IN-DEPTH

Pharmaceutical Intellectual Property And Competition

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Pharmaceutical Intellectual Property and Competition

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In-Depth: Pharmaceutical Intellectual Property and Competition (formerly The Pharmaceutical Intellectual Property and Competition Law Review) provides a practical overview of pharmaceutical intellectual property issues, including patent linkage and exclusivities, and related competition concerns. With a focus on recent developments, it is a useful tool for managing global risks in this area – analysing the key elements of the relevant legal and regulatory regimes across major jurisdictions worldwide.

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India

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Summary

Introduction

This chapter provides an overview of India's legislative and regulatory framework for drug and biologic approvals, drug pricing mechanisms, and patent regulations as well as the processes addressing intellectual property disputes associated with generic and biosimilar products. We also outline the interplay between intellectual property and antitrust law in India and discuss how strategies involving pharmaceutical intellectual property may come under scrutiny from a competition angle. Overall, the Indian policy and systems are designed to strike a balance between the competing interests of fostering pharmaceutical innovations, ensuring public health, and promoting generic industries.

Year in review

This review offers an update on the landscape of pharmaceutical intellectual property and antitrust issues while focusing on India's significant policy, regulatory, and judicial developments in the sector during the past year. A pivotal moment occurred in July 2023 when the Delhi High Court delivered a landmark judgment on the conflicting zone between patent and competition laws. In reconciling the two statutes, it held that the Competition Act deals with the anticompetitive agreements and abuse of dominant position generally and there is clear legislative intent that the Patents Act being special law would override the Competition Act as regards anticompetitive behaviour by a patentee. In particular, any anticompetitive practice of a pharmaceutical patent holder would be addressed exclusively by the statutory patent authority and IP courts. The ruling marks a tectonic shift in Indian jurisprudence prompting pharmaceutical innovators to recalibrate their IP strategy.

The recently constituted specialised IP courts continued to provide efficacious and expeditious resolution of patent litigations and appeals. The current review of decisions reflects the balanced approach adopted by Indian courts in the adjudication of pharmaceutical patent cases. On one hand, enforcement of patent rights remained intact, with owners of valid patents receiving interim injunctive and other forms of relief in the event of infringements. On the other hand, courts continued to be watchful to check any attempt at anticompetitive practices using evergreening, line extensions, or serial patenting strategies. In appropriate cases, courts have allowed the patent applicant to submit post-filing evidence to establish the patentability requirements. Biologics innovators obtained favourable orders against biosimilar manufacturers in cases of alleged non-compliance with drug regulations and guidelines. The defence of public health factors (affordability and accessibility to drugs) may be considered in infringement proceedings, nonetheless, it is not a complete exception to a legally valid patent, and interim relief may be granted.

Patents Amendment Rules, 2024 have been notified introducing several provisions aimed at simplifying the process of obtaining and managing patents. The procedure of pre-grant oppositions has been streamlined to curb fraudulent oppositions and simultaneously encourage genuine oppositions. The frequency of filing the statements of working of

patents has been reduced. On the policy front, the new National Pharmaceuticals Policy, 2023 has been drafted to simplify drug and licensing regulations.

Legislative and regulatory framework

Drug regulations

The Central Drugs Standard Control Organization (CDSCO) under the Directorate General of Health Services, Ministry of Health & Family Welfare (MoHFW), is designated as the National Regulatory Authority (NRA). The primary legislation and regulations for the Indian pharmaceutical sector comprise the Drugs and Cosmetics Act, 1940 (DCA) and the rules framed thereunder, viz., Drugs and Cosmetics Rules, 1945 (DCR) and the New Drugs & Clinical Trial Rules, 2019 (NDCT Rules).

