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IMPLICATIONS OF FORM- 27 AMENDMENTS INTRODUCED IN 2024 PATENT RULES

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ABSTRACT

An invention that offers novel technical solutions, such as new products or processes, is granted exclusive rights by a patent. The Indian Patents Act of 1970¹²⁷⁴ requires patent holders and licensees to fully commercialize their patents in India, assuring public benefit through commercial exploitation. As required by Section 146(2)¹²⁷⁵, compliance necessitates the submission of Form 27 statements outlining the scope of patent exploitation. Changes that went into effect in 2024 changed the submission schedule from annual to triennial, which decreased the frequency of compliance for patents awarded after April 2023. This change tries to make reporting easier and define concepts like "adequate extent," which were controversial before. Examining Form 27's function after the modification, the paper concentrates on how it affects applications for compulsory licenses of newly issued patents.

KEYWORDS: Working Statement, Form- 27, Compulsory License, Patent Amendment Rules 2024

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¹²⁷⁴ THE PATENTS ACT, 1970 ACT NO. 39 OF 1970

¹²⁷⁵ THE PATENTS ACT, 1970 S 146(2), ACT NO. 39 OF 1970

INTRODUCTION

A patent is an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. Technical information about the invention must be disclosed to the public in a patent application to get a patent.¹²⁷⁶

All patent holders and licensees are required by the Indian Patents Act of 1970¹²⁷⁷ to fully commercialize their patents within India. Within acceptable and practical bounds, this clause seeks to foster innovation and guarantee that patents awarded in India are fully exploited for the benefit of the Indian public. In India, a patent is said to have been "worked" if it has been commercially exploited, which means that the patented goods are either produced domestically, imported into India, or both. Section 146(2)¹²⁷⁸ of the Indian Patents Act mandates that every patent holder and licensee provide information on the extent to which the patented invention has been commercially utilized in India. In India, compliance with the Patents Act, 1970¹²⁷⁹ mandates that every patentee or licensee must submit a statement detailing the extent of commercial use of their granted patent within Indian territory. This requirement is encapsulated in Form 27 of the "2003 Patent Rules¹²⁸⁰." Failure to adhere to the filing timelines may result in penalties such as imprisonment for up to six months, a fine, or both, as stipulated under section 122(1)(b) of the Patents Act¹²⁸¹. Previously, the law necessitated filing this information annually within three months from the end of the calendar year, with March 31st being the deadline. However, a lack of clarity in Form 27, especially regarding terms like "adequate extent" and "fullest extent that is reasonably practicable," led to ambiguity and

non-uniform compliance, as highlighted by a Public Interest Litigation (PIL) filed before the Delhi High Court in 2015¹²⁸². The 2024 revisions have modified the rules for submitting working statements for patents. Previously, patent holders had to provide a working statement for each fiscal year, due on September 30 of the following year. This was because the statement needed to be submitted within six months of the start of the next fiscal year.

For instance, the working statement for the fiscal year 2022–2023 (April 1, 2022–March 31, 2023) had to be submitted by September 30, 2023. However, patents granted on or after April 2023 are exempt from this yearly requirement. The first working statement for these newer patents, covering the period from April 1, 2023, to March 31, 2024, is due by September 30, 2024. According to the new modification, the working statement must now be provided once every three fiscal years. This three-year term begins immediately following the fiscal year in which the patent was awarded, and the statement must be submitted within six months after the end of each term. For example, if a patent is awarded during the fiscal year 2023–2024, the patent holder will need to present a working statement covering the fiscal years 2024–2025, 2025–2026, and 2026–2027. The deadline for this statement is September 2027. The deadline for submissions can also be extended. Upon request, the working statement submission deadline may be extended by up to three months. This extension is requested using Form 4 and is contingent upon the Controller approving the postponement. Additionally, the newly simplified Form-27 includes objective response options, making it easier for patentees to provide information about the working of their patent.

