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The Disclosure Mandate: Strengthening the Reporting Requirements under Section 8 of the Indian Patents Act

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1 Introduction and Background

INDIA'S Patents Act, 1970 provides for an important mandate through Section 8 that requires patent applicants to disclose specific information about the status of their corresponding foreign patent applications. Additionally, applicants must give an undertaking of continuously updating the patent office regarding foreign filings related to the same or substantially the same invention. This provision is designed in a manner to enhance transparency within the patent system, fostering accountability and oversight, particularly impacting access to medicines.

This paper addresses the relevance of Section 8, particularly through the lens of access to medicines, and explores how this provision balances intellectual property (IP) protection and the imperative to respect genuine inventions.

Industry groups, backed by multinational pharmaceutical corporations, have long advocated for removing this provision. Furthermore, a leaked IP chapter of the draft United Kingdom-India Free Trade Agreement (UK-India FTA) on which negotiations are ongoing seeks to remove the legal consequences for non-compliance with the provision.[1] In early March 2024, India and the European Free Trade Association (EFTA) announced they had signed an FTA that would weaken the Section 8 requirement under Indian patent laws.[2] This change was preceded by a draft amendment to the Patents Rules published in August 2023, which solicited public feedback and proposed changes similar to those in the EFTA-India FTA.[3] Just a week after signing the FTA, on 15 March 2024, the Patents (Amendment) Rules

were finalized, implementing the new proposals regarding Section 8.[4] These rules appear to wither away the responsibilities of patent applicants under Section 8, potentially diluting the provision's impact.

By 2005, India was required to fully align its patent laws with the World Trade Organization (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement), with the granting of pharmaceutical product patents. India utilized the flexibilities allowed by the TRIPS Agreement, incorporating various provisions such as anti-evergreening provisions and transparency and disclosure requirements into its laws. Section 8 is one such transparency and disclosure requirement that was there in the original 1970 Patents Act, which was later amended to make it a continuing responsibility for patent applicants to ensure accountability.

At a time when there is growing international consensus[5] on promoting patent quality and transparency, particularly in the context of access to medicines and patent information, any removal or dilution of Section 8 provisions would deprive the Indian Patent Office of its ability to avoid granting unmerited patents and to monitor and enforce transparency requirements. This, in turn, would pose a risk of overlooking critical evidence in patent examination, opposition and revocation proceedings.

This paper delves into the provisions of Section 8, examining its legislative intent, scope and how courts have interpreted it. It also critically analyzes the section's interplay between the obligations of disclosure and the consequences of non-compliance. Additionally, the paper analyzes how Section 8 can play a pivotal role in maintaining patent quality by preventing grants of frivolous patents, particularly in the context of the evergreening of patents, as well as addressing information asymmetry. Furthermore, it builds a case for retaining the implementation of this provision as it were and offers recommendations to enhance its effectiveness in line with its intended purpose.

2 Statement and Undertaking Regarding Foreign Applications

UNDER Section 8 of the Patents Act in India, patent applicants must provide information and update the Indian Patent Office regarding all foreign patent applications, including the status of such applications, filed for the same or substantially the same inventions in countries outside India.[6] The legislative intent and implementation of Section 8 within the Patents Act, 1970 bear the imprints of the Ayyangar Report (see below), aiming to strike a balance between private rights and public interest. Although compliance with Section 8 is mandatory, its implementation, enforcement and the consequences of non-compliance have sparked debates. This section looks at the obligations and practical implications of Section 8, scrutinizing its mandatory nature and enforcement, including the evolving judicial interpretations.

Box 1: Section 8 of the Indian Patents Act, 1970

Section 8: Information and undertaking regarding foreign applications

(1) Where an applicant for a patent under this Act is prosecuting either alone or jointly with any other person an application for a patent in any country outside India in respect of the same or substantially the same invention, or where to his knowledge such an application is being prosecuted by some person through whom he claims or by some person deriving title from him, he shall file along with his application or subsequently within the prescribed period as the Controller may allow—

a) a statement setting out detailed particulars of such application; and

b) an undertaking that, up to the date of grant of patent in India, he would keep the Controller informed in writing, from time to time, of detailed particulars as required under clause (a) in respect of every other application relating to the same or substantially the same invention, if any, filed in any country outside

India subsequently to the filing of the statement referred to in the aforesaid clause, within the prescribed time.

(2) At any time after an application for patent is filed in India and till the grant of a patent or refusal to grant of a patent made thereon, the Controller may also require the applicant to furnish details, as may be prescribed, relating to the processing of the application in a country outside India, and in that event the applicant shall furnish to the Controller information available to him within such period as may be prescribed.

a. Overview of Section 8

The disclosure mandate under Section 8(1) requires a patent applicant in India to file a statement and an undertaking relating to all corresponding foreign applications filed for the same or similar invention in any country outside India.[7] This statement and undertaking have to be filed by all patent applicants in India in Form 3, including any person who claims or derives a title for filing such patent applications.[8] In the absence of any foreign applications, the applicant shall file a statement to that effect.[9]