The DCA, DCR, and NDCT Rules regulate new drug approval, import, manufacture, distribution and sale of drugs. Under DCA, CDSCO is responsible for the approval of drugs, conduct of clinical trials, laying down the standards for drugs, control over the quality of imported drugs in the country, and coordination of the activities of State Drug Control Organizations for uniform enforcement of DCA. While the central government issues marketing approval for new drugs, state governments grant licences to manufacture new drugs for sale or distribution. The NDCT Rules replaced the previous regime concerning clinical trials under Part XA and Schedule Y of the DCR. Since 2019, NDCT Rules have regulated all new drugs, investigational new drugs for human use, clinical trials, bioavailability, and bioequivalence (BA/ BE) studies.[1]

Further, DCR requires a drug manufacturer to furnish an undertaking that its proposed brand or trade name shall not lead to any confusion or deception in the market and that such or similar brand or trade name is not already in existence with respect to any drug in India based on search in the relevant databases.[2] Moreover, the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 prohibits misleading advertisements of drugs and remedies alleged to possess magic qualities in certain cases.

Drug pricing

By exercising powers conferred by the Essential Commodities Act, 1955, the Indian government has notified the Drugs (Price Control) Order, 2013 (DPCO) to control or regulate the pricing of certain drugs and ensure equitable availability of life-saving drugs at a reasonable price. The National Pharmaceutical Pricing Authority (NPPA) is entrusted to implement and enforce the DPCO. Drug price regulation is based on the 'essentiality of drugs' as laid down in the National List of Essential Medicines (NLEM), a dynamic list declared by the MoHFW under the DPCO.

In 2013 DPCO employed a price control mechanism for scheduled drug formulations (all essential medicines included in the NLEM), whether branded or generic, and a price monitoring mechanism for non-scheduled formulations (all non-essential medicines).[3] A division bench of the Delhi High Court clarified that the government or NPPA has the power to fix and revise prices of scheduled formulations only and it can merely monitor

the change in MRP of non-scheduled formulations.[4] Thus, non-scheduled formulations are not under a price control regime. A manufacturer of a non-scheduled formulation may increase its maximum retail price by 10 per cent per year and not beyond this limit.[5] Moreover, in the public interest and extraordinary circumstances, the government may fix the price of any drug, even non-scheduled ones.[6]

Patent regulations

The grant and validity of patents and rights thereunder are governed by the Indian Patents Act, 1970 (IPA) and the Patents Rules, 2003. At the Indian Patent Office (IPO), the Controllers of Patents are trusted to decide on patent applications under IPA. The orders of the Controllers can be appealed to a High Court. India has a first-to-file system for granting patents. The term of every patent granted is 20 years. India does not allow the extension of patent terms.

Section 2 of IPA requires an invention to satisfy the fundamental patentability criteria of novelty, inventive step, and industrial applicability. Besides, pharmaceutical innovations must not be a subject matter as proscribed from patentability under Section 3 of IPA. The main provisions are:

1. Inventive step: the invention must involve a technical advance compared to the existing knowledge and not be obvious to a person skilled in the art.
2. Follow-on innovations: Section 3(d) of IPA bars the patentability of the mere discovery of a new form of a known pharmaceutical substance unless it significantly enhances the therapeutic efficacy of that substance. It also prohibits patenting the mere discovery of any new property or new use for a known pharmaceutical substance.
3. Synergism: as per Section 3(e) of IPA, a patent would not be granted to a combination of known pharmaceutical substances unless it exhibits a synergistic effect.

A patent enforcement action or infringement suit under Section 104 of IPA, can be initiated before a district court or higher. However, if a defendant in an infringement action counterclaims the patent's invalidity, the suit and the counterclaim are automatically transferred to the High Court for further adjudication. Moreover, Section 105 of IPA enables an applicant to seek a declaration of non-infringement.

Under Section 13(4) of IPA, the grant of a patent does not guarantee its validity. The IPA expressly enables a challenge to the validity of a patent at various stages:

1. Pre-grant opposition under Section 25(1) before the IPO;
2. Post-grant opposition under Section 25(2) before the IPO;
3. Revocation petition under Section 64(1) before the High Court; and
4. A counterclaim seeking revocation in a suit for infringement under Section 64(1) before the High Court.

Antitrust laws

In India, participants in the pharmaceutical sector are also subject to the competition law. The framework and key provisions of the Indian antitrust law are discussed in 'Competition enforcers'.

