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PHARMACEUTICAL IP
PATENTS & DATA EXCLUSIVITY

Section 3(d), Compulsory Licensing, Evergreening Doctrine, and TRIPS Flexibilities for the Indian Pharma Sector

Pharmaceutical Intellectual Property

Section 3(d), Compulsory Licensing, Evergreening Doctrine, and TRIPS Flexibilities for the Indian Pharma Sector

A Practitioner's Handbook for the Pharmaceutical Industry

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FOREWORD

India's pharmaceutical patent regime sits at the intersection of innovation incentives and public health access. The Patents Act, 1970, as amended in 2005 to comply with the TRIPS Agreement, introduced product patents for pharmaceuticals — ending the era of process-only patents that fuelled India's generic industry. But the 2005 amendment also embedded a unique safeguard: Section 3(d), which bars patents on new forms, derivatives, salts, polymorphs, and combinations of known substances unless they demonstrate "significantly enhanced efficacy." This provision — upheld by the Supreme Court in the landmark Novartis AG v. Union of India (2013) — is India's primary defence against pharmaceutical "evergreening."

This volume provides a practitioner's guide to Section 3(d), compulsory licensing under Section 84, the data exclusivity debate, and the intersection of patent strategy with drug regulatory approvals.

PART I — THE SECTION 3(d) FRAMEWORK

Chapter 1: The Anti-Evergreening Provision

1.1 Statutory Text

Section 3(d) of the Patents Act, 1970 provides that the following are not inventions within the meaning of the Act:

Explanation: "salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."

1.2 Novartis v. Union of India, (2013) 6 SCC 1

The Supreme Court upheld the rejection of Novartis's patent application for the beta-crystalline form of imatinib mesylate (Glivec), holding that "efficacy" under Section 3(d) means therapeutic efficacy — not mere bioavailability or physical

properties. The Court established that an applicant claiming a new form of a known substance must demonstrate a significant enhancement in the drug's ability to produce the intended therapeutic effect.

1.3 Post-Novartis Jurisprudence

PART II — COMPULSORY LICENSING

Chapter 2: Section 84 — Compulsory Licence on Application

2.1 Grounds for Compulsory Licence

Under Section 84(1), any person interested can apply for a compulsory licence on the following grounds, three years after the grant of a patent:

(a) The reasonable requirements of the public with respect to the patented invention have not been satisfied

(b) The patented invention is not available to the public at a reasonably affordable price

(c) The patented invention is not worked in the territory of India

2.2 The Nexavar Compulsory Licence — India's Only CL

In March 2012, the Controller of Patents granted India's first (and only) compulsory licence to Natco Pharma for Bayer's sorafenib tosylate (Nexavar, kidney/liver cancer). The Controller found all three Section 84(1) grounds satisfied: Nexavar was priced at approximately ■2.8 lakh per month; Natco offered it at ■8,880 per month; and Bayer was importing the drug rather than manufacturing it in India.

The IPAB upheld the CL in 2013, rejecting Bayer's appeal. The Bombay High Court dismissed Bayer's writ petition in 2014. The Supreme Court declined special leave. The CL remained in force until the patent expired in 2020.

Chapter 3: Section 92 — Compulsory Licence in Public Health Emergencies

Section 92 permits the Central Government to issue a compulsory licence at any time after the grant of a patent if a national emergency or extreme urgency arises, or for public non-commercial use. Unlike Section 84, there is no three-year waiting period. This provision was considered — but not invoked — during the COVID-19 pandemic for remdesivir and other critical drugs.

PART III — DATA EXCLUSIVITY

Chapter 4: The Unresolved Question

India does not currently provide statutory data exclusivity for pharmaceutical test data. Article 39.3 of the TRIPS Agreement requires protection against "unfair commercial use" of undisclosed test data submitted to regulatory authorities, but does not mandate a specific period of data exclusivity.

The Satwant Reddy Committee Report (2007) recommended a limited data protection regime — but no legislation has been enacted. India's position is that TRIPS Article 39.3 requires protection against dishonest commercial use (i.e., regulatory authorities must not directly disclose the data to competitors), but does not require preventing regulatory authorities from relying on the data for subsequent generic approvals.

Practical implication: Indian generic manufacturers can obtain regulatory approval by referencing the innovator's data (through the abbreviated new drug application pathway) without a data exclusivity waiting period — a significant advantage for the generic industry.

PART IV — PATENT STRATEGY FOR INDIAN PHARMA

Chapter 5: Pre-Grant Opposition (Section 25(1))

India's pre-grant opposition mechanism allows any person to file a representation opposing a patent application before it is granted. Grounds include: the invention is obvious; it is not patentable under Section 3 (including Section 3(d)); prior art anticipation; and insufficient disclosure.

The Patents (Amendment) Rules, 2024 tightened the pre-grant opposition timeline, requiring the opponent to submit all evidence and arguments within a compressed schedule. This has increased the importance of early patent-landscape monitoring.

Chapter 6: Post-Grant Opposition (Section 25(2))

Any person interested can file a post-grant opposition within one year of the patent publication date. The grounds are identical to pre-grant opposition, but the procedure involves a constitution of an Opposition Board by the Controller.

Chapter 7: Patent Linkage and Regulatory Approvals

India does not formally recognise patent linkage — that is, CDSCO does not check patent status before granting marketing approval for generic drugs. The Supreme Court in Bayer v. UoI (2014) held that the Drug Controller cannot refuse approval on patent grounds. However, innovator companies frequently seek interim injunctions against generic launches, creating a de facto linkage through the courts.

APPENDIX A — KEY IP TIMELINE FOR PHARMA COMPANIES

REFERENCES

Patents Act, 1970 (as amended 2005, 2023, 2024)

Patents (Amendment) Rules, 2024

Novartis AG v. Union of India, (2013) 6 SCC 1

Natco Pharma Ltd. v. Bayer Corporation, CL Application No. 1/2011 (Controller of Patents, Mumbai)

Natco Pharma v. Novartis AG, 2024:DHC:3198-DB (Delhi HC)

Chugai Seiyaku Kabushiki Kaisha v. Controller of Patents (Delhi HC, 2022)

TRIPS Agreement, Articles 27, 28, 31, 39.3

Satwant Reddy Committee Report on Data Exclusivity (2007)

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