The patent applicant shall file the statement and undertaking along with their patent application or subsequently within six months from the date of filing the application.[10] The statement shall set out the detailed particulars of foreign applications, such as the country's name, application number, the status of such applications, etc.[11] Further, the undertaking requires that the patent applicant shall keep the Controller of Patents informed from time to time of every other corresponding application filed subsequent to the statement.[12] Prior to the 2024 amendment to the Patents Rules, the time within which the applicant shall keep the Controller informed was six months from the date of such filing.[13] This is now changed after the 2024 amendment.[14]

The disclosure of the status of the foreign patent applications is also one of the criteria for evaluating and approving a patent application.[15] At any time before the disposal of the patent application, the Controller may also require the patent applicant to furnish additional details under Section 8(2) relating to the processing of foreign applications.[16] The Controller can ask for information pertaining to objections on novelty and patentability of the

invention, claims of application allowed, search and examination report, claim amendments or any other particulars as the Controller may require. The information had to be furnished within six months from the date of such communication by the Controller.[17]

i. Mandatory and continuing responsibility of disclosure

Section 8(1) of the Patents Act is a mandatory provision the applicant must fulfil while applying for a patent.[18] It obliges the patent applicant to file a statement regarding corresponding foreign applications with their application or within six months from the application's filing date.[19] Furthermore, when a consequence is explicitly provided, such as in the present case where non-compliance could result in the patent being revoked, the rule should be understood as mandatory.[20]

Section 8(1) is a statutorily facilitated voluntary compliance requirement by the applicant. In contrast, Section 8(2) pertains to situations where the Controller of Patents requests for details to be furnished regarding the processing of applications in other countries. In such cases, the applicant becomes duty-bound to provide these details.[21] Failure to do so empowers the Controller under Section 15 of the Patents Act to refuse a patent application on the grounds of non-compliance with the requirements of the Act – solidifying its mandatory nature.

Under Section 8(1)(b) and Form 3, patent applicants must give an undertaking to keep the Controller informed in writing from time to time about the details regarding the corresponding foreign applications. According to the previous Patents Rules, this requirement had to be fulfilled by the applicant within six months.[22] The requirement to furnish details under Section 8 was not a one-time requirement. Instead, as courts have also observed, it places a continuous responsibility on the patent applicant to inform the Controller about any developments, including filing subsequent foreign applications relating to the same or substantially the same invention.[23] This meant that whenever a corresponding foreign application was filed or updated, the applicant had to notify the Controller within six months.

In practice, this requirement was met by filing a Form 3 every six months, capturing all changes and filings regarding corresponding foreign

applications within that period, instead of updating the Controller within six months whenever there was an update. This furnishing of details from time to time – whether there is a request from the Controller or not – had to be done by the patent applicant on their own accord.[24]

Figure 1: Form 3 before the Patents (Amendment) Rules, 2024

FORM 3

THE PATENTS ACT, 1970

(39 of 1970)

and

THE PATENTS RULES, 2003

STATEMENT AND UNDERTAKING UNDER SECTION 8

(See section 8; Rule 12)

1. Name of the applicant(s).	I/We..... .... hereby declare:
2. Name, address and nationality of the joint applicant.	(i) that I/We have not made any application for the same/substantially the same invention outside India Or (ii) that I/We who have made this application No.....dated .....alone/jointly with ....., made for the same/ substantially same invention, application(s) for patent in the other countries, the particulars of which are given below:

Name of the country	Date of application	Application No.	Status of the application	Date of publication	Date of grant

3. Name and address of the assignee	(iii) that the rights in the application(s) has/have been assigned to..... .... that I/We undertake that upto the date of grant of the patent by the Controller, I/We would keep him informed in writing the details regarding corresponding applications for patents filed outside India within six months from the date of filing of such application. Dated this.....day of.....20.....
4. To be signed by the applicant or his authorized registered patent agent.	Signature. .....
5. Name of the natural person who has signed.	(.....).
	To The Controller of Patents, The Patent Office, at.....
Note.- Strike out whichever is not applicable.	

ii. Obligatory or discretionary consequence for non-compliance?

Not disclosing information as required by Section 8 is listed as a ground for patent opposition or revocation.[25] Additionally, non-compliance, ideally, should lead to the refusal of the patent application by the Controller of Patents as per Section 43 of the Patents Act.[26] However, it's important to note that in practice, the patent office has often been lenient in enforcing Section 8 compliance and rarely rejects a patent application for this reason.

