

Safe Harbor Provision in European Patent Law: The Research & Bolar Exemptions

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This article covers the most recent developments regarding the European Research Exemption, which permits the use of patented inventions for research purposes, as well as the European Bolar Exemption, which allows generics manufacturers to obtain authorization or approval under pharmaceutical law even before relevant patents expire. The article outlines and discusses the conditions for these two exemptions to apply and the limits and restrictions pertaining thereto. It also explains how the exemptions are applied in individual European countries. Finally, it reviews the proposed amendments published in April 2023 as part of the new European Pharmaceutical Package as well as the new Article 27 of the European Unified Patent Court Agreement introduced in June 2023.

Introduction

To incentivize innovation, patent law grants exclusivity to patent holders for a certain time, particularly patent holders in research-intensive sectors such as pharmaceuticals. However, strict enforcement of exclusivity rights may also hinder innovation and delay access to medicines. To balance these interests, two key exemptions from patent protection exist: the research exemption⁶¹ and the Bolar exemption⁶².

Research Exemption

The research exemption is a statutory limitation of the patent holder's exclusive right of exploitation, permitting third parties – under specified conditions – to examine, investigate, and test patented inventions for the purpose of generating new knowledge. Its underlying rationale is to foster scientific and technological advancement while avoiding undue curtailment of the patentee's rights.

The research exemption has its origin in the United States. Although it remains uncoded in U.S. statutory law, its scope and application have been shaped by case law. The foundational case *Whittemore v. Cutter*⁶³ in 1813 marked the beginning of this legal doctrine, with subsequent decisions further refining its contours.⁶⁴

In the EU, almost all member states have now introduced a research exemption in their respective national jurisdictions although there is no uniform research exemption in EU law. A significant point of reference remains Article 27 of the 1975 Community Patent Convention, which, although it never entered into force, has nevertheless exerted considerable influence

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⁶¹ Also known as 'experimental privilege' or the 'experimental use exemption'.

⁶² Also known as 'Roche-Bolar-Exemption' or 'market authorization privilege'.

⁶³ *Whittemore v. Cutter* 29 Fed. Cas. 1120 (C.C.D. Mass. 1813) (No 17, 600): Judge Story declared that it was not the intention of the legislator to hinder or penalize research activities through the grant of patent protection.

⁶⁴ See, eg, *Sawin v. Guild* 21 Fed. Cas. 554, No. 12,391 (C.C.D. Mass. 1813).

on national legislation. This provision is in line with Article 30 of the TRIPS Agreement, which permits limited exceptions to patent rights under national law. Consequently, many European jurisdictions have adopted the wording of Article 27 either verbatim or in slightly modified form, ultimately shaping the contours of today's research exemption.

Bolar Exemption

The Bolar exemption also originated in the United States following a 1984 decision by the U.S. Court of Appeals for the Federal Circuit.⁶⁵ Roche had sued *Bolar Pharmaceutical Co.* for patent infringement. In response, Congress subsequently enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, which introduced 35 U.S.C. § 271(e). Under this provision, pharmaceutical manufacturers are permitted to undertake studies and clinical trials necessary for obtaining marketing authorization, even if the relevant patent of a third party is still in effect. Its aim is to ensure that generic or reference medicinal products can be introduced to the market immediately upon expiry of the relevant exclusive rights (commonly referred to as "Day-1-entry"), thus forestalling any unforeseen attempt to prolong market exclusivity.

Fragmented application of the European Bolar Exemption

Although the EU and some member states initially criticized the Bolar exemption – going so far as to initiate a WTO dispute settlement proceeding⁶⁶ concerning the corresponding Canadian provisions – it later changed track. Influenced in part by the U.S. Bolar exemption, in 2004 the EU introduced its own version of the Bolar exemption with Directive 2004/27/EC, amending Directive 2001/83/EC. Article 10(6) of the amended Directive provides a legal basis for allowing generic manufacturers to conduct the studies and trials required for obtaining regulatory approval before a patent has expired. The aim was to enable generic manufacturers to prepare for market entry immediately upon patent expiry (Day-1-entry). Subsequently, all EU Member States incorporated a Bolar exemption into their national legislation. However, since the exemption was introduced as a Directive, and the specific wording was left to the individual Member States, implementation and interpretation of the national Bolar regulations vary considerably in the various EU countries.

