) as the nodal organization for the promotion, creation and commercialization of IP assets. (p. 18)

5.1.2 Promoting licensing and technology transfer for IP; devising suitable contractual and licensing guidelines to enable commercialization of IP. (p. 20)

5.2 Promote collaborative IP generation and commercialization efforts between R&D institutions, industry, academia and funding agencies. (p. 19)

5.3.5 Regulating IP created through public funded research by a suitable law. (p. 19)

public policy. Moreover, these licensing provisions hinder research and prevent access to the very medicines that have resulted from government funding.

Publicly-funded research has an important role to play in meeting treatment needs in developing countries. Policies that align R&D in developing countries with public health have the potential to incentivise the development of medical technologies (vaccines, diagnostics and medicines) that can be crucial for neglected diseases like malaria, tuberculosis, paediatric HIV/AIDS and kala-azar. Thus, research, licensing and patenting decisions made by public research institutes and universities directly affect accessibility of medicines to those living in developing countries.

Largely funded by government grants, Yale University developed the research of the antiviral, stavudine. In accordance with the Bayh-Dole Act, Yale patented the results and licensed the patent exclusively to the pharmaceutical company Bristol-Myers Squibb (BMS). The company then sought to enforce the patents very strictly. In 2000, in the middle of the AIDS epidemic in South Africa, the drug cost more than US\$1600 per year. Students, alumni, and MSF successfully pressured Yale to renegotiate with BMS to permit generics in South Africa, as well as to reduce the BMS price to \$55. Unfortunately, U.S. universities have not systematically changed their practices to ensure that their publicly-funded research is available to the poor people of the world.

The HIV/AIDS community has struggled to access a number of HIV medicines patented and exclusively licensed to pharmaceutical companies. Antiretrovirals such as didanosine, ritonavir and tenofovir (developed with government funds) are unaffordable and unavailable to patients in a number of countries. The cancer drug, imatinib—developed with critical inputs from scientists and resources from publicly-funded institutions and then exclusively licensed to Novartis—has also been out of reach for most patients.

Knowledge Ecology International (KEI), a not for profit organisation, independently analysed the R&D costs of imatinib. The National Institute of Health (NIH), National Cancer Institute and charities like the Leukemia Society supported most of the early research and testing of imatinib. Once it was established that STI 571 (imatinib) was a promising drug, Novartis was convinced to invest in further testing. Novartis outlays were relatively small. After adjusting for the risks of failures and the opportunity cost of capital, the Novartis investments in the Phase II trials are estimated at \$38 to \$96 million. However, it has earned billions from the drug since it was first approved in 2001. In the US, in 2001, Novartis charged \$4,540 for a month of treatment; now it charges \$8,488.

Ultimately, the biggest drawback of the US Bayh Dole model is that it considers patenting as “the [only] incentive” to promote “creativity and innovation” whereas patents should be just one of the ways for doing so (with necessary safeguards to avoid abuses). Ultimately, it impedes emerging alternative mechanisms of research and technology transfer.



The draft policy too narrowly focuses on patenting, ignoring the fact that public sector research institutions in India contribute in multiple ways: 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 by adversely affecting the contribution made by these economic inputs.

The Think Tank should ensure the increasing amount of publicly-financed R&D in India results in affordable and accessible biomedical innovations.

#### **Key references:**

1. “Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination”. Report of the Consultative Expert Working Group on Research and Development Financing and Coordination, April 2012.<sup>i</sup>
2. “Fatal Imbalance. The Crisis in Research and Development for Drugs for Neglected Diseases”, MSF, September 2001<sup>ii</sup>.
3. R&D Cost for Gleevec, Knowledge Ecology International, April 2013<sup>iii</sup>
4. “The drug and vaccine landscape for neglected diseases (2000–11): a systematic assessment”, *The Lancet*, December 2013<sup>iv</sup>.
5. Kesselheim A, Wang B, Avorn J. “Defining ‘innovativeness’ in drug development: a systematic review”. [Online] *Clinical Pharmacology and Therapeutics* 2013; 94(3): 336. [Cited 2014 Nov 21]<sup>v</sup>.
6. The Review on Antimicrobial Resistance, Chaired by Jim O’Neil, ‘Antimicrobial Resistance: Tackling a crisis for the health and wealth of nations’<sup>vi</sup>
7. “Is Bayh Dole good for developing countries? Lessons from the US Experience”, *Plos Biology*, October 2008<sup>vii</sup>.
8. UAEM White Paper on the Proposed Indian Bayh-Dole Analogue<sup>viii</sup>.

## **II. Over emphasis on IP enforcement, criminalisation and failure to qualify “counterfeit”**

### ***Excessive IP enforcement threatens to restrict access to lifesaving medicines***

MSF is deeply concerned that the Think Tank has not proposed any meaningful safeguards against the very real risk of over-enforcement and abuse by IP rights holders. The draft policy<sup>4</sup> fails to recognise that enforcement of intellectual property rights (IPR), and the monopolies that they entail, needs to be balanced with sufficient space for competition.