New drugs and biologics – approval, incentives and rights

New drugs

The drug manufacturer or importer must obtain marketing authorisations for new drugs from the Central Licensing Authority (CLA). The Drug Controller General of India (DCGI), the head of the CDSCO, is CLA. On the successful completion of a clinical trial in India, CLA grants marketing approval for new drugs. No new drug shall be manufactured for sale unless it is approved by CLA. A manufacturing licence for new drugs is granted by the State Licensing Authority (SLA). Based on the clinical trial, safety and efficacy data of the new drug must be submitted for the manufacturing licences to be granted.

As per Rule 2(w) of New Drugs & Clinical Trial Rules, 2019, a 'new drug' means:

1. a drug, including active pharmaceutical ingredient or phytopharmaceutical drug, which has not been used in the country to any significant extent, and has not been approved as safe and efficacious by the CLA with respect to its claims;
2. a drug approved by the CLA for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form (known as the 'subsequent new drug');
3. a fixed-dose combination (FDC) of two or more drugs, approved separately for certain claims and proposed to be combined for the first time in a fixed ratio, or where the ratio of ingredients in an approved combination is proposed to be changed with certain claims including indication, route of administration, dosage and dosage form;
4. a modified or sustained release form of a drug or novel drug delivery system (NDDS) of any drug approved by the CLA; or
5. a vaccine, recombinant Deoxyribonucleic Acid (r-DNA) derived product, living modified organism, monoclonal anti-body, stem cell-derived product, gene therapeutic product or xenografts, intended to be used as a drug.

The drugs covered under (a), (b), and (c) shall be considered new drugs for four years from the date of their marketing approval by the CLA and the drugs referred to in (d) and (e) shall always be deemed new drugs.

Data exclusivity

India does not interpret Article 39.3 of the TRIPS as an obligatory provision offering explicit regulatory (data and market) exclusivity. Utilising policy space, India has no data exclusivity akin to those that prevailed in the United States and Europe. However, limited data exclusivity is ostensibly available in India. An approved new drug [(a), (b), and (c) above] of an innovator or originator ceases to be a new drug beyond four years from the date of its marketing approval by the CLA. Within this four-year window, any subsequent applicant (including a generic competitor) seeking fresh marketing approval for the same drug cannot rely upon the originator's clinical data and must submit independent clinical evidence to obtain the marketing approval. Even if a drug is not patentable, such form of data exclusivity is available as long as it continues to be a 'new drug' under drug regulations.

Patented new drugs

All manufacturers producing a 'new drug' patented under the IPA are exempted from price control for five years from the date of commencement of their commercial marketing in India.[7] Earlier, such an exemption was available to patented new drugs not produced elsewhere and developed through indigenous research and development. However, DPCO was amended in 2019 to remove the 'local' condition.[8] Thus, the existing exemption regarding new drugs covered by product patents would attract pharmaceutical multinational companies to launch their new drugs in India. However, if a new drug is covered by a process patent, the 'local' condition still applies to claim price control exemption.[9]

Orphan drugs

An 'orphan drug' means a drug intended to treat a condition that affects not more than five lakh persons in India.[10] The manufacturer or sponsor may apply to the CDSCO for the expedited review process if the new drug is an orphan drug.[11] CDSCO may also relax local Phase IV clinical trial requirements for an orphan drug.[12] Moreover, orphan drugs as decided by MoHFW are exempted from price control.[13]

Post-filing data for patent applications

Indian courts acknowledge the inherent complexities and protracted nature of the drug development process, and it may not be possible to provide all data (such as clinical trial data or empirical evidence of a drug's efficacy) at the time of filing the patent application.-[14] No specific time bar has been provided in the IPA that prevents an applicant from submitting post-filing data. However, post-filing data can only be taken into account to confirm the existence of the inventive step, or significant enhancement in therapeutic efficacy, which is found embedded in the specification and not to rely upon the same to establish such step or enhancement for the first time.[15]