Similarly, the courts have generally been reluctant to revoke a patent or to refuse to grant an interim injunction solely due to non-compliance with Section 8, especially in cases of non-adherence to continuous voluntary disclosure by patent applicants as mandated under Section 8(1).[27] This reluctance is based on the interpretation that the word "may" in Section 64(1), which deals with patent revocation, suggests that the consequence of non-compliance is not mandatory.[28] Additionally, it is further justified that the use of "may" implies that the provision is discretionary rather than obligatory, implying that the power to revoke patents, as granted under Section 64(1), holds an element of discretion at the hands of the court.[29]

The courts have now introduced willingness and ill-intent elements to Section 8(1) before invoking Section 64 for patent revocation. They emphasize that when revoking a patent under Section 64 for violation of Section 8(1), it is necessary to show a deliberate, wilful suppression of information required under Section 8(1) for mala-fide reasons on the applicant's part.[30] The courts have also held that since Section 64(1) is of a "directory" nature, substantial compliance may be sufficient to fulfil the object of Section 8(1), unlike mandatory rules which require strict adherence.[31] It was also held that these factors relating to the applicant's intent – except in cases of patent and manifest violation of Section 8(1) – have to be considered even in the interim stage before rejecting a claim for temporary injunction in a suit for infringement.[32]

A patent can be granted under Section 43 if the application is not in contravention of any of the provisions of the Patents Act.[33] Consequently, any omission to comply with the provisions of the Act, including Section 8, should be grounds for not granting a patent. Likewise, patents granted against the provisions of the Act should be revocable under Section 64.

As mentioned above, courts currently interpret the revocation of patents under Section 64 for non-compliance with Section 8(1) as having some discretionary element due to the word "may" in Section 64(1). However, the word "may" is preceded and limited by "subject to the provisions contained in this Act". It means, under Section 64(1), the word "may" should imply discretion only when the provisions of the Act allow discretion, but when complying with the provisions is mandatory, such as in Section 8, "may" becomes mandatory. This interpretation is further justified by the fact that if patent revocation under Section 64(1) is based on novelty and inventive steps, courts do not have the discretion not to revoke the patent. Non-compliance with Section 8 should be treated similarly as it is also one of the grounds for revocation under Section 64(1).

The Act clearly states that failure to disclose information as required by Section 8 is a ground for revocation. The applicant secures a patent monopoly subject to complete disclosure of information as required under the Act. Neither Section 8(1) nor Section 64(1) says that the failure of disclosure must be deliberate or with malicious intent, and as such, there is no reason to qualify such failures with the applicant's intent. Furthermore, when there is a failure of disclosure under Section 8(2) – when the Controller of Patents

Box 2: IPAB ruling on Section 8 on patent applications related to Ganfort and Combigan

The Intellectual Property Appellate Board (IPAB) has previously revoked patents due to non-compliance with explicit requests of the Controller under Section 8(2). The pharmaceutical corporation Allergan obtained patents for bimatoprost/timolol (marketed as Ganfort) and brimonidine/timolol (marketed as Combigan) for treating glaucoma and reducing eye pressure. Ajanta Pharma filed two revocation applications (ORA/20/2011/PT/KOL and ORA/21/2011/PT/KOL) before the IPAB against these granted patents on the grounds of obviousness and non-compliance with Section 8. Ajanta alleged that Allergan did not disclose necessary information under Section 8(1) regarding foreign patent applications, including their numbers and status before the patent grant. Ajanta also claimed that despite the Controller's request for documents related to foreign applications, Allergan didn't provide complete information, violating Section 8(2). The IPAB, in both cases, found Allergan to have withheld information required to be furnished under Section 8 and held that the patent had to be revoked on the grounds of non-compliance with Section 8. The IPAB also determined that the claims lacked obviousness and did not deserve a patent.

requests explicitly information on foreign filings – the courts have strictly revoked patents or refused to grant temporary injunctions.[34]

There is no reason not to treat both Section 8(1) and Section 8(2) equally and ensure stringent compliance on an equal footing. Non-compliance with Section 8, whether with the voluntary requirement or with the request of the Controller of Patents, should have strict liability and attract the provisions of refusal or revocation of a patent, as the case may be, without any qualifications.

b. Legislative intent and rationale of Section 8

The recommendations of the 1959 Report on the Revision of the Patents Law by Shri Justice N. Rajagopala Ayyangar (hereinafter Ayyangar Report) played an essential role in shaping Indian patent law, leading eventually to the enactment of the Patents Act, 1970 by the Parliament of India.[35] Like much of the provisions of the Patents Act, 1970, Section 8 of the current law is primarily based on the Ayyangar Report, which throws light on the rationale behind this provision.

The Ayyangar Report implies that the statement of information and undertaking regarding foreign applications would be beneficial in ensuring a proper examination of the same or substantially the same patent application, thereby ensuring a balance between private rights and public interest.[36] Justice Ayyangar's recommendation to operationalize this goes beyond merely requiring the filing details of foreign patent applications.[37] He had also recommended disclosing information regarding objections raised, orders passed on the grounds of novelty or patentability and any amendments made to the specifications and claims in those foreign countries.[38] This comprehensive approach was intended to strengthen the examination process, aiding the Indian Patent Office by providing it with information on international applications that could trump the novelty of an invention.[39]

Box 3: Ayyangar Report on statement and undertaking regarding foreign patent applications

> *"It would be of advantage therefore if the applicant is required to state whether he has made any application for a patent for the same or substantially the same invention as in India in any foreign country or countries, the objections, if any, raised by the Patent Offices of such countries on the ground of want of novelty or unpatentability or otherwise and the amendments directed to be made or actually made to the specification or claims in the foreign country or countries upto the date of acceptance of the application…. As publication abroad before the relevant date would also constitute anticipation, this information would be of great use for a proper examination of the application." [Paragraph 350, Ayyangar Report]*