---

<sup>4</sup> **Objective 3: Legal and Legislative Framework**

3.6.4 Guidelines for authorities whose respective jurisdictions impact administration or enforcement of IPRs such as patents and biodiversity. (p. 13)

Over the past few years, the government (particularly the Ministry of Commerce) has been increasingly concerned about the proliferation of enforcement measures that have targeted legitimate generic medicines produced in India. These measures have manifested themselves in various insidious forms: as part of customs regulations (EC Council Regulation no. 1383/2003), international treaties (the Anti-Counterfeiting Trade Agreement) and free trade agreements.

IP enforcement policies increase the risk of harmful delays, seizures or even the destruction of legitimate generic medicines. IP rights holders regularly apply such enforcement tactics to deter competition from generic manufacturers.

For example, in 2008-09, at least 20 shipments of legitimate Indian generic medicines were seized in transit through the EU. Among them was a blood pressure drug in transit to Brazil and HIV drugs en route to Nigeria, purchased by the Clinton Foundation. These incidents became the subject of a WTO complaint by India and Brazil against the EU and the Netherlands. On-going efforts by the European Commission to continue expanding enforcement powers via new customs regulation (No. 608/2013 replacing no. 1383/2003) , with the likelihood that such measures could lead to seizures of medicines in transit, have been opposed by the Government of India once again.

Another example is the IP enforcement provisions proposed in the EU-India FTA, which were drafted by EU negotiators, with the intention of undermining the production and dissemination of generic medicines, and which may influence the manner in which domestic courts handle disputes over IPR. From legitimate medicines being blocked from leaving India when a multinational company claims that their IP is being infringed upon, to third parties – such as treatment providers – being embroiled in court cases simply for buying or distributing generic medicines, the proposed measures may have long-lasting, unintended consequences that restrict access to medicines.

---

### **Objective 6: Enforcement and Adjudication**

To strengthen the enforcement and adjudicatory mechanisms for combating IP violations, piracy and counterfeiting; to facilitate effective and speedy adjudication of IP disputes; to promote awareness and respect for IP rights among all sections of society. (p. 20)

6.2 Strengthen the enforcement mechanisms to ensure better protection of IP rights by:

6.2.1 Establishing a centralized 'Multi-Agency Task Force' for coordination between the various agencies and providing direction and guidance on strengthening enforcement measures; creating a nation-wide database of known IP offenders. (p. 21)

6.3 Facilitate IP dispute resolution through different measures including:

6.3.1 Recommending designation of a specialized patent bench in the High Courts of Bombay, Calcutta, Delhi and Madras for speedy disposal of patent cases and providing infrastructural support such as video conferencing;

6.3.2 Recommending the designation of one IP court at the district level depending on the number of IP cases filed. (p. 22)

### Defining the term “counterfeit”

The term counterfeit is mentioned 11 times in the draft policy. The IP Think Tank needs to view the anti-counterfeit issue in the context of steps taken by the European Union and other developed countries to introduce excessive IP enforcement to limit competition from generics. Under TRIPS, “counterfeit” clearly denotes a wilful infringement of trademark on a commercial scale and does not extend to patent infringement or civil trademark disputes. From a public health point of view, ‘wilful trademark counterfeiting on a commercial-scale’ – a form of fraud with a deliberate intention to exactly copy a product’s branding – presents a legitimate concern. However, some countries are adopting definitions of “counterfeit” that overreach this definition under TRIPS. As we have pointed out above, legitimate generic medicines have been labelled “counterfeit” and arbitrarily seized in transit.

Similarly, the **Anti-Counterfeiting Trade Agreement (ACTA)** is a treaty initiated by Switzerland, Japan, EU and the US for the purpose of establishing TRIPS plus standards for intellectual property rights enforcement. Not surprisingly, ACTA’s overbroad definition of ‘counterfeiting’ and its excessive enforcement provisions left too much room for error. Legitimately-produced generic medicines could be seized and detained. India raised these concerns at the TRIPS Council, and subsequently the EU Parliament struck down ACTA due to concerns raised by the public in 2012. . The Think Tank should clearly limit its discussion to the very specific connotations that the term “counterfeit” has under TRIPS. Failing to do so significantly restricts India from utilizing flexibilities in the TRIPS Agreement, impedes legitimate trade and movement in medicines between developing countries and encourages developed countries to introduce new approaches to defining counterfeits that India has actively opposed.

### *Patent and civil trademark disputes should be the domain of civil proceedings*

A wide range of civil IP disputes over trademarks and patents are commonplace between originator and generic companies. Not all granted patents can be presumed to be valid and claims usually require a substantive technical analysis before any decision can be reached on whether a breach has in fact occurred. As pharmaceutical companies continue to choose phonetically similar brand names derived from the drug’s international non-proprietary name (INN), it is likely that civil trademark disputes will remain a common occurrence. *Such patent and civil trademark disputes should be the domain of civil proceedings.*

The Think Tank discusses criminal remedies for IP enforcement. It is important to note that stringent enforcement provisions and remedies under TRIPS and in particular, the obligation to *criminalize*, only extends to particularly serious examples of trademark counterfeiting and copyright piracy. As such, the vast majority of remedies that are provided for in TRIPS, including patent disputes, require the rights holders to enforce their private IP rights through civil proceedings.

TRIPS does not create any obligation to create a taxpayer-funded “Task Force” to enforce IPR. MSF believes that IP rights are private rights. It is not the responsibility of governments to defend each right but rather to provide the legal system to enforce such rights. Unwarranted enforcement measures by the Multi-Agency Taskforce in the pharmaceutical sector on claims of trademark infringement or patent infringement (that can be handled by courts) will squeeze what little space remains for generic companies to continue to produce lifesaving medicines and could end up undermining the role the judiciary plays in protecting the right to health, and balancing private IPR with the public interest.

