INDIAN JOURNAL OF LEGAL REVIEW [IJLR – IF SCORE – 7.58]

VOLUME 6 AND ISSUE 1 OF 2026

APIS – 3920 - 0001 *(and)* ISSN - 2583-2344

Published by

Institute of Legal Education

https://iledu.in

A COMPREHENSIVE ANALYSIS OF MARCH 2024 AMENDMENTS, SHORTENED REQUEST FOR EXAMINATION DEADLINES, AND FORM 27 MODIFICATIONS

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BEST CITATION - S.RENUKA, A COMPREHENSIVE ANALYSIS OF MARCH 2024 AMENDMENTS, SHORTENED REQUEST FOR EXAMINATION DEADLINES, AND FORM 27 MODIFICATIONS, *INDIAN JOURNAL OF LEGAL REVIEW (IJLR),* 6 (1) OF 2026, PG. 392-408, APIS – 3920 – 0001 & ISSN - 2583-2344. DOI - https://doi.org/10.65393/BABJ6166

ABSTRACT

India's Ministry of Commerce and Industry has, on March 15, 2024, notified the Patents (Amendment) Rules, 2024, thereby marking a major development in the Indian patent system. The amendments have made drastic changes to the patent prosecution timelines, opposition procedures, and patent working disclosure requirements. The article discusses in detail the three key changes: the shortening of Request for Examination (RFE) deadlines from 48 months to 31 months based on the priority date; the speeding up of the opposition review timelines for both pre-grant and post-grant oppositions; and the major change in the Form 27 working statement from annual to triennial filing intervals with significantly simplified information disclosure. The study's methodology includes an in-depth legal doctrinal analysis, case law scrutiny, and a comparative approach to jurisprudence. It has evaluated the consequences of the new patent rules for patent applicants, patent holders, and public interest groups, especially in the pharmaceutical industry. The article pinpoints significant research gaps related to empirical enforcement data, compulsory licensing under Section 83-84, and access to medicines implications, while also suggesting methodological frameworks for future studies.

Keywords: Patent Rules 2024, Request for Examination, Form 27, Working Requirements, Opposition Timelines, Pharmaceutical Patents, India, Patentability, Patent Prosecution

1. INTRODUCTION

The Indian patent system has always been a major player in the dual role of the innovation promoter and the public welfare protector, a very tough yet reasonable balance that was laid down in the Patents Act, 1970, and then through the 2005 amendment with the introduction of Section 3(d) and the 2023 Jan-Vishwas Act amendments ran over that.[1014] Big changes were made by the Indian government on March 15, 2024, through the Patents (Amendment) Rules, 2024 that took effect from the date of notification in the Official Gazette.[1015] The changes made with the new rules not only address the problem of backlog in patent application examinations, but also the inefficiency of the procedures, and administrative burdens placed on applicants. They also aim to cut down on the time taken for opposition procedures and streamline patent working disclosure requirements.

The 2024 amendments signify a notable shift in the structure of the Indian patent ecosystem. The Indian patent office has been under constant pressure to clear the backlog of patent applications, which in some cases have

[1014] Patents Act, 1970, § 3(d) (as amended by Patents (Amendment) Act, 2005); Jan Vishwas (Amendment of Provisions) Act, 2023 (revising Section 122 and condonation provisions).

[1015] Patents (Amendment) Rules, 2024, in Ministry of Commerce and Industry notification, Official Gazette, Mar. 15, 2024, available at https://ipindia.gov.in (hereinafter "2024 Amendment Rules").

been pending for examination for several years.[1016] On the other hand, India has managed to be a leading player in providing the world with generic pharmaceuticals while complying with the TRIPS agreement at the same time.[1017] The amendments are indicative of the Government's intention to upgrade patent administration without losing the health and technology access safeguards.

The three main amendments which are discussed in this paper—the RFE timeline reduction (Rule 24B), the opposition timeline acceleration (Rules 55 and 56), and the Form 27 working requirement modification (Rule 131)—are linked together within a wider policy framework that is addressing the examination efficiency and the rationalization of administration. Nevertheless, their effects are not limited to merely providing a proper procedure but also affect patent rights management, technology transfer, and the licensing situations under Sections 83-84 of the Patents Act.[1018]

A structured doctrinal analysis of these amendments along with their legal bases, operational implications, and empirical uncertainties is presented in this article and, at the same time, major research gaps are revealed that need to be filled with concerted efforts from patent scholars, policymakers, and practitioners.

2. LEGAL FRAMEWORK AND STATUTORY FOUNDATIONS

2.1 Constitutional and Legislative Underpinnings

The Indian patent system is based on Article 51(c) of the Constitution of India that states, "The State shall respect and protect the sovereignty of India" and that India would have just international relations, one of which is to comply with international treaties.[1019] This implied that India couldn't escape the TRIPS requirement through the 2005 amendments, and it is still the case with the 2024 amendments.

The Patents Act, 1970, as amended from time to time, lays down the substantive and procedural framework for the grant, maintenance, and enforcement of patents in India. The examination procedure governed by Section 11B is the statutory basis for the Rule 24B amendments that are changing RFE deadlines.[1020] Section 146 is the basis for disclosing working requirements aimed through Rules 131 and 132, which are now greatly altered by the 2024 amendments.[1021]

The procedures of pre-grant and post-grant oppositions are regulated by Sections 25 and 55-62, which provide the substantial background for the shortening of the opposition timeline in amended Rules 55 and 56.[1022] These sections are linked to Section 83, which lays down the legal basis for compulsory licensing that is, among others, failure to work patents commercially on a large scale in India, thus creating a substantive connection between working disclosure requirements and patent maintenance obligations.[1023]

2.2 The 2024 Amendments as Regulatory Response

The amendments for the year 2024 are at the top of the table of regulatory rule-making, taking advantage of Section 160 of the Patents Act, which grants the Controller General of Patents certain powers.[1024] Amendments to

[1016] Indian Patent Office, Annual Report 2022-23 (documenting pending application inventory and examination timelines across technology fields) (on file with author).
[1017] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 (requiring TRIPS minimum patent term of 20 years with no prejudice to compulsory licensing under Article 31).
[1018] Patents Act, 1970, §§ 83-84 (establishing policy framework for patent grant conditioned on working and compulsory licensing mechanisms).
[1019] INDIA CONST. art. 51, cl. (c) (establishing state responsibility to respect and protect national sovereignty and maintain international relations consistent with justice).
[1020] Patents Act, 1970, § 11B (establishing examination framework); Patents Rules, 2003, r. 24B (amended 2024) (prescribing RFE timeline requirements).
[1021] Patents Act, 1970, § 146 (requiring patentees and licensees to file statement regarding working of patented invention on commercial scale in India); Patents Rules, 2003, r. 131-132 (amended 2024).
[1022] Patents Act, 1970, §§ 25, 55-62 (establishing pre-grant and post-grant opposition framework); Patents Rules, 2003, pp. 55-56 (amended 2024).
[1023] Patents Act, 1970, § 83 (establishing that patents are granted "to encourage inventions and to ensure that inventions are worked in India on a commercial scale"); § 84 (permitting compulsory licensing where reasonable requirements of public are not satisfied, including failure to work).
[1024] Patents Act, 1970, § 160 (authorizing Controller General to prescribe forms, procedures, fees, and other matters necessary to implement the Act).

rules, unlike legislative changes, do not require approval from parliament, but they still have to be in line with the law. The power of the Controller to make procedural rules is considered to be authorized by Section 160, which allows for such prescriptions as forms, procedures, and fees that are essential for the implementation of the Act.[1025]

The year 2024 amendments were drafted by the Department for Promotion of Industry and Internal Trade (DPIIT) under the Ministry of Commerce and Industry, which indicates that they are in line with the governmental industrial policy of minimizing the 'ease of doing business' barriers.[1026]This policy framing is very important for interpretive analysis: the amendments not only aim at overcoming procedural inefficiencies but also at bringing the Indian patent prosecution timelines down to the level of the major patent jurisdictions, such as the United States, Europe, and Japan.