Critics argue that the Ayyangar Report was published when technology was not as advanced as now and finding information was cumbersome; hence, there was a need for a provision seeking disclosure of information on foreign patent applications. They argue that technological advancement, unification of patent examination practices and online implementation have since allowed easy access to information relevant to national prosecution of patent applications.[40]

One primary argument against this is that the current law, i.e., Section 8(2), only requires the submission of detailed particulars of a foreign patent application at the Controller's request (rather than requiring proactive, continuous and regular disclosure of detailed particulars) whenever there is an office action in a related foreign application. Section 8(2) remains relevant even today as it helps the Indian Patent Office access information that might not otherwise be available. Moreover, it prevents patent applicants from exploiting the Indian Patent Office's infrastructural limitations, which could restrict its ability to conduct thorough patent searches and cite relevant information during the patent examination process.[41]

The provisions of Section 8 of the Patents Act, when read together with the Ayyangar Report, show that the legislative intent behind the provision is to promote transparency in the patent system and, as a result, ensure high-quality patents, patenting only genuine innovations and thereby reducing anti-competitive practices and safeguarding the freedom to operate for domestic research and development.

3 Challenges to Section 8

THE Patents (Amendment) Rules, international cooperation mechanisms, and free trade agreements present complex challenges in India's patent laws landscape. The Patents (Amendment) Rules, 2024 alter the time frame for applicant disclosures, potentially affecting the quality of patent examinations. Additionally, collaboration between the Indian Patent Office and the World Intellectual Property Organization (WIPO) through the CASE and DAS systems (see below) aims to streamline information exchange but raises concerns about a potential shift in disclosure responsibilities. These developments highlight a contentious debate: finding the right balance between industry interests and ensuring the effectiveness of information disclosure in patent examination and public scrutiny.

a. Patents (Amendment) Rules, 2024

For quite some time, industry lobby groups in India supported by multinational corporations have pushed for diluting Section 8 of the Patents Act. They argue that it is difficult to collate the information as mandated by the provision and adds to the compliance burden.[42]

This pressure to dilute Section 8 has also found its way to FTAs that India was negotiating. As stated above, in early March 2024, India signed an FTA with EFTA. The FTA seeks to negate the legal consequence for non-compliance with Section 8, except in cases of deliberate or wilful suppression of information, as determined by the Controller[43] (see Box 4). A similar effort to dilute the Section 8 provisions can also be seen in the United Kingdom-India FTA negotiations, which are currently ongoing.[44]

Box 4: EFTA-India FTA provisions relating to Section 8 of the Patents Act, 1970

Article 13: Conditions on Patent Applicants

2. A Party may require a patent applicant to provide information concerning the applicant's corresponding foreign application and grants. A mere failure to comply with this requirement, may not result in revocation of or refusal to grant a patent, except where the competent authority determines there is deliberate or wilful suppression of information.

3. A patent granting authority may give due consideration to information concerning the applicant's corresponding foreign application and grants which is publicly available or otherwise available to the granting authority during the patent application process.

On 15 March 2024, perhaps succumbing to these pressures, the Department for Promotion of Industry and Internal Trade (DPIIT) published and notified the Patents (Amendment) Rules, 2024 (hereinafter 2024 Rules).[45] Before notification of the 2024 Rules, a 2023 draft version of these Rules which aimed to amend the Patents Rules, 2003 had been opened to public consultation.[46] The Draft Rules 2023 were opposed by several civil society organizations and patient groups.[47] One of the changes eventually introduced in the 2024 Rules is to alter Rule 12 regarding the implementation of Section 8 of the Patents Act, 1970.

Table 1: Comparison of Rule 12 (regarding implementation of Section 8) before and after the Patents (Amendment) Rules, 2024

Rule 12: Statement and undertaking regarding foreign applications [Before Patents (Amendment) Rules, 2024]	***Rule 12: Statement and undertaking regarding foreign applications [After Patents (Amendment) Rules, 2024]***
(1) The statement and undertaking required to be filed by an applicant for a patent under sub-section (1) of section 8 shall be made in Form 3.	*(1) The statement and undertaking required to be filed by an applicant for a patent under sub-section (1) of section 8 shall be made in Form 3.*
(1A) The period within which the applicant shall file the statement and undertaking under sub-section (1) of section 8 shall be six months from the date of filing the application.	*(1A) The period within which the applicant shall file the statement and undertaking under sub-section (1) of section 8 shall be six months from the date of filing the application.*
Explanation. — For the purpose of this rule, the period of six months in case	*Explanation.—For the purpose of this rule, the period of six months in case*

of an application corresponding to an international application in which India is designated shall be reckoned from the actual date on which the corresponding application is filed in India.	*of an application corresponding to an international application in which India is designated shall be reckoned from the actual date on which the corresponding application is filed in India.*
(2) The time within which the applicant for a patent shall keep the Controller informed of the details in respect of other applications filed in any country in the undertaking to be given by him under clause (b) of sub-section (1) of section 8 shall be six months from the date of such filing.	*(2) The time within which the applicant for a patent shall keep the Controller informed of the details in respect of other applications filed in any country in the undertaking to be given by him under clause (b) of sub-section (1) of section 8 shall be three months from the date of issuance of first statement of objections under sub-rule (3) of rule 24B or sub-rule (8) of rule 24C.*
(3) When so required by the Controller under sub-section (2) of section 8, the applicant shall furnish information relating to objections, if any, in respect of novelty and patentability of the invention and any other particulars as the Controller may require which may include claims of application allowed within six months from the date of such communication by the Controller.	*(3) The Controller may, use accessible and available databases, for considering the information relating to applications filed in a country outside India.* *(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 these rules, the Controller may condone the delay or extend the time for filing Form 3 for a period up to three months upon a request made in Form 4.*

