

*A submission on the Shortcomings in the Patents Act, 1970 & Patents Ordinance that impact right to health, their impact & proposed amendments by health groups*

*Legislation on Patents till date by the government:*

<u><i>1970</i></u>	<u><i>Patents Act</i></u>
<u><i>1995</i></u>	<u><i>TRIPS Agreement</i></u>
<u><i>1999</i></u>	<u><i>The first amendment of the Patents Act to comply with TRIPS</i></u>
<u><i>2002</i></u>	<u><i>The second amendment of the Patents Act to comply with TRIPS</i></u>
<u><i>2004</i></u>	<u><i>The third amendment - Patent Ordinance</i></u>

Some facts:

- Product Patent is the grant of a monopoly right to the patent owner to manufacture, price, market, sell etc. Only the patent owner or the agent authorised by him/her through a licence can produce the patented medicine. It is an absolute right and unless the government has the political will to exercise an effective price control & compulsory licence mechanism.
- The challenge before lawmakers during the implementation of TRIPS patent regime is to provide strong public interest provisions to curb the abuse of patent monopoly.
- Amendments have been undertaken to comply with TRIPS. In fact, the govt has complied with “TRIPS PLUS” standards i.e. more than what is required under TRIPS
- Amendments did not use the flexibilities available under TRIPS to protect public health
- 70 amendments to the Patents, Act have been made by the recent Patent Ordinance. All are not related to TRIPS compliance and need to be evaluated in the context of their impact on health, agriculture, software etc.

The table below deals with following issues in the context of the Patents Act, 1970 & the Patents Ordinance:

- *Definition of Invention and its impact on scope of Patentability*
- *Addition of the word 'mere' in Sec. 3 that defines what are not inventions by the Patent Ordinance*
- *The introduction of quick examination by the Patent Ordinance*
- *Amendments by the Patent Ordinance to the requirements of publication*
- *Limited immunity offered by the Patent Ordinance*
- *The Compulsory Licence Mechanism*
- *Royalty to patent owners i.e. pharmaceutical companies*
- *Deletion of safeguard of parliament scrutiny for amendments by government by abrogating important issues to Rule making*

<u>Shortcomings in the Patents Act, 1970 &amp; Patents Ordinance that impact right to health</u>	<u>TRIPS Requirement</u>	<u>Impact</u>	<u>Proposed amendments to use TRIPS flexibilities by Health Groups</u>
<i>Scope of Patentability &amp; the Definition of Invention</i>			
<p>1. Till date we had no product patents, therefore a <u>'loose definition of invention'</u> did not result in frivolous or ever greening of patents. Sec 2 of the Patents Act gives a broad definition of patents that needs to be addressed in the context of a new patent regime.</p>	<p>It is not required under TRIPS to expand the scope of patentability. There is no bar on restricting the scope of patentability.</p> <p>The Article 27(1) of TRIPS requires patents for innovations that are new, involve an innovative step and are capable of industrial application. This should be used to our advantage to prevent secondary patents.</p>	<p>We will not be able to restrict the number of product patents. Many frivolous patent applications may get cleared.</p>	<p>To prevent misuse of the product patent regime, restrict the scope of patentability. This will make more drugs available for generic manufacturing:</p> <p>Inventions can be defined as those involving 'novelty, inventive step &amp; industrial application.</p> <p>To avoid frivolous claims and secondary patents exclude 'formulations, salts, esters, polymorphs, hydrates, isomers, metabolites, combinations, new delivery systems, change in purity level or particle size' etc of a known chemical entity from the scope of patentability</p>

<p><b>2. Evergreening of Patents</b> The Ordinance amends Sec 3 of the Act, which describes what are not inventions i.e. essentially what are not patentable. After the amendment Sec 3 of the Act now reads as:</p> <p><i>What are not inventions:</i> <i>(d) The discovery of any new property or 'mere' new use for a known substance.</i></p> <p>As per the legal interpretation now only <i>mere new use is not patentable but new use is patentable.</i></p>	<p>There is no requirement under TRIPS to change or expand the scope of patentability</p>	<p>Will result in drug companies evergreening of patents, i.e. patenting of old medicines by making minor changes and claiming it as new inventions or patenting of new use of an old drug.</p> <p>We will not be able to restrict the number of patents. This increases the chances of many frivolous patents escaping public scrutiny.</p> <p>If we allow secondary patents Indian companies will have to withdraw a number of products that they introduced in India after 1995. The patented substitutes of these will cost many folds for Indian patients.</p>	<p>Remove the word 'mere' (added by the patent Ordinance) from Sec. 3. This will ensure that pharma companies can not apply for product patent for the new use/dosage of old drugs.</p>
<p><i>3. In the section 3, micro-organisms are excluded from the list on 'what are not inventions'</i></p>	<p>Article 27(3)b of TRIPS provide for mandatory review of patenting of micro-organisms. Patenting of micro-organism is not required as a TRIPS obligation</p>	<p>Will impact research related to treatment of diseases caused by micro-organisms. Restrict all research activities related to micro organisms.</p>	<p>Section 3 of the Amended Patent Act 1970, which deals with 'what are not patents', should be worded in such a way to deny claims for patenting micro organisms. [Identification of a new micro-organism is a discovery, not an invention]</p>