Indeed, India needs to protect judicial discretion in the area of IP enforcement. Multinational pharmaceutical companies often seek injunctive relief in their efforts to ward off generic competition. In patent infringement cases, courts have often refused to automatically hand out these injunctive reliefs that ban the availability of a generic product in the market. To ensure that there is no violation of the Indian Constitution’s guarantee to the right to life, Indian courts distinguish drugs from other cases of IP infringement. Much like US courts, Indian courts have argued that they must weigh the public interest, including the potential risk of denying patients access to life-saving medicines, in determining the appropriate remedy.

For instance:

In 2008, an India court (*F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Limited*) applied the test whether the patients would suffer irreparable hardship if the 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 19 March 2008;

In a landmark decision a US court (*eBay Inc v. MercExchange*) denied a permanent injunction to serve the needs of the public.

More recently, the Federal Circuit (*Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc.*) majority agreed with the district court that the medical need for these products trumped the patentee’s right to an injunction and ruled that “it was in the public interest to allow competition in the medical device arena.” No. 2010-1510 (Fed. Cir. February 10, 2012),

The Think Tank should be careful that its policies and recommendations to the government on IP enforcement do not undermine public interest, judicial discretion and India’s position internationally as it raises objections and concerns on the issue of excessive enforcement measures and a TRIPS plus definition of ‘counterfeit’ to protect trade in generic medicines.

## Key References:

1. Intervention by India – TRIPS Council June 2009, Agenda item ‘M’ – OTHER BUSINESS – Seizure of generic drug consignments at EC ports<sup>ix</sup>.
2. Intervention delivered by India at WTO TRIPS Council on IP Enforcement Trends noting concerns with ACTA and TPPA, 28 Feb 2012<sup>x</sup>.
3. India's intervention on 'TRIPS plus IPR Enforcement' as delivered at the WTO TRIPS Council on 9 June 2010<sup>xi</sup>.
4. “The Enforcement Provisions of the EU-India FTA: Implications for Access to Medicines”, Briefing Document, January 2013<sup>xii</sup>.
5. L.L.C., 547 U.S. 388 (2006)<sup>xiii</sup>.

### III. Exclusion of Pharmaceuticals from proposed Utility Models legislation

While new legislation has been proposed in the utility models (petty patents) section, the draft policy does not specify the subject matters that will fall under the ambit of this legislation. We request that policy makers exclude pharmaceuticals from utility model protection for the following reasons:

With respect to medicines, one of the greatest risks that the utility model may pose the potential for its use to unfairly extend monopolies as well as enable frivolous IP protection for new use or minor modifications of known medicines, often referred to as “evergreening”. Such patent applications are designed to prevent and delay generic competition and thus deter lower prices and greater access to essential medicines.

When the Indian Patent Act was amended years ago, patient and public health groups were collectively relieved that Section 3(d), which prohibits the patenting of insignificant or minor improvements of known compounds, as well as the opportunity to object to patent applications before and after a patent has been granted (pre- and post-grant oppositions), were included. This effectively prevented pharmaceutical companies from being able to obtain IP protection in India for pharmaceutical substances that were not actual inventions, such as combinations or minor modifications of formulations of known compounds.

By including provisions in its patent law stipulating that patents should only be granted on substances that are truly new and innovative, a country’s legislature, for the first time, emphasized stricter patentability criteria for pharmaceuticals. Section 3(d) therefore strengthened the inventive step test and helped safeguard against the granting of frivolous patents, for example on key first- and second-line HIV medicines.

However, if India introduces utility model protection for pharmaceuticals, pharmaceutical companies could begin seeking utility model protection on minor improvements of known medicines, even if these medicines do not meet patentability criteria. This is because requirements for acquiring a utility model are less stringent than for patents, with the test of inventive step being absent or its requirements being much lower. Additionally, utility model applications are not usually accompanied with substantive examination prior to registration. Since utility models provide the same exclusive rights as patents, the rights holder can utilize the protection granted to stop generic producers from making and selling affordable generic versions of medicines for several years.

As illustrated in DIPP's Discussion Paper on Utility Models released in May 2011 (p. 11), almost all countries that have enacted a utility model system have explicitly excluded (a) chemical and biological products, such as pharmaceuticals, (b) method for the diagnosis or treatment of diseases and (c) processes from utility model protection. Many of these countries have explicitly stated that this exclusion is in the interest of the public. Additionally, medical devices that are critical for detection and treatment should also be exempted from any potential utility model protection.

Patents on new pharmaceutical compounds in India already discourage generic production and affect India's vital role as the "pharmacy of the developing world." It is important that Indian law and policy do not impose additional barriers to generic production of medicines by adopting utility models without expressly excluding pharmaceuticals. Recognizing the potential risks to generic competition, MSF would also like to emphasize the absence of any obligation under the TRIPS Agreement to adopt utility model protection vis-à-vis pharmaceuticals.