The 2024 Rules modify the timeline for submitting information under Section 8 from the earlier prescribed disclosure within six months from the date of the foreign filings (or developments related to such filings) to three months from the date of issuance of the first statement of objections, commonly known as the first examination report (FER).[48] This amendment through the Rules aims to substitute the ongoing continuous reporting obligation with what is likely to be a one-time requirement as the FER is usually issued only once. However, this change goes against the Patents Act, which mandates a "time to time" disclosure of detailed particulars of foreign patent applications up until the grant of the patent and not just after the issuance of the FER.[49]

This change in timelines related to Section 8 obligations raises concerns because the status of foreign applications can change during various stages of the patent prosecution in India – from the issuance of the FER to the filing of the FER response, the Controller's hearing, and ultimately, the disposal of the patent application by the Indian Patent Office. The provision's objective is to help the Indian Patent Office gather necessary information relating to a patent application and make a well-informed decision before disposing of a patent application in India. However, this decision-making process typically does not happen immediately after the issuance of the FER. Patent prosecution timelines vary from one country to another, meaning updated information may not be available when the Indian application reaches the disposal stage. The amendment would limit the provision of updated information only up to the issuance of the FER rather than providing timely updates until the patent is granted, as mandated by the legislation. Therefore, the 2024 amendment to the Rules is in contradiction to the Patents Act.

In addition, previously, in operationalizing Section 8(2) of the Patents Act, the Rules explicitly allowed the Controller the authority to summon any information, including objections in respect of novelty and patentability of an invention made by foreign patent offices.[50] However, the 2024 Rules deleted that element and placed the onus on the Controller to use publicly available databases to access information related to patent applications outside India.[51] This is also a direct consequence of the provisions of the EFTA-India FTA, which requires the Controller to give due consideration to publicly available information regarding corresponding foreign applications.[52]

Further, the 2024 Rules introduced Rule 12(4) in connection with Section 8(2) of the Patents Act. This new rule suggests that the Controller can now direct the applicant to furnish only a fresh statement and undertaking in Form 3, and this can only be requested after providing written reasons for doing so.[53] However, this power to request only a fresh Form 3 is not very beneficial in effectively examining patent applications as it merely involves supplying basic patent information (e.g., patent application, publication and grant numbers, patent application status, and date of filing), compared with the previous rule, which allowed the Controller to summon examination reports and dockets from specific foreign patent offices.[54]

Essentially, these new Rules are aimed at limiting the Controller's powers to requesting only basic patent information, preventing them from obtaining detailed patent prosecution information related to similar foreign applications.

Figure 2: Form 3 after the Patents (Amendment) Rules, 2024

"FORM 3
THE PATENTS ACT, 1970
(39 of 1970)
and
THE PATENTS RULES, 2003
STATEMENT AND UNDERTAKING UNDER SECTION 8
(See sub-rule (2) and (3) of Rule 12)

1. Name of the applicant(s).	I/We..... .... hereby declare:
2. Name, address and nationality of the joint applicant.	(i) that I/We who have made the application for patent number ..... in India, dated ....., alone/jointly with ....., (ii) that I/We have not made any application for the same/substantially the same invention outside India Or (iii) that I/We have made for the same/ substantially same invention, application(s) for patent in the other countries, the particulars of which are given below:

Name of the country	Date of application	Application No.	Status of the application	Date of publication	Date of disposal

3. Name and address of the assignee	assigned to .... (ii) that I/We undertake that upto the date of grant of the patent by the Controller, I/We would keep him informed in writing regarding the details of corresponding applications for patents filed outside India in accordance with the provisions contained in section 8 and rule 12. Dated this.....day of.....20.....
4. To be signed by the applicant or his authorized registered patent agent.	Signature. .....
5. Name of the natural person who has signed.	(.....).
	To The Controller of Patents, The Patent Office, at.....
Note. - Strike out whichever is not applicable;";	

These new changes could burden the Controller further, considering the Indian Patent Office's already strained resources. It remains to be seen if the Controller can manage the additional time and effort required to implement this change. The new Rules not only dilute the continuing responsibility of the applicant but also transfer the burden from the patent applicant to the Controller, who may not always be aware of and/or able to access all relevant information necessary for a proper examination of a patent application that is otherwise readily available to the applicant. This shift could result in less thorough examinations, potentially missing critical information, thereby compromising the ability to safeguard patent quality and prevent unmerited patent grants.