<i>Examination of the Patent Application</i>			
<p>The introduction of conditions for <u>quick examination</u> by the Patent Ordinance in the absence of any investment in capacity building of patent examiners or patent office can result in frivolous product patents being granted. At present the number of patent examiners is only 150 as compared to USA, which has 3000. As per the Ordinance the time frame of the examination of patent application is left to the Rules. The Rules provide 1-3 months for the preparation of examination report as compared to the earlier 18 months.</p>	<p>Not required under TRIPS</p>	<p>Grant of frivolous patents. Currently there are approximately 6000 product patents applications for drugs pending in the mailbox. In the absence of pre-grant opposition, these 6000 applications would escape public scrutiny. E.g. The Gleevec Case, please find the details below</p>	<p>The earlier time limit for examination preparation report should be re-introduced. Provisions for the capacity building of patent examiners and patent office should also be incorporated in amendments.</p>
<i>Publication &amp; Right to Information</i>			
<p><u>Publication:</u> As per the Ordinance, minimum particulars regarding the patent application that were mandatory for publication [under Sec. 11A] were deleted. Further after the acceptance of specification and examination but before the granting of the patent, there was a requirement of publication of the fact of specification and the specification itself [under Sec. 23] which has again been deleted. The Ordinance requires publication of patent application only and not complete specification. The Rules too are silent on the minimum information that is mandatory for publication.</p>	<p>There is no requirement under TRIPS</p>	<p>This will impact the right to information of the people and parties who oppose a frivolous product patent.</p>	<p>Any Amendment should:</p> <ul style="list-style-type: none"> <li>- clearly specify the minimum information that is mandatory for publication.</li> <li>- also require that <u>all</u> of the following be published before the grant of patent               <ol style="list-style-type: none"> <li>a. acceptance of specification by the patent office and</li> <li>b. specification itself</li> </ol> </li> </ul>

<i>Stopping production of available generic medicines</i>			
<p><u>No immunity for continuing generic production of drugs already in the market once the product patent is granted.</u> Under the Ordinance immunity is only against damage suits for past production of the patented drug</p>	<p>Blanket immunity can be given under Article 30 of the TRIPS agreement</p>	<p>Withdrawal of generic drugs already in the market after the grant of the patent. People who are on cheap generic drugs will be forced to switch over to expensive patented drugs or discontinue their treatment</p>	<p>Amendment should include immunity for continued production of generic drugs which are in the market at the time of the product patent regime coming into force.</p>
<i>Exceptions to Exclusive Patent Rights</i>			
<p>1. Compulsory licences have seldom been issued in India. The need for compulsory licences was tempered by the availability of generic drugs in the absence of product patent protection of patented drugs. With the product patent regime being introduced, procedures provided for Compulsory Licensing in the Patent Act should be simplified for its effective working. <u>However there was no amendment to address cumbersome procedures for compulsory licences.</u> Currently the provisions in the Patents Act &amp; Patent Ordinance (sec. 82-94) are unclear &amp; bureaucratic in nature with no time limit for grant of the compulsory licence, e.g. Provisions such as Sec. 84, Patent Act 1970 need to reviewed.</p> <ul style="list-style-type: none"> <li>As per Sec. 84 an application for the grant of compulsory licence can be made to the Controller of Patents only after the expiration of three years from the date of the grant of a</li> </ul>	<p>The Doha Declaration explicitly recognises (for which India fought hard) the right of member states to grant compulsory licence and the freedom to determine the grounds of granting compulsory licence.</p> <p>Article 8 allows for action against abuse of patent rights i.e. high price, demand remaining unsatisfied etc.</p>	<ul style="list-style-type: none"> <li>Delays and bureaucratic barriers will dissuade Indian generic manufacturers from applying for compulsory licences.</li> <li>Multinational companies also have the further option of delaying the grant of compulsory licences by exercising their right to oppose it.</li> <li>It may take years for the compulsory licence to be granted.</li> </ul>	<p>Provisions in the Act should also be simultaneously amended to simplify &amp; clarify the compulsory licence mechanism. Countries like Canada etc have in their legislation effective provisions for compulsory licence. Section 84 should include that before applying for a compulsory licence, an applicant may not wait for more than 150 days to get a voluntary licence from the patent holder and that under section 87(4) the controller of patents may not take more than 100 days to hear opposition to the grant of compulsory licence and decide the case.</p>

