

To  
The Secretary  
Department for Promotion of Industry and Internal Trade  
Ministry of Commerce and Industry, Government of India  
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Subject: Comments on the Draft Patent (Amendment) Rules, 2023.

This submission presents comments on the “Draft Patent (Amendment) Rules, 2023, (“Draft Rules”) released by the Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry.

The submission is divided into two parts- General Comments and Specific Comments on the Draft Amendment Rules.

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This submission was made on September 22, 2023 as per deadline prescribed for comments i.e. thirty days from the publication of the Draft Rules in the Gazette of India (August 23, 2023).

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### Part 1: General Comments

#### **1. Accountability, Transparency and Openness Related Concerns**

The Draft Patents (Amendment) Rules, 2023<sup>2</sup> [hereinafter “Draft Rules”] were introduced on [Aug 23 2023] with an open call for comments on the draft rules within the next 30 days, i.e., Sept 22, 2023. While the call for comments on the draft rules is appreciated, it is noted that there have been no public calls for stakeholder consultations for the drafting of these proposed amendments. There is also no stated information as to who has drafted the current proposed amendments. This lack of information is concerning as this undermines the well expounded democratic principles of due process, transparency and openness. For example, the Supreme

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<sup>2</sup> ‘The Draft Patents (Amendment), Rules, 2023,’ Ministry Of Commerce And Industry (Department for Promotion of Industry and Internal Trade, Government of India, access at <<https://ipindia.gov.in/writereaddata/Portal/Images/pdf/248296.pdf>>.

Court has held in *Global Energy Ltd. v. Central Electricity Regulatory Commission* (SCC p. 589, para 71):

*All law-making, be it in the context of delegated legislation or primary legislation, has to conform to the fundamental tenets of transparency and openness on one hand and responsiveness and accountability on the other. These are fundamental tenets flowing from due process requirement under Article 21, equal protection clause embodied in Article 14 and fundamental freedoms clause ingrained under Article 19. A modern deliberative democracy cannot function without these attributes.*

We have seen successful examples of implementation of these democratic principles in action vis-a-vis the consultation process adopted by the Telecom Regulatory Authority of India<sup>3</sup> and the recent approach of giving opportunity for consultation to all the stakeholders on the Digital India Bill<sup>4</sup>. Further, the importance of diverse and inclusive stakeholder consultations are well recognised in the international context as well.<sup>5</sup> Comparing this with the practice at home, no

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<sup>3</sup> 'Consultation', Telecom Regulatory Authority of India, access at <https://www.trai.gov.in/release-publication/consultation>.

<sup>4</sup> For instance, see the tweet from the Minister of State regarding the stakeholder consultation for the Digital India Bill, access at [https://twitter.com/Rajeev\\_Gol/status/1633442554736967680?ref\\_src=twsrc%5Etfw%7Ctwcamp%5Etw%5Eetembed%7Ctwterm%5E1633442554736967680%7Ctwgr%5E3bf81e45a5c5721a78b1c696f3330335a4ce1336%7Ctwcon%5Es1\\_c10&ref\\_url=https%3A%2F%2Fgovernment.economictimes.indiatimes.com%2Fnews%2Fgovernance%2Fmos-it-rajeev-chandrasekhar-to-consult-stakeholders-on-digital-india-bill-in-bengaluru%2F98506059](https://twitter.com/Rajeev_Gol/status/1633442554736967680?ref_src=twsrc%5Etfw%7Ctwcamp%5Etw%5Eetembed%7Ctwterm%5E1633442554736967680%7Ctwgr%5E3bf81e45a5c5721a78b1c696f3330335a4ce1336%7Ctwcon%5Es1_c10&ref_url=https%3A%2F%2Fgovernment.economictimes.indiatimes.com%2Fnews%2Fgovernance%2Fmos-it-rajeev-chandrasekhar-to-consult-stakeholders-on-digital-india-bill-in-bengaluru%2F98506059).

<sup>5</sup> Among international bodies, the Cybercrime Convention Committee (T-CY) of the Council of Europe invited stakeholders to submit written or participate in online meetings regarding the draft 2nd Additional Protocol to the Budapest Convention (access at: <https://www.coe.int/en/web/cybercrime/protocol-consultations>). Among developed countries, stakeholder consultation is followed strictly, as in the United States, where it involves a consultation process when negotiating new trade agreements and making legislative changes (access at: <https://ustr.gov/about-us/policy-offices/press-office/blog/2014/February/a-note-on-stakeholder-consultation>). The FDA in the US engaged in several Patient and Consumer Stakeholder Discussions on the Medical Device User Fee Amendments 2022 Reauthorization (access at: <https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2022-mdufa-v>). The European Directorate for the Quality of Medicines & Healthcare (EDQM) sought the opinions of stakeholders on its Draft Guidelines for Medication Review in 2022 (access at: <https://www.edqm.eu/en/-/stakeholder-consultation-draft-guidelines-for-medication-review>). In the UK, stakeholders in the pension industry and the general public were invited to provide suggestions for the Private Pensions Policy and Regulation (access at: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/220361/pen-scheme-disclosure-consultation-jan2010.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/220361/pen-scheme-disclosure-consultation-jan2010.pdf)). The Swedish Government conducted stakeholder consultations for its Pandemic Law in 2020 (access at: <https://www.loc.gov/item/global-legal-monitor/2020-12-11/sweden-government-sends-pandemic-law-for-stakeholder-consultation/>). The Australian government sought feedback on an exposure draft of the Online Safety Bill to improve Australia's online safety legislation (access at: <https://www.infrastructure.gov.au/have-your-say/consultation-bill-new-online-safety-act>). Even in developing countries, such as Brazil, the government has sought stakeholder opinions on the draft Normative Instruction (IN) for new transfer pricing rules (access at: <https://kpmg.com/us/en/home/insights/2023/07/tnf-brazil-public-consultation-on-new-transfer-pricing-rules.html>) and the Brazilian Internet Bill of Rights (access at: <https://www.oecd-ilibrary.org/sites/3f9009d4-en/1/3/6/index.html?itemId=%2Fcontent%2Fpublication%2F>

public consultation circular for any input from other research bodies and public stakeholders seems to have been released.