Generic drugs

Generic drugs are not defined in the DCA and rules made thereunder. However, generic drugs are generally those that contain the same amount of the same active ingredient or ingredients in the same dosage form and are intended to be administered by the same route of administration as that of branded medicine.[16] Further, drugs manufactured in

India, whether generic or branded, are required to comply with the same standards as prescribed in the DCA, DCR, and NDCT Rules for their quality.[17]

However, a generic drug may undergo an abbreviated regulatory review upon referencing an already-approved drug. After the lapse of the four-year window from the date of marketing approval of an innovator's new drug, a generic drug manufacturer or importer is not required to conduct clinical trials and it can rely on clinical data generated by the innovator to obtain marketing approvals for its drug. Before April 2017, generic drug manufacturers were not obligated to prove their bioequivalence to their branded/innovator congeners. To ensure the efficacy of generic drugs, the DCR has been amended providing that the applicant including the generic manufacturer is required to submit the result of the bioequivalence to obtain a manufacturing licence from SLA for certain drugs (falling under Category II and Category IV of the Biopharmaceutical Classification System), even though they are not new drugs.[18] DCR has been further amended, making it mandatory for all drugs, that the applicant must submit evidence of stability, safety of excipients, etc. to SLA before granting a product manufacturing licence.[19]

Bolar exemption

Section 107A of the IPA carves out an exception for the use of the patented product or process during its term for research or regulatory approvals both in India and abroad. The Bolar exception facilitates timely entry of generic drugs by exempting certain activities such as research and development and obtaining regulatory approvals from patent infringement actions. The manufacturers of generic drugs would be able to commence their activities immediately upon the expiry of the patent in the public health interest.

Biologics and Similar Biologics

A biologic is derived from living organisms or their cells. Unlike traditional pharmaceutical drugs that are typically synthesised through chemical processes to create small-molecule drugs, biologics are produced using intricate biotechnological methods involving recombinant DNA technology, controlled gene expression, and antibody production. A similar biologic (biosimilar) product is defined as being 'similar' in terms of quality, safety, and efficacy to an approved reference or innovator biologic based on comparability.[20-] Under regulations, biologics including biosimilars continue to be a 'new drug' forever.[21] Therefore, the manufacturers of biosimilars must conduct clinical trials in India to obtain marketing approval.

The 'Guidelines on Similar Biologics' (2016) lay down the regulatory pathway for a similar biologic claiming to be similar to an already authorised reference biologic. The demonstration of bio-similarity depends upon detailed and comprehensive product characterisation, and preclinical and clinical studies carried out in comparison with an approved reference/ innovator biologic. The Biosimilar Guidelines thus underscore the balance between developing similar biologics within the framework of existing (reference) biologics and adhering to the stringent standards for maintaining the integrity and efficacy of these biosimilars. The authorities involved in the approval process of biosimilars include the Institutional Bio-Safety Committee (IBSC), the Review Committee on Genetic Manipulation (RCGM), the Genetic Engineering Appraisal Committee (GEAC), and CDSCO. A biosimilar can also go through an abbreviated review process and the extent of clinical trials required is to be considered by the concerned authorities.[22]

Since DCGI or CDSCO does not determine the rights of manufacturers of innovator drugs at the time of granting approvals to other new drug manufacturers, manufacturers of innovator drugs may file a civil suit challenging approvals to protect their rights in relation to their drugs.[23] For instance, in Roche v. DCGI & Ors., the court recorded the prima facie finding that the process of obtaining approval was flawed due to non-adherence to the statutory provisions of DCA, DCR, and the Biosimilar Guidelines.[24]

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Patent linkage

Patent linkage refers to linking the patent status of innovator drugs with the grant of marketing/ manufacturing approval for generic drugs. Patent linkage is not available in India as such linkage would delay the entry of generic medicines. In Bayer Corporation v. Union of India, the Delhi High Court clarified and confirmed the absence of patent linkage under the Indian legal system.[25] The drug regulator (DCGI) need not ensure the protection of a patent by refusing marketing approval to a generic manufacturer only because the drug in question is patented.[26] However, the patent holder is entitled to seek appropriate remedies under IPA to enforce and protect its patent from infringement.