Legal uncertainties under Bolar

Today, all EU Member States - and also Switzerland - recognizes, at least in principle, a Bolar Exemption for experimental activities carried out by generic manufacturers to obtain a marketing authorization.⁶⁷ However, as mentioned, the precise scope of Bolar differs between the different countries. For example, Germany, Spain, France, the UK and Switzerland construe their national Bolar Exemption more broadly, applying it not only to generics but also to originators, and moreover not only to studies performed for the purpose of obtaining European marketing authorizations but also to activities for obtaining marketing authorizations outside the EU. In The Netherlands and Belgium, on the other hand, the Bolar Exemption is treated more narrowly and is restricted to activities related to obtaining marketing

⁶⁵ *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, Fed. Cir. 1984.

⁶⁶ World Trade Organization, 'Canada – Patent Protection of Pharmaceutical Products' WT/DS114/R (WTO, 17 March 2000) < https://www.wto.org/english/tratop_e/dispu_e/7428d.pdf > accessed 26 March 2025.

⁶⁷ For an overview of the Bolar exception in EU member states (selection), see: Stief, GRUR Int 2024. 824

authorizations for generics and biosimilars.⁶⁸ Additionally, their exemptions only apply to activities carried out for authorizations within the EU.

Third-party suppliers

Due to variations in national laws across Europe, it remains unclear whether third-party suppliers, such as companies providing active or auxiliary substances without conducting their own marketing authorization procedures, can invoke the Bolar exemption. Polish⁶⁹ and German courts had already dealt with this issue in 2012 and 2013 in *Polpharma v. Astellas Pharma*. In 2012, the Düsseldorf Regional Court⁷⁰ adopted a restrictive interpretation, holding that suppliers are only covered if they themselves pursue the purpose of conducting studies or regulatory procedures. However, in 2013 the Higher Regional Court of Düsseldorf⁷¹ took a more permissive view. It held that API suppliers may benefit from the exemption if the delivery serves a purpose covered by the Bolar clause and the supplier takes sufficient precautions to ensure the protected use of the substance. The court referred preliminary questions to the CJEU, but the case was settled before a ruling was issued.

In July 2024 the Italian Supreme Court ruled in *Boehringer Ingelheim v. Sicor and Teva*⁷² that the Bolar exemption may extend to third-party API manufacturers, but only under strict conditions. Such manufacturers must act on behalf of a company actively pursuing marketing authorization. Also, the activity must be strictly limited to that purpose. In that case, the Court denied the exemption because the API was produced without a definite order linked to clinical trials. The Court rejected general declarations of intended regulatory use as insufficient.⁷³ This restrictive interpretation could impact API sourcing in Europe, potentially accelerating the shift to Asian production sites.

Research Tools

A particularly complex and still not settled issue in European patent law concerns the applicability of the research and Bolar exemption to patented research tools. These tools, such as assays, cell lines, or analytical methods,⁷⁴ are frequently used in experimental contexts, including in bioequivalence studies and in regulatory submissions. However, European courts have not yet clarified whether such uses fall within the scope of the research and Bolar exemption. Since these tools are specifically designed to facilitate research, exempting their use could undermine their patentability in practice. This, in turn, may reduce incentives for innovation in the research tools sector and have a long-term negative impact on scientific progress.⁷⁵

⁶⁸ But the Belgian Code of Economic Law provides a broader exemption under Art XI.34 §1.b.

⁶⁹ Sąd Najwyższy, Decision of 23.10.2013 – IV CSK 92/13

⁷⁰ Regional Court Düsseldorf, BeckRS 2013, 1711

⁷¹ Higher Regional Court Düsseldorf, GRUR-RR 2014, 100 - *Market authorization privilege*.

⁷² Corte Suprema Di Cassazione, Decision of 5.7.2024 – No. 18372.

⁷³ See in detail on the decision of the Italian Supreme Court: Stief, GRUR-Prax 2024, 595.

⁷⁴ Cf. Holzapfel, GRUR 2006, 10 (11).

⁷⁵ E.g. Haedicke, Patentrecht, 6th edition 2022, chapter 7 para. 21; Holzapfel, GRUR 2006, 10 (16f.).