**Recommendation: We recommend that the following information be shared with the Indian public via official notifications:**

- 1. The authors of the draft rules**
- 2. Whether any stakeholder consultations were done, with or without a public notice for the same**
- 3. If such stakeholder consultations were done, then a copy of the minutes from those meetings, or a disclaimer that such minutes were not maintained.**

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## **2. Inclusion and Participation**

**Comment:** In order to realise the above mentioned principles of Accountability, Transparency and Openness, it is vital for a reasonable chance to be given to the public to **Deliberate, Respond and Interact** with the legislative process for real inclusion and public participation. While it is appreciated that 30 days were given to share comments on the draft rules, looking at the practice of other ministries one can see that generally 45 days are granted to receive stakeholder feedback. For instance, the Ministry of Labour and Employment fixed 45 days for seeking objections and suggestions in the Draft Central Rules on The Code on Wages, 2019,<sup>6</sup> Draft Central Rules on The Occupational Safety, Health and Working Conditions Code, 2020,<sup>7</sup> and Draft Central Rules on The Code on Social Security, 2020.<sup>8</sup> Similarly, for the Draft of the Drugs and Magic Remedies (Objectionable Advertisements) (Amendment) Bill, 2020, the Ministry of Health and Family Welfare gave 45 days for suggestions/comments/objections.<sup>9</sup> In

[3f9009d4-en&\\_csp\\_=58441e4f472b28727da7676f095f1968&itemIGO=oced&itemContentType=book&fbclid=IwAR3NesK78-yC7MALzqUkW3FPJqMAN5tMdKDeWkxsZqLbcj-2PKFJjba5qGQ>](https://www.gov.wales/sites/default/files/consultations/2018-01/160201ndf-statement-of-participation-en.pdf)); 'Proposals relating to the Statement of Public Participation for the National Development Framework- Draft Statement of Public Participation,' Welsh Government, access at <https://www.gov.wales/sites/default/files/consultations/2018-01/160201ndf-statement-of-participation-en.pdf>> 'Disclosure of Information: Proposed Amending Regulations and Response to Earlier Consultation', Department for Work and Pensions, UK, access at [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/220361/pen-scheme-disclosure-consultation-jan2010.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/220361/pen-scheme-disclosure-consultation-jan2010.pdf)>.

<sup>6</sup> 'Occupational Safety, Health and Working Conditions Code, 2020,' Ministry of Labour and Employment, Government of India, access at [https://labour.gov.in/sites/default/files/gazette\\_notification.pdf](https://labour.gov.in/sites/default/files/gazette_notification.pdf)>.

<sup>7</sup> 'Occupational Safety, Health and Working Conditions Code, 2020,' Ministry of Labour and Employment, Government of India, access at <https://vgnli.gov.in/sites/default/files/Draft%20central%20rules%20on%20Code%20on%20OSH-2020.pdf>>.

<sup>8</sup> 'Code on Social Security, 2020,' Ministry of Labour and Employment, Government of India, access at <https://vgnli.gov.in/sites/default/files/Draft%20central%20rules%20on%20Code%20on%20Social%20Security-2021.pdf>>.

<sup>9</sup> 'Draft of the Drugs and Magic Remedies (Objectionable Advertisements) (Amendment) Bill, 2020, Ministry of Health and Family Welfare, Government of India, access at

several foreign jurisdictions, the practice is similar, providing longer durations for public stakeholders to provide their comments on the legislation<sup>10</sup>

However, the time period is short for stakeholder consultation in Draft Patents Amendment Rules, 2023, being only 30 days, especially in light of the significant changes it brings about.

**Recommendation: We recommend that an extension of 2-4 weeks be given for increasing the ability for more stakeholders to participate in this democratic process, and further enrich the outcome of the same.**

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### **3. Efficiency of Patent Application Disposal Rate vis-a-vis Quality of Patent Grants**

**Comment:** It is noted and commendable that several of the draft amendments are directed towards increasing the speed of disposal of patent applications. Given the currently uncertain timelines, this is a very welcome move. At the same time, as can be seen from some of the specific comments mentioned below, some of these proposed amendments towards efficiency come at the cost of quality safeguards which had been put in place to ensure that only truly inventive inventions are granted exclusion rights. It is important to ensure that speed and quality go hand in hand, rather than oppose one another.

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<<https://main.mohfw.gov.in/sites/default/files/Draft%20of%20the%20Drugs%20and%20Magic%20Remedies.pdf>>.

