Third World Network's Submission to the Department for Promotion of Industry and Internal Trade (DPIIT)
Pertaining to the Draft Patent (Amendment) Rules, 2023

The Ministry of Commerce and Industry had proposed and published the Draft Patent (Amendment) Rules, 2023 (hereinafter the "draft Rules") on August 23, 2023. We welcome DPIIT's initiative to solicit views from all stakeholders and hence we wish to submit our comments and suggestions on the same. While the stated objective of the proposed amendments is to expedite the process of granting patents, many proposed changes in the draft Rules have raised critical concerns which will affect public interest safeguards and lead to granting patent monopolies against the provisions of the Patents Act especially under Section 3. This submission touches upon three broad issues that may severely impede access to affordable medicines. The three issues are:

I. Pre-grant Opposition
II. Working of Patents Requirement
III. Information on Foreign Filing Requirements

I. PRE-GRANT OPPOSITION:

The proposed draft Patent Rules seek to amend Rule 55, which governs the procedural aspects of filing pre-grant oppositions. These proposed amendments include the introduction of a filing fee for pre-grant opposition and the requirement for the Controller to determine the "**maintainability of representation**".

S.No	Proposed Change	Current Rule	Impact on Access
1	Granting the Controller discretionary authority to determine "maintainability" of the pre-grant opposition application i.e., who may file a pre-grant opposition.	The current system allows 'any person' to file the pre-grant opposition.	a) Gives arbitrary powers to the Controller, raising concerns about predisposition and undue influence b) Will lead to increased litigations
2	Introduction of a variable fee which can range from a minimum of INR 20,100 for individuals; INR 40,000 for companies to a steep amount depending on the nature of application filed by the patent applicant	No fee for filing pre-grant oppositions	The introduction of the proposed fees will impose significant financial burden and raise additional barriers for patients, patients' organizations, and civil society organizations for filing pre-grant oppositions

a. Requiring the Controller to decide the 'maintainability of the representation'

Under the proposed amendment the Controller will now decide on the '**maintainability of the representation**'. The procedure for pre-grant opposition under the existing rules provides a two-step process. First, the opposition is entertained only "*if the Controller is of the opinion that application for patent shall be refused or the complete specification requires amendment*". Hence the applicant will be informed about the opposition only if the Controller, in her/his opinion is satisfied about the merits of the opposition. Any opposition which lacks merit is dealt in the first step by the Controller. Once the Controller finds merit in the submissions in the pre-grant opposition he/she issues a copy of the notice of opposition to the applicant and the Act and Rules have set clear timelines for reply from the applicant, hearing and deciding on the opposition and application. This satisfaction is a subjective satisfaction based on the merits of the opposition, after hearing the opponent in a detailed hearing and can be perceived to be a valid checkpoint for evaluating the merit of the application.

However, the proposed amendment grants arbitrary and discretionary powers to the Controller in deciding who has the right to file a pre-grant opposition. This exceeds the scope of what is contemplated in Section 25(1) of the Patents Act. The proposal to provide powers to the Controller to decide on the maintainability of the pre-grant application without examining the merit of the application, the government seems to be following the "doctrine of colourable legislation" i.e. what cannot be mandated by the Act, is indirectly being pursued through an amendment in the rules.

From a legal point, maintainability can be raised only when there is a question of jurisdiction or if the grounds are beyond Section 25 (1) or *locus standi* and not on any other ground. The Act in its present form allows **'any person'** to file a pre-grant opposition **any time before the granting of patents** in accordance with the grounds mentioned in section 25(1)(a) to (k). Further, according to Section 25 (1) of the Patents Act "*the Controller shall, if requested by such person for being heard, hear him and dispose of such representation in such manner and within such period as may be prescribed*".

