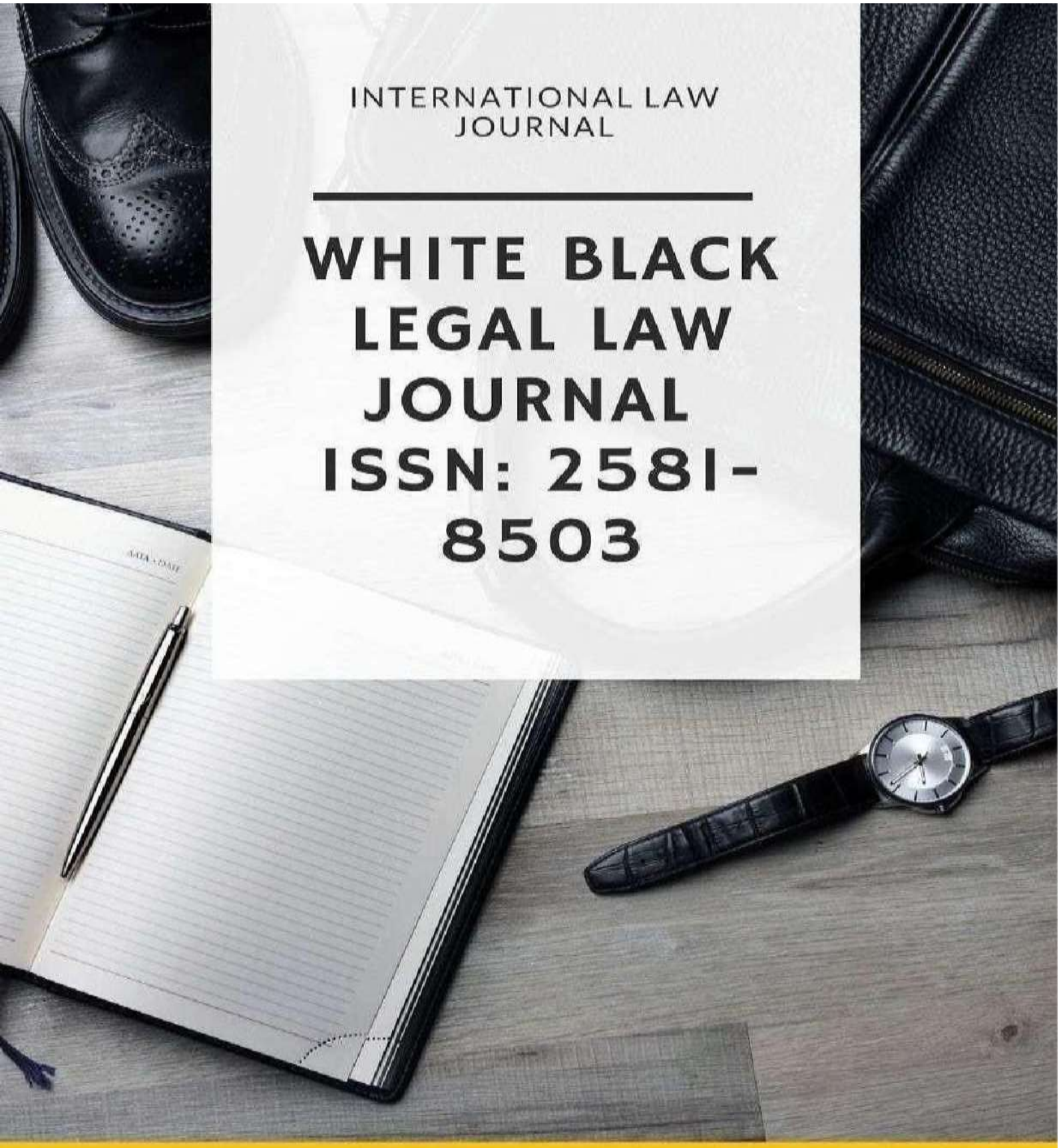

INTERNATIONAL LAW JOURNAL

WHITE BLACK LEGAL LAW JOURNAL

ISSN: 2581-8503

Peer - Reviewed & Refereed Journal

The Law Journal strives to provide a platform for discussion of International as well as National Developments in the Field of Law.

WWW.WHITEBLACKLEGAL.CO.IN

DISCLAIMER

No part of this publication may be reproduced, stored, transmitted, translated, or distributed in any form or by any means—whether electronic, mechanical, photocopying, recording, scanning, or otherwise—without the prior written permission of the Editor-in-Chief of *White Black Legal – The Law Journal*.