<sup>10</sup> In the UK, The Government Code of Practice on consultation advises that a minimum of 12 weeks is appropriate for public consultations unless there are good reasons for a shorter period (access at <<http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44420.html>>). For instance, when the Welsh Government furthered the Proposals relating to the Statement of Public Participation for the National Development Framework, its Draft Statement of Public Participation allowed a convenient 84 days for public feedback (access at:

<<https://www.gov.wales/sites/default/files/consultations/2018-01/160201ndf-statement-of-participation-en.pdf>>). For the proposed amendments to regulations covering disclosure of information requirements in occupational, personal, and stakeholder pension schemes, the British Government allowed 56 days for stakeholder feedback (access at:

<[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/220361/pen-scheme-disclosure-consultation-jan2010.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/220361/pen-scheme-disclosure-consultation-jan2010.pdf)>). Amongst developing countries, the draft of the Personal Data Protection (PDP) Law in Indonesia was released for public comment and underwent multiple rounds of consultation and amendment for 7 months between end January 2020 and early September 2022 prior to the release of a final draft (access at:

<<https://fpf.org/blog/indonesias-personal-data-protection-bill-overview-key-takeaways-and-context/>>). Italy opened to public consultation for its Internet Bill of Rights for four months (access at:

<[https://itsrio/wp-content/uploads/2018/02/v5\\_com-capa\\_pages\\_miolo\\_Brazil-Internet-Bill-of-Rights-A-closer-Look.pdf](https://itsrio/wp-content/uploads/2018/02/v5_com-capa_pages_miolo_Brazil-Internet-Bill-of-Rights-A-closer-Look.pdf)>). In Brazil, the public consultation for the Civil Rights Framework for the Internet lasted for 45 days (access at:

<<https://bibliotecadigital.fgv.br/dspace/bitstream/handle/10438/16672/Privacy%20and%20Surveillance%20in%20the%20Digital%20Age.pdf>>).

This is especially relevant as a majority of India's patent filings are still done by foreign applicants.<sup>11</sup> Indicatively, as per the data available in the latest Annual Report 2021-22, in the year 2021-22: :

Applications by foreign applicants: 36,932

Applications by domestic applicants:29,508

Grants to foreign applicants: 23,676

Grants to domestic applicants: 6,397.

Thus there is a strong need to ensure that only truly inventive applications receive the benefit of an efficient and high quality Indian patent system, while Indian local manufacturers are not unduly restricted from pursuing their own legitimate economic activity.

#### **Recommendations:**

**1) It is recommended that all the patent quality safeguards currently in place in the scheme of the Patent Act are revisited specifically with the intent to strengthen them proportionately to the increase in speeds of disposal, so as to ensure that the Indian IP landscape receives the best of both worlds, efficiency and quality.**

**2) It is recommended that the Annual Reports published by the CGPDTM include rigorous data on the working of the patent system, so as to ensure evidenced-based changes can be brought about, as required.**

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## **Part 2: Specific Comments on the Draft Amendment Rules**

### **1. Proposed Changes to the Pre-Grant Opposition Mechanism**

The Draft Amendment Rules introduces many changes in the process and substance of filing pre-grant oppositions before the Controller. Our comments and suggestions on them are grouped as below:

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<sup>11</sup> Praharsh Gour, 'Who's Filing These Patents, and Are They Working Alright? Looking at the Data from the IPO Annual Reports' (Spicyip), access at <https://spicyip.com/2023/07/whos-filing-them-patents-and-are-they-working-alright-looking-at-the-data-from-the-ipo-annual-reports.html>.

## 1.A Fees for Pre-Grant Opposition

**Proposed Amendment:** 13. In the principal rules, for Table I of THE FIRST SCHEDULE, the following table shall be substituted, namely,

Number of Entry	On what payable	Number of the relevant Form	For e-filing		For physical filing	
			Natural person(s) or startup(s) or small entit(y)/(ies) or educational institution(s)	Other(s), alone or with natural person(s) or startup(s) or small entit(y)/(ies) or educational institution(s)	Natural person(s) or startup(s) or small entit(y)/(ies) or educational institution(s)	Other(s), alone or with natural person(s) or startup(s) or small entit(y)/(ies) or educational institution(s)
9	(i) On notice of opposition to grant of patent under section 25(2);	7	Aggregate of amounts actually paid in respect of entries 1, 2, 12, 27, 28, 29, as may be applicable	Aggregate of amounts actually paid in respect of entries 1, 2, 12, 27, 28, 29, as may be applicable	Not allowed	Not allowed
	(ii) On filing representation opposing grant of patent under	7A	Aggregate of amounts actually paid in respect of entries 1, 2, 12, 27, 28, 29, as	Aggregate of amounts actually paid in respect of entries 1, 2, 12, 27, 28, 29, as	Not allowed	Not allowed

	section 25(1).		may be applicable	may be applicable		
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**Comments:** It isn't clear what the purpose of this proposed rule is or how it fits into the scheme of the Act. Presently, there is no fee for filing a pre grant opposition. As per the draft rules, this will change, and the pre-grant opponent will have to pay fees equal to the aggregate of amount paid by the applicant in applying (Entry 1), filing complete specification (Entry 2), requesting for publication (Entry 12), requesting for examining its application (Entry 27), requesting for expedited examination (Entry 28), converting examination under 24B to expedited examination (Entry 29). Realistically, the amount specified under Entry 28 and 29 should not be applied simultaneously as they cater to different purposes. However, the proposed amendment isn't clear on how, after determining the maintainability (discussed separately below), the application will be expedited i.e. as an application seeking expedited examination up front or an application seeking conversion from being normally examined to being examined in an expedited manner.