3. MODIFICATION OF REQUEST FOR EXAMINATION (RFE) TIMELINES: RULE 24B

3.1 Previous Regulatory Regime

Before the March 15, 2024, amendments were made, Rule 24B(1) stipulated that the applicants should submit a Request for Examination (Form 18) within a period of 48 months from the priority date or the filing date of the patent application, whichever was earlier[1027]. This 48-month window (roughly four years) was out of sync with the Patent Cooperation Treaty (PCT) national phase entry deadline of 31 months from the priority date, which was provided for in the PCT Regulations.[1028]

The practical effect of this misalignment was quite large for those who wanted to have international patent protection, especially those going through the PCT route. An applicant could file a PCT international application, do the international search and preliminary examination in 30 months, and then at the 31-month mark file the Indian national phase application. But according to the pre-amendment rules, this applicant could wait 17 months (48 months from priority) to file the RFE, thus creating a period when the Indian application was still in the pre-examination state. [1029]This period contributed to the backlog in patent examination and prolonged the overall prosecution timeline in India.

3.2 The Amended Regime: Temporal Synchronization

Under the modified Rule 24B(1), applicants are now required to submit the RFE within 31 months from the earlier of the priority date or the filing date.[1030] This changes in the patent procedure timelines create the same period as set by PCT and make it very close to the filing of patents in other countries, thus aligning the Indian patent prosecution timelines with those of the main patent jurisdictions.[1031]

Important Transitional Provision: An important grandfather clause has been included in the amendments: applications filed before March 15, 2024, still go by the old 48-month deadline, not the new 31-month standard.[1032] Yet, PCT applications that were filed before March 15, 2024, but have a national phase in India starting on or after March 15, 2024 will have the new 31-month limit applying to them, which is calculated from their international filing date or priority date.[1033]This retroactive application to some previously filed applications puts a lot of practical complexities, as the applicants will have to change their filing strategies for the

[1025] Patents Rules, 2003, r. 1 (establishing rules authorized under Section 160).
[1026] Department for Promotion of Industry and Internal Trade (DPIIT), Ease of Doing Business Initiatives (documenting patent rule amendments as part of broader regulatory modernization) (on file with author).
[1027] Patents Rules, 2003, r. 24B(1) (pre-amendment version).
[1028] Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 900 U.N.T.S. 195, r. 22.1(b) (establishing 31-month deadline for national phase entry in PCT member states).
[1029] This temporal gap created practical challenges for applicants managing PCT portfolios, requiring separate prosecution timelines in India compared to other major patent jurisdictions.
[1030] Patents Rules, 2003, r. 24B(1) (amended 2024).
[1031] Comparative analysis with USPTO (18-month examination), EPO (24-30 months), and JPO (3-year request window) demonstrates alignment with international practice.
[1032] Patents (Amendment) Rules, 2024, Transitional Provision (applications filed before Mar. 15, 2024 continue under 48-month timeline).
[1033] This retroactive application creates complexity for PCT applicants filed internationally before Mar. 15, 2024 but entering Indian national phase after that date, subjecting them to the new 31-month timeline from their international filing/priority date.

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existing PCT portfolios whose national phase begins after the amendment effective date.

3.3 Procedural Implications and Extension Mechanisms

The hastened timeline comes with massive operational effects. Applicants will now have a mere 31 months to decide on a full prosecution strategy for examination, which will involve the preparation of each and every detailed manifestation of the claims, technical specifications, sketches, and answers to the expected objections under Indian patent law, and so forth.[1034] For pharmaceutical applicants, the timeline necessitates an expeditious internal review of clinical and preclinical data, especially in the case of anticipating the Section 3(d) analysis that proving enhanced therapeutic efficacy will be required. [1035]

According to Rule 24B(1)(vi), RFE filing deadline can be extended, but it will be very costly. Amended Rule 138 grants an extension beyond the initially set 31-month deadline for six months for large entities at a monthly fee of INR 50,000.[1036] Consequently, the total extension cost for a six-month extension is INR 300,000 (almost USD 3,600), which is a considerable amount that effectively leads to a two-tiered system where companies with enough resources can buy flexibility over timelines whereas smaller applicants face strict deadline constraints.

3.4 Comparative Analysis: Alignment with Global Standards

The deadline imposed by the RFE at 31 months brings the Indian practice much closer to the examination procedures in the biggest patent jurisdictions:

- **United States:** The USPTO allows for the examination to take place within 18 months of publication (usually 18 months after the application), after which the applicant can continue the prosecution.[1037]

- **European Patent Office:** The EPO grants an average of 24-30 months for the examination of applications from the date of filing, and the applicants are allowed to request the examination at any time during the first 6 months of the priority period.[1038]

- **Japan:** The JPO allows a request for examination within 3 years of application with the examination being finished within 18-24 months on average subsequently.[1039]

A new 31-month deadline set in India is in unison with the PCT harmonized timeline, and it allows the multinational applicants to form their international prosecution strategies more easily and to face less administrative friction.[1040]The quality of examination and the length of time to grant do, however, remain a question in India: the rule change is concerned with the filing deadline synchronization but does not deal with the examination substantive timelines which are dependent on the capacity of patent offices and the availability of examiners' resources directly.[1041]

3.5 Implications for Pharmaceutical Patent Prosecution

The compressed RFE timeline holds great importance for pharmaceutical applicants. In India, pharmaceutical patents undergo intensified examination under Section 3(d), where showing of "enhanced efficacy"[1042] is a

[1034] The compressed timeline is particularly challenging for pharmaceutical applicants requiring extensive clinical and preclinical data compilation for Section 3(d) efficacy demonstration.
[1035] Novartis AG v. Union of India, (2013) 6 SCC 281 (Supreme Court establishing that Section 3(d) requires demonstration of "enhanced therapeutic efficacy," a quantitatively significant improvement establishing non-obviousness).
[1036] Patents Rules, 2003, r. 138 (amended 2024) (providing extension up to six months at INR 50,000 per month for large entities; concessional rates for individuals, startups, small entities, educational institutions).
[1037] 35 U.S.C. § 122 (b) (establishing 18-month publication window); continuation practice under 35 U.S.C. § 120 permits extended prosecution without formal deadline constraints (subject to patent term adjustments and statutory disclaimers).
[1038] European Patent Office, Guidelines for Examination, Part-A, Ch. IV (establishing 24-30 month average examination period with applicant-initiated examination request available within 6 months of priority).
[1039] Japanese Patent Office, Patent Prosecution Manual (establishing 3-year request window with examination typically completing within 18-24 months of request).
[1040] Coordination of international prosecution strategies is facilitated when national examination request deadlines align with PCT harmonized timelines, reducing administrative complexity for applicants managing multinational portfolios.
[1041] Patent office examination capacity and examiner availability are critical variables affecting FER issuance timelines, independent of RFE deadline modifications.
[1042] Novartis AG v. Union of India, 2013 SCC 6, 281 (establishing Section 3(d) efficacy standard for pharmaceutical patents); Bayer Corporation v.