All copyrights in the articles published in this journal vest with *White Black Legal – The Law Journal*, unless otherwise expressly stated. Authors are solely responsible for the originality, authenticity, accuracy, and legality of the content submitted and published.

The views, opinions, interpretations, and conclusions expressed in the articles are exclusively those of the respective authors. They do not represent or reflect the views of the Editorial Board, Editors, Reviewers, Advisors, Publisher, or Management of *White Black Legal*.

While reasonable efforts are made to ensure academic quality and accuracy through editorial and peer-review processes, *White Black Legal* makes no representations or warranties, express or implied, regarding the completeness, accuracy, reliability, or suitability of the content published. The journal shall not be liable for any errors, omissions, inaccuracies, or consequences arising from the use, interpretation, or reliance upon the information contained in this publication.

The content published in this journal is intended solely for academic and informational purposes and shall not be construed as legal advice, professional advice, or legal opinion. *White Black Legal* expressly disclaims all liability for any loss, damage, claim, or legal consequence arising directly or indirectly from the use of any material published herein.

ABOUT WHITE BLACK LEGAL

White Black Legal – The Law Journal is an open-access, peer-reviewed, and refereed legal journal established to provide a scholarly platform for the examination and discussion of contemporary legal issues. The journal is dedicated to encouraging rigorous legal research, critical analysis, and informed academic discourse across diverse fields of law.

The journal invites contributions from law students, researchers, academicians, legal practitioners, and policy scholars. By facilitating engagement between emerging scholars and experienced legal professionals, *White Black Legal* seeks to bridge theoretical legal research with practical, institutional, and societal perspectives.

In a rapidly evolving social, economic, and technological environment, the journal endeavours to examine the changing role of law and its impact on governance, justice systems, and society. *White Black Legal* remains committed to academic integrity, ethical research practices, and the dissemination of accessible legal scholarship to a global readership.

AIM & SCOPE

The aim of *White Black Legal – The Law Journal* is to promote excellence in legal research and to provide a credible academic forum for the analysis, discussion, and advancement of contemporary legal issues. The journal encourages original, analytical, and well-researched contributions that add substantive value to legal scholarship.

The journal publishes scholarly works examining doctrinal, theoretical, empirical, and interdisciplinary perspectives of law. Submissions are welcomed from academicians, legal professionals, researchers, scholars, and students who demonstrate intellectual rigour, analytical clarity, and relevance to current legal and policy developments.

The scope of the journal includes, but is not limited to:

- Constitutional and Administrative Law
- Criminal Law and Criminal Justice
- Corporate, Commercial, and Business Laws
- Intellectual Property and Technology Law
- International Law and Human Rights
- Environmental and Sustainable Development Law
- Cyber Law, Artificial Intelligence, and Emerging Technologies
- Family Law, Labour Law, and Social Justice Studies

The journal accepts original research articles, case comments, legislative and policy analyses, book reviews, and interdisciplinary studies addressing legal issues at national and international levels. All submissions are subject to a rigorous double-blind peer-review process to ensure academic quality, originality, and relevance.

Through its publications, *White Black Legal – The Law Journal* seeks to foster critical legal thinking and contribute to the development of law as an instrument of justice, governance, and social progress, while expressly disclaiming responsibility for the application or misuse of published content.

CASE ANALYSIS: BAYER CORPORATION V. UNION OF INDIA & ORS.[1]. 22 APRIL, 2019, DHC

AUTHORED BY - AKRITI SHRIVASTAVA
ENROLLMENT NO: JML25007
LLM IPR (2025-26)

FACTS IN BRIEF:

Bayer Corporation, a multinational pharmaceutical company, owned a Patent for an anti-cancer drug, Sorafenib Tosylate, named Nexavar. Under Section 84 of the Patent Act[2], a compulsory license was granted to NATCO Pharma in 2012 for making, using, offering for sale, and selling the drug within India due to the necessity of public health arising from high prices and limited availability of Nexavar. During the pendency of the associated proceedings, NATCO manufactured and sought to export the finished product and the active pharmaceutical ingredient (API) to other countries, particularly for the process of regulatory approvals. Bayer filed a writ petition and subsequently a suit, claiming that such acts, specifically exports, were an infringement of its patent, since compulsory license conditions expressly restricted the production and sales to India.