Particular	For Individuals	For Companies
Fees for Pre-grant opposition / Cost borne by applicant	1600 + 2500 + 4000 + 8000 + 4000 = 20,100	8000 + 12500 + 20000 + 60000 + 40000 =1,40,500

Indicatively, it appears the aggregate for these entries can range from INR 20,100 to INR 1,40,500, plus any fees for additional pages at various stages.

This represents a change of material nature, as it introduces a significant charge and performs a financial gate-keeping role for the function of aiding the patent office in ensuring quality patents are granted. Indicatively, India's per capita Net National Income is INR 98,374<sup>12</sup>, which means that a very large chunk of the country is financially excluded from participating in this process. In other words, if a large multinational company steals local knowledge from an indigenous innovator and tries to patent it, it is very unlikely that innovator will be able to take any steps to point this out to the examiner, beyond relying on the mercy of a third party.

It is important to note that the Act, in Section 25(1) specifically opens out the pre-grant opposition process to "any person", as opposed to those with qualified locus as mentioned in other parts of the patent prosecution process. This material change therefore introduces an artificial qualification to the open-ended allowance of the Act.

There is also no reason mentioned as to why financial gatekeeping is being imposed in a process that aids the country's socio-economic progress as clearly observed in the Ayyangar Committee Report, wherein it was emphasized that the [pre-grant] opposition is an extension of

<sup>12</sup> 'Per Capita Income,' Ministry of Statistics & Programme Implementation, Government of India, access at <<https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1945144>>.



the investigation during the examination process.<sup>13</sup> A similar sentiment was shared by the Delhi High Court in *UCB Farchim v. Cipla*<sup>14</sup> where the court had held that pre-grant opposition is for the aid of the examiner.

Finally, there is **no officially published data** regarding the impact that pre-grant oppositions have had in the patent prosecution process. While some have expressed concerns about pre-grant oppositions delaying the examination process, there is no official data to show the average time-taken between the various stages of the examination process. Additionally, there are several instances where pre-grant oppositions have “coincided” with the abandonment of patent applications<sup>15</sup>, giving strong reason to investigate the extent to which patent applications are frivolously filed and whether there is a need for incentivising more pre-grant oppositions.

As the goals of the Patent Act are to ensure high quality patents in the country, it is recommended in all instances of abandonment of patent application, to make provision for costs under Rule 63 mandatory in nature instead of discretionary, and to institute a reward for those pre-grant opponents whose oppositions successfully aids the patent office in rejecting or otherwise disposing of an application without it becoming a grant.

#### **Recommendations:**

- 1. Fees or charges for filing pre-grant oppositions are kept at nil.**
- 2. Mandatory costs returned to opponents for successful pre-grant oppositions**
- 3. Reward fund for serial successful pre-grant opponents.**

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### **1.B Internal Inconsistency with regard to Expediting Applications with Pre-grant Oppositions.**

**Proposed Amendment:** (8) *An application for a patent, in which a representation for opposition has been filed and found maintainable, shall be examined in accordance with rule 24C.”*

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<sup>13</sup> Para 2010, Ayyangar Committee Report, access at [https://ipindia.gov.in/writereaddata/Portal/Images/pdf/1959-Justice\\_N\\_R\\_Ayyangar\\_committee\\_report.pdf](https://ipindia.gov.in/writereaddata/Portal/Images/pdf/1959-Justice_N_R_Ayyangar_committee_report.pdf).

<sup>14</sup> M/S UCB Farchim SA v. M/S Cipla Ltd. & Ors, W.P.(C) No. 332 of 2010, access at <https://delhicourts.nic.in/Feb10/UCB%20FARCHIM%20SA%20VS.%20CIPLA%20LTD.pdf>.

<sup>15</sup> Some examples include: Novartis’ patent application no. 1972/DELNP/2010 against which a pre-grant opposition was filed by Natco; Takeda / Foresight’s patent application no 7357/DELNP/2011 against which a pre-grant opposition was filed by Indian Pharmaceutical Alliance; AstraZeneca’s patent application no. 6560/DELNP/2009 against which a pre-grant opposition was filed by Indian Pharmaceutical Alliance, Bristol Myers and Squibb’s patent application no. 806/DELNP/2010 against which many pre grant oppositions were filed; Novartis’ Patent Application no. 5209/DELNP/2010 against which a pre grant opposition was filed by the Indian Pharmaceutical Alliance, Astellas’ patent application no 1871/DELNP/2005 against which a pre grant opposition was filed by the Indian Pharmaceutical Alliance.

***Comments:*** The default expediting of applications with pre-grant oppositions filed against them (as proposed in draft rule clause 7 as Rule 55(8)) opens the possibility of internal conflict of procedure and misuse. Under the current Rules, only certain types of patent applicants are eligible to expedite their application process based on the payment of certain fees. With these proposed amendments, any applicant can get the benefit of expedited examination without generally meeting the prescribed qualifications nor even paying up the higher fees for such an examination. Thus incentivising frivolous oppositions fronted by patent applicants, for the benefit of quicker processing.

