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DRAFT PATENT AMENDMENT RULES UNDERMINE PRE-GRANT OPPOSITION

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The draft patent amendment rules made public on August 23 this year could hugely benefit big pharma but turn out to be disastrous for patients in India and in countries in the global South, which rely on generic drugs manufactured in India, in accessing affordable drugs and vaccines.

The draft rules released by the Department for Promotion of Industry and Internal Trade for stakeholder comments have made a few significant changes that will create needless hurdles in pre-grant opposition of patents. First, the draft amendment rules have introduced a variable fee for filing pre-grant oppositions. The proposed introduction of fees can run into thousands of rupees and thus impose a significant financial burden on civil society organisations and patients' groups filing pre-grant opposition.

The most important change is about granting the controller the power to determine the maintainability of representation by individuals or civil society organisations to file pre-grant oppositions.

"Pre-grant opposition is an important public health safeguard against patent evergreening and unmerited monopolies. It is one sure way to ensure that quality-assured and affordable generics remain accessible," says Leena Menghaney, India Head and Global IP Advisor, Medecins Sans Frontieres – Access Campaign. But the amendment in the draft patent rules threatens the safeguard against extending the duration of patent protection on completely frivolous grounds. Big pharma has lobbied for years to remove essential safeguards from India's patent laws.

"The purpose of the draft amendment rules to pre-grant opposition is to knock out people whom they don't want [to challenge the granting of patents]. This is wrong. How will the controller decide the maintainability and on what basis? There is no guiding factor. This will create more problems," Anand Grover, senior advocate at the Supreme Court told *The Hindu;* Mr. Grover had represented the petitioners in the Bedaquiline pre-grant opposition. "Today there is no problem. Anyone can file a pre-grant opposition and the controller has to adjudicate on merit."

Mr. Grover further added: "The [government] is favouring the companies, and pharma companies don't want pre-grant opposition. But since they can't do away with that, they are making the process difficult. They are introducing the maintainability criterion but there should be a rational basis. If the pre-grant opposition has grounds of pre-grant, then how is it not

maintainable? The controller will decide on an arbitrary basis [about maintainability], which is wrong."

The draft rules on who is eligible to file a pre-grant opposition comes at a time when on September 13 this year Nandita Venkatesh from India and Phumeza Tisile from South Africa were listed in the *Time* magazine's 100 emerging leaders globally who are defining the next generation of leadership. The reason for being chosen in the select club: their stellar role in successfully thwarting Johnson & Johnson's attempt to extend the patent protection for its oral drug Bedaquiline through evergreening. Bedaquiline is a very important drug for treating multidrug-resistant TB.

Both Nandita and Phumeza are TB survivors who lost their hearing due to the use of the highly toxic Kanamycin injection to treat MDR-TB. They both filed the pre-grant opposition along with Network of Maharashtra people living with HIV (NMP+). The duo was supported by Médecins Sans Frontières.

In March this year, the Indian Patent Office struck down J&J's evergreening attempts by ruling that making a derivative of quinoline in its salt form (fumarate) was obvious and did not involve any inventive step, and is therefore non-patentable.

Currently, the Patents Act explicitly permits "any person" to file a pre-grant opposition without the discretion of the Controller. But as per the draft patent amendment rules, the maintainability of the petitioners who file a pre-grant opposition will not be automatic but will be determined by the Controller.

While "any person" can currently file a pre-grant opposition, only interested persons can file a petition when it comes to opposing patents that have already been granted. "In many instances, big pharma had questioned the maintainability of petitioners opposing patents and delayed cases for long periods. Bringing in maintainability of representation in pre-grant opposition will face the same fate as big pharma can always contest the Controller's decision regarding maintainability of petitioners," says Ms. Menghaney.

"Bringing in maintainability of representation in the pre-grant opposition will be the first major amendment to the Indian Patent Act. The provision of pre-grant opposition in the India Patent Act is unique in the world, the reason why big pharma has been opposed to it as they want continued control over the market and charge high prices for their products. Any weakening of the provision will be disastrous for patients as they will not be able to afford the high price of medicines and the generic drug industry will be affected too," says Dr Biswajit Dhar, Vice President, Council for Social Development.

There have been innumerable instances when pre-grant opposition filed by patient groups and civil society organisations have resulted in the rejection of patent protection extension sought by big pharma based on frivolous claims of "novel invention".

For instance, in May 2006, in the case of Tenofovir disoproxil fumarate (TDF), a first line antiretroviral used for treatment of people living with HIV, the pre-grant opposition was filed against Sahara by the Indian Network of People Living with HIV/AIDS and the Delhi Network of Positive People. The pre-grant opposition was based on the ground that the drug consists of a previously known compound.

In another instance, Boehringer Ingelheim's patent application for its paediatric form of the anti-AIDS drug Nevirapine was rejected in 2008 based on a pre-grant opposition filed by socio-legal group Lawyers Collective on behalf of patients' groups in May 2006. The rejection was on the

grounds that new forms of known substances cannot be patented unless there is a significant enhancement of efficacy.

Other high-profile attempts at evergreening that failed due to pre-grant opposition filed by patients' groups and civil society organisations include Glivec (imatinib mesylate), Zidovudine/Lamivudine (first line HIV medicines) and Lopinavir/Ritonavir (second line HIV medicines).

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