Therefore the Controller has no option but to carry out the hearing on the merit of the pre-grant opposition. Thus, the pre-grant opposition system under section 25(1) of the Patents Act, 1970, is summary in nature. The proposed power for the Controller to decide on the "maintainability" of the application violates the above mentioned provision of the Patents Act. Further, there are well founded apprehensions that the proposed rules grant unreasonable and subjective power to the Controller for allowing or disallowing an opposition. Sometimes such powers can be used to disallow oppositions which use the same prior art (as submitted by the applicant) but with different arguments.

By allowing 'any person' to file a pre-grant opposition, the current provision permits a broad participation of researchers, patient, civil society and health organizations, and market competitors to oppose a patent application by submitting information and analysis to patent examiners, under an adversarial administrative process. The provision assumes that in case the patent examiners miss out on any critical information regarding the prior art relevant to the patent, other interested parties or actors such as researchers and competitors may have information relevant to the validity of the patent, since they are active in the technology area. Hence the public is encouraged to bring that information to the attention of the Patent Office, such that the examiners would be better positioned to make the right decisions about the grant of the patent.

This was an extremely judicious and non-partisan way of adjudicating matters and was akin to a peer review of the information at the examiner's hand. However, if this proposed amendment is allowed, the Controller will get discretionary power to reject the opposition without going into the merit of the case. By vesting absolute power in the hands of the Controller, the system has the potential of being manipulated and hence effective checks and balances are needed to avoid propositions of misuse of powers.

Another implication of this proposed change is that this will expose the institutions especially the Patents Office to the risk of undue influence from the applicants to exercise the discretion in their favour.

b. Introduction of the Concept of Dynamic/Variable Fees to be paid by the Opponent

One of the sweeping changes proposed in the draft Rules regarding pre-grant opposition is the introduction of a variable/dynamic fee for filing a patent opposition. According to the current rules, no fee is charged for filing a pre-grant opposition. However, as per the new draft rules a concept of dynamic fees which is highly variable in nature has been introduced.

Under the proposed changes the fee for opposition now depends on the aggregate amount that has been paid by the patent applicant. The aggregate amount will be calculated based on numerous factors like patent specifications, the number of claims, sequence listings and requests for examination or expedited examination. The fee can now vary from a few thousand to a steep amount depending on the complexity of the patent application being opposed. Thus, the minimum fee can range from a minimum of INR 20,100 for individuals to INR 40,000 for companies. The draft Rules have linked the filing of a patent opposition with the amount paid by the patent applicant which in the case of pharmaceutical patents are Transnational Corporations (TNCs) with deep pockets. By pegging entities with different financial strengths – major TNCs with huge paying capacities against individuals, patient associations, and civil society organizations, the draft rules are heavily skewed in favour of TNCs and have very little to offer for the citizens.

This is treating the unequal equally and violates the provisions of Article 14 of the Constitution and denies access to justice.

Importance of Pre-Grant Opposition

One of the main reasons that has always been cited for bringing such changes is to prevent the delays in the grant of patent and to rule out the filings of frivolous patent oppositions. It is pertinent to note that the delays in grant of a patent are not due to the pre-grant opposition but due to some systemic lacunas plaguing the system. The annual report of the Indian Patent Office for 2021-2022 discloses that against the 69,613 published patent applications only 481 pre-grant oppositions were filed i.e. 0.69% of the total published applications and for a larger time period i.e. from 2005-2022 the Patent Office published 1,376,014 patent applications and granted 193,465 patents. The number of per-grant applications filed during this period was only 4,870, i.e. 0.35% of the published applications. This is a very inconsequential percentage to fix the onus of delay in adjudication of patent grant on the pre-grant opposition provision.