This article aims to examine the role of Form 27 and analyze the impact of recent amendments

¹²⁷⁶ 'What is Patent' accessed on 26. 06. 2024 at <https://www.wipo.int/en/web/patents/>

¹²⁷⁷ Id at 1

¹²⁷⁸ Id at 2

¹²⁷⁹ Id at 1

¹²⁸⁰ THE PATENTS RULES, 2003

¹²⁸¹ THE PATENTS ACT, 1970 S 122(1)(b), ACT NO. 39 OF 1970

¹²⁸² Shweta Sharma, Amendments to Form 27 (Indian Patent Act) – Evaluating the Commercial Applicability of a Patent accessed on 27.06.2024 at < <https://sagaciousresearch.com/blog/amendments-to-form-27-indian-patent-act-evaluating-the-commercial-applicability-of-a-patent/> >

to it, particularly in relation to applications for compulsory licenses. It will explore how these changes might affect applications for compulsory licenses on newly granted patents.

PURPOSE OF WORKING STATEMENT

According to Section 83 of the Indian Patents Act, 1970¹²⁸³, which is captioned "General principles applicable to working of patented inventions," patents are awarded in order to encourage ideas and make sure that they are used as quickly and fully as possible for commercial purposes in India. It also highlights the fact that patents ought to make the advantages of the patented innovation reasonably accessible to the general public. The Indian Patents Act requires all patentees and licensees to provide an annual statement of the functioning of a patented invention to the Indian Patent Office in order to uphold these standards. Section 146 of the Indian Patents Act, 1970¹²⁸⁴ and Rule 131 of the Indian Patents Rules, 2024¹²⁸⁵ both specify this criterion.

KEY CHANGES INTRODUCED IN FORM 27

1. **Filing Deadline and Frequency:** The Annual Working Report (AWR) needs to be submitted every three fiscal years, starting with the fiscal year immediately following the year the patent was issued. Each report must be filed within six months after the conclusion of the three-year period. For example, if a patent was granted in the fiscal year 2021-2022, the first reporting period would begin in the fiscal year 2022-2023 and cover the fiscal years 2022-2023, 2023-2024, and 2024-2025. The AWR for this period would need to be submitted by September 30, 2025.
2. **Approximate Revenue Reporting:** The amended Form 27 requires patentees/licensees to report only the approximate revenue or value accrued in India through the manufacturing or

import of the patented invention. This simplifies compliance, addressing concerns over exact reporting and confidentiality.

3. **Removal of Licensee/Sub-licensee Details:** The requirement to disclose details of licensees and sub-licensees has been eliminated, alleviating confidentiality concerns for patent portfolio owners and managers.
4. **Elimination of Public Requirement Statement:** The controversial requirement to state whether the public requirement for the patented product was met partly/adequately/to the fullest extent at a reasonable price has been removed, offering relief to patentees.
5. **Single Form for Related Patents:** Patentees can now file one Form 27 for related patents if the revenue or value accrued cannot be separately determined for each patent, streamlining the filing process.
6. **Word Limit for Non-working Statements:** A 500-word limit is now imposed for explaining reasons for not working on the patented invention and outlining steps taken or planned to work on it.
7. **Import Details Simplified:** Specific details on country-wise importation of patented products are no longer required, further easing reporting requirements.
8. **Signature and Mandatory Filing Note:** The form now requires signatures from the patentee/licensee or their authorized agents, emphasizing compliance with Section 146 of the Patents Act, 1970 and Rule 131(1) of the Patent Rules, 2003.
9. **Clarity on Joint Filing:** Multiple owners of a patent have the option to file Form 27 jointly, while each licensee must file individually, clarifying filing procedures.¹²⁸⁶