Competition enforcers

Competition law in India aims to foster competition and protect Indian markets against anticompetitive practices by enterprises. The Competition Act, 2002 prohibits:

- anti-competitive horizontal agreements and anti-competitive vertical agreements – that cause an appreciable adverse effect on competition (AAEC) in India (Section 3);
- abuse of dominant position by enterprises ((Section 4); and
- regulates combinations (mergers, amalgamations, and acquisitions) to ensure that there is no AAEC in India. (Sections 5 and 6).

The Competition Commission of India (CCI), a statutory authority under the Competition Act, is the competition regulator in India. The CCI enforces antitrust rules in the pharmaceutical and healthcare sectors to ensure that effective competition is not undermined in these markets. The CCI looks into cases and investigates anticompetitive practices or attempts by the innovator pharmaceutical company to delay the generic drug's market entry or to foreclose the market. While determining whether an agreement has an AAEC under Section 3, CCI considers the following factors:

1. creation of barriers to new entrants in the market;
2. driving existing competitors out of the market;
3. foreclosure of competition by hindering entry into the market;
4. accrual of benefits to consumers;
5. improvements in the production or distribution of goods or services; and
6. promotion of technical, scientific, and economic development.

Section 26 of the Competition Act empowers the CCI to ascertain if there is a prima facie case of anticompetitive practice. If a prima facie case is found, CCI directs the Director General to investigate the matter. The orders of the CCI can be appealed to the National Company Law Appellate Tribunal (NCLAT).

So far, the CCI has received more than 55 cases from the pharmaceutical sector, pertaining mostly to the pharmaceutical distribution segment.

Anticompetitive behaviour

Patents and competition law

The allegations of anticompetitive practice by the patent holder are assessed under the provisions of the Indian Patents Act. IPA empowers the Controller of Patents to grant a compulsory licence if the reasonable requirements of the public are not satisfied, the patented invention is not available to the public at a reasonably affordable price, or the patented invention is not worked in India. In particular, Section 84(7) of IPA declares that the reasonable requirements of the public are not satisfied:

1. if the refusal of licence results in existing trade or industry, or development thereof, or establishment of a new trade or industry in India, or the trade or industry of any person or class of persons or manufacturing in India is prejudiced;
2. if refusal of licence results in the establishment or development of commercial activities in India being prejudiced;
3. if conditions imposed by the patentee result in the use of patented articles, or manufacture, use or sale of material not protected by the patent, or establishment or development of any trade or industry in India is prejudiced;
4. if conditions such as exclusive grant back, or prevention of challenges to the validity of patent, or coercive package licensing are imposed by the patentee; and
5. if working of the patented invention in India on a commercial scale is being prevented or hindered by importation of the patented article.

In Monsanto v. Competition Commission of India (2023), a division bench of the Delhi High Court explained the interplay between the IPA and the Competition Act and, resolved the perceived repugnancy between the two statutes.[27] The factors that the CCI considers when assessing an AAEC or abuse of dominant position under Sections 3 or 4 of the Competition Act are nearly identical to those that the Controller will consider while granting a compulsory licence in terms of Sections 84(6) and 84(7) under Chapter XVI of IPA. However, the Patents Act being the special statute must prevail over the Competition Act on the issue of anti-competitive agreements and abuse of dominant position by a patentee in exercise of its rights under IPA.[28] The CCI has no power to investigate in this respect. As concluded by the division bench, Chapter XVI of IPA is a 'complete code' in itself on all issues regarding unreasonable conditions in agreements of licensing of patents, abuse of status as a patentee, inquiry in respect thereof, and reliefs to be granted therefor.[29]