It is noteworthy that according to the Economic Survey of India, the major reason for the delay in India's patent application is due to the low number of patent examiners in India. The number of patent examiners in India in 2020 was 615 as opposed to 13,704 in China, 8,132 in United States and 1,666 in Japan, which leads to a huge delay. Data also reveals a huge pendency of disposing pre-grant opposition representations in India. As per the annual reports, the Patent Office received 4,671 representations for pre-grant oppositions from 2007-2008 to 2021-2022 and a mere 1,535 (32.86%) were disposed of during this period. In a recent study on pre-grant opposition, of the pre-grant applications filed between 2016 to 2021 (250 as per the study), a major reason for the delay in the disposal of pre-grant opposition application can be accounted to the delay from the Patent Office i.e. delays in sending the notice of opposition to the patent applicant (129) and issuing the notice of hearing (82).

The data from the same study also busts the myth propagated by Pharmaceutical TNCs that the patent grant is delayed by oppositions filed by the people lacking credentials – a pejorative term being circulated called 'benaami/frivolous oppositions' with a motive of delaying the grant of patent. The study found that only 16 oppositions were filed by individuals without proper credentials and 24 due to multiple pre-grant oppositions. It is noteworthy that many of the multiple pre-grant opposition applications are filed by reputed companies. Interestingly the list of serial opposition contains many multiple opposition filed by well-known pharmaceutical companies. In many instances, the application may be well known and the product may already be marketed/produced by many generics. Hence, it may warrant many oppositions by competitors whose business will be affected by the frivolous patent applications.

Pre-grant opposition forms the edifice to prevent the grant of unmerited patents on medicines and in multiple cases have ensured the timely availability of quality-assured, affordable generic

medicines. Recently because of a pre-grant opposition, a secondary patent for the tuberculosis (TB) drug Bedaquiline (the parent application was rejected a few years back and consequently the applicant filed a secondary application with similar claims) was denied in India following successful patent oppositions by two TB survivors and a patients' group. This successful patent opposition has resulted in a sharp decline in the price of Bedaquiline and increased its affordability for lakhs of TB patients in India.

The table below lists a few oppositions that have been successfully opposed in India: (*Source of excerpts: Abrol, D and Ors. 'Pharmaceutical Product Patents and TRIPS implementation', Working paper 191, Institute of Studies in Industrial Development, New Delhi, March 2016. Available at http://www.isid.org. in/pdf/WP191.pdf*)

Generic Name	**Flexibilities - Successful Opposition, Compulsory Licence Etc.**
Darunavir	Method for the synthesis of an intermediate of darunavir (Prezista) rejected u/s 25 (1)(e), (f), section 3(d); darunavir Rejected u/s 25(1)(e), (f),(g), 3(d)
Sorafenib Tosylate	Compulsory License Issued
Erlotinib Hydrochloride	Patent was granted with amended claims (Need details on both patents). Subsequently, the patent was upheld against infringement by Cipla; Roche settled patent dispute with Glenmark in January 2016
Gefitinib	Patent rejected u/s 25(1)(e), 3(d), 2(1)(j)
Adefovir Dipivoxil	Adefovir dipivoxil Rejected u/s 25(1)(e),2(1)j, 25(1)(f), 3(d)
Tenofovir Disoproxil Fumarate	Patent for tenofovir (TD) rejected u/s 25(1)(e), (f), (g), 3(d); Patent for tenofovirdisoproxilfumarate (TDF) rejected u/s 25 (1)(b), (e), (f), 3(d); Patent for tenofovirdisoproxilfumarate + emtricitabine rejected u/s 25(1)(e), (f), 3(d), 3(e), 2(1)(ja)
Imatinib Mesylate	Patent for imatinib mesylate rejected u/s 25(1)(e), (f), 3(d), 25(1)(g)
LOPINAVIR In Combination With Ritonavir	Patent on lopinavir + ritonavir deemed abandoned; Patent for lopinavir rejected section 15 (Applicant's agent did not appear for hearing)
Oxcarbazepine	Rejected u/s 25(1)(d), (e)
Oseltamivir Phosphate	Oseltamivir Rejected u/s 25(1)(e), (g), 3(d)
Tolterodine Tartrate	Patent granted after amended claims.
Abacavir Sulfate	Patent withdrawn due to pre grant opposition
Cefepime Hydrochloride	Cefepime/ amikacin - Applicant ordered to narrow down claims to only those supported by example & test data.
Nevirapine	Nevirapine hemihydrate pre grant, 25(1)(e), 3(d), 3(e)
Valsartan	Amlodipine + valsartan rejected u/s 25(1)(e); valsartan Rejected u/s 25(1)(b), (c), (d),(e), (f), (g), (h)
Glatiramer Acetate	Rejected u/s 25(1)(e), 2(1)(j), 3(d)
Atorvastatin Calcium	Rejected u/s 2(1)(g), 3(d); Amlodipine + atorvastatin rejected u/s 25(1)(e),3(d), 3(e), 25(1)(g)

