



Campaign for Access to Essential Medicines
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Mr. D.V Prasad
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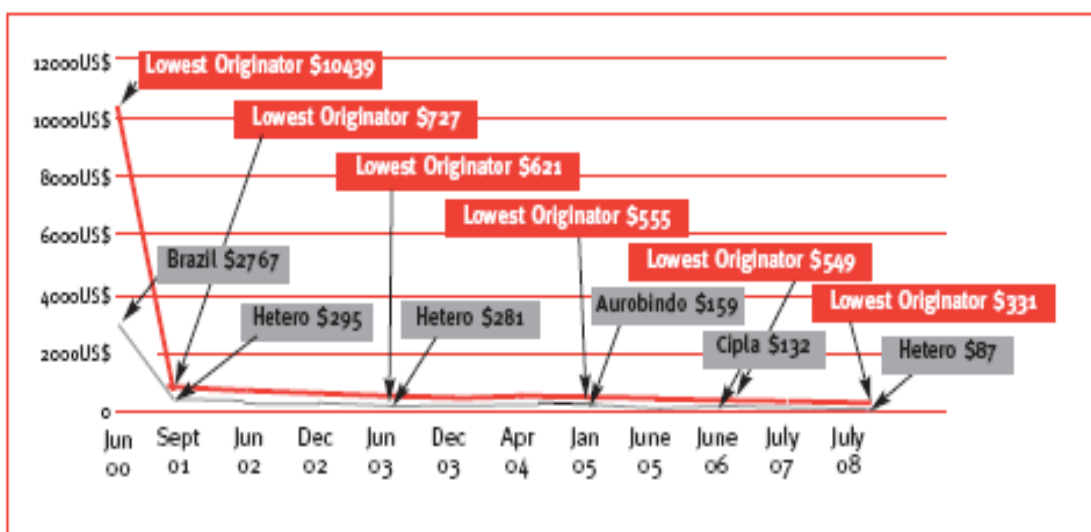
**Re: Submission on utility models
 Excluding pharmaceuticals to prevent barriers to generic production**

Dear Mr.Prasad,

Médecins Sans Frontières (MSF) – Campaign for Access to Essential Medicines welcomes the Department's initiative to seek views and suggestions on the subject of utility models.

As an independent international medical humanitarian organization, MSF treated its first AIDS patients in 2000. At that time, the epidemic had killed 16 million people and 33.6 million people were living with HIV worldwide, the majority in poor countries. Since 2003, an estimated six million people living with HIV in developing countries have received treatment for HIV and AIDS, largely due to the availability of safe, effective and affordable generic antiretrovirals (ARVs) from India. Increasing access to ARVs has resulted in substantial declines in AIDS related deaths as well as declines in HIV prevalence and incidence, with evidence showing that treatment reduces the transmission of HIV.

Today, MSF treats 170,000 people living with HIV/AIDS in developing countries, while procuring about 80% of AIDS medicines from Indian manufacturers, prequalified by the World Health Organization (WHO). These AIDS medicines are not only affordable but also adapted for use in resource limited settings, as generic companies have been able to develop simple to use fixed-dose combinations (FDC) and pediatric formulations of ARVs, in the absence of patent barriers.



Graph 1: Competition as a catalyst for price reductions. The fall in the price of first-line combination of stavudine (d4T), lamivudine (3TC), and nevirapine (NVP).

It is for this reason that MSF would like to express its concern about the proposed introduction of the utility model as an alternate tool for the protection of intellectual property rights (IPR) in India, and its potential to undermine public health safeguards in the Indian Patent Act, affecting access to affordable generic medicines from India.

The Utility Model and access to affordable medicines

With respect to medicines, one of the greatest risks that the utility model may pose is the potential for its use to unfairly extend monopoly as well as enable frivolous intellectual property protection for new use or minor modifications of known medicines, often referred to as *evergreening*.¹

When the Indian Patent Act was amended six years ago, patient and public health groups were collectively relieved at the inclusion of Section 3(d) – *prohibiting the patenting of insignificant or minor improvements of known compounds* – as well as the opportunity to object a patent before and after it is granted (pre- and post-grant oppositions). This effectively prevented pharmaceutical companies from being able to obtain intellectual property protection in India for pharmaceutical substances that are not actual inventions, such as combinations or minor modification of formulations of known compounds.

Such patent applications are designed to prevent and delay generic competition that could lead to lower prices and thus greater access to essential medicines.² For the first time, a country's legislature emphasized stricter patentability criteria for pharmaceuticals by including provisions in its patent law stipulating that patents should only be granted on substances that are truly new and innovative. Section 3(d) therefore strengthened the inventive step test and helped safeguard against the granting of frivolous patents on key first and second line AIDS medicines.³

However if India introduces utility model protection without excluding pharmaceuticals, such patent applications on minor improvements could subsequently be branched- or split-off to utility model applications, especially if pharmaceutical companies anticipate that patent applications on minor improvements of known medicines do not meet the patentability criteria and will be refused, in particular on grounds of lack of inventive step.

Pharmaceutical companies could therefore start seeking utility model protection on minor improvements of known medicines, as (a) 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; (b) utility model applications are not usually accompanied with substantive examination prior to registration.

Since the utility model provides the same exclusive rights as patents, the right holder can use the protection granted to stop generic producers from making and selling affordable generic versions of medicines for several years.

Exclude pharmaceuticals from utility model protection

As illustrated on page 11 of the DIPP Consultation Report, almost all the 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

¹ In Germany, for example, the law on utility models has even been extended to new uses of known substances. For more, see Alexa von Uexkull. June 2006, Patent World # 183. 'A Clever Move, Utility Models for second medical use inventions in Germany'. Available from: <http://mobile.vossiusandpartner.com/pdf/Clevermove1.pdf>

² December 5, 2006, v.175 (12), 1508–1509, Canadian Medical Association Journal. 'Supreme Court rules against drug patent evergreening'. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1660583/pdf/20061205s00006p1508.pdf>

³ India's patent law does not consider improvements or new forms of known medicines to be patentable. Based on this law, the Indian Patent Office on 11 June 2008 rejected the patent application filed in 1998 by German pharmaceutical company Boehringer Ingelheim for nevirapine syrup, used in the treatment of children living with HIV/AIDS. The patent application related to a syrup formulation of nevirapine - a new form of a known drug first invented in 1989, and thus older than the 1995 cut-off that India's Patents Act considers eligible for patenting. Patent decision available from: http://124.124.220.67/patentdecisionsearch/display_uploaded.asp?application_number=2485-DEL-1998-164

these countries have justified this with an expressed reference to public interest.⁴ In addition, medical devices that are critical for detection and treatment should also be exempted from any potential utility model protection.

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.⁵

Already, patents on new pharmaceutical compounds in India discourage generic production and affect India's vital role as the "pharmacy to the world," providing safe and affordable life-saving treatments. Against this background, it is important that the Indian law and policy don't impose additional barriers to generic production of medicines by adopting utility models without expressly excluding pharmaceuticals.

Kind regards,



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⁴ Dr K.S. Kardam. Assistant Controller of Patents and Designs, India Patent Office. "Utility Model - A Tool for Economic and Technological Development: A Case Study of Japan." Available www.ipindia.nic.in/research_studies/FinalReport_April2007.pdf

⁵ Carlos M. Correa. University of Buenos Aires, August 2002. 'Protection and Promotion of Traditional Medicines: Implications for Public Health in Developing Countries'. Available from: <http://apps.who.int/medicinedocs/pdf/s4917e/s4917e.pdf>