Evergreening or line extension

'Evergreening' is a term used to label practices wherein a trifling change is made to an existing product, and claimed as a new invention. The robust patentability

standards under IPA may be applied to curb evergreening and anti-competitive practices. According to Section 3(d) of IPA, follow-on drugs or derivative pharmaceutical innovations must demonstrate an additional therapeutic efficacy over and above the known substance. Section 3(d) thus acts as a second tier of qualifying standards for follow-on pharmaceutical products leaving the door open for genuine inventions, and simultaneously checking any attempt at repetitive patenting or extension of the patent term on spurious grounds.[30] This clause prevents the 'evergreening of patents' by prohibiting patents of incremental inventions involving only minor or slight improvements that extend the life of patents that are about to expire.[31] It, therefore, ensures generic competition by patenting only novel and genuine pharmaceutical inventions. Through this anti-evergreening clause, India strives to balance international patent obligations and its commitments to protect and promote public health.[32]

In the context of enforcement of patents concerning drugs, the courts are vigilant towards attempts by the patentee that aim at evergreening an invention that does not involve an inventive step, namely, a technical advance.[33] In an infringement case where the defendant set up a credible challenge to invalidity, the court refused the interim injunction to ensure generic competition for the production of follow-on drugs by reinforcing the doctrine of obviousness-type double patenting.[34]

If patents for the same inventive concept can be granted more than once, successively in time, it will prevent others from using the new product invented by the patentee until such time as the patentee successively keeps on obtaining such patents.[35] In certain cases of selection inventions, attempting to patent both the genus and species patent may amount to evergreening or layering of patent protection, which is impermissible under the Indian patent law. The second patent (species) for such a compound that was fully covered by the first patent (genus) would be vulnerable to invalidity due to lack of novelty and inventive step.[36]

Therefore, by filing multiple patents using the line extension or double patenting strategy a patentee may artificially extend the protection period beyond 20 years causing AAEC in the market, resulting in higher prices of drugs and denial of market access as no other competitor can enter the market.

Sham or vexatious litigation

From a competition perspective, litigation may be termed frivolous and vexatious when it is initiated by a dominant undertaking to cause anti-competitive harm through the inappropriate use of adjudicatory, government processes or legal rights. Usually, the objective behind such litigation is to either subdue a competitor by increasing operational costs or delay the entry of a competitor into the market.

As per CCI precedents, the following needs to be examined to determine whether litigation or legal recourse is an abusive conduct by a dominant player:

1. whether a case filed against an enterprise on an objective view is baseless and appears to be an instrument to harass the enterprise; and
2. whether the legal action appears to be conceived with an anti-competitive intent to eliminate or thwart competition in the market.

Therefore, the lawsuit in question must be objectively baseless so that no reasonable litigant could realistically expect success on its merits and, it is filed not to protect a legitimate right but to prevent a competitor.

In re Macleods Pharmaceuticals Limited v. Boehringer Ingelheim Pharma (2023) before the CCI, the filing of several patent infringement suits by innovators (patentees) against the generic competitors and giving notices to third parties such as medical practitioners to not engage with the competitors were not found to be a case of vexatious litigation or abuse of dominant position.

Refusal to deal

The CCI has held that firms may choose their trading partners as long as the exercise of such autonomy does not affect the fair functioning of the markets.[37] Depending upon the market power held by firms, their conduct on refusal to deal may lead to foreclosure of the market for other players. A refusal to deal, total or partial, could also have underlying valid justifications with commercial consideration.[38]

In re Swapan Dey v. Vifor International (2022), the CCI highlighted that the freedom to choose its trading partner is not absolute. However, not every company may seek access to the patent, unless it demonstrates that there is indeed a need for such access, based on the existing supply conditions of an essential product/facility as against its demand by the consumers, to affect the market adversely by non-dealing on the part of the entity (patentee) with significant market power. Any company requesting for grant of access to the patent should also demonstrate its ability to the patent holder, to satisfy the requirements specified for receipt of the grant of license.