Pre-grant opposition functions as a peer-reviewing mechanism to improve the quality of granted patents and prevent granting of frivolous patents. Various studies have shown that the Patent Office has granted many secondary patents in violation of the provisions of the Patents Act. For instance, patents being granted on older medicines like Ibuprofen (IN409038) a drug discovered in 1961 and Paracetamol (IN233919). It is important to note that the absence of pre-grant opposition would make patent examination process less informed and would likely increase the number of post-grant cases before the Patent Office. Costs associated with the patent opposition system could rise significantly. Furthermore, the public will lose an opportunity to address frivolous monopolies. This would create market uncertainty for generics firms, and lead to low-quality patents and unjustified drug monopolies until post-grant challenges could reach a successful conclusion.

Recommendations: Amending the rules to include dynamic fees for filing a pre-grant opposition should be avoided as it limits the ability of the public to file oppositions. Further, granting arbitrary powers to the Controller on the maintainability of the patents should not be allowed. To rule out the filing of frivolous oppositions the Patent Office should ask for credentials of the person filing the opposition and ensure transparency and effectiveness of this important provision.

II. WORKING OF PATENTS:

Patent working norms are pivotal to India's patent system. In exchange for the grant of monopoly, the patentees are required to work their patented invention, as far as practicable, for the public benefit, by ensuring that patented products are available in adequate quantities and at reasonable prices. Patent rights granted are a *quid pro quo*, that is in exchange for the exclusive rights granted to the patentee, the patentees are required to both disclose the invention and work the same within the jurisdictions where the patent has been granted. Therefore it is critical to ensure that the patentees and their licensees make a full and complete disclosure of the patent working information.

Presently, under Rule 131, patentees are required to file a working statement every financial year. This statement is filed through Form 27, which details how the invention is worked in India, including revenue and any manufacturing or import information associated with the patent. Form 27 has always been a sore point for TNCs especially in the pharmaceutical domain because of its effectiveness to bring the knowledge about products, especially drugs, into the public domain.

Before a 2020 amendment, Form 27 was extensively elaborate and required the patentee to not only fill the quantum of product sold, the value of the product, whether the product was being worked in India/imported and the requisite licensing information. In the 2020 amendment, the government eliminated the information on the number of units (quantities of manufactured or imported patented inventions) and licensing details of the invention that is either manufactured or imported in India. In its current state Form 27 also suffers from considerable ambiguity and omits to ask patentees for a number of important particulars that are necessary for an effective assessment of the commercial working of patented inventions.

However, the proposed draft rules have completely neutralised vital inputs including information on total revenue and manufacturing and product import information, and extended the interval for submitting the working statement from annually to once every three financial years. Instead of addressing the critical gaps that existed post the 2020 amendments, the draft rules have completely overlooked the lacunas and have further shrunken all the necessary information that was made available

in the public domain. Form 27 was the only authentic and validated source of information that was available to the citizens of India and the two amendments have created a complete information asymmetry and completely abrogated the citizens' right to information.