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prerequisite for new forms of known substances, such as polymorphs, salts, esters, and metabolites. Compared to most patent jurisdictions, this one requires the preparation of traditional patent specifications along with the collection of data proving enhanced therapeutic efficacy.[1043]

In the case of **Novartis AG v. Union of India (2013),** the Supreme Court made a great impact by ruling that Section 3(d) requires demonstration of "enhanced therapeutic efficacy," which is a quantitatively significant improvement, rather than just an incremental improvement.[1044] This legal standard puts a considerable burden of proof on pharmaceutical applicants especially where clinical trial data required to be generated, compiled, and evaluated within the 31-month examination period.[1045]

For those who apply for divisional applications (which will be discussed later in Section 6), the compressed RFE timeline brings about the strategic pressures as well. From now on, under Rule 13(2A) which has been amended, divisional applications can be filed voluntarily without controller objection but still will have the same 31-month RFE deadline, calculated from their priority date (which is taken from the parent application).[1046] Thus, applicants need to align their divisional filing strategy with the overall prosecution timing.

4. ACCELERATION OF OPPOSITION TIMELINES: PRE-GRANT AND POST-GRANT OPPOSITION

4.1 Pre-Grant Opposition Framework: Amended Rule 55

Previous Regime: Before the 2024 amendments, the process of pre-grant opposition was as follows: (1) the aggrieved party made a representation according to Section 25 and Rule 55(1); (2) the Controller gave notice to the applicant; (3) the applicant submitted a response and evidence usually in three months; (4) the opponent submitted counter-evidence; (5) debates were held; and (6) the Controller finally ruled on the opposition and patent application with a reasoned order.[1047]

Amended Regime: One of the most important changes brought about by the 2024 amendments were related to Rule 55(3), which stated that it was now mandatory for the Controller to first do a prima facie examination of the opposition representation.[1048] In case the Controller finds that there is no prima facie case of opposition, the opposition is dismissed straight on procedural grounds without further examination. In this way, the Controller acts like a gatekeeper, allowing only those oppositions to cross which have a sufficient factual or legal basis.[1049]

The gatekeeper function is performed in the following manner:

Prima Facie Case Established: If a prima facie case is made, then the Controller gives notice to the applicant, and the applicant is required to file a response within two months (this is a reduction from three months).[1050]

2. No Prima Facie Case: If a prima facie case is not established, the Controller informs the opponent and:

- If the opponent asks for a hearing, the Controller allows the hearing and issues a

Natco Pharma Ltd., 2012 SCC OnLine Del 1476 (relying on Form 27 to establish NEXAVAR non-working as compulsory licensing justification).

[1043] The NOVARTIS standard requires applicants to demonstrate "enhanced therapeutic efficacy" through comparative data, clinical evidence, or mechanism-of-action studies—burdens not typically required in other patent jurisdictions.

[1044] Novartis AG v. Union of India, 2013 SCC 6, 281 (establishing quantitative efficacy threshold for Section 3(d)).

[1045] Pharmaceutical applicants must balance accelerated prosecution timelines against requirements to compile clinical and preclinical evidence supporting Section 3(d) efficacy demonstration within the 31-month examination window.

[1046] Patents Rules, 2003, r. 13(2A) (amended 2024) (permitting voluntary divisional filing for inventions disclosed in provisional/complete specification or prior divisional applications).

[1047] Patents Rules, 2003, r. 55 (pre-amendment version) (establishing opposition procedure without prima facie gatekeeping or timeline acceleration).

[1048] Patents Rules, 2003, r. 55(3) (amended 2024) (requiring Controller to ascertain prima facie maintainability and dispose of opposition where prima facie case is not made out).

[1049] The gatekeeper function delegates to Controller significant discretionary authority regarding sufficiency determination, creating potential for inconsistent application across patent offices.

[1050] Patents Rules, 2003, r. 55(4) (amended 2024) (reducing applicant response time from three months to two months).

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reasoned order within one month of the hearing, thus disposing of the opposition.[1051]

- If no hearing is requested, the Controller issues a reasoned order within one month of notifying the opponent, rejecting the opposition.[1052]

Acceleration Mechanism: The updated rule 55(5B) indicates that in case the opposition is established at least in the 1st stage, the application "will be examined" under the provisions of expedited examination applicable to it[1053]. Expedited examination necessitates the issuance of a First Examination Report (FER) in 2-4 months, which is a dramatic increase of the examination process by about 4-6 months when compared to standard FER timelines of 8-12 months.[1054]

4.2 Post-Grant Opposition Acceleration: Amended Rule 56

Previous Timeline: Pre-amendment Rule 56(4) stipulated that the Opposition Board had to present its report along with suggestions within three months after filing for opposition.[1055]

Amended Timeline: The altered Rule 56(4) shortens this period to two months, a one-third decrease in the review time.[1056] The timeline reduction applies to the review of all grounds for post-grant opposition, including those under Sections 64 (revocation on grounds of anticipation, lack of inventive step, or lack of utility) and 62 (challenge on administrative grounds such as inequitable conduct).[1057]

Practical Implications: In fact, the two-month timeline creates operational pressure on the Opposition Board to conduct swift scrutiny of massive evidence, prior art documentation, and technical arguments. For complicated pharmaceutical patents that refer to several references, comparative efficacy data, and synergistic effect arguments, the limited analysis time may reduce the thoroughness of the analysis.[1058]

4.3 Filing Fees as Opposition Deterrent

The 2024 amendments imposed filing fees for pre-grant oppositions, which had previously been unencumbered, in conjunction with the timeline reductions.[1059] The Controller now charges fees for filing pre-grant opposition; thus, there is a two-fold impact: (1) discouragement of unmeritorious oppositions, and (2) raising the cost barrier for patent disputes by generic companies, civil rights groups, and public interest lawyers.[1060]

This fee structure brings up issues of public health. Only civil society groups and generic manufacturers operating under limited budgets may have to deal with even tougher barriers to patents they view as lacking inventiveness or infringing on patentability limitations set by law.[1061] The People's Dispatch analysis (2024) argues this fee structure effectively "proffers arbitrary power to patent controllers" while putting public interest challengers in a very disadvantageous position in terms of resources compared to the well-capitalized multinational patent holders[1062].

4.4 Prima Facie Gatekeeping and Substantive Implications

[1051] Patents Rules, 2003, r. 55(3) (amended 2024) (establishing procedure where no prima facie case is established but opponent requests hearing).

[1052] Id. (establishing abbreviated procedure where opponent does not request hearing following prima facie dismissal).

[1053] Patents Rules, 2003, r. 55(5B) (amended 2024) (requiring expedited examination where prima facie opposition case is established).

[1054] Patents Rules, 2003, r. 24C (amended 2024) (establishing 2-4 month expedited examination FER issuance timeline compared to standard 8-12 month timelines).

[1055] Patents Rules, 2003, r. 56(4) (pre-amendment version).

[1056] Patents Rules, 2003, r. 56(4) (amended 2024).

[1057] Post-grant opposition grounds are established under Patents Act, 1970, § 64 (challenging patent validity on grounds including anticipation, lack of inventive step, lack of utility, added matter, improper inventorship, and procedural defects).

[1058] Complex pharmaceutical patents frequently involve multiple prior art references, pharmacokinetic and pharmacodynamic data, and comparative efficacy arguments requiring thorough Opposition Board analysis, potentially constrained by compressed timelines.

[1059] Patents Rules, 2003, Schedule I, Form 59 (amended 2024) (establishing pre-grant opposition fees).

[1060] Opposition filing fees create two-fold deterrent effect: reducing frivolous oppositions while increasing costs for resource-constrained opponents (generic manufacturers, civil society organizations).

[1061] Civil society organizations and public interest litigants frequently operate on grant-funded budgets with constrained resources for patent opposition filing, creating asymmetric cost burdens relative to well-capitalized multinational patentees.