Price discrimination

The CCI propounds that all price differentiations may not be discriminatory, more so when the same is based on reasonable classification of consumers to which they are offered.[39] The prices offered in government procurement may not be comparable with the products being sold on the open market on quantity criteria (bulk v. individual buying) as well as purpose criteria (public purpose or distribution free of cost v. private consumption).[40]

Special considerations

Public health interest

In Indian jurisprudence, the courts would look at the public interest in granting an injunction, as access to life-saving drugs and their pricing is an important facet of the Indian patent regime. The three general principles for granting or denial of an injunction are a prima facie case, the balance of convenience, and irreparable injury. In patent infringement suits concerning drugs, the fourth dimension of public health interest factors including affordability and accessibility to drugs has been added by Indian courts to the well-established triple test for interim reliefs.

In India, public health interest has been recognised both as a separate factor and as a tie-breaker factor for the balance of convenience. For instance, in AstraZeneca v. Intas Pharmaceuticals (2020), the court noted a big price differential (250 to 350 per cent) between the plaintiffs' patented antidiabetic drug and the defendants' generic drugs and held that the balance of convenience would tilt in favour of the defendants and, therefore, refused the interim injunction. A similar stand on significant price gap and affordability was reinforced recently in Boehringer Ingelheim Pharma v. Vee Excel Drugs (2023). However, in Merck Sharp and Dohme Corp. v. Glenmark Pharmaceuticals (2015), an interim injunction was granted by noting that the price differential (30 per cent) between the patentee's drug and the infringing products was not so startling as to compel the division bench to consider the public health interest dimension.

However, the defence of public health interest is not a complete exception to a legally valid patent and it is not interpreted too broadly as it would undermine the patentee's rights, and upholding the patent enforcement is also in the public interest.[41] Where a granted patent is prima facie found to be valid and infringed and is being exploited without a licence from the patent holder, the balance of convenience is always in favour of restraining further infringement even if the drug in question is needed for treating various serious ailments, including cancer.[42]

Clearing the way

As an equitable principle, while exercising discretion in granting injunctions the court may consider whether the infringer defendant has 'cleared the way' before exploiting the patent in question by filing any pre-grant or post-grant opposition or revocation petition or declaration of non-infringement.[43] Where litigation is bound to ensue if the defendants introduce their product, the defendants could have avoided the interim injunction if they had cleared the way first. In Eisai Co. Ltd. v Satish Reddy (2019), the balance of convenience for the grant of an interim injunction tilted in favour of the patentees as the defendants had not 'cleared the way' before obtaining marketing approval for the launch of the infringing drug.[44] The defendants were aware that there may be a possible challenge to their product, but they chose to seek the marketing approvals without first invoking revocation proceedings or attempting to obtain a licence.

Doctrine of equivalent (DOE)

In a few instances, the US-style doctrine of equivalent has been recognised by Indian courts.[45] DOE protects patent rights from being infringed by infringers using the colourable method of making some minor, insubstantial variations to escape the reach of the patent. In cases of non-literal infringement, the purposive construction or the 'triple identity' test (substantially the same function, in substantially the same way and to yield the same result) may be applied by courts.

Outlook and conclusions

The draft National Pharmaceuticals Policy, 2023 (NPP) envisages regulatory harmonisation of India's drug standards with international best practices, reducing

compliance burdens and simplifying the licensing system. The new NPP also envisions strengthening the Indian Patent Office and facilitating patent applications by fast-tracking the examination. The enforcement of pharmaceutical intellectual property continues to be strengthened and robust. India sternly prohibits infringement of a valid patent, and it may not be possible for competitors to argue public health interests to justify infringing drugs to circulate in the market. In recent years, the creation of the Intellectual Property Division in the High Courts has given further impetus to speedier adjudication of patent disputes. Patent rules have been amended recently to curb impostors and fraudulent pre-grant opposition.

Indeed, multiple patents can be filed for different aspects of a particular pharmaceutical drug, if patentability criteria are met. However, serial patenting to evergreen a particular monopoly is not permissible in India. Such anti-competitive attempts will be screened through patentability standards and validity challenges. The validity of patents is to be tested before the courts under the provisions of the Indian Patents Act. The question of the validity of patents is not looked into by the competition authority (CCI) for want of subject matter competence. Moreover, following the High Court's pronouncement last year, it is now settled that the Indian Patents Act per se provides adequate safeguards against anti-competitive licensing of patents and abuse of dominant status by a patentee, and the CCI's jurisdiction is completely ousted on that count. The tussle between intellectual property and competition law will be resolved conclusively when the Supreme Court issues its final judgment on the CCI's appeal against the ruling of the High Court.