***Recommendation: It is recommended that the proposed amendment specify that only those applicants who are already entitled to avail of expedited procedures be permitted to have their applications expedited under the proposed amendment.***

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### ***1.C “Maintainability of the Representation”***

#### ***Proposed Amendment:***

*7. In the principal rules, in rule 55:*

*in sub-rule (3), for the word ‘representation’, the words ‘representation, the Controller shall first decide the maintainability of the representation and thereafter’ shall be substituted;*

***Comments:*** The proposed amendment does not specify what will be the criteria adopted by the Controller to determine “maintainability”, nor is it clear what the purpose of this proposed rule is or what its role is in the scheme of the Act. The introduction of any additional barrier to a safeguarding provision must be clear in its definitions as well as purpose. Currently, aside from limiting an existing safeguard provision, its lack of clarity also gives rise to multiple interpretations. For example, It is unclear if these criteria will be the same as the grounds prescribed under Section 25(1), or something else altogether. If it is the former, the proposed amendment introduces redundancy as the Controller is already required to consider the representation made by the “any person” before issuing the notice to the Applicant<sup>16</sup>. And thus, by adding an extra step to determine the vague “maintainability” not only imposes a burden on the Controller, but also waters down the legislatively granted ability given to any person to file a pre-grant opposition by subjecting it to the discretion of the Controller. In case of the latter, the rule simply does not explain what the criteria for such determination shall be.

Furthermore, the proposed amendments do not specify whether the opponent will be given an opportunity to be heard by the Controller, or if there is an appellate mechanism against the Controller's orders on the maintainability. This could inadvertently result in parties approaching

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<sup>16</sup> Rule 55 (3), Draft Patent (Amendment) Rules, 2023.

the High Court or Supreme Court under writ jurisdiction in an appeal, adding to the existing backlog in the courts<sup>17</sup>.

**Recommendations:**

- 1. The proposed amendment should either be rescinded, or should expressly define and justify any criteria for determination of maintainability, keeping the provisions of Section 25 (1) and the nature of pre-grant opposition in mind.**
  - 2. If the proposed amendment is kept, a clear requirement for reasoned statements and appellate procedures should be included.**
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**1.D Conflict between Rule 55(5) and Draft Rule 55(6)**

**Proposed Amendment:** after sub-rule (5), the following shall be inserted namely,-

*“(6) After considering the representation and submission made during the hearing if so requested, the Controller shall proceed to either reject the representation and granting the patent or accepting the representation and refusing the grant of patent on that application, ordinarily within three months from completion of above proceedings.”*

**Comments:** It isn't clear what the purpose of this proposed rule is or what its role is in the scheme of the Act. The proposed amendment essentially reproduces the substantive content of the Rule 55(5). Presently, Rule 55(5) states that the Controller shall decide on the opposition and either accept or reject the application in 1 month from the proceedings. Now the proposed amendment introduces another clause with a deadline of 3 months.

**Recommendations:**

- 1. The language of the proposed amendment should clearly state the obligation on the Controller with regard to the pre-grant opposition.**
  - 2. Alternatively, if the intent is to set a time limit on the duration of disposing a pre-grant opposition, then instead of adding a new sub-rule, duration mentioned in Rule 55(5) should be amended to “Three months” from “One month.”**
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**2. Dilution of the Working Requirement**

The proposed amendment drastically compromises the safeguard provided under Section 146 (2) r/w Rule 131 by proposing that the patentee/ licensee should file such this statement only once every three years and removing important current Form 27 particulars (row 4 and 5).

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<sup>17</sup> E Courts India Services, Government of India, access at <[https://ecourts.gov.in/ecourts\\_home/](https://ecourts.gov.in/ecourts_home/)>.

These particulars currently require patent holders to state details of the approximate revenue/ value accrued in India and to explain why the patent was not worked in cases of unworked patents.

**2.A Removal of the Requirement to File Information About Revenue Generated by the Patentee/ Licensee and Reasons for Non Working**

**Proposed Amendment:** Proposed From 27 as below:

1. Insert name, address, nationality, patent number(s).	I/ We, the Patentee(s)/ Licensee ....., in respect of patent number(s) ....., furnish this statement, (Explanation: One form may be filed in respect of multiple patents, provided all of them are related patents and are granted to the same patentee(s)).		
2. State the financial year to which the statement relates.	in respect of the financial year .....		
3. Worked / not worked. Please state whether each patent in respect of which this form is being filed is worked or not worked.	Patent Number(s)	Worked [Tick ( ) if applicable]	Not worked ( ) if Tick ( applicable]

	The facts and matters stated above are true to the best of my/ our knowledge, information and belief. Dated this ..... day of ..... 20.....
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<p>4. To be signed by Patentee(s) / Licensee / Authorised Agent furnishing statement.</p>	<p>Signature(s) .....</p> <p>To The Controller of Patents, The Patent Office, at .....</p>
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**Comments:**

This new proposal is contrary and ultra-vires to the legislative requirement under Section 146 (2) of the Patents Act. Specifically, Section 146(2) requires patentees to furnish information , “.... *as to the extent to which the patented invention has been worked on a commercial scale in India*”. By removing any details of quantity or even quantum, the proposed rule stands in violation of Section 146(2) which requires information as to “the extent” of working of the patent. Further, by removing any details as to the type of working, the proposed amendment also stands in violation of Section 146(2) which requires information as to whether it has been worked on a “commercial scale” or not.

The purpose of having a patent regime is to ensure development of the national economy and not merely to reward the inventor for their innovation.<sup>18</sup> The obligation on the patentee/ licensee to file the Working Statement is a key safeguard to ensure this. This filing ensures that the Patentee/ licensee is forthcoming about the use of its patent in India, making it available to the public, and thus helps in keeping monopoly/ patent abuse at bay. Owing to its importance in keeping a check against patent abuses, many countries have a working statement requirement in one form or the other.<sup>19</sup>

The newly proposed Form 27 removes the substantive obligations under Row 4 and 5, which require patentees/ licensees to provide the information about the value accrued to them and provide the reason for non-working of the patent. The draft amendments propose that the patentee/ licensee should merely tick whether the patent was worked or not without giving any substantive information about the extent of the working or reasons for non-working.