[1062] People's Dispatch, India's Newly Amended Patent Rules Threaten Affordable Medicines in the Global South (Apr. 5, 2024), https://peoplesdispatch.org (arguing opposition fee structure and prima facie gatekeeping effectively restrict public interest patent challenges).

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The adoption of prima facie gatekeeping opens up large areas of concern in terms of substance. The pre-amendment practice allowed all oppositions no matter how weak, to be subjected to a substantive examination.[1063] The amended regime gives the Controller the power to turn down oppositions that do not have a prima facie basis without a substantive hearing.[1064]

Nonetheless, this discretionary gatekeeping authority still lacks explicit statutory guidance on what exactly is understood by a "prima facie case" of opposition. The Patents Act in its Section 25 lays down grounds for pre-grant opposition which are almost identical to the grounds for post-grant opposition as per Section 64, but the Standards for addressing prima facie sufficiency are still not established.[1065]

From the perspective of jurisprudence, the Indian courts are still to come up with a well-defined standard for prima facie assessment in opposition cases. The non-existence of precedents can lead to different interpretations and applications of the law by different patent examiners, patent offices in various regions, and appellate courts.[1066] Patent controllers might establish varying practices when it comes to the sufficiency of the evidence in prima facie cases, thus causing unpredictability for the practitioners of opposition and possibly deterring the legit patent challenges that lack immediately obvious merit.

5. MODERNIZED WORKING REQUIREMENTS: FORM 27 AMENDMENTS UNDER RULE 131

5.1 Legal Framework: Section 146 and Patent Working Principles

The Patents Act, Section 146 sets forth the legal basis for disclosure of working requirements, which is a must for patent holders and licensees to report "working of the patented invention on a commercial scale in India"[1067]. This is the provision that turns into practice the policy principles underlying Section 83, which states that patents are granted "to encourage inventions and to ensure that, in India, the inventions are worked on a commercial scale, that is, to the maximum extent that is reasonably practicable, and without causing any undue delay"[1068].

The public patent working requirement operates as an accountability mechanism, meaning that the government can keep track of patent usage and decide if the applications for patents are positive for India's technology and economy[1069]. This government function provides the basis for compulsory licensing decisions under Section 84, which allows for issuing of compulsory licenses when "the reasonable requirements of the public" are not met, partially based on the evidence of the patent working situation[1070].

5.2 Frequency Modification: From Annual to Triennial Filing

Previous Requirement: Up until March 15, 2024, the former Rule 131 mandated annual submission of Form 27 which started in the fiscal year right after the patent grant and was to be done on a yearly basis thereafter[1071]. This yearly submission created a great deal of administrative work for the patent holders who managed large portfolios because they had to gather financial and operational data every

[1063] Pre-amendment practice extended substantive examination to all oppositions regardless of apparent merit, providing comprehensive review opportunity but contributing to examination backlog.
[1064] The amended gatekeeping function creates potential for inconsistent application without explicit statutory guidance or precedent establishing prima facie sufficiency standards.
[1065] Patents Act, 1970, § 25 (establishing pre-grant opposition grounds substantially equivalent to post-grant grounds under § 64); absence of precedent regarding prima facie assessment creates interpretive uncertainty.
[1066] Controllers across different patent offices and jurisdictions may develop divergent practices regarding prima facie case assessment, creating unpredictability and potential forum-shopping incentives for opposition practitioners.
[1067] Patents Act, 1970, § 146 (requiring patentees and licensees to submit statement regarding working of patented invention on commercial scale in India).
[1068] Patents Act, 1970, § 83 (establishing policy principle that patents are granted "to encourage inventions and to ensure that inventions are worked in India on a commercial scale, to the fullest extent that is reasonably practicable, without undue delay").
[1069] Patent working requirements operate as accountability mechanisms enabling government monitoring of patent utilization and assessment of social utility.
[1070] Patents Act, 1970, § 84 (permitting compulsory licensing where "reasonable requirements of the public" are not satisfied); Form 27 evidence regarding working status provides evidentiary foundation for such assessments.
[1071] Patents Rules, 2003, r. 131 (pre-amendment version) (requiring annual Form 27 filing commencing in financial year following grant).

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year for each patented invention or group of related patents[1072].

Amended Requirement: Amended Rule 131(1) and Rule 131(2) have one filing every three financial years as a filing obligation, that is, the first filing will be made at the end of the third financial year after the patent has been granted and so on.[1073] Every three years expiring period needs to be reported and filed within six months after the expiration.[1074] The year in which the patent was granted is not counted for the filing purpose, which means that the first filing would have to be done in the second year after the grant of the patent.[1075]

Illustration of Amended Timeline: If a patent is granted during the financial year of 2024-25, then the first Form 27 for 2025-26, 2026-27, and 2027-28 will be due with the deadline of September 30, 2028, for filing.[1076] This is an enormous cut in the reporting frequency when compared to the prior annual requirement that lasted the entire 20-year patent term.

Extension and Condonation Mechanisms: Amended Rule 131(2) allows for the filing deadline to be extended by:

- A statutory extension of up to three months upon filing of Form 4 under Rule 131(2).[1077]

- An additional extension of up to six months under the general condonation provisions of Rule 138, at a cost of INR 50,000 per month (for large entities).[1078]

Nevertheless, Rule 137(2) sharply limits condonation of delay where the original filing deadline has already passed under the previous rules and thus prevents retroactive filing for missed deadlines under the pre-amendment annual requirement.[1079]

5.3 Substantive Content Simplification

The 2024 amendments have made a radical change to the information content of the Form 27, so now the qualitative disclosure is much less detailed and instead the qualitative disclosure is much simplified.

"Worked" Status: If the invention is patented and it is marked as "worked," the updated Form 27 does not request any additional information at all.[1080] In the past, patent holders had to disclose specific amounts or values related to the manufacture and importation of the patented product in India along with a detailed breakdown of the revenues from manufacturing as compared to the revenues from imports.[1081] The total financial disclosure requirement of this detailed nature has been wiped off completely.

"Not Worked" Status: For the patents that are marked as not worked, the updated Form 27 requires choosing one reason from the following pre-defined categories:

- The patented invention is undergoing development or commercial trial

- The patented invention is under review/approval with regulatory authorities

- Licensing is being considered

- Any other (with brief specification).[1082]

In the past, patent holders had to justify the non-working with an explanation giving reasons and also saying what steps were being taken for the commercialization of the invention.[1083]

[1072] Annual Form 27 filing requirements created substantial administrative burden particularly for patentees managing large portfolios, necessitating annual financial compilation and administrative submission costs.
[1073] Patents Rules, 2003, r. 131(1)-(2) (amended 2024) (establishing triennial filing requirement with six-month filing window following expiry of three-year period).
[1074] Amended Rule 131(2) provides filing deadline six months following expiry of three-year period, creating flexible window compared to fixed annual deadlines.
[1075] The year of grant is excluded from calculation, commencing the first three-year period in the financial year immediately following grant.
[1076] Office of the Controller General of Patents, Frequently Asked Questions on Form 27 (Aug. 26, 2024), https://ipindia.gov.in (providing illustrative timelines for various patent grant scenarios).
[1077] Patents Rules, 2003, r. 131(2) (amended 2024) (allowing statutory extension of three months for Form 27 filing deadline).
[1078] Patents Rules, 2003, r. 138 (amended 2024) (providing further extension up to six months upon payment of INR 50,000 per month for large entities).
[1079] Patents Rules, 2003, r. 137(2) (amended 2024) (barring condonation of delay where filing deadline expired under pre-amendment rules).
[1080] Amended Form 27 requires only "yes" checkbox where patent is worked, with no supplementary financial or operational details required.
[1081] Pre-amendment Form 27 required detailed disclosure of "approximate revenue or value accrued in India" with separate enumeration of manufacturing versus import revenues, along with brief operational description
[1082] Amended Form 27 provides predefined reason categories (development/trial, regulatory review, exploring licensing, other with specification) permitting simplified categorical selection.
[1083] Pre-amendment Form 27 required narrative explanation of non-working reasons and description of steps being taken to commercialize invention.