b. WIPO CASE and DAS systems

WIPO has introduced two proprietary information systems – Centralized Access to Search and Examination (CASE) and WIPO Digital Access Service (DAS). WIPO CASE provides a platform to share information regarding search and examination among participating patent offices.[55] WIPO DAS aims to enable secure exchange of priority documents and similar documents between patent offices.[56]

In November 2019, the Indian Patent Office published the "Manual of Patent Office Practice and Procedure, Version 3.0" (hereinafter the Patent Manual).[57] This Manual makes a reference to the Indian Patent Office's arrangement with WIPO regarding access to patent information.[58] The Indian Patent Office-WIPO cooperation agreement aims to facilitate the exchange of data between these offices, including Indian patent documents, search and examination reports through WIPO's two information systems.[59]

One important point of contention from the Patent Manual is its efforts to shift the responsibility of disclosing information under Section 8 from the patent applicant to the examiner and the Controller using the WIPO information systems.[60] This raises concerns as it could potentially burden the already resource-constrained Indian Patent Office. Moreover, this apparent transfer of burden clearly contradicts the legislative provision that mandates the patent applicant to bear the responsibility for fulfilling the requirements of Section 8.

It is often argued that the information sought under Section 8 can be accessible by patent offices through the WIPO CASE and DAS systems. Yet, it is important to note that these proprietary systems lack transparency and are not accessible to the general public. The availability of the information under Section 8 to the public is important in enabling the public to provide relevant information to the patent office through opposition and revocation mechanisms.[61] This public input to the patent office facilitates rigorous scrutiny of patent applications.

Unfortunately, the WIPO CASE system only provides public access to information that participating patent offices have authorized.[62] Moreover, the WIPO DAS system is entirely inaccessible to the public.[63] Adding to these limitations, the participation of fewer than 40 patent offices in these information systems means that the Controller will still lack complete information as required under Section 8 for all countries unless provided directly by the patent applicant.[64] This situation increases the burden associated with relying solely on the WIPO CASE and DAS systems, which can inadvertently circumvent specific disclosure requirements under the Indian Patents Act.

4 Importance of Section 8 in Ensuring Patent Quality, Transparency and Access to Medicines

THE grant of high-quality patents is important for maintaining the system's credibility. This issue becomes even more relevant as patent systems worldwide are now granting patents for inventions that may not be sufficiently novel, lack inventive step, and are often described vaguely.[65] Transparency and accountability in the patent system play an essential role in granting quality patents, and Section 8 serves as a means to achieve that goal. By necessitating the disclosure of the status of foreign patent filings on the same or similar inventions, this provision significantly promotes transparency, increases public trust in the patent system, and, in turn, increases the overall quality of patents granted in India.

Transparency and granting high-quality patents are intrinsically connected to the seamless functioning of the patent system, as they are intertwined with various other aspects. These include preventing frivolous patent grants, addressing information asymmetry, and balancing patent rights and public interest. Section 8 of the Indian Patents Act, one of the procedural safeguards, empowers the Indian Patent Office to make informed choices by effectively handling information asymmetry and ensuring the system's fairness.

The following part discusses these aspects in general and specifically in the context of medicines patents. Although Section 8 is a general requirement that applies to all patent applications filed in India regardless of sector, the provision plays a unique role in ensuring access to medicines.

a. Addresses information asymmetry

According to the Patents Act, the Controller of Patents must ensure that a patent is granted only when they are convinced that the invention meets the criteria for patentability according to existing laws.[66] This involves considering the relevant and the closest prior art related to the invention. To ensure quality patent examination and decision-making, the examiner and the Controller should necessarily have all relevant information. However, the patent office often may not have access to all necessary information from various sources, including those in the hands of the patent applicant, during the patentability assessment.[67]

Furthermore, the patent prosecution process involves technical and legal components while determining the patentability of an invention. Notably, there is a clear difference in legal acumen between the applicant and the patent office.[68] Since patentability requirements also involve legal interpretations, the Controller must have a certain level of legal training to ensure accurate examination and the rejection of low-quality patents. In some cases, the Delhi High Court has even recommended that Controllers undergo training in issuing judicial orders to improve the quality of patent decisions.[69] This can be partly attributed to the lack of legal expertise on the part of the Controllers.

The presence of these asymmetries – lack of technical information and limited legal expertise within the patent office – contributes significantly to the problem of maintaining patent quality. Section 8 addresses this imbalance by requiring the applicant to inform the Controller of all developments in pending applications for the same or substantially the same invention in other countries. However, it is important to note that the provision does not require disclosure of similar Indian applications. In the current form, it only requires disclosure of foreign patent applications for the same or substantially the same invention. If a requirement were in place to disclose all similar and related applications, whether filed outside or within the country, it could potentially further reduce the problem of evergreening patents.