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<sup>18</sup> First Patent Statute of 1623 (UK) and in Article 5(A)(2) of the Paris Convention where the term ‘abuses’ [of patent rights] included ‘failure to work’. This rationale was also discussed in the Ayyangar Committee Report at para. 38.

<sup>19</sup> Thomas Cottier, Shaheez Lalani, Michelangelo Temmerma, ‘Use It or Lose It: Assessing the Compatibility of the Paris Convention and TRIPS Agreement with Respect to Local Working Requirements’ 2014 Journal of International Economic Law 17(2), 437–471, <<https://academic.oup.com/jiel/article-abstract/17/2/437/2849603?redirectedFrom=fulltext>>.

Concerningly, this represents the 2nd set of dilutions to the working requirement, after Form 27 was already diluted in the Patent Amendment Rules 2020.<sup>20</sup>

Outside of the information being valuable for its own sake in showing the working of an invention, the information provided in the working statement assists in utilizing other patent levers like compulsory licenses,<sup>21</sup> and seeking revocation of patents<sup>22</sup>, in case these rights are abused. In the context of essential inventions like life saving drugs, Form 27 has provided significant backing to the demands of the patients to ensure timely and affordable availability of these drugs. For instance, the information disclosed in this form proved very crucial in passing the first compulsory license of the country for the anti cancer drug Sorafenib/Nexavar.<sup>23</sup> Similarly, during the Covid-19 pandemic, generic companies relied extensively on the information shared in Form 27 seeking compulsory licenses to manufacture certain drugs.<sup>24</sup> Apart from generic companies, different patient groups too rely on Form 27 filings to put across their demands for affordable access to medicines. For instance in 2017 TB patient groups, relying on information available in Form 27 filings, requested the government for making Delamanid available.<sup>25</sup>

Furthermore, Indian Courts have also relied on these filings and have categorically refused to grant an interim injunction owing to non-working of the suit patent. In *Franz Xaver Huemer v. New Yash Engineers*<sup>26</sup> the Delhi High Court had categorically stated that if a patent is not worked then an injunction cannot be granted against the respondent. Similarly, in *FMC v. GSP Crop Science*,<sup>27</sup> the Delhi High Court refused to grant an interim injunction over alleged infringement of a patent on Chlorantraniliprol due to non-working of the suit patent. Working of a patent was again stressed in an order as recent as 4 August 2023, in *Enconcore N.V v. Anjani Technoplast* where the Delhi High Court modified the ex-parte interim injunction owing to non working of the patent.<sup>28</sup>

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<sup>20</sup> Pankhuri Aggarwal, 'Indian Government Significantly Dilutes Patent Working Disclosure Norms' (Spicyip), access at:

<https://spicyip.com/2020/11/indian-government-significantly-dilutes-patent-working-disclosure-norms.html>.

<sup>21</sup> Patents Act, 1970, s 84.

<sup>22</sup> Patents Act, 1970, s 85.

<sup>23</sup> Orders from the IPO and IPAB.

<sup>24</sup> For instance, Natco relied on Form 27 to seek CL to manufacture Baricitinib. Similarly, Bajaj Healthcare also made a similar application relying on the information available in Form 27. In the context of Nexavar Form 27 filing, if the presently proposed Form-27 would have been used to indicate working of the patent, then the Controller would not have known about the miniscule quantity of the drug being worked in 2010 and thus would have hampered a key rationale behind passing the first compulsory license in India.

<sup>25</sup> Letter to MoH (2017), The Delhi Network of positive People, access at:

[https://msfaccess.org/sites/default/files/MSF\\_assets/TB/Docs/TB\\_LettertoIndianMoHDelamanid\\_ENG\\_2\\_017.pdf](https://msfaccess.org/sites/default/files/MSF_assets/TB/Docs/TB_LettertoIndianMoHDelamanid_ENG_2_017.pdf).

<sup>26</sup> Franz Xaver Huemer vs New Yash Engineers, AIR 1997 Delhi 7, access at:

<https://indiankanoon.org/doc/254672/>.

<sup>27</sup> Fmc Corporation & Ors. vs Gsp Crop Science Private Limited, CS(COMM) 662/2022, access at:

<https://indiankanoon.org/doc/197664/>.

<sup>28</sup> Enconcore N.V. vs Anjani Technoplast Ltd. & Anr., CS(COMM) 382/2019 and CC(COMM) 27/2019, access at: <https://indiankanoon.org/doc/82804251/>.

**Recommendations:**

**1) It is recommended that this proposed amendment in its current form be deleted entirely.**

**2) It is recommended instead that the pre-2020 Form 27 requirements be reinstated through an amendment to the draft rules, so as to properly ensure that the requirement under Section 146 is fulfilled, and that dependent patent levers and flexibilities are not rendered futile. Specifically, it is recommended that the requirement to disclose the following are reinstated:**

- A. Quantum of the patented product manufactured in India or imported into India;**
  - B. Country wise details of the value and quantum of the patented product imported into India;**
  - C. The licenses and sub-licenses granted during the year; and**
  - D. Statement on whether public requirement has been met at a reasonable price.**
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**2.B Reducing the Frequency to File Form-27 to Once Every 3 Financial Year**

**Proposed Amendment:** (2) *The statements referred to in sub-rule (1) shall be furnished once in respect of every period of three financial years, starting from the financial year commencing immediately after the financial year in which the patent was granted, and shall be furnished within six months from the expiry of each such period:*

*Provided that the Controller may condone the delay in filing of such a statement upon a request made in Form 4.”*

**Comments:** The proposed amendments change the requirement of filing Form 27 from being required every 6 months, to once every 3 years. Combined with the proposed dilution (as mentioned above), the patent holder would merely have to inform the Patent Office of whether it has worked the patent or not, once every three years, without any details or evidence whatsoever. In essence, this makes Form 27 a mere paper formality with no substance behind it, and defeats the entire purpose of Section 146 of the Patents Act.