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Published by
Institute of Legal Education
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The updated form is moving from narrative justification to categorical selection which means simplifying the compliance burden but, at the same time, it may lead to reduced information quality and lack of substantive explanation.

Licensing Availability Disclosure: The updated Form 27 makes an innovative requirement that the patent holder confirms whether the patent is "available for licensing." [1084] If "YES" is selected, the patent holders may optionally provide email and contact information for licensing inquiries[1085]. This licensing availability provision seeks to overcome the barriers to licensing and to facilitate technology transfer. It is in line with the policy principle of Section 83(c) that patent rights should "contribute to the promotion of technological innovation and to the transfer and dissemination of technology."[1086]

Import-as-Working Clarification: Amended Form 27 contains an unequivocal statement that "patented invention will not be deemed to be 'not worked' solely on the basis that the patented product has been imported in India, provided the conditions specified under the Patent Act, 1970 are satisfied."[1087] This clarification resolves a long-standing issue regarding the patent "working" status of importation under Indian law, stating that importation is sufficient working unless there is a countervailing statutory constraint.[1088]

5.4 Multiparty Filing and Related Patent Aggregation

The Ministry of Commerce has approved the amendments to Form 27.

1. Related Patent Aggregation: A single Form 27 can be filed for a number of related patents granted to the same patentee(s) if the revenues or values from each invention cannot be segregated.[1089] This consolidation measure lightens the administrative burden for large patent portfolios while still requiring the disclosure for the aggregated patent group.[1090]

2. Joint Filing by Multiple Licensees: The pre-amendment note "each licensee shall file this Form individually" has been removed from the amended form, implying that multiple licensees of the same patent can now file a joint Form 27, subject to Controller's discretion.[1091] This mends the disclosure inconsistency caused by complex licensing structures in which several licensees are involved in the working of a single patent.

5.5 Comparative Analysis and Public Health Implications

The changes to Form 27 are like a huge step down in the working disclosure requirements, and thus the implications of these changes for public health and transparency are really big.

Reduced Transparency: The removal of the revenue disclosure in numbers means that the third parties, civil society organizations, and regulators can no longer get a picture of the patent's working or the extent of commercialization success through Form 27 documents.[1092]A patentee can say that the patent is "worked" with just a few units of manufacturing or imports, as there is no quantitative accountability, thus public understanding of the patent's utility is limited.

Compulsory Licensing Challenges: Section 84 compulsory licensing applications are partly based on Form 27 evidence to show that the "reasonable requirements of the public" are not

[1084] Amended Form 27 includes entry: "Whether the patent is available for licensing: Yes/No."
[1085] Where licensee indicates "YES," optional provision for email and contact information facilitates licensing inquiries from interested parties.
[1086] Patents Act, 1970, § 83(c) (establishing policy principle that patent rights should "contribute to the promotion of technological innovation and to the transfer and dissemination of technology").
[1087] Amended Form 27, Note 3 (clarifying that importation constitutes sufficient working absent statutory constraint).
[1088] The import-as-working clarification addresses longstanding interpretive debate regarding whether importation satisfies Section 146 "working" requirement or whether local manufacturing is exclusively required.
[1089] Amended Form 27 permits consolidated filing for related patents "provided that the revenue or value generated from each individual invention cannot be segregated."
[1090] Consolidated Form 27 filing for related patent groups simplifies compliance procedures for large portfolios while maintaining disclosure requirements at aggregated level.
[1091] Amended Form 27 omits pre-amendment language requiring individual Form 27 filing by each licensee, indicating joint filing permissibility subject to Controller discretion.
[1092] Elimination of quantitative revenue/value disclosure prevents third-party assessment of magnitude of patent working or commercialization success.

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APIS – 3920 - 0001 *(and)* ISSN - 2583-2344

Published by

Institute of Legal Education

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satisfied.[1093] Section 84(7) states that reasonable requirements are not met if "the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation of the patented article."[1094] Without the Form 27 data in numbers, the applicants seeking compulsory licenses are left with a flimsy evidentiary foundation for their claim of inadequacy of patent working.

The U.S. Trade Representative's 2023 Special 301 Report slammed India's reporting requirements as "excessive," worrying that the loosening of disclosure standards might not be enough for the monitoring of patent working.[1095] In contrast, however, the civil society organizations and public health advocates have argued that the further softening of Form 27 requirements is simply pouring over the transparency that is vital for compulsory licensing oversight.[1096]

Access to Medicines Considerations: The pivotal case **Bayer Corporation v. Natco Pharma Limited (2012)** was heavily reliant on the evidence provided under Form 27 which reflected non-working to conclude that the cancer medication NEXAVAR (sorafenib) was not distributed in India at prices that patients could afford, thus, granting a compulsory license to Natco was justified.[1097] Under the new regime of Form 27, proving non-working or inadequate working will necessitate positive proof rather than mere Form 27 assertions, which might lead to a complication in the future compulsory licensing because of working inadequacy.

6. DIVISIONAL APPLICATION FLEXIBILITY: RULE 13(2A)

6.1 Statutory and Jurisprudential Development

According to the Patents Act, Section 16, "The division of applications is permitted 'at any time before the grant' of the parent patent for inventions 'disclosed in the provisional or complete specification' but only in a few claims."[1098] In the past, patent office practice in India confined divisional applications to cases where: (1) the applicant was narrowing the scope of claims by amending them to overcome objections, thereby granting; or (2) the Controller had raised objections to the unity of invention, leading to the separation of the various inventive concepts.[1099]

The Supreme Court in **Syngenta Limited v. Controller of Patents and Designs (2023)** overruled the latter interpretations and cleared the way for divisional applications irrespective of whether the inventive concept was originally claimed or a unity objection was raised.[1100] The Court's ruling was based on the straightforward interpretation of Section 16, which states, "inventions disclosed in the provisional or complete specification," as covering all subject matter that is disclosed and not just the originally claimed subject matter.[1101]

6.2 The 2024 Amendment: Codification of Progressive Jurisprudence

The amended Rule 13(2A gives the Syngenta interpretation its codification by stating in unequivocal terms: that "a patent applicant may, if he wishes, apply for one or more additional applications under section 16, including in respect of an invention disclosed in

[1093] Form 27 evidence regarding working status informs compulsory licensing assessments regarding whether "reasonable requirements of the public" are satisfied under Patents Act, 1970, § 84.

[1094] Patents Act, 1970, § 84(7) (establishing that reasonable requirements are deemed unsatisfied where working is "prevented or hindered by importation of the patented article").

[1095] Office of the U.S. Trade Representative, 2023 Special 301 Report (Apr. 2023), https://ustr.gov (criticizing India's reporting requirements as "excessive").

[1096] Civil society organizations and public health advocates argue that Form 27 simplification undermines transparency essential for compulsory licensing oversight and public health monitoring.

[1097] Bayer Corporation v. Natco Pharma Ltd., 2012 SCC OnLine Del 1476 (relying on Form 27 evidence demonstrating NEXAVAR non-working as compulsory licensing justification).

[1098] Patents Act, 1970, § 16 (permitting divisional applications "at any time before the grant" for inventions "disclosed in the provisional or complete specification").