The table below enumerates the key changes in the Working Requirements and the impact it will have on access to medicines:

S. No	Proposed Change	Current Rule	Impact on Access
1	Removal of all the important information from Form 27 including quantum of units sold, value of the product sold, whether the invention is being worked or imported and licensing information	Requires disclosure of information on value and whether patented invention is manufactured in India or imported.	The effective use of public health safeguards depends on the availability of the information in the public domain. In the absence of such information neither the government nor private parties can use compulsory license in an effective manner.
2	Increasing the time duration of submission of working statements from yearly to once in three years	Requires the working statement to be filed for each financial year	Delays the information available and prevents the ability to monitor the non-availability of patented invention at a reasonably affordable price on issues of vital importance to national development such as public health.

A close scrutiny of Form 27 also revealed that the quality of information furnished by the patentees was poor and erroneous. There are instances where the drug has been marketed while the information provided states that the product is still in the research and development stage. For example, in the case of a drug **Delamanid manufactured by Otsuka pharmaceuticals**, the patentee in Form 27 stated that the product was still under commercial research while the drug was being marketed internationally. Equipped with information provided in Form 27, patient groups and civil society raised concerns about the patents not being worked and consequently Otsuka applied for a marketing approval in India. Thus, Form 27 is an important public health tool to check on working of the patent and to hold the patentee responsible for disclosing authentic information to the government and the public at large.

The changes proposed in the new draft rules will have deleterious impacts on the **use of compulsory license**. The data on the working requirement was crucial from a public health perspective and was one of the foundations on which the only compulsory license was granted in India. Based on the information in Form 27, the applicant NATCO (a domestic generic firm) was successful in convincing the authorities that the drug NEXAVAR was not being worked within the territory of India.

By allowing the companies to file the working requirements in three years and atrophying the need to spell the quantum and value of products sold, or any import information, it is impossible from a public perspective to determine the number of patients treated and the unmet medical need. This lack of information will severely affect the generic firms' ability to file for compulsory licenses in India.

Lack of information in Form 27 will also place the generic firms in a disadvantageous position in infringement lawsuits, as they often rely on information available in Form 27.

While the need of the hour is to make drugs affordable and accessible, the proposed draft rules have paved the way for making medicines unaffordable and accessibility onerous and have also lost sight of the very intent of the lawmakers while drafting the Act to balance the private rights of the patentee against the public interests.

Recommendations: The dilution of Form 27 as proposed in the draft rules should be completely avoided. There is in fact a need to reform Form 27 to seek information on the quantum, value and information on the working of the invention in India including details on import and licensing. The extension of time period for filing working requirement to three years should not be allowed and the current framework of filing the information in each financial year should be retained. This would enable the implementation of the legislative intent behind enforcing Sections 83, 84, 85 and 100 of the Patents Act.

III. INFORMATION ON FOREIGN FILING REQUIREMENTS:

As per Section 8 of the Indian Patents Act, patent applicants are required to periodically disclose all foreign applications and any related developments pertaining to the patent application being filed in India. The inclusion of this obligation under Section 8 was for sound justifiable reasons and was a well thought out legislative intent. Section 8 is an important tool for the knowledge of the Controller/examiner since the grant or rejection of an application in other jurisdictions empowers the patent Controller/examiner to demand necessary information from the patentees. As there is persistent presence of public interest in grant and non-grant of patents, Section 8 is not just for the knowledge of the Controller/examiner, it is an important information tool for the public and was aimed at improving transparency and accountability of the Patent Office.

The current Rule 12(2) requires that to comply with Section 8 of the Patents Act, the patent applicants must submit the information every six months from the date of filing of such foreign application. The filing of this information is an on-going process, and the patent applicant must update the disclosure of foreign patent applications regularly.