Evolving Legal Framework in EU Pharmaceutical Law

The growing pressure to harmonize the interpretation of the Bolar exemption across the EU has led to currently ongoing European reform initiatives, particularly the EU Pharmaceutical Package and the establishment of the Unified Patent Court.

a) EU Pharmaceutical Package

At least arguably, restrictive interpretations of the Bolar Exemption in some Member States hinder administrative procedures such as pricing, reimbursement rules and tenders. This may conceivably lead to a *de facto* “patent linkage”, which the European Commission generally deems inadmissible. To address these problems, the EU Commission presented a proposal⁷⁶ in April 2023 aimed at reforming pharmaceutical legislation within the EU.⁷⁷ The initiative proposes a major revision of existing rules.⁷⁸

The draft reform of the Bolar exemption, as introduced in Article 85 of the proposed legislation, significantly expands the scope of the Bolar exemption compared to the present situation under Article 10(6) of Directive 2001/83/EC. The proposed text explicitly extends the exemption beyond generics and biosimilars to also include hybrid and bio-hybrid medicinal products (Article 85 para. (a) lit. (i)). Also, it covers activities necessary not only for obtaining marketing authorization, but also for conducting health technology assessments (Article 85 paragraph (a) lit. (ii)) and for pricing and reimbursement procedures (Article 85 paragraph (a) lit. (iii)).

Article 85 para. (b) of the draft Directive further exempts from patent protection activities that serve exclusively the objectives defined in Article 85 para. (a). These include, among others, the submission of a marketing authorization application, as well as offering, production, sale, supply, storage, import, use, and acquisition of patented medicinal products or processes –now explicitly also by third parties and service providers. However, it is not yet clear under what conditions the supply to third parties is covered by the exemption. Since the draft does not mention that the exemption is limited to applications for marketing authorization within the EU, it can be assumed that also activities carried out for the purpose of a non-EU market authorization would fall within the scope of the new Bolar exemption.

Following its review in April 2024, the European Parliament introduced several amendments to clarify and refine the scope of the proposed new legislation.⁷⁹ The revised version no longer ties the Bolar to the use of a reference medicinal product, but instead centers on the performance of necessary studies, trials, and related activities. References

⁷⁶ See European Commission, ‘Proposal for a Directive of the European Parliament and of the Council on the Union Code Relating to Medicinal Products for Human Use, and Repealing Directive 2001/83/EC and Directive 2009/35/EC’ COM(2023) 192 final, 2023/0132(COD), 26 April 2023.

⁷⁷ For an overview of the new draft Directive, see Stief/Grabow, PharmR 2023, 317.

⁷⁸ Communication from the Commission - Reform of pharmaceutical legislation and measures to combat antimicrobial resistance, COM(2023) 190 final, p. 3 f.; see also Kühnen, Handbuch der Patentverletzung, 16th edition 2024, E. para. 1120.

⁷⁹ European Parliament legislative resolution of April 10 2024, COM(2023)0192 – C9-0143/2023 – 2023/0132(COD), <

[https://www.europarl.europa.eu/RegData/seance_pleniere/textes_adoptes/definitif/2024/04-10/0220/P9_TA\(2024\)0220_EN.pdf](https://www.europarl.europa.eu/RegData/seance_pleniere/textes_adoptes/definitif/2024/04-10/0220/P9_TA(2024)0220_EN.pdf)> accessed 26 March 2025.

to specific types of medicines have been removed, and the exemption now applies in general to marketing authorizations and their variations. The Parliament also added the term “approval” in the context of pricing and reimbursement to better reflect regulatory terminology. A key addition is the inclusion of “subsequent practical requirements” related to these activities, ensuring that follow-up steps remain within the exemption’s protective scope.⁸⁰

Overall, amended Article 85 reflects an effort to harmonize and modernize the exemption across the EU, aligning it more closely with the practical realities of pharmaceutical development and market access. The final package is expected to come into force in 2026.

b) UPCA Bolar Regulation

With entry into force of the Unified Patent Court Agreement (UPCA)⁸¹ and the launch of the Unified Patent Court (UPC) on June 1, 2023, a new era of cross-border patent protection and enforcement within the EU began. With Article 27 lit. (b) lit. (d), the UPCA introduced harmonized research and Bolar exemptions.

The Bolar exemption under Article 27 lit. (d) UPCA excludes from patent infringement those acts permitted under Article 10(6) of Directive 2001/83/EC, notably studies for the regulatory approval of generic and biosimilar medicines. However, by directly referencing the Directive, it does not extend to studies involving innovative medicinal products or new therapeutic indications. Moreover, the exemption applies only to marketing authorizations within the EU. In an era of increasingly international clinical trials, this territorial restriction appears outdated and may hinder Europe’s attractiveness as a research location. And, unlike several member state provisions, the UPCA Bolar does not explicitly allow third-party suppliers or service providers to benefit from the exemption. Article 26(3) UPCA further stipulates that indirect infringers generally cannot invoke it.