[1099] Historical Indian patent office practice restricted divisional applications to instances where unity objections were raised or claims were substantially amended, constraining divisional scope.

[1100] Syngenta Ltd. v. Controller of Patents & Designs, 2023 SCC OnLine Delhi 1282 (establishing that divisional applications are available for all disclosed inventive concepts independent of original claims or unity objections).

[1101] The *Syngenta* Court emphasized that plain statutory language—"inventions disclosed"—encompasses all disclosed subject matter, not merely originally-claimed inventions.

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APIS – 3920 - 0001 *(and)* ISSN - 2583-2344

Published by

Institute of Legal Education

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the provisional or complete specification or a further application filed under section 16."[1102]

This wording gives the following rights explicitly:

1. Divisional filing can be voluntarily done irrespective of the Controller's objection.[1103]

2. The scope of divisional claims is enlarged to any invention disclosed, not just to those claimed originally.[1104]

3. Application of "divisional of divisional" is allowed, resulting in infinite generations of divisional filings.[1105]

This amendment not only opens up but also synchronizes Indian patent practice with the US patent law provisions of continuation and continuation-in-part applications (35 U.S.C. § 120), where there is a possibility of filing an unlimited number of sequential continuations for covering any disclosed subject matter.[1106]

6.3 Strategic Implications for Pharmaceutical Patents

The option of filing a divisional application can be viewed as a means to indulge in substantial portfolio optimization. A single patent specification in the pharmaceutical area could reveal:

- New chemical entities (compounds, salts, polymorphs)

- Pharmaceutics (formulations, dosage forms)

- Production processes (chemical synthesis, purification)

- Therapeutics (indications, dosing)

- Medical devices or delivery systems.

Before the 2024 amendments, applicants experienced practical uncertainty about the divisional application scope, limited by office practice and examiner directives. The revised Rule 13(2A) and Syngenta case law grant unambiguous rights for the submission of individual divisional applications embracing each of these inventive concepts, as long as each divisional contains separate, non-overlapping claims as per Section 16(3).[1107]

Section 3(d) Considerations: The broadened divisional method opens up strategic options for handling Section 3(d) objections. In cases where a parent application is refused under Section 3(d) on the grounds that the substance is merely a new form of a known substance without any therapeutic efficacy being claimed, the applicants may go ahead and submit divisional applications with claims for:

- Different salt or ester forms that possess particular pharmacokinetic properties

- Combination therapies that use the compound with enhanced effects

- Separation of therapeutic methods or indications along with supporting efficacy data

- Manufacturing processes that result in improved formulations[1108]

This divisional tactic allows for the splitting up of technical disclosures which could result in the avoidance of Section 3(d) objections, by restricting claims to the parts illustrating enhanced efficacy, while keeping broader claims in different divisional applications.

6.4 Temporal and Procedural Implications

Divisional applications take on the original filing date of the parent application thus preserving the priority chain's consistency.[1109] On the other hand, divisional applications that are submitted

[1102] Patents Rules, 2003, r. 13(2A) (amended 2024) (codifying *Syngenta* principles through explicit textual authority for voluntary divisional filing covering disclosed inventions).

[1103] Amended Rule 13(2A) explicitly permits divisional filing "if he so desires," removing requirement for Controller-initiated unity objection as predicate for divisional filing.

[1104] The expanded scope encompasses any disclosed inventive concept, including embodiments not originally claimed and inventions disclosed solely in dependent claims or examples.

[1105] Amended Rule 13(2A) explicitly permits divisional applications "in respect of...a further application filed under section 16," codifying "divisional of divisional" permissibility.

[1106] 35 U.S.C. § 120 (permitting unlimited continuation applications covering any disclosed subject matter); Indian practice now aligns more closely with U.S. continuation regime.

[1107] Patents Act, 1970, § 16(3) (requiring distinct, non-overlapping claims between parent and divisional applications to avoid double-patenting objections).

[1108] Divisional application strategy permits disaggregation of technical disclosures, potentially narrowing claims to aspects demonstrating Section 3(d) efficacy while preserving broader claims in separate applications.

[1109] Divisional applications inherit priority date from parent application under Patents Act, 1970, § 16 (permitting priority chain preservation).

INDIAN JOURNAL OF LEGAL REVIEW [IJLR – IF SCORE – 7.58]

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APIS – 3920 - 0001 *(and)* ISSN - 2583-2344

Published by

Institute of Legal Education

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after the approval of the parent patent cease to be divisional and thus, cannot claim divisional rights.[1110]This results in a time limitation: divisional applications have to be lodged before the parent patent is granted, consequently, it fosters a timely divisional strategy during the prosecution stage.

Moreover, Rule 24B's changes now allow a faster publication and examination process for divisional applications that have been filed while the parent application is still being prosecuted, thus, motivating a filing of divisional applications early on in the process for the sake of portfolio optimization.[1111]

7. INTERCONNECTED EFFECTS AND SYSTEMIC IMPLICATIONS

7.1 Compressed Timeline Cascade

The interaction of the amendments brings about the temporal cascade effect:

1. The 31-month RFE deadline (Rule 24B) limits the time for consultation about the prosecution strategy formulation.

2. The examination of applications with prima facie opposition being accelerated (Rule 55(5B)) which is going to be implemented causes the opposite scenario for the applicant; the applicant will have to prepare not only opposition responses but also FER responses at the same time.

3. 2-month Period for Opposition Board to review (Rule 56) reduces the duration of appellate examination which in turn may lead to lack of thoroughness in post-grant opposition adjudication.

4. Triennial Form 27 filing (Rule 131) lowers the frequency of reporting but establishes three-year blocks for the assessment of compulsory licensing, which might lead to delay in intervention in the case of non-working situations.

All these factors in the cascade combine to create an atmosphere of rapid patent prosecution that is in line with the global timelines, however, it might also come with the risks of granting patents prematurely, not conducting a thorough prior art examination, and limiting the opportunity for a thorough opposition review.[1112]

7.2 Administrative Burden Redistribution

There is a huge administrative burden redistribution due to the amendments:

- Reduced burden on patentees: Triennial Form 27 filing, simplified content requirements, and voluntary divisional filing reduce compliance and strategic planning obligations.

- Increased burden on patent office: Compressed RFE deadlines and expedited opposition reviews require large examiner capacity and computational resources.

- Altered burden on patent challengers: Prima facie opposition gatekeeping with opposition filing fees creates barriers for public interest opposition while expedited review timelines reduce opportunities for comprehensive prior art search and analysis.

7.3 Harmonization and Divergence from TRIPS Minimums

India's patent system is significantly moving towards patent jurisdiction alignment through the 2024 amendments in procedural timelines but retaining the section 3(d) patentable subject matter safeguard, and not the only one.[1113] On the other hand, they create divergence from the minimum requirements of TRIPS in two points:

1. Opposition fee introduction: TRIPS Article 62(1) allows "opposition, cancellation, and other administrative proceedings," but TRIPS jurisprudence allows cost-neutral access, and Article 41 mandates fair and equitable

[1110] Once parent patent is granted, divisional application rights are extinguished under Patents Act, 1970, § 16; divisional applications must be filed before grant.

[1111] Amended Patents Rules, 2003, r. 24B (establishing expedited publication and examination timelines for divisional applications filed during parent prosecution).

[1112] The temporal cascade creates expedited prosecution environment potentially introducing risks of premature grant, reduced prior art examination depth, and abbreviated opposition review periods.

[1113] The amendments achieve harmonization with major jurisdictions in procedural timelines while maintaining substantive patentability safeguards, particularly Section 3(d).

procedures that are accessible to all parties.[1114] The introduction of opposition fees could limit access to the challenge mechanisms in a manner contrary to the equity principles implied by TRIPS, although such limitation is not explicitly mandated.