A plain reading of the scheme of Section 8, including the headnote, makes it very clear that the disclosure of information and undertaking pertains to foreign patent applications only.[70] The courts have also settled that Section 8 only mandates the disclosure of patent applications filed outside India and not within.[71] However, while deciding an interim injunction application, a division bench in *Roche v. Cipla* had taken a contrary view where it noted that the patent applicant is under an obligation to disclose an application made in India on the same or substantially the same invention as well because the Controller cannot be presumed to have knowledge of all domestic applications as well.[72]

The primary reason for requiring disclosure of information regarding foreign patent applications when examining Indian applications is to ensure that the patent office has all the necessary details for a comprehensive assessment. The purpose of such disclosures is defeated if the patent office does not have complete knowledge about all related applications for the same or substantially the same invention, including those filed in India.

In the case of medicines, it is often seen that there are multiple patent applications filed for the same drug, sometimes in different patent office jurisdictions within India. These similar applications may not be reviewed by the same Controller, and without knowledge of all related applications, a comprehensive examination may not occur. Consequently, in order to better examine a patent application, it is important that the patent office is aware of all office actions taken on related and similar applications filed even in India.

Extending the scope of these disclosure requirements to encompass all related Indian applications for the same or substantially the same inventions would also alert the patent office to potential evergreening in medicine patent applications.

b. Prevents frivolous and evergreening patents

The international Patent Cooperation Treaty (PCT) has made it easier for multinational corporations to seek patent protection across multiple countries. However, it has also raised concerns about the proliferation of frivolous patents. In the last decade, there has been a significant increase

in patent applications and grants, which are often taken as indicators of innovation.[73] However, such an increase does not necessarily correspond to a rise in genuine innovation.[74] The steady increase in patents, rampant across sectors, could be attributed to the low standard of patentability[75] and lack of resources for proper examination at patent offices. For instance, in the United States and China, many patent applications are filed and granted, but the quality of these patents remains a critical concern.[76] In response to the large number of patent applications and concerns about patent quality, governments are now implementing corrective measures to address these issues and prevent potential misuse of the patent system.[77]

In the context of patents on medicines, poor-quality and frivolous patents directly affect the accessibility and affordability of essential lifesaving drugs. Pharmaceutical companies aim to prolong their monopoly on a medicine beyond the patent term of the original compound and delay the entry of lower-priced generic competition. They do so by seeking multiple secondary patents for different aspects of the same medicine, such as new uses, forms, combinations, manufacturing techniques, delivery mechanisms, and routine improvements – commonly known as "evergreening".[78] The problem of evergreening to extend the monopoly on medicines is rampant across the pharmaceutical sector globally. Despite existing safeguards against evergreening in India, a 2018 study of pharmaceutical patent grants in the country revealed that 72% of granted patents for pharmaceuticals are secondary patents, which have been granted for marginal improvements over previously known drugs.[79]

i. Disclosure of patents substantially the same as compound patents

Section 8 can tackle the issue of evergreening by requiring applicants to not only disclose corresponding applications but also submit details of "substantially the same" inventions in accordance with the provision. In the context of medicine patents, it means information on all patent applications on different forms of the same medicine or compound (e.g., salt forms, polymorphs, etc.), which would be substantially the same as their compound patents or vice versa, should be required to be disclosed to comply with Section 8.

The defendants in *Roche v. Cipla*[80] and *Merck v. Glenmark*[81] argued that the secondary patent applications (e.g., polymorph and salt form applications) were not disclosed during the prosecution of the original compound patent applications, and such non-disclosure constituted non-compliance with Section 8. The defendants put forward this argument to invalidate the patent in an infringement suit against them. The courts have not definitely decided whether "substantially the same" includes secondary applications.[82] Thus, there is a lack of clarity on the exact scope of the words "same or substantially the same" inventions under Section 8.[83] Since there is no definite ruling, it should be clarified through either the Rules or the Manual that all related patents or applications, including secondary applications, should be disclosed within the ambit of Section 8.

Box 5: Section 8 compliance in the bedaquiline fumarate salt patent application filed in India

Janssen, a part of the pharmaceutical corporation Johnson & Johnson (J&J), filed a secondary patent application (1220/MUMNP/2009) to the Indian Patent Office on the fumarate salt of bedaquiline. The Indian Patent Office rejected the application in March 2023. Bedaquiline is a crucial drug recommended by the World Health Organization (WHO) for treating drug-resistant tuberculosis, a significant public health challenge. Besides the secondary patent, Janssen also held a primary patent on the base compound of bedaquiline, which expired in July 2023. If the secondary patent for the fumarate salt of bedaquiline were granted, it could have potentially extended J&J's monopoly until December 2027, preventing Indian generic manufacturers from introducing affordable generic versions for an additional four years.

Two pre-grant oppositions were filed against the fumarate salt patent application to oppose the grant of the secondary patent. One of the grounds for opposition was the application's non-compliance with Section 8 of the Patents Act, as the applicant had failed to communicate to the Controller the rejection of their patents in Brazil and Argentina. Only after the opponents pointed it out did the applicant file updated information. Ironically, the applicant questioned the opponents' reliance on Section 8 non-compliance for failing to update the rejection information while simultaneously using the same provision to show the grant of corresponding patents in other jurisdictions to argue for granting the patent in India.

Although the secondary patent application was rejected in India on its merits, the Controller, in their order, stated that the objection related to Section 8 no longer applied after the applicant provided the necessary information after it was pointed out by the opponents.