Compared to broader member state rules and the current legislative proposal under Article 85 of the draft EU pharmaceutical regulation, the UPCA framework is clearly more restrictive. It remains to be seen whether the UPC will interpret these provisions narrowly or adopt a more pragmatic, innovation-friendly approach.⁸²

Outlook

The evolving regulatory and judicial landscape highlights the increasing necessity for clearly defined and uniformly applied exemptions from patent protection in the pharmaceutical sector. The proposed reform of the Bolar exemption and the parallel development of a unified patent litigation system present both opportunities and challenges. While the EU aims to strengthen its position as a hub for pharmaceutical innovation and clinical research, legal uncertainties and divergences between national and supranational jurisdictions remain. A coherent and innovation-friendly interpretation of the exemption will be crucial to ensure that regulatory flexibility does not come at the expense of legal certainty.

⁸⁰ Cf. Meyer/Grabow, Managing IP, EU seeks harmonisation of privilege for generic market entry, 9 January 2025, <<https://www.managingip.com/article/2e9idap95klfotg86ilvk/sponsored-content/eu-seeks-harmonisation-of-privilege-for-generic-market-entry>> accessed 26 March 2025.

⁸¹ Agreement on a Unified Patent Court, 2013/C 175/01, published in the Official Journal of the European Union on June 20, 2013.

⁸² See in detail Stief GRUR Int 2024, 824 (835 ff.).

Federal Circuit Affirms that Medical Devices are Only Listable in the Orange Book if They Claim the Active Drug Ingredient

By: Josh Goldberg and Leia Dingott⁸³

The Court of Appeals for the Federal Circuit (CAFC) affirmed the decision by the U.S. District Court in New Jersey, which ordered the delisting of five U.S. Patents owned by TEVA on the ground “that the Inhaler Patents contain no claim for the active ingredient at issue, albuterol sulfate,” but instead “are directed to components of a metered inhaler device.” *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of N.Y., LLC*, No. 23-20964, -- F. Supp. 3d --, 2024 WL 2923018, at *6, *7 (D.N.J. June 10, 2024) (“Delisting Order”). Accordingly, moving forward, patents for a medical device product are only Orange Book listable in the U.S. if they include claims directed to the active drug ingredient.

In its decision, the CAFC gave a thorough background explaining how the U.S. Food and Drug Agency (FDA) approves applications to market drugs and how the Orange Book is used. The CAFC explained that the FDA requires a company to submit a new drug application (NDA) before the company can market the drug. The NDA must include full reports showing that the drug is safe and effective, a full description of the components and manufacturing process for the drug, proposed labelling for the drug, and information on patents claiming the drugs as explained in the Federal Food, Drug, and Cosmetic Act (“FDCA”). See 21 U.S.C. § 355(a), (b). The FDA will approve the drug if the reports show that the drug is safe and effective. *Id.* § 355(d).

The CAFC continued to explain that before 1984, a company seeking approval for a generic drug containing the same active ingredient as the brand-name drug manufacturer had to file its own NDA with its own clinical trials, even though the FDA had already determined that the active ingredient in the drug was safe and effective. See *United States v. Generix Drug Corp.*, 460 U.S. 453, 454, 461 (1983). The CACF explained that a full set of trials to prove that the generic was safe and effective was costly, time consuming, and often involved infringement of one or more patents for the name brand drug. *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984), superseded by statute, *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003).

The Hatch-Waxman Act, which was enacted in 1984, changed the approval process for generic drugs to bring generics to market faster. See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585. The Hatch-Waxman Act introduced an Abbreviated New Drug Application (ANDA), which allowed a company with a proposed generic product to show bioequivalence to a name brand drug as shown in an approved NDA rather than having to conduct and submit separate clinical trials to show safety and efficacy. See 21 U.S.C. § 355(j). Congress also created a safe harbor granting immunity from patent infringement when the activity was “solely for uses reasonably related to the development and submission” of information to the FDA. 35 U.S.C. § 271(e)(1). The provision overturned the *Roche* decision from 1984.