Endnotes

1 Notification GSR 227(E) dated 19 March 2019 ^ Back to section

2 Notification GSR 828(E) dated 6 November 2019 ^ Back to section

3 DPCO 2013, paragraphs 13, 14, 20 ^ Back to section

4 Union of India v. Bharat Serums & Vaccines Ltd (2023:DHC:8164-DB) ^ Back to section

5 DPCO 2013, paragraph 20 ^ Back to section

6 DPCO 2013, paragraph 19 ^ Back to section

7 DPCO 2013, paragraph 32(i) (amended by SO 39(E) dated 3 January 2019) ^ Back to section

8 Order SO 39(E) dated 3 January 2019 ^ Back to section

9 DPCO 2013, paragraph 32(ii) ^ Back to section

10 New Drugs & Clinical Trial Rules 2019, Rule 2(x) ^ Back to section

11 New Drugs & Clinical Trial Rules 2019, Second Schedule ^ Back to section

12 New Drugs & Clinical Trial Rules 2019, Rule 80(7) Back to section

13 DPCO 2013, paragraph 32(iv) (inserted by SO 39(E) dated 3 January 2019) Back to section

14 Ischemix LLC v. Controller Of Patents (2023:DHC:8496) Back to section

15 Id. Back to section

16 PIB Press Release ID 1705065 dated 16 March 2021 Back to section

17 Id. Back to section

18 Notification GSR 327(E) dated 3 April 2017 Back to section

19 Notification GSR 360(E) dated 10 April 2018 Back to section

20 Guidelines on Similar Biologics (2016) Back to section

21 New Drugs & Clinical Trial Rules 2019, Explanation of Rule 2(x) Back to section

22 Boehringer Ingelheim v. DCGI & Anr (2019:DHC:5391), Order dated 23 February 2024 in CS(COMM) 159/2024 Back to section

23 Roche v. DCGI & Ors, (2016:DHC:3153), See also F Hoffmann La Roche v. DCGI & Ors, (2023:DHC:6522) Back to section

24 Roche v. DCGI & Ors, (2016:DHC:3153) Back to section

25 Bayer Corporation v. Union of India & Ors (2010:DHC:771-DB) Back to section

26 Id. Back to section

27 Monsanto Holdings Pvt Ltd v. Competition Commission Of India (2023:DHC:4783-DB) Back to section

28 Id. Back to section

29 Id. Back to section

30 Novartis v. Union of India, [2013] 13 SCR 148 Back to section

31 Review of IPR Regime in India, Parliamentary Standing Committee Report (2021) Back to section

32 Id. Back to section

33 AstraZeneca v. Intas Pharmaceuticals Ltd (2020:DHC:3125) Back to section

34 Id. Back to section

35 AstraZeneca v. Intas Pharmaceuticals Ltd (2021:DHC:2116-DB) Back to section

36 Natco Pharma v. Novartis (2024:DHC:3198-DB) Back to section

37 Hiveloop Technology v. Britannia Industries, CCI order dated 16 June 2022 Back to section

38 Id. Back to section

39 Swapan Dey v. Vifor International, CCI order dated 25 October 2022 Back to section

40 Id. Back to section

41 Merck Sharp and Dohme Corp. v. Glenmark Pharmaceuticals (2015:DHC:2712-DB) Back to section

42 Pharmacyclics LLC v. Hetero Labs Limited (2023:DHC:9246) Back to section

43 Merck (2015:DHC:2712-DB) Back to section

44 Eisai Co Ltd v. Satish Reddy (2019:DHC:2476) Back to section

45 FMC Corporation v. Natco Pharma Limited (2022:DHC:5311-DB), See also 2024:DHC:1945 Back to section

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