#### **Key References:**

1. Uexkull, Alexa von. "A Clever Move, Utility Models for second medical use inventions in Germany", *Patent World* # 183, June 2006<sup>xiv</sup>.
2. "Supreme Court rules against drug patent evergreening", *Canadian Medical Association Journal*, v.175 (12), 1508-1509, December 5, 2006<sup>xv</sup>.
3. Discussion Paper: Utility Models, Department of Intellectual Property & Promotion, May 2011<sup>xvi</sup>.
4. Utility model –a tool for economic and technological development: A case study of Japan, Dr.K.S.Kardam, April 2007<sup>xvii</sup>

## **IV. Disclosure of INN for ensuring transparency in the IP system**

MSF welcomes the recommendation made by the Think Tank in the draft policy to foster clarity and transparency in the IP system. Furthermore, the draft policy explicitly provides direction to modernize and strengthen IP administration for efficient, expeditious and cost effective grant and management of IP rights and related user-oriented services.

The Indian Patent Office (IPO) has a globally recognised, pro-active system of publishing documents (including applications and related details; first examination reports; oppositions; and rejection or acceptance of orders) in a web-based searchable database. In comparison to other countries like South Africa where information availability concerning the patent status of the drug is extremely challenging, the Indian public's access to information has significantly improved.

To ensure further transparency in the Indian patent system and to make it more user friendly, MSF recommends a mandatory requirement of disclosure of INN (International Non-Proprietary Names) in all patent applications (particularly their title and abstracts) related to pharmaceuticals. While this was initially proposed by the IPO, no decision has yet been announced.

### **Why do we need the INN name as part of the patent abstract/ and search field?**

Routinely, the same medicine has numerous patent applications. Patent applications can cover one or more specific features, including 'process' (the process to manufacture the molecule); 'formulation' (e.g., powders, tablets and capsules, injectables, syrups, dispersible tablets, etc.); dosage (route, regimen); combinations (e.g., a fixed-dose combination when different drugs are combined in the same pill); new use; and derivatives (salts, prodrugs, crystals, polymorphs). A scrupulous examination of each patent application in which the same drug is embedded is essential in order to obtain a precise patent landscape of a particular medicine. It is even more difficult to complete drug patent searches and understand the patent status of medicines because pharmaceutical companies usually file several patent applications related to the same drug, and often, spread them across different patent offices in India.

With titles that are deliberately vague and meaningless, patent applicants seem to conceal the known INN. For example, GSK's patent application for an obvious formulation of lamivudine in India (479/CAL/1998) was entitled "Pharmaceutical Compositions" while its application for a salt form of abacavir (872/CAL/98) was entitled "A Novel Salt".

The majority of abstracts published by patent offices relating to pharmaceuticals do not identify the relevant drug/s. Usually, applicants for patents avoid revealing not only the INN but also the chemical structure/formula when they file the abstract. The implementation of Section 10(4)(d)—that an abstract must provide technical information on the invention—should be enforced strictly by the patent office.

Disclosure of INN by the applicant to the IPO would serve as an essential tool to further improve not just transparency and accessibility of patent information but also assist in examination and effective management of patent applications across different patent offices.

As is common in AusPat (the online Australian patenting system), online patent searches on the Indian patent database [www.ipindia.nic.in](http://www.ipindia.nic.in) should in the near future have a specific 'pharmaceutical name' search field. For example, one of the earliest patents on trastuzumab (a cancer drug) on AusPat can be tracked by merely searching for 'trastuzumab' in the

'pharmaceutical name' search field. Requiring the identification of the INN in the title of a patent application would greatly assist the IPO in its administration of its patent search database (IPAIR). Rather than sorting through thousands of applications with ambiguous titles and complicated chemical structures and formulas, the examiner or any other user who is interested in patent applications relating to a particular drug—for example, daclatasvir—would need only to search for this word in the title of the patent application and access the necessary documents.

#### **Key References:**

1. "Submission on the issue of disclosure of the INN in patent applications related to pharmaceutical inventions", MSF Access Campaign, September 2014<sup>xviii</sup>.
2. Correa C., "Guidelines for the examination of pharmaceutical patents: developing a public health perspective" (Working Paper), ICTSD-UNCTAD-WHO, January 2007<sup>xix</sup>.

### **V. Article 39.3 of TRIPS - pharmaceutical test data**

#### *Data exclusivity threatens access to medicines even in the absence of a patent barrier*

The draft policy has reiterated the government's position by stating 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."

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 Free Trade Agreement (FTA) negotiations, Indian negotiators from the Commerce Ministry rejected patent term extensions and data exclusivity as being "well beyond" international trade rule obligations. In doing so, the government established its position on the issue clearly: "On [the] IPR issue, whatever is discussed has to be in compliance with the TRIPS commitment," and publicly assured that India will continue to ensure that the high-quality generic drugs it produces are accessible to all countries.

Since data exclusivity is a long-standing demand of the US and EU pharmaceutical companies, we reiterate some of our concerns to the Think Tank. While India has unequivocally rejected the proposal during the FTA negotiations with the EU, it is likely to be part of the bilateral talks with US officials, future FTA negotiations including EFTA negotiations (led by Switzerland) and if India and US negotiate a FTA in the future.