<p>patent. The Section also requires the person making the application to set out the nature of interest and provides an opportunity for the patent holder to oppose the application (i.e. pre-grant opposition for compulsory licenses).</p> <ul style="list-style-type: none"> <li>• Again Section 84(4) clause 6 stipulates that the controller on receiving the application from a domestic manufacture for compulsory licence will direct the applicant to justify the reasons.</li> </ul> <p>All these procedures are open ended without time limits</p>			
<ul style="list-style-type: none"> <li>• Sections 92 (3) of the amended Act describes about the government use of patents in case of national emergency or extreme emergency. However what constitute emergency need to be clearly defined in broad terms.</li> </ul>	<p>Article 31.b of TRIPS allows government use without the authorisation of the patent holder for public non-commercial use and in case of national emergency or extreme emergency. Doha declaration has clarified individual countries right to determine what constitute a emergency.</p>	<p>India has huge disease burden in not just in communicable disease but also in non-communicable disease. The scope of Compulsory Licensing for disease emergencies will be limited to handful of diseases.</p>	<p>Section 92(3) of the amended Act have only given examples of public health crisis. It should be interpreted in broad terms.</p>

<p>2. Compulsory licence for export of patented pharmaceutical products: The Ordinance requires compulsory licenses not only by India but also for the importing country.</p> <p>“92A. (1) Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, <u>provided compulsory licence has been granted by such country.</u></p>	<p>TRIPS permits the grant of compulsory licences by India to generic manufacturers for export purpose to countries with no or insufficient manufacturing capacity in the pharmaceutical sector. There is no requirement of CL to be issued by the importing country.</p>	<p>Indian Drug Companies will not be able to export to Least Developing Countries (LDC) in the absence of a compulsory licence granted by the LDC. With no patent regimes, the question of granting a compulsory licence does not arise for LDCs. This provision only helps Multi - National Companies who want to block generics from entering countries that desperately need cheap drugs without which the vast number of their citizens will surely die a premature death as the AIDS crisis in those countries has so tragically shown.</p>	<p>Remove the requirement of CL from the importing country with no or insufficient manufacturing capacity in the pharmaceutical sector from the Patent Ordinance.</p>
<p><i>Parallel Importing</i></p>			
<p>Section 48 of the amended principal Act does not include provisions for exhaustion for Patent Rights. This provision is required to allow import of patented medicines from a cheaper international source.</p> <p>Section 107A(b) does permit import, but only from a person duly authorized by the patentee to sell it in that country.</p>	<p>Article 28 of TRIPS about exclusive rights to the patent holder also include right to import. However Doha declaration [paragraph 5(d)] clarifies each country to establish its own regime with own exhaustion patent conditions.</p>	<p>One patented medicine is available in different countries at different prices. The existing provisions in the Act may cause delay in importing it from a cheapest international source [parallel import].</p>	<p>Incorporate patent exhaustion conditions in the Act to limit the exclusive right of patentee only for the first sale. This will ease parallel imports since the innovator’s right is exhausted in the first sale and it should have no say over subsequent resale.</p>