**Recommendation: It is recommended that the proposed amendment be deleted entirely and the requirement of filing Form 27 every 6 months be continued.**

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### **3. Filing of Particulars about Foreign Applications**

#### **3.A Subjecting Form 3 Filing to a Condition Precedent**

**Proposed Amendment:** 2. In the Patents Rules, 2003, hereinafter referred to as the 'principal rules', in rule 12:

*(i) in clause (2), for the words 'six months from the date of such filing', the words 'two months from the date of issuance of first statement of objections' shall be substituted;*

**Comments:** The proposed amendment seeks to remove the requirement for applicants to file particulars of every other foreign application of the same invention and replaces it with requiring the applicant to keep the Controller informed of such foreign filings within 2 months of the date of issuance of Statement of Objects. Presently, the requirement is that the applicant keeps the Controller informed about such foreign applications within 6 months from the date of filing. However, now such a filing is contingent on the issue of a statement of objections whereas no such condition precedent is prescribed under Section 8 which requires it to file particulars of all the subsequent foreign applications when he is prosecuting a foreign application on the same invention.

Furthermore, it is unclear if "statement of objections" here would mean objections issued by the Indian Patent Office or the patent office where the application has been filed. If the first, then it would mean that this proposed rule is subjecting the applicant to make a one time filing i.e. two months from the date of issuing the statement of objections and in such a case the applicant will not be required to inform the Controller about the future developments in the prosecution of that application. If latter, then it would mean these particulars have to be filed only when a patent office abroad issues an objection. Regardless of the interpretation, inclusion of such a condition precedent by procedural amendment is per se ultra vires and should be re-considered.

**Recommendation:** *The proposed amendment should be rescinded.*

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#### **3.B Shifting the Burden on the Controller to be Informed**

**Proposed Amendment:** *(ii) for clause (3), the following clause shall be substituted, namely,-*

*"3. The Controller shall consider the information relating to processing of the application in a country outside India that is accessible using public databases.*

*4. The Controller may, under sub-section (2) of section 8, for reasons to be recorded in writing, direct the applicant to furnish a fresh statement and undertaking in Form 3 within two months from the date of such communication by the Controller.*



5. Notwithstanding anything contained in the sub-rules (1), (2) or (3), the Controller may condone the delay in filing of Form 3 upon a request made in Form 4.”

**Comment:** It isn't clear what the purpose of this proposed rule is or what its role is in the scheme of the Act. Presently Section 8(2) read with Rules 12(3) mandates the applicant to furnish information about objections on novelty and patentability of the invention if required by the Controller. However, the proposed rule drastically shifts the onus on the Controller to be informed by relying on information available in public databases and pass a speaking order if any information is required from the applicant. Such a shift goes against the scheme of the provision, which as explained in *Fresenius Kabi Oncology Limited v. Glaxo Group Limited*,<sup>29</sup> is to ensure disclosure and keep a check on the conduct of the applicant. Considering that this is information that can greatly aid the examination or post-examination processes, and that applicant's are seeking to exclude others from using a particular invention they seek to claim as theirs, it can be said to be a basic duty of the applicant to provide this information. In contrast, it is difficult to imagine that the already overburdened patent office examiners have sufficient time, resources and incentives to do an open-ended search on public databases across the world for each invention. As patent applicants already hold this information, there is no rational reason to convert the duty to disclose while seeking a patent, into an additional burden for the patent examiners.

**Recommendation:** *The proposed rule should be rescinded.*

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#### **4. Omnibus Extension of Deadline**

**Proposed Amendment:** 12. Rule 138 of the principal rules shall be substituted by the following rule, namely,-

"138. Power to extend time prescribed.-

(1) The time prescribed by these Rules for the doing of any act or the taking of any proceeding thereunder may be extended by the Controller for a period of up to six months, if he thinks it fit to do so and upon such terms as he may direct.

(2) Any request for extension of time under this rule shall be made in Form 4 before the expiry of the period of up to six months mentioned in sub-rule (1)"

**Comments:** The proposed amendment increases the extension under Rule 138 from 1 month to 6 months and prescribes that the request can be filed at any time before the expiry of the additional 6 months. It further proposes to make this provision an omnibus extension clause instead of the existing rule, which limits its application to only a few deadlines.<sup>30</sup>

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<sup>29</sup> *Fresenius Kabi Oncology Limited v. Glaxo Group Limited*, ORA 22 of 2011/PT/KOL & M.P.No. 140 of 2012..

<sup>30</sup> Patents Act, 1970, r 138(1). Rule 138 (1) presently restricts extension against the time prescribed in clause (i) of sub-rule (4) of rule 20 [time for processing application filed corresponding to international application designating India], sub-rule (6) of rule 20 [Translated claims against claims filed in international application], rule 21 [Deadline to file Priority document], sub-rules (1), (5) and (6) of rule 24B

It is not clear if this extension can be availed after the expiry of the existing extensions as provided within the specific rule or will this 6 month include such extension period within itself. For instance under Rule 24B (5) the time for putting an application in order after receiving the first examination report shall be six months which can further be extended by 3 months. As per the present proposal it is unclear if this means that the time limit for this submission can further be extended by 6 months or not.