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The Hatch-Waxman Act also included a patent-term extension (PTE) for patents claiming an FDA-approved product because obtaining FDA approval often takes longer than getting a patent granted by the USPTO. See 35 U.S.C. § 156(a).

The changes brought by the Hatch-Waxman Act sped up the process for generics getting approved but did not deal with the litigation risk that the generic company took by marketing a drug covered by an NDA holder's patent. Therefore, Congress created a new act of infringement to resolve patent disputes pre-approval. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). The new provision made submitting an ANDA a technical act of infringement. 35 U.S.C. § 271(e)(2)(A). One remedy for an eventual finding of infringement is setting the effective date of approval no earlier than the date that the brand's patent would expire. *Id.* § 271(e)(4)(A).

Congress also prohibited the FDA from approving an ANDA that would infringe a "listed patent", i.e., any patents submitted by the NDA holder to the FDA for inclusion in the Orange Book (aka Approved Drug Products with Therapeutic Equivalence Evaluations). To be included in the Orange Book, the NDA holder must submit "the patent number and expiration date of each patent" related to the drug for which approval is requested to the FDA. 21 U.S.C. § 355(b)(1)(A)(viii).

A generic company submitting an ANDA must include, as a part of their application, an appropriate patent certification for any patents listed in the Orange Book for the relevant NDA drug product. There are four certifications that the generic applicant can make as part of their ANDA: 1) "such patent information has not been filed." *Id.* § 355(j)(2)(A)(vii)(I); 2) "such patent has expired." *Id.* § 355(j)(2)(A)(vii)(II); 3) "the date on which such patent will expire." *Id.* § 355(j)(2)(A)(vii)(III); and 4) "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.* § 355(j)(2)(A)(vii)(IV).

For certifications 1 and 2, the FDA may approve the ANDA immediately, as there is no potential patent infringement of a listed patent. For certification 3, the FDA may wait until the relevant patent(s) expire before approving the ANDA. For certification 4, the process is more complicated. The generic applicant sends the patent owner a Paragraph IV notice that gives the patent owner 45 days to file an infringement suit for the technical act of infringement of filing the ANDA. *Id.* § 355(j)(5)(B)(iii). If the patent owner files an infringement suit within 45 days of the notice, the approval of the ANDA shall be effective after a thirty-month period from the date of the notice. *Id.* If the patent owner does not sue, then the approval may be effective after the 45 days have lapsed.

Some argue that this 30-month stay in approval may entice patent owners to improperly list patents in connection with their NDA. The FDA does not police the patents listed in the NDA on the basis of not having sufficient patent-law expertise to determine the listability of any submitted patent information. This was an important issue addressed by the CAFC in their decision.

The CAFC then discussed TEVA's NDA for ProAir® HFA Inhalation Aerosol, described in NDA No. 021457, Amneal's ANDA with a Paragraph IV certification indicating Amneal's belief their proposed generic product would not infringe any claim of any patent listed in the Orange Book for this product, and the District Court's delisting order.

TEVA listed patents for a metered dose inhaler that can be used with albuterol sulfate in the Orange Book. However, none of the patents listed by TEVA specifically claim an active ingredient, only a medicament canister. While the FDA did approve the NDA as a drug because of the active ingredient used in the final product, the CAFC explained that a device-drug combination product does not become a drug just because it is regulated as a drug.

Amneal submitted an ANDA to obtain approval for a similar device with a Paragraph IV certification, arguing that the nine patents listed by TEVA would not be infringed by their proposed generic device. TEVA then sued Amneal for infringement on, ultimately, five of the Orange Book listed patents. Amneal, in turn filed counterclaims against Teva, including a request for an order that TEVA be required to delist the five patents, which did not include claims for an active ingredient as required for listing in the Orange Book.

The CAFC performed a statutory interpretation *de novo* as an issue of law. In the review, the CAFC focused on the language of the relevant statute and the broader context of drug approval to determine the meaning in the relevant statute.

TEVA argued that their patents were properly listed in the Orange Book because the patents “claim the drug” by reading on, or referring generally to, the drug. In other words, TEVA argued that a patent claims a drug if the patent would be infringed by use of the drug. The CAFC **rejected** this interpretation. The CAFC explained that TEVA’s interpretation would allow far more patents to be listed in the Orange Book and goes directly against the plain language of the relevant statute. The CAFC pointed out that the listing provision of the relevant statute identifies “infringing” and “claiming” as two distinct requirements. The CAFC asserted that it would have been redundant of Congress to include two different clauses for the same requirement. The Court also referred to the patenting statutes, specifically 35 U.S.C. § 112, which defines the written description and claim requirements in a patent application. When the claims and specification are read together the claims define the invention. Therefore, the CAFC concluded that claims are of primary importance and identify the “invention.”