MSF views data exclusivity as a backdoor route to monopoly status. It would require India to amend drug regulatory legislation (Drugs & Cosmetic Act) and would prohibit the Drugs Controller General of India (DCGI) from registering a more affordable version of a medicine as long as "exclusivity" lasts over the clinical trial data - usually 5 to 10 years. Exclusivity is triggered as soon as a pharmaceutical company submits data to a drug regulatory authority



on a new drug and on any new formulation of an old medicine. Since a pharmaceutical manufacturer is not permitted to place a generic pharmaceutical product on the market without registering with the DCGI, it is an effective barrier to generic competition. The key concern is that multinational pharmaceutical companies can astutely utilize data exclusivity to ensure that they have a monopoly on off-patent products. Data exclusivity, thus, protects pharmaceutical companies from price-busting generic competition.

A case study of how data exclusivity (DE) raises the price of medicines even when no patent exists was published by the New England Journal of Medicine.

*Colchicine: How a traditional medicine in the US was monopolised  
through data exclusivity*

- *Extracted from plants of the genus Colchicum (autumn crocus, Colchicum autumnale, also known as "meadow saffron")*
- *Used particularly as a therapeutic agent in the treatment of gout; has a history of 3000 years; cannot be patented*
- *Tablet formulation was widely available as a generic prescription drug in the United States since the 19th century*
- *It costs almost nothing to produce but was granted marketing exclusivity after US FDA accepted a **1 week trial** of the drug done by a company & was then bound to grant DE*
- *The company enforced its exclusivity rights forcing other manufacturers off the market & **the drug price rose 50 times from \$0.09 to \$4.85***

A further concern is the complexity that data exclusivity will bring to the current exports of generic medicines. For the registration of generic versions of medicines from India, stability studies and bioequivalence studies are routine requirements of the WHO pre-qualification programme and for regulatory authorities and procurers who wish to import drugs. Additionally, producing batches of generic medicines for the purpose of conducting stability tests and bioequivalence data requires a manufacturing license. Again, if a drug is not registered by the Central Drugs Standard Control Organisation (CDSCO), a manufacturing license cannot be issued by the state drug control organisations. Therefore, data exclusivity in India will also impede exports of generic medicines to other developing countries.

There is no doubt that data exclusivity will be an additional economic burden for developing countries. For example, an Oxfam study showed that data exclusivity provisions included in the 2001 Jordan-U.S. Free Trade Agreement resulted in the delay of registration of generic versions of 79% of medicines between 2002 and mid-2006. Without generic competition, Jordan spent an additional US\$6.3 - \$22.04 million on the selected drugs during this time period. The study also found that prices of the same medicines were up to 800% higher than in neighbouring Egypt.

Data exclusivity provisions in FTA negotiations or even a bilateral commitment to the US that places additional barriers to the registration of life-saving medicines, should be

avoided. It is important to note that from an international/legal perspective, there is no obligation to grant such exclusivity on pharmaceutical data.

**Key references:**

1. “All Costs, no Benefits: How TRIPS-plus Intellectual Property Rules in the US–Jordan FTA Affect Access to Medicines”. Oxfam Briefing Note, Oxford, March 2007<sup>xx</sup>.
2. “Data Exclusivity and Other TRIPS Plus”, WHO SEARO Briefing Note, March 2006<sup>xxi</sup>.
3. Kesselheim, A., Solomon, D., “Incentives for Drug Development - The Curious Case of Colchicine”, *N Engl J Med* 2010; 362:2045-2047<sup>xxii</sup>.
4. Anand Sharma Chairs Consultative Committee of Parliament on Challenges in IPR- International and Domestic, Press Release by Ministry of Commerce & Industry, 29 March 2011<sup>xxiii</sup>.
5. “India against inclusion of data exclusivity in any FTA”, PTI, 6 April 2011<sup>xxiv</sup>.
6. “India-EU free-trade pact could stifle generics industry”, *The Lancet*, Volume 377, Issue 9774, Pages 1305 - 1306, 16 April 2011<sup>xxv</sup>.

**VI. Think tank observations on TRIPS and TRIPS plus provisions**

We welcome the suggestion 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 of the draft policy). For the benefit of the IPR Think Tank, MSF would like to list TRIPS plus provisions that deter access to affordable medicines.

**Regressive TRIPS plus provisions tabled in free trade agreements that impede or delay access to affordable medicines**

Proposed Provision	Impact on Access to Medicines
<p><b><u>LOWERING THE BAR OF PATENTABILITY</u></b></p> <p><b>→ WHAT THIS MEANS:</b></p> <p>India would be required to patent new use or obvious modifications of existing medicines.</p> <p><b>→ PROPOSAL TABLED IN</b></p>	<p>Patents eventually run out - but not if pharmaceutical companies are provided opportunities to perpetually extend or renew monopolies. By applying for patents on obvious modifications and ‘new use’ of existing medicines, companies try to obtain multiple patents on known substances. India currently limits this practice, known as “evergreening,” under section 3(d) of the Patent Act. Preventing patents from being granted too easily on new use or on obvious improvements of existing drugs has protected generic competition in many therapeutic areas, including HIV, TB and</p>