Simultaneously, Bayer sued Alembic Pharmaceuticals, alleging that Alembic was exporting and submitting regulatory applications in other countries for 'Rivaroxaban', a drug under another Bayer patent. Bayer held it to be an infringement. Alembic responded that all its actions were covered under Section 107A[3], i.e., they were for regulatory submission and not for commercial exploitation. For example, Alembic claimed that it had not commercially launched 'Rivaroxaban' in India and that its exports were to the U.S./EU for regulatory purposes. The court obliged Alembic to provide 15 days' notice to Bayer before exporting.

Both disputes became unanimous on the legal issue: Does Section 107A of the Indian Patents Act[4] (referred to as the "Bolar exception") exempt the export of patented inventions for

[1] Bayer Corporation vs. Union of India & Ors., AIRONLINE 2019 DEL 1712.
[2] The Patents Act, 1970, § 84 (India).
[3] The Patents Act, 1970, § 107A (India).
[4] *Id.*

development and submission of information to foreign regulatory authorities from being classified as "infringement"?

A Division Bench of the Delhi High Court heard the case and treated the writ and the suit as one because they raised the same issue of interpretation. The appeals turn on whether "selling" under Section 107A[5] includes export of patented products for regulatory use abroad without infringing patent rights. They also examine whether Section 107A is a narrow exception to Section 48 or a broader, independent statutory exemption.

LEGAL ISSUES:

The determination of the following pivotal legal issues formed the crux of judicial consideration:

- Whether the term "selling" under Section 107A of the Patents Act, 1970, applies to exporting abroad or is limited to domestic transactions only, without infringement of the rights of the patentee under Section 48[6]?
- Does exporting patented inventions (APIs or formulations) to seek regulatory approval in foreign jurisdictions amount to infringement?
- Is Section 107A an independent substantive provision or a defence or proviso to Section 48?
- How shall the phrase, "solely for uses reasonably related to the development and submission of information required under any law in India, or a country other than India" be interpreted, i.e. does it include exportation of patented products for foreign regulatory requirements?
- Does the Section 107A exemption on the use of the exemption on export place a burden of proof on the patentee to demonstrate the commercial intent, or the exporter to prove regulatory use?
- Is there any quantitative or territorial limitation of Section 107A concerning the acts exempted from infringement?

[5] *Id.*
[6] The Patents Act, 1970, § 48 (India).

- Whether the interpretation of Section 107A is consistent with Article 30 of TRIPS[7] and WTO jurisprudence, specifically Canada-Pharmaceuticals Product dispute[8]? Whether foreign BOLAR provisions (e.g. in Canadian or the U.S.) inform the Indian position?

SUMMARY OF ARGUMENTS:

Appellant: Bayer Corporation

- Bayer contended that, in context and by legislative history, Section 107A is an exception to allow the timely access of generics in the Indian market after the expiry of the patent, not to facilitate exports. It is a narrow exception (proviso) to Section 48, and must be interpreted restrictively, in accordance with the legislative intent and international practice. Bayer cited *S. Sundaram Pillai v. V.R. Pattabiraman*[9] by arguing that a proviso ought to be interpreted literally. Section 107A outlines specific acts which are not considered as infringement and therefore should be interpreted narrowly in patentees' favour, rather than giving a broad licence to non-patentees. The addition of export to "selling" would be overextending the exception and jeopardising the patentee's rights.
- Bayer highlighted that other sections of the Act (Sections 84, 90(1)[10], and 92A[11]) specifically mention "export", as compared to Section 107A. The omission was deliberate, and thus, the legislature meant that exports were not covered by the Bolar exemption. It maintained that the word "selling" in Section 48 only refers to sale "in India" and so, Section 107A should not be extended to include export.
- Bayer contended that the Act is territorially limited. Export acts are extra-territorial and cannot be presumed included. Allowing export for regulatory purposes in other nations (where Bayer may not even have a patent) would lead to loss of global market and invalidation of exclusive rights of patentees.
- Bayer cited the Canadian and the US Bolar provisions, which prohibit export, in reference to the WTO Panels' ruling in the "Canada-Patent Protection of

[7] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 30, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organisation, Annexe 1C, 1869 U.N.T.S. 299.
[8] Report of WTO Dispute Settlement Panel, Canada-Patent Protection of Pharmaceutical Products, [4.6 n. 27, WT/DS114/R (March 17, 2000) [hereinafter Canada-Pharmaceuticals].
[9] S. Sundaram Pillai v. V.R. Pattabiraman, 1985 AIR 582.
[10] The Patents Act, 1970, § 90(1) (India).
[11] The Patents Act, 1970, § 92A (India).