Infringement, on the other hand, is governed by a different statute (35 U.S.C. § 251) and occurs when someone other than the inventor makes, uses, sells, or imports the claimed invention without authorization. Claims are given their ordinary meaning based on the words used inside the patent document itself. Further, someone can infringe a patent without meeting all the claim elements when there is equivalence between the elements of the accused product or process and the claimed elements of the patented invention. A product that infringes a patent claim can also include more than the elements of the claim.

Referring again to the written description requirement with respect to the relevant patents, the CAFC gave an example from oral arguments to illustrate the difference between claims and infringement. A large item such as a car can infringe a patent for a steering wheel even if the patent application did not describe the car itself.

Lastly, the CAFC described that the interpretation outlined in the opinion contrasts with the Patent Term Extension (PTE) provisions of the Hatch-Waxman Act, which extends the term of a patent that “claims a product.” 35 U.S.C. § 156(a)(4). The CAFC concluded its statutory analysis by stating that both relevant statutory provisions and case law establish that what a patent claims and what infringes a patent are distinct concepts. What is claimed in TEVA’s patents are distinct from what may infringe TEVA’s patents.

Next, the CAFC discussed whether the device itself was a drug, or whether an actual chemical must be claimed in the patent. The CAFC again turned to statutes and case law to determine that medical devices and chemical compounds, or drugs, have distinct approval pathways under U.S. law and cannot be conflated as the same thing. Patents listed in the Orange Book are required to include at least one claim directed to an active ingredient, while all TEVA's asserted patents for a metered dose inhaler device do not include any claims for the active drug ingredient, albuterol sulfate. The CAFC concluded TEVA's argument that a claim requiring the presence of "an active drug" was far too broad to particularly point out and distinctly claim the drug approved in TEVA's NDA as required by 35 U.S.C. § 112.

Accordingly, the CAFC affirmed that Teva is required to delist the patents at issue from the Orange Book for the ProAir® HFA Inhalation Aerosol, and lifted the stay, thereby permitting Amneal to launch their generic product.

Supreme Court of Canada to Hear Appeal Regarding Methods of Medical Treatment

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Abstract

The Supreme Court of Canada has granted Pharmascience Inc. leave to appeal in *Pharmascience Inc. v. Janssen Inc. et al.*, a recent Federal Court of Appeal decision. The Federal Court of Appeal held that the claims in Janssen's patent (Canadian Patent No. 2,655,355) relating to a long-acting form of paliperidone palmitate were directed to patent-eligible medical uses and vendible products rather than unpatentable methods of medical treatment.

As claims directed to medical uses and vendible products are patentable in Canada, while claims directed to methods of medical treatment are not patentable, the distinction between these categories is of critical importance to the validity of many pharmaceutical patents. *Janssen* is a rare opportunity to obtain jurisprudence from the Supreme Court of Canada relating to this frequently litigated topic.

Introduction

On September 19, 2024, the Supreme Court of Canada granted leave to appeal⁸⁵ in *Pharmascience Inc. v. Janssen Inc. et al.*⁸⁶ This case will give the Supreme Court an opportunity to weigh in on whether certain dosing regimens are unpatentable methods of medical treatment in Canada, and more broadly, to develop Canadian jurisprudence regarding the patentability of pharmaceuticals.

Methods of Medical Treatment in Canadian Law

Canadian case law prevents methods of medical treatment from being patented, with such methods being considered to lie outside of the statutory definition of an "invention"⁸⁷ as defined in the *Patent Act*.⁸⁸ However, medical use claims (e.g., the use of Compound X to treat Disease Y) are patent-eligible, provided that such claims do not require or limit the exercise of skill and judgment by a physician.

The distinction between a non-patentable method of medical treatment and a patentable use claim is often a fine line. Although a claim may nominally recite a medical use, it can be invalid for being actually directed to a method of medical treatment if practicing the claimed invention would require or limit the skill and judgment of a physician.