2. Reducing Form 27 disclosures: TRIPS Article 39.3 gives the option to protect undisclosed data and at the same time does not require the disclosure of the working of the product. The simplification of the Form 27 has cleared the way for no disclosure that at times can be interpreted as going beyond TRIPS minimums, possibly getting in tune with TRIPS-minimum straightening out principles.[1115]

8. IDENTIFIED RESEARCH GAPS AND METHODOLOGICAL CONSIDERATIONS

8.1 Empirical Implementation Data Gaps

Gap 1: Patent Examination Timeline Empirical Data

The reduction of the RFE deadline to 31 months was aimed at speeding up the examination process. However, the official patent office sources are still not providing any empirical data on actual examination timelines such as the time from RFE filing to FER issuance, the time from FER to grant, or the total duration of the prosecution for the period after the amendment.[1116]

Research Question: Will the 31-month RFE deadline end up shortening total prosecution timelines or will it just be a case of administrative pressure being front-loaded without any proportionate reduction in examination periods? It would be valuable to conduct a comprehensive analysis of grant timelines in relation to different technology fields and entity types (large entities, startups, small entities, educational institutions).

Gap 2: Opposition Filing and Approval Rates

The data post amendment for pre-grant opposition filing and rejection rates, and approval rates of substantive opposition is still kept confidential by the patent office. The imposition of opposition fees and prima facie gatekeeping was aimed at filtering out the silly opposition cases, but no empirical proof of the filtering effectiveness has been provided.[1117]

Research Question: What proportion of post-amendment oppositions are dismissed at prima facie stage? Has opposition filing volume increased or decreased following fee introduction? Do dismissal rates vary by technology field (pharmaceutical, information technology, biotechnology) or opponent type (competitor, generic manufacturer, civil society)? Comparative analysis with pre-amendment opposition patterns would establish baseline data.

Gap 3: Form 27 Compliance and Working Pattern Data

The patent office has not systematically released data regarding Form 27 filing compliance rates, working claim percentages, or reasons for non-working since the 2024 amendments. The CGPDTM Annual Report 2022-23 indicates only 8.3% of active licenses are worked and 82.52% remain unworked (per Form 27 filings), but post-amendment compliance patterns remain unavailable.[1118]

Research Question: What proportion of patentees comply with the new triennial Form 27 requirement? What percentage of patents are reported as "worked" versus "not worked"? Has the simplified Form 27 resulted in increased false reporting of working status? Do patterns vary by sector (pharmaceutical, information technology, biotechnology)? Disaggregated data by patentee size and nationality would illuminate differential compliance patterns.

[1114] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 62(1) (permitting opposition and cancellation procedures); art. 41 (requiring fair and equitable procedures).
[1115] TRIPS Article 39.3 permits protection of undisclosed test data but does not mandate working requirement disclosure; Form 27 simplification aligns with TRIPS-minimum principles.
[1116] Official patent office data regarding post-amendment examination timelines, FER issuance periods, and grant rates remain unavailable from public sources as of the article submission date.
[1117] Empirical data regarding opposition filing frequencies, prima facie rejection rates, and opposition approval rates remain proprietary; comparative analysis with pre-amendment patterns would establish baseline data.
[1118] Indian Patent Office, Annual Report 2022-23 (indicating 8.3% of active licenses worked, 82.52% unworked per Form 27 filings).

8.2 Substantive Patent Rights and Compulsory Licensing Implications

Gap 4: Compulsory Licensing Threshold Assessment

The requirement of filing Form 27 every three years creates blocks of assessment that last for three years preceding the next disclosure of working. Such a time gap could make it impossible to timely recognize the non-working situations that can be compulsorily licensed under the provision of Section 84.[1119] There is no empirical study on the timelines of compulsory licensing applications and their connection to the Form 27 evidence cycles.

Research Question: How many compulsory licensing applications under Section 84 have been substantially relying on Form 27 evidence since 2012 (the Natco decision)? What are the time relationships between Form 27 filings, non-working identification, and compulsory licensing application initiation? Will the three-year reporting cycle lessen the frequency of licensing based on working inadequacy?

Gap 5: Section 3(d) Jurisprudence and Pharmaceutical Patent Grant Rates

The amendment made in 2024 relating to divisional applications (Rule 13(2A)) will give rise to several new strategic alternatives for the parties aiming to avoid the Section 3(d) objections simply by creating more divisions. However, there is still no empirical research to show whether the increased divisional filing has led to an increase in pharmaceutical patent grants or altered the use of Section 3(d) objections.[1120]

Research Question: Have there been changes in pharmaceutical patent grant rates after the amendment? Are applicants relying more on divisional strategies to overcome Section 3(d) objections? What is the ratio of pharmaceutical patents granted through divisional versus parent applications? Has the expanding option for divisional units created the risk of "evergreening" since it permits the segregation of non-obvious technical disclosing through the filing of divisional applications?

8.3 Access to Medicines and Public Health Implications

Gap 6: Working Requirement Effectiveness and Public Health Impact

The triennial Form 27 reduction and content simplification were framed as reducing patentee burden, but the public health implications remain unresearched. Working requirements act as mechanisms to guarantee patents contribute to public welfare and to uncover non-working situations that are eligible for compulsory licensing.[1121]

Research Question: Has the patent office's ability to watch patent working and locate non-working situations been compromised by Form 27 changes? Has the removal of quantitative revenue disclosure lessened the transparency available to generic manufacturers, civil society, and healthcare systems for judging patent utility? What is the link between the quality of Form 27 data and the outcomes of the subsequent compulsory licensing decisions?

Gap 7: Opposition Gatekeeping and Patent Challenge Efficacy

The introduction of prima facie opposition gatekeeping and opposition filing fees was not meant to limit "frivolous" oppositions but rather to shrink the volume of illegitimate public interest challenges, especially those by civil society organizations and public interest litigants with meager resources, who would be most affected by the fee.[1122]

Research Question: The introduction of the opposition fee has had an impact on the

[1119] The triennial Form 27 filing creates three-year visibility gaps during which non-working situations remain undetected, potentially impeding timely compulsory licensing applications.
[1120] Empirical research into post-amendment pharmaceutical patent grant rates and Section 3(d) application patterns remains unavailable; such analysis would illuminate divisional strategy impacts.
[1121] Working requirements operate as mechanisms ensuring patents contribute to public welfare and identifying non-working situations eligible for compulsory licensing intervention.
[1122] Opposition fee introduction and prima facie gatekeeping may collectively restrict public interest opposition while providing competitive opponents resources to overcome gatekeeping barriers.

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APIS – 3920 - 0001 *(and)* ISSN - 2583-2344
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pattern of opposition filings by the different types of entities (competitors, generic manufacturers, civil society, public interest litigants). What is the ratio of the civil society opposition filings which are dismissed at the prima facie stage? Is the dismissal rate related to the quality of the opposition or just to the resource differences between the opponents? Have there been a decrease in the opposition filings by generic manufacturers and civil society organizations after the amendment?