5 Conclusion and Recommendations

IN the ever-evolving landscape of patent laws, Section 8 of the Indian Patents Act is an important tool for promoting transparency, upholding patent quality and facilitating access to medicines. The disclosure requirements prescribed under Section 8 align with the legislative intent of promoting genuine innovation while safeguarding the public interest and enhancing accountability within the patent system. This provision acts as a safeguard against unwarranted extension of patent monopolies on medicines, effectively addresses information asymmetry, and ensures that patents are not granted based on false suggestions or misrepresentations.

Over the years, compliance with Section 8 has declined, and the consequences of such non-compliance have not been enforced strictly. Therefore, there is an urgent need to strengthen its implementation rather than diluting it any further and ensure that patent applicants diligently comply with the disclosure requirements. Beyond being a legal obligation, it is also crucial for maintaining the integrity of the patent system.

Recommendation for developing countries

It is recommended that countries, particularly those with resource-constrained patent offices, require applicants to submit a statement of information regarding corresponding foreign applications for similar inventions, which will enable them to strengthen their patent examination process. This statement should detail the patent filing status, objections raised, decisions on novelty or patentability, and any amendments to specifications and claims in those foreign jurisdictions. This will provide patent offices with valuable international insights, aiding in the efficient

assessment of novelty, obviousness and patentability, and ensuring the grant of quality patents.

Recommendation for India

In India, the recently signed EFTA-India FTA includes provisions related to Section 8, which have to be implemented. However, implementing these provisions does not require any change to the Patent Rules. The FTA does not require diluting the continuous responsibility to update the status of foreign patent applications to a one-time requirement. The provision requiring the Patent Controller to refer to public databases for information regarding foreign applications can be met through a due diligence mechanism incorporated into the patent office practice through changes in the Patent Manual, without altering the Rules. This practice could complement the requirement for patent applicants to furnish information.

The recently incorporated 2024 Rules exceed the requirements introduced in the EFTA-India FTA. Therefore, it is recommended to recall the amendment and reinstate the earlier provisions. To further enhance the effectiveness of Section 8 of the Indian Patents Act, the following recommendations are proposed:

1. Patent applicants should have a continuous responsibility to provide information under Section 8 until the patent application is disposed of, ensuring that the Controller has the latest information when deciding on the application.
2. The legal consequences of non-compliance with Section 8, including the rejection of patent applications, and patent revocations, should be strictly enforced by the patent office and courts.
3. Disclosure of information pertaining to patent applications in respect of the "same or substantially the same invention" should include disclosure of information about all similarly related applications, whether filed within the country or outside. In the context of medicines, this would mean disclosure of all secondary patent applications related to the same medicine.
4. Patent applicants should furnish the information under Section 8 in an affidavit on oath to ensure stricter compliance, as the applicants can then be prosecuted for deliberately giving incorrect information.

Endnotes

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13. The earlier Rule 12(2), The Patents Rules, 2003 ["The time within which the applicant for a patent shall keep the Controller informed of the details in respect of other applications filed in any country in the undertaking to be given by him under clause (b) of sub-section (1) of section 8 shall be six months from the date of such filing."]. However, the Patents (Amendment) Rules, 2024 have altered this.
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17. The earlier Rule 12(3), The Patents Rules, 2003 ["When so required by the Controller under sub-section (2) of section 8, the applicant shall furnish information relating to objections, if any, in respect of novelty and patentability of the invention and any other particulars as the Controller may require which may include claims of application allowed within six months from the date of such communication by the Controller."]. However, the Patents (Amendment) Rules, 2024 have now deleted this.

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82. While the division bench in *Roche v. Cipla* seems to suggest in passing that, in the present set of facts, disclosing secondary patent applications during the prosecution of the primary application might not be necessary, the court did not definitively decide whether "substantially the same" includes secondary applications due to contradictory arguments raised by the defendant in their defence against infringement. The defendant argued that their product corresponded to the secondary patent application for which the plaintiff was granted a US patent (but rejected in India). They contended that their product was different from the plaintiff's primary patent and was not the same invention. Consequently, under Section 8, the defendant cannot claim that the secondary application was "substantially the same" as the original primary application.
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THE DISCLOSURE MANDATE: STRENGTHENING THE REPORTING REQUIREMENTS UNDER SECTION 8 OF THE INDIAN PATENTS ACT

Section 8 of India's Patents Act mandates that patent applicants must inform and regularly update the Indian patent office about the status of corresponding applications filed in other countries. This provision aims to facilitate a rigorous examination of patent applications. However, its implementation and enforcement are being undermined due to pressure from industry groups and unfavourable trade agreements, among other factors.

A weakened Section 8 compromises the quality and integrity of the patent examination process in India, leading to the grant of many undeserving patents. This is particularly concerning in the pharmaceutical sector, where patent evergreening is rampant. Allowing low-quality, frivolous patents can impede access to medicines. Instead of diluting the effect of Section 8, its implementation and enforcement should be strengthened to safeguard patent quality, ensure an enabling environment for competition and domestic research and development, and strike a balance between patent rights and public interest.

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