However, the proposed draft Rules seek to amend Rule 12(2) by substituting the on-going obligation with a one-time requirement. The proposed change requires filing a statement within '***two months from the date of issuance of the first statement of objections***' (FER). Thereafter, the Controller may request a fresh Form 3 at any time, to be submitted within 2 months from the date of communication by the Controller. It is important to note that this proposed amendment is in contravention of the legislative requirement under Section 8, which mandates keeping the Controller informed periodically until the patent is granted. By including such provision, the government seems to be following the doctrine of colourable legislation because something which is not mandated by the Act is being indirectly incorporated through the draft Rules.

Such a provision is bound to create impediments and raises serious concerns about the transparency and accountability of the Patent Office. This is because the status of the patent applications in different jurisdictions may vary considerably after the issuance of FER and hence through a one-time submission, the patent applicant may keep a lot of vital information concealed. Section 8 provides a potent lever in the hands of the examiner to check the legality of information submitted by the applicant. The lack of access to verifiable information supplied in Section 8 thus directly impacts the possibility of granting frivolous applications which may deny consumers and the wider public the potential to access more

affordable patented inventions, a concern most starkly felt in patented medicines and public health. The examples below add support to our comments.

Patent/Application Numbers	**Patent Applicant**	**Drug In Question**	**Relevant Information Not Disclosed**
10670/DELNP/2014	Concert Pharmaceuticals, Inc	Deuterated Ruxolitinib	Form 3 failed to reveal that the patent was invalidated in US
220/DELNP/2005	Janssen Pharmaceutica NV	Bedaquiline (Crucial drug-resistant TB drug)	Form 3 failed to reveal that the patent was rejected in Egypt (EG2003070704)

The draft Rules further state that "***The Controller is responsible for overseeing the progress of related applications using information that's publicly accessible. If necessary, the Controller can request further details from the applicant, provided a written explanation is given***". This provision shifts the burden of obtaining the legal status of corresponding application from the applicant to the Controller.

It is important to emphasize that not all public databases are easily accessible, for instance intellectual property websites of countries like Brazil, Korea, Indonesia, Malaysia, China. These websites have linguistic barriers and some of them seek a local mobile number for accessing the database. In certain countries the prosecution details are in local languages (foreign to outsiders) and hence inaccessible. For instance, in the pilot project on a Patent Prosecution Highway (PPH)[1] the Indian patent office did not have the translated versions of the Japanese examination report (deciphered from Right To Information access).

Further, the global dossier containing patent application information from the WIPO[2] CASE (Centralized Access to Search and Examination) and WIPO DAS (Digital Access Service) lacks information from countries such as Brazil, Korea or Egypt. It is also important to understand that these WIPO databases are not public databases as they are not accessible to the public. Without knowledge of rejection of applications in a foreign jurisdiction, it is impossible for the Controller to seek information from the applicant. Does the proposed amendment suggest that the Controller will monitor every application filed at the Indian Patent Office and seek information on them when required? This provision seems to be another roadblock for revocation of unmerited patents since Section 8 was added as a ground for opposition by the 2005 amendment.

Section 8 has a positive attribute – it serves as a reminder to the patentee that the Patent Office takes the filing of correct information seriously and hence dissuades the applicant from supplying wrongful information. Thus, this provision ensures that the applicant does not make false statements and thereby getting those patents granted which are frivolous and detrimental to the citizens of the country. We therefore strongly feel that a blatant dilution of an important statutory mandate will enable the patentees

[1] PPH is aimed at speeding up patent examination: an application determined to be patentable in patent office A is eligible to have an accelerated examination in patent office B of another country, using a simple procedure upon an applicant's request.
[2] World Intellectual Property Organization

to evade both Patent Office and public scrutiny of the true extent on which the grant of the patent is conditioned.

Recommendations: Given the sheer importance of fostering more transparency, Section 8 must be retained to ensure supply of the information. The proposed amendment will simply overburden the Controller Office and hence rather than following the current norm of updating the information under Section 8 every six months, the need to update Section 8 should be done when there is any change in the status of foreign filing applications.

We hope that the above comments and recommendations by us will receive serious consideration by your office.

Sincerely,

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