<p><b>WHICH FTAs:</b></p> <ul style="list-style-type: none"> <li>• US (anticipated in future India-US FTA negotiations)</li> <li>• EFTA (currently being negotiated between India and Switzerland, Iceland, Norway and Liechtenstein)</li> </ul>	<p>cancer.</p> <p>Both the US and the Swiss negotiators (EFTA) are likely to ask for the removal of section 3(d), aiming to relax the legal framework for examining patent applications in India. Without such provisions, multinational pharmaceutical companies are likely to obtain patents far more widely in India, effectively blocking generic competition.</p>
<p><b><u>PROHIBITING PRE-GRANT OPPOSITIONS</u></b></p> <p><b>→ WHAT THIS MEANS:</b></p> <p>India would have to forbid challenges to weak or invalid patents until after they have been granted.</p> <p><b>→ PROPOSAL TABLED IN WHICH FTA:</b></p> <ul style="list-style-type: none"> <li>• US (anticipated in future India-US FTA negotiations)</li> </ul>	<p>Under Section 25 of the Indian Patent Act, third parties are allowed to oppose a patent application by providing information to the patent office before a patent is granted. These initiatives are known as ‘pre-grant’ patent oppositions. Given the large volume of patent applications on pharmaceuticals, examiners often miss information related to a patent application under consideration. If attention is drawn to information that shows the patent application is, for example, for a ‘derivative’ or a ‘new use’ of a known drug, or does not meet patentability criteria, the likelihood of a patent being wrongly granted is reduced. Thus, by aiding a number of rejections of key second-line medicines for HIV such as darunavir, lopinavir and ritonavir by the Indian patent office, patent oppositions have provided an important public health safeguard.</p> <p>Once negotiations start, the US is likely to ask for the removal of this system. Without opposition from patient groups and generic competitors, it is more likely that weak or invalid patents could be granted, effectively blocking generic competition.</p>
<p><b><u>INTRODUCING DATA EXCLUSIVITY</u></b></p> <p><b>→ WHAT THIS MEANS:</b></p> <p>India would have to delay the registration of generic</p>	<p>Data exclusivity would prohibit the Drugs Controller General of India (DCGI) from registering a generic medicine as long as the clinical trial data retains its exclusivity (usually 5 to 10 years). In addition to bio-equivalence data that is currently required, domestic producers will additionally</p>

<p>versions of medicines - even when there is no patent on that medicine.</p> <p><b>→ PROPOSAL TABLED IN WHICH FTA:</b></p> <ul style="list-style-type: none"> <li>• US (anticipated in future India-US FTA negotiations)</li> <li>• EFTA (currently being negotiated)</li> <li>• Was also tabled initially as a part of the EU FTA negotiations, but was withdrawn under public pressure</li> </ul>	<p>have to submit their own safety and efficacy data to register the generic medicines. This will oblige them to repeat clinical trials, which takes years and involves costs that the generic companies usually cannot afford. More importantly, the repetition of clinical trials raises serious ethical concerns.</p> <p>Exclusivity is triggered as soon as a pharmaceutical company submits data to the Drug Regulatory Authority on a new drug and, more frequently, on any new formulation of an old medicine. As long as a competitor cannot be registered as a result of exclusive rights over pharmaceutical test data, pharmaceutical companies can enjoy monopolies that allow them to charge high prices – even when a drug has been found not to deserve a patent or the patent has expired.</p>
<p><b>EXTENDING PATENT TERM DURATIONS</b></p> <p><b>→ WHAT THIS MEANS:</b></p> <p>To compensate for delays in the regulatory process, India would be required to extend the 20-year patent monopoly by at least 5 years.</p> <p><b>→ PROPOSAL TABLED IN WHICH FTA:</b></p> <ul style="list-style-type: none"> <li>• US (anticipated in future India-US FTA negotiations)</li> <li>• Was also tabled initially as a part of the EU FTA negotiations, but was withdrawn under public pressure</li> </ul>	<p>Currently, patents on drugs in most countries last for 20 years from the date of filing. A straightforward way to extend a company's monopoly over a drug is to simply extend the life of the drug's patent beyond 20 years.</p> <p>The extra years added to the patent are extra years in which the patent holder can maintain a monopoly position and continue to charge artificially high prices for the drug, free from generic competition.</p>

<p><b>INTRODUCING PATENT LINKAGE</b></p> <p><b>→ WHAT THIS MEANS:</b></p> <p>India’s drug regulatory authority (the Drug Controller of India) would be forced to link regulatory approval of generic medicines with the patent status of the medicine, and would be prohibited from approving generic medicines until patents have expired.</p> <p><b>→ PROPOSAL TABLED IN WHICH FTA:</b></p> <ul style="list-style-type: none"> <li>• US (anticipated in future India-US FTA negotiations)</li> </ul>	<p>Currently, a drug’s patent status and its registration status are evaluated by two separate entities. Linking patent status and the registration of medicines ensures that the drug regulatory authority has to withhold marketing approval for a generic version of a patented drug, regardless of whether the patent granted is valid or not.</p> <p>The DCGI lacks the necessary resources and expertise to assess whether a drug is patented or not and whether the patent is still valid. It would be more likely to enforce all patents including invalid ones – turning the Indian drug regulator into a patent police, and thus, wasting public resources that are much needed for ensuring the safety and efficacy of medicines in India.</p> <p>Patent linkage also undermines the Bolar provision – Section 107A of the patent law that allows producers to manufacture a generic version of a patented drug to conduct tests and obtain necessary marketing approval (or registration) in advance, so that a more affordable generic can be put on the market as soon as the patent expires. It can also undermine the use of a compulsory license since a license would not automatically lift the bar on registration by the drug regulatory authority until the patent term has ended.</p>
<p><b>INTRODUCING NEW FORMS OF IP ENFORCEMENT</b></p> <p><b>→ WHAT THIS MEANS:</b></p> <p>By giving multinational pharmaceutical companies free rein to demand that regressive IPR laws be enforced, the Indian judiciary would be unable to balance IPR with the people’s right to</p>	<p>Enforcement provisions can have a range of detrimental effects on the production of and trade in generic medicines by affecting how the Indian courts can handle disputes over IPR. The impact can have broad consequences: multinational pharmaceutical companies could claim that their IP is being infringed upon and block legitimate medicines from leaving India to other developing countries; third parties—such as treatment providers like MSF—could become subject to legal action simply for buying or distributing generic medicines.</p>

