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To
The Secretary,
Department for Promotion of Industry and Internal Trade
Udyog Bhawan,
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Thank you for the opportunity to provide written comments regarding the Draft Patents (Amendment) Rules, 2023 (hereinafter the 'Draft Rules') made public on August 23, 2023, by the Department for Promotion of Industry and Internal Trade (DPIIT)

Public Citizen is a nonprofit consumer advocacy organization with over 500,000 members and supporters. Public Citizen's Access to Medicines Program works with partners across the United States and around the world to make medicines available for all through tools in policy and law. Public Citizen is concerned about the impact of the Draft Rules on access to affordable medicines, diagnostics, and vaccines for patients in India and other developing countries.

We understand that the amendments aim to streamline the patent office's operations and expedite patent processing timelines. However, certain amendments could dilute critical protections, affecting people's right to file pre-grant oppositions, compulsory licences and transparency in the patent system.

The following are the concerns of Public Citizen with the Draft Amendment Rules 2023:

1. **Pre-grant opposition:** The proposed Draft Rules seek to amend Rule 55, which governs the procedural aspects of filing pre-grant oppositions. The proposed

amendments to pre-grant opposition procedures threaten an essential tool for preventing patent applicants from gaining patent monopolies based on weak or erroneous information, for improving the quality and efficiency of patent office examinations, and safeguarding access to medicines.

a. The suggested insertion in Rule 138, for the introduction of fluctuating and excessive fees for filing pre-grant oppositions, deviates from the current practice of filing with no fees. Under the proposed change, the filing fee could potentially reach a substantial amount, especially for complex patent applications like those related to medicines. Furthermore, a fee has also been introduced for giving notice for attending the hearing before the Controller. This arrangement will create a substantial financial barrier for individuals, patient groups, and civil society organizations working on access to medicines to provide essential information to the patent office to ensure unmerited patent applications are not granted. Furthermore, this move lacks an explanation of the rationale behind the imposition of fluctuating and excessive fees for the applicants filing the pre-grant opposition. It is important to acknowledge the fact that in cases of pre-grant opposition filed before the Controller for unmerited drug patents, applicants are predominantly patients or patient groups with limited financial resources. It is noteworthy to mention here that in March 2023, a secondary patent for the new TB drug bedaquiline was turned down following successful opposition by two TB survivors and a patient group. As a result, the price of the drug was reduced by 55 percent.

b. The suggested insertion in Rule 55 of the clause that the Controller shall first decide the maintainability of the representation. This allocates discretionary powers to the Controller for accepting or rejecting the pre-grant application without looking at the merits of the same. The suggested clause exceeds the scope outlined in Section 25(1) of the Patents Act, which explicitly permits “any person” to file a pre-grant opposition without the necessity of the Controller to determine the eligibility of the individuals to do so. Moreover, this will give the stakeholders an opportunity to influence the Controller and threatens an important mechanism for improving the accuracy of patent claims and preventing pharmaceutical monopolies based on unmerited patents.

Recommendations:

- Avoid amending the Patent Rules to introduce fees for filing pre-grant oppositions that could limit quality oppositions, leading to the grant of unmerited patents.
- Ensure that the Controller does not possess any subjective powers when it comes to the maintainability of representation. The current practice of formally seeking identity proofs from patent opponents should be maintained. This practice establishes credibility and ensures verification, which is an objective standard in line with the Patents Act. By following this practice, a fair and just decision can be reached, and the integrity of the patent system can be upheld.

2. **Working of patents and compulsory licences:** In order to prevent the abuse of patent rights, section 83 of the Patents Act ensures that a patented invention is being utilised (worked) sufficiently and does not impede protection of public health. When patent holders refuse or fail to share how their patents are worked, it hinders the scrutiny of market practices that can foster monopolies, stifle competition, and could be detrimental to the public interest. In return for exclusive patent rights, patentees are required not only to disclose the patent to the public but also to work them. Under the current Rule 131, patentees are required to file a working statement every financial year. As per the law, the statement filed through Form 27 provided information on the quantum, value, manufacturing/importing specifics, licensing details and working of inventions in India. However, the 2020 amendment removed this information, replacing it with a broad disclosure of information on value and whether the patented invention is manufactured or imported. The timely disclosure of detailed information concerning the working of a patent is crucial to understanding whether a patented medicine is meeting the needs of the public. Failure to sufficiently work a patent serves as one of the grounds for a compulsory licence and revocation of the patent under the Indian Patents Act. Under the proposed Draft Rules, the opportunity to gain information on patent workings through Form 27 will be lost.
    a. The proposed Draft Rules extend the interval of filing Form 27 statements from once every year to once every three years. As per the Indian Patents Act, if, even after two years of granting the compulsory licence, a reasonable requirement of the public is not met, or if the patented invention is not available to the public at a reasonably affordable price, the patent may be revoked. Extending the interval for filing working statements and removing the requirement to disclose

how a patent is worked decreases transparency and could significantly impact competitors' ability to request a compulsory licence based on evidence of non-working. The ability to apply for compulsory licence is crucial to facilitating generic entry and ensuring medicines are made available to the public at affordable prices. Additionally, generic manufacturers will be at a disadvantage in infringement lawsuits, as they often rely on the non-working of patents as a defence against injunctions. Even the government may not be in a position to assess the impact of a patent on affordability and access to medicines. The crucial information on the working of the patent is available only through the Form 27 statement.

In the past, working statements have been used to push pharmaceutical corporations to make their drugs available to the Indian public. Otsuka Pharmaceuticals holds six different patents for Delamanid, a WHO-approved treatment for drug-resistant tuberculosis, in India. A perusal of the working statements from Otsuka revealed that the patented drug was not being made available in India. However, Otsuka applied for marketing approval in India after patient groups and civil society raised concerns about the non-working of patents, based on the information provided through Form 27.

Recommendations:

- Avoid amending the Patent Rules to remove critical information such as quantum, value, and manufacturing/importing specifics and extending the time period of filing this information to once in three years.
- Maintain requirement of filing the working statements annually with all information on how the patent is worked, including whether manufactured in India or imported, total value and quantum of the patented invention and details on licences.

3. **Transparency in the patent system:** Under Section 8 of the Indian Patents Act, after the application for patent is filed until the grant/refusal of the patent, the Controller may ask the applicant to furnish information within a specified time, relating to processing/filing status of the patent in countries outside India. Rule 12(2) compliments this good practice aimed at improving transparency and accountability within the patent system. However, the proposed Draft Rules seeks to amend Rule 12(2) by substituting

the ongoing reporting obligation with a "one-time" requirement within "two months from the date of issuance of the first statement of objections" (FER). It is important to note that the proposed amendment contravenes the law under Section 8 of the Indian Patents Act. Maintaining the existing transparency requirement is significant for the effective monitoring of patent applications. Removal of this clause could lead to missing critical evidence in patent examination, opposition, and revocation procedures, thereby potentially resulting in unmerited patent grants. This may be another hindrance to access to medicines.

Recommendations:

- Revise the Patent Rules to mandate filing updated information when there are changes in the status of any corresponding foreign application, with a specific requirement for updated information before a Controller hearing. This aligns with legislative periodic disclosure requirements and provides examiners and the Controller with timely status updates of corresponding foreign applications.

In conclusion, Public Citizen urges the Government of India to take into account these critical concerns and take decisive action in amending the proposed Draft Rules. India, known as the pharmacy of the world, must address the serious implications of the proposed amendments for access to medicines and the well-being of patients. The proposed amendments will significantly impact generic competition and supply both within India and worldwide.

We appreciate the opportunity to comment. Thank you.

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