<i>No ceiling on Royalty to Patent Owner</i>			
<p>The 2002 amendment <u>removed the ceiling of 4% royalty to MNCs</u> for generic production under a compulsory licence or production for public non-commercial use by the government</p>	<p>No requirement under TRIPS to remove ceiling</p>	<p>Multi National Pharmaceutical Companies are demanding a minimum royalty of 40% that will impact the price of generic drugs produced under a compulsory licence and even the drugs produced by the government for public non-commercial use.</p>	<p>Fix a reasonable ceiling on the royalty to Multi National Pharmaceutical Companies for generic production under a compulsory licence or production for public non-commercial use by the government</p>
<i>Pre &amp; Post Grant Opposition of Patent</i>			
<p>Pg 8, Sec. 23 of the Patent Ordinance has substantially amended Sec 25 &amp; Sec 26 of the Act, which was related to Pre Grant Opposition. This amendment substantially alters the nature of the right of pre-grant opposition as it stood under the Patents Act before the Amendment. The amendment substantially limits the grounds for opposition, which were available under S. 25 of the Act to patentability and wrongful furnishing of information. It alters the right to be heard with a provision for a <i>written submission</i>. According to the Ordinance <i>'the person making a representation referred to in that sub-section shall not become a party to any proceedings under this Act and 'the Controller shall consider and dispose of such representation in such manner and within such period as may be prescribed'</i>. <u>Further the Rules issued to implement the Ordinance restrict post grant opposition by stipulating time limits.</u></p>	<p>No obligation under TRIPS to change pre- grant opposition</p>	<p>Currently there are approximately 4300 product patents applications for drugs by Multinational Pharmaceutical Companies pending in the mailbox. In the absence of pre-grant opposition, these 4300 applications will escape public scrutiny. Absence of an effective pre-grant opposition mechanism could lead to grant of frivolous patents. Time limit for post grant opposition is in the advantage of pharmaceutical companies.</p>	<p>As the Act stood before the amendment, after the Patent Controller's examination for patentability, novelty and priority, the patent application is published, whereupon any member of the public <i>had</i> the right to make objections against the patent application. The objector was treated as a party and had the right to participate in all the proceedings in the grant of the patent. This procedure was based on the understanding that the public is vitally concerned with the ultimate effect of a grant of a monopoly. The original Act as per Sec 25(2) specifically required that 'Where any such notice of opposition is duly given, the Controller shall notify the applicant and [may, if so, desired give] to the applicant and the opponent an opportunity to be heard before deciding the case'. <u>Retain the pre-grant opposition procedure of the original Patent Act, 1970.</u></p>

***Amendments by Rule Making***

<p>Many important issues such as timelines for publication and examination etc have been removed from the Act and abrogated to rule making power of the government.</p> <p>The Ordinance took away important safeguards and limitations imposed by the statute, and made it at the discretion of the government by virtue of the Rules. As a result, the government and the Patent Office can now tamper with the various time lines by <u>amending the Rules</u> as and when it requires. Under the Ordinance, 7 types of time limit will be determined by the Patent Office through the Rules and not by the statute. E.g. Sec 11A for example where timeline for publication has been mentioned as ‘eighteen months’, under the Patent Ordinance has been substituted by the words ‘as prescribed’ by the rules. The excessive and unbridled delegation to the Office is further increased by the following provision: <i>‘the central government may, if it is satisfied that circumstances exist, which render it practically not possible to comply with such condition of previous publication, dispenses with such compliance’</i>. As a result, in future the public will not be given an opportunity to offer its comments to the Rules before their amendment.</p>	<p>Not required by TRIPS</p>	<p>The safeguard of parliament scrutiny has been removed for amendments affecting important aspects of publication, examination etc.</p>	<p>Reinstate the previous timelines and safeguards as before the Ordinance. A debate on what should be delegated to Rule making in the Statute should be initiated in Parliament.</p>
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Gleevec Case:

- In April 1992 (Switzerland), Novartis filed the original patent application for “Imatinib mesylate”, a drug which is the only effective treatment for Chronic Myeloid Leukaemia, and obtained a patent. The patent application included wide spectrum compounds of “Imatinib mesylate” including salts.
- In July 1998 in Australia, Novartis filed a patent application for a patent claiming  $\beta$ -crystalline form of the salt of “Imatinib mesylate” as an invention and obtained a patent for it in Australia. 25,000 people in India are diagnosed with Chronic Myeloid Leukaemia (CML) annually.
- The drug “Imatinib mesylate” is the available treatment. Generic versions of “Imatinib mesylate” produced by Indian manufacturers were available to patients at Rs. 8,500 (170US\$) to 12,600 (252 US\$) per month per person.
- In 2003 in India on the basis of the Australian patent in 1998 and withholding the fact that the original molecule of “Imatinib mesylate” was patented in 1992 and not in 1998, Novartis obtained an Exclusive Marketing Right in India for “Imatinib mesylate”.
- On the basis of the EMR, Novartis obtained High Court injunctions against six generic drug manufacturers of “Imatinib mesylate” preventing them from manufacturing it. Novartis’s Branded version of Imatinib mesylate “Gleevec” is priced at Rs 120,000 (US\$ 2400) per month per person. Generic versions were available at Rs. 8,500 (170US\$) to 12,600 (252 US\$) per month per person.
- The injunctions affected access to treatment of 25,000 CML patients annually.

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