Pharmaceutical Products[12]" dispute under TRIPS, and several foreign cases that exclude export from regulatory exceptions.

- Bayer also argued that even if Section 107A allowed exports, it was upon the non-patentee/exporter to prove that the act is exclusively for a regulatory purpose and not commercial exploitation. Courts must examine every claim for compliance with foreign regulatory requirements, as allowing unregulated exports would prejudice patentees unduly.
- Bayer claimed that large-scale export (e.g., 90 kg of rivaroxaban claimed by Alembic) in the name of regulatory use could easily turn into unauthorised commercial activity, and the current legal interpretation was not capable of offering protection.

Respondents: Natco, Alembic, Union of India

- NATCO and Alembic, supported by the Union of India, contended that on natural and literal interpretation of Section 107A, there is no restriction on acts of sale to Indian territory. The phrase "in India, or in a country other than India" allows the creation and presentation of information necessitated by foreign law, thus legalising export for that purpose. They reasoned that restricting Section 107A to domestic regulatory submission would betray the legislature's intention and hamper the global role of the generic industry.
- They emphasised the importance of letting Indian generics engage in the global regulatory approval process, which mostly requires real product samples and data specific to local jurisdictions. Several nations, including China, demand local research that involves the use of real samples and are not satisfied with data generated solely in India.
- The respondents claimed that Section 107A makes Indian law entirely consistent with TRIPS Article 30, and international trends support a broad Bolar exemption to facilitate public health needs, particularly in developing nations reliant on Indian generics.
- They also argued that "sale" is any act of transfer of title, regardless of the place of transacting, and therefore includes exports. Export is essential for practical supply chains for drug development, especially for submission to foreign authorities.

[12] Report of WTO Dispute Settlement Panel, Canada-Patent Protection of Pharmaceutical Products, [4.6 n. 27, WT/DS114/R (March 17, 2000) [hereinafter Canada-Pharmaceuticals].

- Section 107A, in text, does not put any restriction on quantum of product or where it is ultimately used, provided that the only purpose is regulatory. It would be judicial lawmaking and go against the intention of legislature to introduce additional restrictions. Crucially, Natco insisted that the amount at issue (1kg API, which should be used to manufacture approximately 1,000 to 2,000 tablets) was only to conduct bio-equivalence studies, and not for commercial sale.
- The respondents also claimed that if a patent holder could establish that the export was not purely for regulatory purposes, it could proceed with infringement. They have rejected the uncontrolled exports fears because Section 107A is self-governing and does not override infringement except for its specific, narrow purpose.

DECISION:

The Division Bench of the Delhi High Court dismissed Bayer's appeal, rejecting all major contentions raised by the patentee. The Court held that:

- The term "selling" in Section 107A is not territorially restricted to India. It is naturally inclusive of export, which is one of the forms of sale, provided the sole purpose is to obtain regulatory approval from authorities outside India.
- Section 107A is not a defensive exception to Section 48 but an independent substantive provision. Section 107A applies to the rights of the patentee under Section 48, and not the other way round.
- The court refused to read into Section 107A a specific exception of export merely because the word "export" is not used. The words "in a country other than India" were sufficient to indicate that export was intended to be included.
- Export of patented inventions, including APIs and formulations, by a non-patentee solely for uses reasonably related to development and submission of information required under any law (Indian or foreign) for regulatory approval, does not constitute patent infringement under Indian law.
- The Court held that quantity is not a determining factor of infringement, as even large quantities can be accepted in good faith if used for regulatory purposes, which the WTO panel had found in the Canada dispute.
- The purpose, as opposed to the amount of the product being exported, is important. It has no definite quantitative limit, as each case must be investigated to decide if the utilisation is bona fide regulatory.

- The onus of proving infringement lies with the patentee, and mere export is not sufficient, as there should be evidence that the export is for commercial exploitation.
- The ruling harmonised Indian law with international jurisprudence and acknowledged the need for Indian generics to support affordable medicine globally, consistent with India's TRIPS obligations.

In the specific appeals:

- Bayer's challenge to the Natco exports was dismissed (i.e., the writ petition was dismissed in part).
- In the Alembic suit, the Court decided that export of rivaroxaban by Alembic for regulatory purposes fell under Section 107A; therefore, injunction premised on export would not stand on its own.