<p>health.</p> <p><b>→ PROPOSAL TABLED IN WHICH FTA:</b></p> <ul style="list-style-type: none"> <li>• EU (currently being negotiated)</li> <li>• US (anticipated in future India-US FTA negotiations)</li> </ul>	<p>If India agrees to these clauses, the Indian judiciary will have its hands tied and will no longer be able to balance IPR with people’s right to health. This is in direct contravention to a country’s right to place public health above IP rights.</p>
<p><b>INTRODUCING INVESTMENT CLAUSES</b></p> <p><b>→ WHAT THIS MEANS:</b></p> <p>Corporations make effective use of the investor-to-state dispute mechanism hidden in these agreements to sue governments; thus, seeking damages over domestic health policies outside of domestic courts.</p> <p><b>→ PROPOSAL TABLED IN WHICH FTA:</b></p> <ul style="list-style-type: none"> <li>• US (anticipated in future India-US FTA negotiations)</li> <li>• EU (currently being negotiated)</li> </ul>	<p>The investment chapter of FTAs could expand multinational companies’ ability to sue the Indian government when it regulates policies in the public interest. India could thus be prevented from rejecting, overriding or revoking a drug patent to increase access to a medicine, or from implementing drug price controls.</p> <p>Investor-state dispute mechanisms in the investment chapter can be used to sue outside of domestic courts, with large sums of damages being claimed in investor-friendly arbitration forums (such as the ICC, ICSID, UNCITRAL) to generate rulings that favour the claims of multinational companies over the government’s right and need to regulate policies in the interest of public health. Corporations have already filed several such disputes against governments in order to force a reversal of governmental public health policies and judicial decisions on patentability (for example tobacco company Phillip Morris vs. Uruguay; Phillip Morris vs. Australia; and drug company Eli Lilly vs. Canada). Key countries like South Africa and Australia have already announced their intention to exclude investor-state dispute mechanisms from future international trade deals.</p>

**Key References:**

1. “Trading Away Health: What to Watch Out for in Free Trade Agreements”, Briefing Document, MSF (2013)<sup>xxvi</sup>.

## **SUMMARY OF KEY RECOMMENDATIONS**

**India has demonstrated sound leadership and judgment in both promoting pharmaceutical innovation and protecting access to medicines. Raising the bar on patentability in the patent law has enabled India to promote meaningful biomedical innovation and guard against the practice of ever-greening whilst maintaining the country's status as the leading supplier of generic medicines.**

**In light of the threats to access to medicines posed by IP provisions that go beyond TRIPS requirements—as well as the mounting evidence pointing to IP hindering, rather than supporting, needed medical innovation—MSF recommends the Think Tank and the government to consider the following recommendations when formulating its IP Policy:**

1. The quality of examination and patents should not be weakened in order to increase the quantity of patents granted in India, whether by domestic or foreign entities or by individuals.
2. Any decisions on IP policy in India, especially on pharmaceuticals, must be made in a transparent, evidence-based manner and not as a result of enormous bilateral or industry pressure placed upon the Government of India.
3. India should maintain its balanced approach to IP enforcement and avoid the introduction of TRIPS plus measures—domestically—or as part of free trade agreements. The term “counterfeit” should be clearly defined as per the TRIPS agreement.
4. The TRIPS agreement does not entail any obligation to create a taxpayer-funded “Task Force” to enforce IP. IP rights are private rights. It is not the responsibility of governments to defend each right but rather to provide the legal system to enforce such rights. Patent and civil trademark disputes should be the domain of civil proceedings.
5. In the interest of public health, the IP policy should exclude chemicals/biological material/method of treatment and medical devices from the utility model system.
6. Mandatory disclosure of international non-proprietary name (INN) in patent applications (title and summary) to the Indian Patent Office is necessary to build a modern, transparent database on pharmaceutical patents and for greater co-ordination among the patent offices.
7. The intellectual property system and the drug regulatory system are administered separately and function independently. Efforts to integrate these two systems via

data exclusivity, “linkage” or other means are likely to have negative implications for access to medicines. India would be well advised to keep these systems separate, and to reject any efforts to make connections between the two.