¹²⁸³ THE PATENTS ACT, 1970 S 83, ACT NO. 39 OF 1970

¹²⁸⁴ THE PATENTS ACT, 1970 S 146, ACT NO. 39 OF 1970

¹²⁸⁵ THE PATENTS RULES, 2024 R 131

¹²⁸⁶ Id at 9

ROLE OF COMPULSORY LICENSE

If an invention is patented, its owner has the sole right to prevent others from profiting from it. This means the innovation cannot be created, used, imported, sold, or distributed without the owner's permission. This privilege, granted by the Indian government, lasts for 20 years from the date of publication. However, this exclusivity is not absolute; third parties may be granted forced licenses to utilize the patent under specific circumstances. Through a system known as compulsory licensing, the government can allow a third party to manufacture a patented product or process, even if the patent owner has no intention of using the invention. This is usually seen more in life sciences and pharma patents. This provision is included in the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement of the WTO¹²⁸⁷. According to Article 31 of TRIPS¹²⁸⁸, the license must primarily serve the domestic market, adequate compensation must be provided to the patent holder, and the entity seeking the license must have unsuccessfully attempted to obtain a voluntary license on reasonable commercial terms. This balances the rights of patent holders with public interests, ensuring that patents do not unnecessarily restrict access to important innovations. Section 84(1) of the Indian Patents Act, 1970¹²⁸⁹, outlines the rationale behind compulsory licenses and emphasizes that when granting such licenses, the considerations specified in this section must be taken into account. The Act imposes an obligation on patent holders to actively utilize their patents in India. A compulsory license can be issued under the Act after a period of three years from the patent's grant date, based on specific grounds:

1. The reasonable needs of the public regarding the patented invention have not been fulfilled.

2. The patented invention is not available to the public at a reasonably affordable price.

3. The patented invention is not being worked within the territory of India.

According to the Act, the reasonable needs of the public are deemed unsatisfied if:

- The patent holder refuses to grant licenses on reasonable terms, leading to prejudice in trade or industry, inadequate supply of the patented article, failure to develop a market for export of the article manufactured in India, or hindrance to commercial activities in India.

- The patent holder imposes restrictive conditions on the use of the patented invention.

- The patented invention remains unworked in India.

- Commercial-scale use of the patented invention in India is obstructed by imports.¹²⁹⁰

Indian generics manufacturer Natco Pharma Ltd. obtained the country's first mandatory license for Bayer's proprietary kidney cancer medication, Nexavar, in 2013. Based on inconsistencies in Bayer's working statements submitted to the Indian Patent Office, Natco's licensing request was based on the company's claim that Bayer had neglected to supply Nexavar to the Indian populace at reasonable prices. While Natco suggested selling Nexavar for 8,800 rupees (about \$150) each month, Bayer priced the medication at 280,000 rupees (about \$4,500) per month for a dosage of 120 tablets. Bayer was accused by Natco of failing to fully exploit the patent in India at a reasonable cost, in addition to failing to meet local demand.¹²⁹¹

IMPLICATIONS OF THE AMENDMENT

Let's consider a hypothetical situation to understand better. XYZ Motors owns a patent for a novel solution for EV batteries. Previously, XYZ Motors had to disclose comprehensive

¹²⁸⁷ Trade-Related Aspects of Intellectual Property Rights accessed on < https://www.wto.org/english/tratop_e/trips_e/trips_e.htm >

¹²⁸⁸ TRIPS A 31 accessed on < https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm >

¹²⁸⁹ THE PATENTS ACT, 1970 S 84 (1), ACT NO. 39 OF 1970

¹²⁹⁰ IAM Dealing with compulsory licensing in India accessed on < <https://www.lexology.com/library/detail.aspx?g=3a2aedbb-20c1-4137-b5b1-ab1dfb0ff312> >

¹²⁹¹ Bayer Corporation v. Natco Pharma Limited, 2014(60) PTC 277 (BOM)

production and sales data regularly through Form 27 as per patent rules. However, the transparency has decreased due to the new requirement to file Form 27 only once every three years without specific quantity specifications. Now, imagine that another company, GreenDrive Co., requests a license, claiming that XYZ Motors is not fully utilizing its invention. Because of the three-year reporting cycle, GreenDrive Co. must gather evidence of inadequate output or unavailability in the market for the entire time covered by the Form 27 submission. This extended period makes it difficult for GreenDrive Co. to collect timely and specific evidence showing underutilization during the current reporting cycle. The delay in gathering and presenting relevant information weakens GreenDrive Co.'s case for quick action, potentially postponing their ability to enter the market competitively. Additionally, by delaying Form 27 filings for an extended period, XYZ Motors can maintain its market exclusivity without presenting updated proof of public benefit or sufficient use. Without convincing proof that XYZ Motors' patent serves the public interest, this circumstance could impede progress in EV battery technology, suppress competition, and uphold XYZ Motors' dominating position in the market. Thus, although the updated Form 27 aims to simplify reporting, it introduces complexity that could hinder technical innovation and fair competition.