From the proposed fees structure in Schedule 1, it is clear that the provision on fees for existing extensions under Entries 4 (i) (ii) and (iii) have been retained. Thus, it can be presumed that the omnibus deadline is over and above the additional extensions already prescribed. This is contradictory as on one hand the amendment tightens the deadlines for different provisions across the Rules but then on the other hand provide such an omnibus extension on a payment of hefty fees ranging from INR 10,000- INR 55,000 per month.

Perhaps one of the reasons for such an omnibus extension could have been the frequent cases of lapse on the part of the patent agents.<sup>31</sup> However, if that the is reason then instead of providing an omnibus extension (whose benefits can only be availed by wealthy applicants) a subjective extension clause could have been adopted subject to prima facie satisfaction of the Controller on whether the issue merits extension or not.

**Recommendation: We recommend that instead of such omnibus extension for all the filings, the proposed rule should be modified to state that the extension shall be subjected to prima facie satisfaction of the Controller on the subject matter.**

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[Time prescribed for getting an application in order after issuance of First Examination Report], sub-rules (10) and (11) of rule 24C [Deadline to put application in order after first examination report in expedited examination], sub-rule (4) of rule 55 [Time to applicant to respond to pre grant opposition], sub-rule (1A) of rule 80 [period for payment of renewal fees] and sub-rules (1) and (2) of rule 130 [application to controller to review or set aside its order], the time prescribed by these rules for doing of any act or the taking of any proceeding thereunder may be extended by the Controller for a period of one month.

<sup>31</sup> Lokesh Vyas, Governance and Supervision of Trademark and Patent Agents: Discussing DHC's Saurav Chaudhary vs. Union Of India (Spicyip),

<<https://spicyip.com/2023/09/governance-and-supervision-of-trademark-and-patent-agents-discussing-dhcs-saurav-chaudhary-vs-union-of-india.html>>; Aparajita Lath, 'Professional Negligence and Attorney Liability?' (Spicyip), access at:

<<https://spicyip.com/2014/01/professional-negligence-and-attorney-liability.html>>; Praharsh Gour, 'Never Gonna Give You Up? Discussing the Recent Patent Application Restorations by Delhi and Madras High Courts' (Spicyip), access at:

<<https://spicyip.com/2022/12/never-gonna-give-you-up-discussing-the-recent-patent-application-restorations-by-delhi-and-madras-high-courts.html>>.

<<https://spicyip.com/2023/09/governance-and-supervision-of-trademark-and-patent-agents-discussing-dhcs-saurav-chaudhary-vs-union-of-india.html>>;

<<https://spicyip.com/2014/01/professional-negligence-and-attorney-liability.html>>;

<<https://spicyip.com/2022/12/never-gonna-give-you-up-discussing-the-recent-patent-application-restorations-by-delhi-and-madras-high-courts.html>>

**5. Form to File Grace Period and Levying Fees on Such Filings**

**Proposed Amendment:** 29A. Grace period.- An application to avail the grace period under section 31 shall be filed in Form 31.

**Comments:** The proposed rule states that the application to avail the grace period of 12 months from the date of exhibition or publication should be filed in Form 31. The newly introduced Form 31 enlists the particulars which are necessary to explain the publication/ exhibition of the invention. However, the fees prescribed for such filing is pretty hefty (INR 11,200 for individuals and INR 84,000 for companies) which is way higher than the fees prescribed for applying for a patent (INR 1600 for individuals and INR 8000 for companies).

**Recommendation:** **We recommend that the fees imposed on Form 31 should be reconsidered and should be brought at par with the fees required for filing a patent application.**

**6. Discretionary Power to Impose Compensatory Costs under Section 136 (2)**

**Proposed Amendment:** In the Fourth Schedule providing the Scale of Costs, the draft rules proposes insertion of a new entry 10.

No. of entry	Matter in respect of which cost is to be awarded	Amount in Rupees	
		Natural person(s) or Startup(s) or Small entit(y)/ (ies) or educational institution(s)	Other(s), alone or with natural person(s) or Startup(s) or Small entit(y)/ (ies) or educational institution(s)
10.	Sub-rule (2) of rule 136	Aggregate of amounts actually paid in respect of entries 1, 2, 12, 27, 28, 29 of the First Schedule, as may be applicable	Twice the aggregate of amounts actually paid in respect of entries 1, 2, 12, 27, 28, 29 of the First Schedule, as may be applicable”.

**Comments:** Rule 136 (2) empowers the Controller to impose compensatory cost, at his discretion, in any proceeding before him which in his opinion is false or vexatious. The proposed amendment to the Scale of Costs under the Fourth Schedule imposes hefty discretionary costs which may extend to INR 20,100 to INR 2,81,000. This addition of hefty dynamic costs comes without a corresponding duty to pass a speaking order. This requirement to pass a speaking

order is paramount and as explained by the Delhi High Court in Smt. Usha Rani v. the Union of India<sup>32</sup>, whether a body is discharging administrative or judicial functions, it must provide for reasons behind the order.

**Recommendation: We recommend that Rule 136 (2) should be amended to explicitly state that while exercising its discretionary power, the Controller should issue a speaking order expressly mentioning the reasons for imposition of the costs.**

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<sup>32</sup> Usha Rani v. UoI W.P.(C) 10876/2022