8. India should safeguard against TRIPS plus provisions, either unilaterally or through trade agreements that could delay the introduction of generic competition or place additional barriers to the production, registration and supply of generic medicines from India.
9. The Think Tank should judiciously evaluate new models of innovation, particularly for those that de-link the cost of R&D from the final price of a medical tool (medicine, diagnostic or vaccine), thereby rewarding innovation whilst ensuring new health products are affordable. New models of innovation are particularly important for drug resistant tuberculosis and neglected diseases for which IP is insufficient to attract R&D.
10. Increasing levels of IP protection or enforcement will not reverse the neglect of biomedical innovation relevant to the health needs of India. India has an opportunity to change the R&D/innovation environment and the Think Tank should recommend that the government increase its public spending on biomedical R&D, fund all phases of R&D, particularly utilizing open approaches to R&D and prize funds as well as the costs of late-stage development, including clinical trials to ensure availability of much needed medical tools in the market at affordable prices. Consultation with the Ministry of Health and Department of Biotechnology are a must.
11. R&D funded by the Government of India should be commercialised on terms and conditions that ensure affordability and availability of any such medical tools that may emerge as a result of the funding. Public funded innovations should be governed by policies and guidelines that encourage open and equitable licensing for research tools and end products which are health related.

---

<sup>i</sup> [www.who.int/phi/CEWG\\_Report\\_5\\_April\\_2012.pdf](http://www.who.int/phi/CEWG_Report_5_April_2012.pdf)

<sup>ii</sup> <http://www.msfaaccess.org/our-work/neglected-diseases/article/958>

<sup>iii</sup> <http://www.keionline.org/node/1697>

<sup>iv</sup> [http://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(13\)70078-0/fulltext](http://www.thelancet.com/journals/langlo/article/PIIS2214-109X(13)70078-0/fulltext)

<sup>v</sup> <http://www.ncbi.nlm.nih.gov/pubmed/23722626>



- 
- vi [http://www.jpiamr.eu/wp-content/uploads/2014/12/AMR-Review-Paper-Tackling-a-crisis-for-the-health-and-wealth-of-nations\\_1-2.pdf](http://www.jpiamr.eu/wp-content/uploads/2014/12/AMR-Review-Paper-Tackling-a-crisis-for-the-health-and-wealth-of-nations_1-2.pdf)
- vii <http://www.plosbiology.org/article/fetchObject.action?uri=info%3Adoi%2F10.1371%2Fjournal.pbio.0060262&representation=PDF>
- viii <http://archive.uaem.org/sites/default/files/archive/uaem-white-paper-on-indian-bd-act.pdf>
- ix <http://www.ip-watch.org/weblog/wp-content/uploads/2009/06/intervention-by-india-seizure-of-generic-drug-consignments-at-ec-ports.pdf>
- x <http://keionline.org/node/1376>
- xi <http://keionline.org/node/864>
- xii [http://www.msfacecess.org/sites/default/files/MSF\\_assets/Access/Docs/Access\\_Brief\\_FTAEnforcement\\_ENG\\_2013.pdf](http://www.msfacecess.org/sites/default/files/MSF_assets/Access/Docs/Access_Brief_FTAEnforcement_ENG_2013.pdf)
- xiii <http://www.supremecourt.gov/opinions/05pdf/05-130.pdf>
- xiv <http://mobile.vossiusandpartner.com/pdf/Clevermove1.pdf>
- xv <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1660583/pdf/20061205s00006p1508.pdf>
- xvi [http://dipp.nic.in/english/Discuss\\_paper/Utility\\_Models\\_13May2011.pdf](http://dipp.nic.in/english/Discuss_paper/Utility_Models_13May2011.pdf)
- xvii [http://www.ipindia.nic.in/research\\_studies/FinalReport\\_April2007.pdf](http://www.ipindia.nic.in/research_studies/FinalReport_April2007.pdf)
- xviii [http://www.ipindia.nic.in/iponew/comments\\_PharmaGuidelines/M%C3%A9decinsSans\\_Fronti%C3%A8res\\_1\\_1September2014.pdf](http://www.ipindia.nic.in/iponew/comments_PharmaGuidelines/M%C3%A9decinsSans_Fronti%C3%A8res_1_1September2014.pdf)
- xix [http://www.iprsonline.org/resources/docs/Correa\\_Patentability%20Guidelines.pdf](http://www.iprsonline.org/resources/docs/Correa_Patentability%20Guidelines.pdf)
- xx <http://www.oxfam.org/sites/www.oxfam.org/files/all%20costs,%20no%20benefits.pdf>
- xxi [http://donttradeourlivesaway.files.wordpress.com/2010/12/global\\_trade\\_and\\_health\\_gth\\_no3.pdf](http://donttradeourlivesaway.files.wordpress.com/2010/12/global_trade_and_health_gth_no3.pdf)
- xxii <http://www.nejm.org/doi/full/10.1056/NEJMc1007963>
- xxiii <http://pib.nic.in/newsite/erelease.aspx?relid=71341>
- xxiv [http://articles.economictimes.indiatimes.com/2011-04-06/news/29388653\\_1\\_data-exclusivity-drug-seizure-issue-data-protection](http://articles.economictimes.indiatimes.com/2011-04-06/news/29388653_1_data-exclusivity-drug-seizure-issue-data-protection)
- xxv <http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2811%2960524-2/abstract>
- xxvi [http://www.msfacecess.org/sites/default/files/Access\\_Briefing\\_WhattoWatchFTAs\\_ENG\\_2013.pdf](http://www.msfacecess.org/sites/default/files/Access_Briefing_WhattoWatchFTAs_ENG_2013.pdf)