The revised Form 27 no longer requires specific information on the quantity of the patented invention, making it difficult to ascertain whether the Patent was being worked in India. There appears to be no valid justification for removing the requirement to disclose the total number of patented devices imported and manufactured in India. This information is crucial for assessing the extent of patent usage and is a key factor in the implementation of the compulsory licensing system.¹²⁹² For instance, in the landmark ***Bayer v. Natco case***, NATCO

Pharma obtained a compulsory license based on Bayer's disclosure in the old Form 27. The main consideration was the quantity of the drug.¹²⁹³ Without accurate data on the amount manufactured and imported, it would have been impossible to determine whether the patent was being worked in India. The requirement to file Form 27 every three years means that there are longer gaps between updates on patent utilization. This delay makes it challenging for those seeking compulsory licenses to prove inadequate use of a patent. Insufficient data may hinder courts from assessing whether patents are being effectively utilized, potentially allowing patent holders to obtain interim injunctions without sufficient evidence. This allows them to block competitors for extended periods without contributing genuinely to the market, which contradicts the equitable principles of Indian patent law. Moreover, fewer Form 27 submissions make it harder to detect practices like evergreening¹²⁹⁴. For instance, in the ***Ticagrelor case***, the Delhi High Court reversed an injunction partly because Form 27s showed identical quantities of the drug sold under different patents, suggesting possible evergreening.¹²⁹⁵ The new regulation makes it more difficult to uncover such activities, potentially enabling patent holders to unfairly extend their monopolies. The relaxation of disclosure standards reduces transparency regarding the actual uses and accessibility of patented technologies. This makes it challenging for regulatory agencies and other interested parties to verify whether patents are truly being used for the public's benefit. In the absence of comprehensive data on public demand, cost, and licensing, patent holders may make compliance claims without evidence. This could lead to the misuse of patent rights, such as using patents to stifle

¹²⁹³ Id at 18

¹²⁹⁴ Sneha Jain & Dr. Vaibhav Tandon, Working requirement under Indian Patent law: A toothless tiger?, accessed on <
https://www.saikrishnaassociates.com/working-requirement-under-indian-patent-law-a-toothless-tiger/?utm_source=mondaq&utm_medium=syndication&utm_content=articleoriginal&utm_campaign=article >

¹²⁹⁵ Astrazeneca Ab & Ors vs P Kumar & Anr AIR 2020 (NOC) 656 (DEL.)

¹²⁹² Id at 9

competition without actively fostering innovation. These changes could disrupt the delicate balance that patent laws are designed to uphold: promoting innovation while ensuring that patented technologies benefit society. If oversight and accountability are diminished without substantially improving public welfare, patent holders may maintain monopolistic control over their technologies.

DO THESE CHANGES BENEFIT THE PATENTEE?

The changes to Form 27 provide patentees with several benefits, including a significant reduction in administrative burdens and much greater compliance flexibility. By removing specified quantum disclosures and transitioning to filing every three years, patent holders can now dedicate more time and resources to crucial tasks such as research and development, as well as market expansion. This ultimately shortens innovation cycles and enhances competitiveness. Additionally, the lowered disclosure requirements offer enhanced protection for market strategies and intellectual property, effectively shielding confidential company information from potential compromise. The simplified compliance procedures save time and money and allow patent holders to focus on meeting market demands and driving new innovations. Although these modifications may raise concerns about transparency and accountability, they are strategically aimed at empowering patent holders with greater operational flexibility and resource allocation. This will stimulate continuous innovation and foster robust economic growth in an ever-changing global landscape.

CONCLUSION

The updated Form 27 offers more flexibility in compliance and reduces administrative burdens for patent holders. However, it also raises questions about accountability and transparency. The changes aim to improve innovation cycles in patent utilization by reducing some disclosure requirements and

increasing filing intervals to three years. While this may benefit patent holders, it could also lead to less transparency in patent utilization evaluations, potentially impacting fair competition and public interest considerations under Indian patent law. Nevertheless, these changes are intended to provide strategic benefits and operational efficiencies for patent holders, fostering innovation and economic growth in response to evolving global challenges. It is crucial to strike a balance that ensures public welfare and incentivizes innovation as these regulatory changes take effect.

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