8.4 Methodological Frameworks for Research Closure

Gap 8: Comparative Jurisdictional Analysis

Timelines of patent examination in India, opposition procedures and working requirement regimes have not been systematically compared with other TRIPS-compliant jurisdictions post-amendments.[1123]

Proposed Research Methodology: Comparative legal analysis of:

- RFE timelines and extension fees regimes in India, U.S., EPO, Japan, Australia

- Opposition timeline and gatekeeping procedures of the comparable jurisdictions

- Working requirement disclosure regimes and enforcement mechanisms worldwide

- Empirical outcomes (grant rates, opposition effectiveness, compulsory licensing frequency) linked to variations in procedural regimes

Gap 9: Multi-Stakeholder Impact Assessment

The amendments have a different impact on multiple groups of stakeholders (applicants, patentees, competitors, generic manufacturers, civil society, patients, healthcare systems), but still there is no comprehensive multi-stakeholder impact assessment.[1124]

Research Question: The introduction of the opposition fee has had an impact on the pattern of opposition filings by the different types of entities (competitors, generic manufacturers, civil society, public interest litigants). What is the ratio of the civil society opposition filings which are dismissed at the prima facie stage? Is the dismissal rate related to the quality of the opposition or just to the resource differences between the opponents? Have there been a decrease in the opposition filings by generic manufacturers and civil society organizations after the amendment?

Proposed Research Methodology: Qualitative research through semi-structured interviews with:

- Patent applicants and practitioners regarding prosecution timeline impacts and strategic adaptation

- Patent office examiners regarding workload, examination resource adequacy, and quality implications

- Compulsory licensing applicants regarding Form 27 evidence adequacy and opposition gatekeeping effects

- Civil society organizations and public health advocates regarding transparency and patent challenge capability impacts

- Pharmaceutical companies regarding divisional strategy implications and Section 3(d) navigation

9. CRITICAL ASSESSMENT: POLICY OBJECTIVES VERSUS IMPLEMENTATION EFFECTIVENESS

9.1 Alignment Between Stated Policy Objectives and Amendment Design

The 2024 amendments were announced within a broader "ease of doing business" policy framework, aiming to reduce procedural impediments while maintaining substantive patent protections and public interest safeguards.[1125] However, the amendments'

[1123] Systematic comparative analysis of Indian patent examination timelines, opposition procedures, and working requirements relative to TRIPS-compliant jurisdictions remains absent in post-amendment scholarship.

[1124] The amendments affect applicants, patentees, competitors, generic manufacturers, civil society, patients, and healthcare systems differentially; comprehensive impact assessment remains unavailable.

[1125] Government announcements framed 2024 amendments within "ease of doing business" policy objectives, emphasizing procedural streamlining and burden reduction.

design reveals potential misalignment between stated objectives and implementation mechanisms:

Objective: Streamline examination timelines

- **Design:** 31-month RFE deadline aligns with PCT timelines.

- **Implementation Risk:** No corresponding reduction in patent office examination capacity or FER issuance timelines; compressed deadline may merely frontload applicant burden without proportionate examination acceleration.

Objective: Reduce examination backlog

- **Design:** Quick examination for opposed applications (Rule 55(5B)); prima facie opposition filtering.

- **Implementation Risk:** Opposing gatekeeping may decrease the number of applications examined per application but at the same time will lead to poor scrutiny of questionable patents which could increase the risk of post-grant revocation.

Objective: Reduce patentee compliance burden

- **Design:** Triennial Form 27 filing; simplification of requirements regarding content.

- **Implementation Risk:** Transparency reduction might jeopardize monitoring of compulsory licensing and public health, thus bearing hidden costs for society in return for the ease of the patentee.

9.2 Potential Unintended Consequences

Consequence 1: Examination Quality and Premature Grant Risk

The shortening of the RFE deadline to 31 months and the fast-tracked examination for an opposed case might lead to or cause:

- Less thorough prior art search

- Not enough assessment of inherent limitations under Section 3(d) for drug patents

- Deterioration of examination report reasoning quality[1126]

Consequence 2: Opposition Chilling Effect

The interplay of prima facie gatekeeping power, prohibition filing costs, and fast-tracked Opposition Board processes may not only discourage public interest oppositions, but also provide competitive adversaries with enough resources to get past the gatekeeping hurdles.[1127] This develops an imbalance of public interest that is most probably against the intention of Section 83 which is to promote innovation and at the same time ensure public welfare.

Consequence 3: Compulsory Licensing Practical Impediment

The requirement of filing Form 27 every three years creates a scenario where non-working situations are not known to compulsory licensing applicants for three years. If this is coupled with simplified Form 27 content, the practical effectiveness of compulsory licensing provisions laid down in Sections 84-94 may be significantly reduced particularly for the cases concerning public health-critical inventions.

10. CONCLUSION AND FUTURE DIRECTIONS

The Patents (Amendment) Rules, 2024, are a huge step forward in modernization of Indian patent procedure which not only aims to bring the patent prosecution timelines into sync with the world but also lessen the administrative burden of the applicants in the process. Among them, the decrease of RFE deadlines to 31 months, speedy opposition review limited to 2-month post-grant Opposition Board timelines, and changing of Form 27 working requirement reporting from once a year to every three years are the very radical changes in procedure.

[1126] Examiner workload intensification may reduce examination report quality, detailed reasoning, and prior art search comprehensiveness, potentially increasing post-grant revocation risk through administrative or substantive defects.

[1127] The combination of prima facie gatekeeping, opposition filing fees, and accelerated Opposition Board timelines creates public interest asymmetry potentially contrary to Section 83 policy balancing.

Nonetheless, these changes are still part of a complicated legal system that weighs the public good against the need for innovation. The effects on patent grant rates, compulsory licensing, and access to medicines in the case of pharmaceuticals have not yet been measured empirically. There are still some critical research areas concerning the effectiveness of the implementation, the impact on different stakeholders, and the alignment between jurisdictions.

Key findings:

1. **RFE Timeline Alignment:** The 31-month deadline provides procedural synchronization with PCT and major jurisdiction timelines which facilitates coordination of international patent prosecution. However, empirical evidence corresponding to reduction in total prosecution timelines and examination quality is still not available.

2. Opposition Procedure Tensions: The prima facie gatekeeping mechanism along with opposition fees are to some extent new and old wine in a same bottle; on the one hand, they promote the efficiency of the proceedings while on the other hand, the public interest, especially in the area of patents, may oppose it because of raising barriers to conducting the opposition.

3. Form 27 Disclosure-Transparency Trade-off: The triennial reporting frequency and content requirement simplification do not only reduce the patent owner's compliance costs, but also greatly limit the transparency of patent working status, thus creating operational barriers to compulsory licensing and restricting the capability of monitoring public health.

4. Divisional Application Flexibility: The codification of Syngenta principles through new Rule 13(2A) offers more room for portfolio optimization but at the same time, it brings the potential of a slower accumulation of pharmaceutical patents that could be in conflict with Section 3(d) anti-evergreening policy.

Future research directions should highlight:

- The systematic empirical collection and analysis of the time periods involved in patent examination that has taken place post-amendment, the opposition filing patterns, and the working requirement compliance rates.
- A comparative analysis of the effectiveness of opposition gatekeeping and sua sponte prior art quality across different fields of technology.
- A study on the compulsory licensing applications where the evidence used in Form 27 has been compared with the licensing decision outcomes.
- A multi-stakeholder qualitative research project that evaluates the different impacts on applicants, competitors, civil society, and healthcare systems.
- Analysis of constitutional and TRIPS compliance of opposition fee systems and their alignment with WTO minimum standards

The 2024 modifications facilitate the unification of procedures with the global patent systems without giving up on the substantial patentability criteria. Nevertheless, the success of these changes in realizing the declared policy objectives and the impacts on the substantive patent rights, compulsory licensing methods, and the access to medicines still lack empirical validation and require thorough post-implementation evaluation. The patent community, including scholars, policymakers, and practitioners, should continuously monitor the implementation results to make sure that the changes not only improve the innovation incentives but also serve the public health objectives as specified by the original policy framework of Indian patent law.