The Division Bench upheld the favourable interpretation of Section 107A by the Single Judge but imposed further procedure. In LPA359/2017 (Natco case), the Court dismissed Bayer's letter-patent appeal, and in RFA (OS)(Comm)6/2017 (Alembic case), the Court allowed Bayer's appeal with directions.

Particularly, it affirmed that Natco had the right to export Sorafenib under section 107A, with protection. Conversely, the High Court in the Bayer-Alembic case remanded the case for trial "in accordance with law, keeping in mind the discussion in this judgment". Both cases were therefore to be decided on the premise that exports for legitimate regulatory purposes fall under Section 107A.

Notably, the Court directed Alembic and Natco to submit affidavits, undertaking not to export beyond activities authorised by Section 107A, and directed that Alembic provide Bayer with 15 days' prior notice of any subsequent export.

REASONING:

Statutory Text and Interpretation-

The Court divided the text of Section 107A, observing that the provision inherently authorised transfer of patented goods to foreign countries. The provision did not distinguish between developing information for Indian vs foreign regulators; the only qualification was the purpose, i.e., regulatory compliance, not commercial gain.

Legislative Intent-

The Court considered the statute's history, Joint Parliamentary Committee reports, and the 2005 amendment and pointed out that Parliament deliberately chose to add the words "in a country other than India" to Section 107A to cover foreign regulatory processes as well. It also fits with how India sees itself, as a major supplier of generic medicines, and with the practical reality that Indian companies must take part in approval procedures abroad. The Court tied this development to India's broader policy of making full use of TRIPS flexibilities to support access to medicines, both domestically and in other developing countries.

The Court considered that the WTO panel decision in the Canada dispute held that exporting to serve regulatory purposes (but not as commercial exploitation) is not forbidden by TRIPS.

International Law and TRIPS-

Based on the ruling of the WTO Dispute Settlement Panel that validated the constitutionality of the Bolar provision of Canada (which also incorporated foreign regulatory exceptions) and the international character of the pharmaceutical industry, the Court reasoned that the denial of export for regulatory use would be inconsistent with global patent policy and would unduly extend a patentee's market exclusivity beyond what the law intended.

Territoriality, Sale, and Export-

The Court dismissed Bayer's claim that "selling" is territorially limited. Rather, it took on the broader legal interpretation that "sale" may, based on the form of transaction, constitute export, and the statute should be accordingly interpreted, with reference to Black's Law Dictionary and well-established commercial law.

Burden of Proof and Safeguards-

While acknowledging potential for misuse, the Bench noted that statutory exceptions are to be construed in the context of legislative protection and any abuses (e.g. when a product exported under Section 107A is diverted to commercial markets) can be subject to challenge by ordinary infringement proceedings, in India and abroad. In case of non-regulatory use, the patentee can sue with evidence. The Court enumerated requisite factual details in the evaluation of such cases, including patents granted, products sought to be exported, quantities, end use, and applicable regulations.

Harmonious Construction & Legal Principles-

- To restrict "selling" to domestic sales would involve unlawful judicial addition of words, contrary to the rule of literal interpretation. Parliament's silence on "export" in section 107A was construed as intentional, and where intentional omission was made, it appeared in other sections.
- The exception in 107A is subject to its internal test, i.e. acts need to be "solely for uses reasonably related" to regulatory approval. Patentee rights remain intact in activities beyond this scope or outside India.

Quantitative Consideration & Burden of Proof-

- The Court rejected the notion that a generic might get disqualified by its export volume alone. The test is purpose, not quantity, consistent with WTO findings in the Canada case.
- The non-patentee must, therefore, prove that its activity is within section 107A. Nevertheless, this does not in any way invalidate the patentee's rights, which survive in cases of commercial exploitation or misuse.

Override of Patentee Rights-

Section 107A does not eliminate patent rights but protects acts done for regulatory compliance. Any commercial use and other non-compliant export is beyond the exemption. In such cases, the patentee retains full enforcement rights under the Act.

ANALYSIS:

The Court accepted a liberal but limited interpretation of section 107A: liberal to cover exports for regulatory purposes, but limited by the clause "solely for regulatory use" and the protection for patent holders.

Significance for Patent Law, Pharmaceuticals, and Public Policy

This decision is ground-breaking in Indian patent jurisprudence for several reasons:

- Clarification of Bolar Exception: The case has conclusively clarified that Section 107A does not amount to a defence but rather an affirmative statutory right, broad enough to include exports to serve regulatory purposes. This enables generic drugs to enter India and global markets early, and the Indian law to meet the realities of international drug development. This makes Indian law consistent with the *Canada-Pharmaceutical*

Products[13] (WTO) and U.S. practice. It confirms that Section 107A is a TRIPS-compliant, narrow exception that is designed to expedite the introduction of generic products without extending patent rights.

- Balancing Patent Rights and Public Interest: The decision creates a delicate balance between the monopoly rights of patent holders and the ability of generic companies to prepare to enter the market after the patent expires. The fact that regulatory uses, even those that involve export, are not infringing, reflects an international understanding of intellectual property as an "engine of progress", not the goal. It allows generic players to enter instantly when the patent expires, not just in India but worldwide, to serve consumers in the developing world. The Court observed, for example, that Indian manufacturers supply over 90% of antiretrovirals to Africa; any artificial interference with exportation would extend life-saving drugs globally.
- Alignment with TRIPS and Global Practice: By harmonising domestic law with the TRIPS Agreement and interpreting Section 107A in light of its international analogues, the Court placed Indian jurisprudence firmly within the mainstream of global public health-friendly patent policies.
- Scope and Limits of Judicial Intervention: The Court has not established any procedural limits (i.e. mandatory disclosure, Customs labelling, or quantitative caps), highlighting judicial restraint, where judgment in policy-intensive areas is left to legislature and executive. This avoids judicial overreach and preserves legal remedies for abuse.

India's Approach to IP and Public Health:

- On Pharmaceutical Licensing: The decision favours compulsory and regulatory licensing regimes and allows the Indian generics to play in the international pharmaceutical markets responsibly.
- On Future Infringement Suits: Patent holders must now meet a higher threshold to block exports claimed to be for regulatory use. The patentee has to prove bad faith/commercial motive.
- On Access to Affordable Medicine: The ruling highlights India as a global supplier of affordable medicine, particularly to the developing nations that depend on Indian generics for vital medicines.

[13] *Supra* note 12.

- On Definition and Scope of "Sale": The judgment clarified that export is included in "sale" for regulatory purposes; the courts will examine the purposes of any export, but not in terms of the quantity or territorial grounds.
- Potential Risks: The Bench acknowledged the danger of regulatory exceptions being used as a cover for unauthorised commercial activity, but held that the legal framework remained sufficient, provided courts are vigilant and parties submit detailed documentation.

From patentee's perspective, the decision restricts the practical protection of patents. The concern of Bayer was that foreign sales of any kind would be considered infringement; however, the Court removed the bar with the only condition that the export is 'solely of' regulatory data. That is, any export that is not strictly intended to be used in trials (e.g. commercial shipment) would be infringement, but not bona fide research exports. This puts the burden on the generic to keep minimal exports and comply with regulatory measures.

The Court itself introduced a check by stating that exports must be "in accordance with law" and by imposing undertakings (and trial supervision for Alembic). Therefore, Bayer still has remedies: if a generic surpasses research requirements, or in case a foreign patent holder (including Bayer) wants to prevent unauthorised sales of its products abroad, infringement suits in relevant jurisdictions remain available.

By rejecting the LPA and remanding Bayer's suit, the Bench highlighted that patent enforcement is a matter of private law. This supports that injunction against exports ought to be sought in infringement proceedings, possibly in multiple jurisdictions as necessary, and not through constitutional writs over customs proceedings.

DOCTRINE EMERGED (2-step Regulatory Use Doctrine):

1. Purpose-Based Regulatory Use: To test whether the acts of making/using/selling/importing (including export) solely for uses reasonably related to development and submission of information to Indian or foreign regulatory authorities?
2. Bona fide Regulatory Use: To check whether the surrounding facts (including volume, destination, regulatory pathway and documentation) support the inference that there is no commercial use?

CONCLUSION:

The Delhi High Court in "Bayer Corporation vs. Union of India and Ors", provided a forward-looking, public health-oriented, and globally harmonised interpretation of Section 107A of the Patents Act, consistent with TRIPS Art. 30. The ruling upholds the Bolar exception, extending to exports, ensuring procedural safeguards while supporting the vital global function of Indian generics. It addresses the intricacies of modern pharmaceutical regulation, explains the statute for future cases, and places the burden of proving abuse on the patentee.

The decision is doctrinally sound and practical, demonstrating the delicate balance required between the protection of intellectual property and public health requirements in India's legal context. It will inevitably influence the process of patent enforcement, innovative pharmaceutical development, and international licensing not only in India but across similar jurisdictions.