For example, a claim reciting the use of ursodeoxycholic acid to treat primary biliary cirrhosis "based on a dose of 13 to 15 mg/kg/day" was found to be invalid as being actually directed to

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⁸⁵ [Pharmascience Inc. v. Janssen Inc. et al.](#), 2024 CanLII 88324 (SCC)

⁸⁶ [Pharmascience Inc. v. Janssen Inc. et al.](#), 2024 FCA 23 ["Janssen FCA"]

⁸⁷ [Tennessee Eastman Co. et al. v. Commissioner of Patents](#), [1974] S.C.R. 111 ["Tennessee Eastman"]

⁸⁸ Patent Act, RSC 1985, c. P-4 ["Patent Act"] at [s. 2](#)

a method of medical treatment.⁸⁹ In that case, the Federal Court found that a physician would have to exercise their judgment to determine the actual dose per kilogram to be administered, based on factors such as the patient's metabolism.

Similarly, claims reciting use of zoledronic acid using “intermittent administration, with a period of at least about one year between a first administration and each subsequent administration”, with dependent claims reciting different dose ranges and frequencies, were held to be directed to methods of medical treatment. The Federal Court determined that, in light of the description, the various ranges of doses and frequencies encompassed the skill and judgment of a physician and that the claims were thus directed to non-patentable methods of medical treatment.⁹⁰

A further distinction is drawn with respect to vendible products (e.g., a tablet containing a dose of an active ingredient). Claims directed to vendible products, including properly formulated Swiss-style claims, are considered patentable. For example, a claim reciting the use of finasteride “for the preparation of a medicament adopted for oral administration useful for the treatment of androgenic alopecia in a person and wherein the dosage is about 1.0 mg” was deemed to be directed to a vendible product (i.e., a medicament having 1.0 mg of finasteride), and was thus deemed to be patentable.⁹¹

The Janssen ‘355 Patent

Pharmascience Inc. defended an infringement action brought by Janssen Inc. on the basis that Canadian Patent No. 2,655,355⁹² was invalid as being obvious and directed to unpatentable methods of medical treatment. The ‘355 Patent broadly relates to the treatment of schizophrenia with a long-acting, injectable formulation of paliperidone palmitate marketed in Canada as INVEGA SUSTENNA™.

At Trial in the Federal Court

At trial,⁹³ the Federal Court identified four broad groupings of claims:⁹⁴

- I. Claims 1 to 16, pertaining to prefilled syringes for administration according to the following dosage regimen:
 - i. a first loading dose of 150 mg-eq of paliperidone (or 100 mg-eq for a renally impaired patient) to be administered on Day 1;
 - ii. a second loading dose of 100 mg-eq (or 75 mg-eq for a renally impaired patient) to be administered one week \pm 2 days after the first loading dose; and

⁸⁹ [Axcen Pharm Inc. v. Pharmascience Inc.](#), 2006 FC 527, at paras. 46 to 48

⁹⁰ [Novartis Pharmaceuticals Canada Inc. v. Cobalt Pharmaceuticals Company](#), 2013 FC 985 at para. 99

⁹¹ [Merck & Co., Inc. v. Pharmascience Inc.](#), 2010 FC 510, at para. 114

⁹² Canadian Patent No. **2,655,355**

⁹³ [Janssen Inc. v. Pharmascience Inc.](#), 2022 FC 1218 [“Janssen FC”]

⁹⁴ *Ibid.* at paras. 34 and 35

- iii. a maintenance dose of 75 mg-eq (or 50-mg-eq for a renally impaired patient) to be administered monthly ± 7 days after the second loading dose and thereafter.
- II. Claims 17 to 32, pertaining to “use of a dosage form of paliperidone ... for treating a psychiatric patient in need of treatment for schizophrenia” according to the dosage regimen above;
- III. Claims 33 to 48, pertaining to “use of paliperidone ... for the preparation of a medicament” for administration to a patient in need of treatment, the medicament being for administration according to the above dosage regimen; and
- IV. Claims 49 to 63, pertaining to a dosage form of paliperidone palmitate for administration to a patient in need of treatment according to the above dosage regimen.

The Federal Court decided that Groups I, III, and IV were all directed to vendible products (i.e., the prefilled syringe, the prepared medicament, and the dosage form). Thus, these groups were, by definition, not directed to unpatentable methods of medical treatment.⁹⁵

Group II was deemed to be directed to a medical use, but not a method of medical treatment. As discussed above, several previous cases had found that dosage ranges could improperly require the exercise of skill and judgment of a physician. Pharmascience argued that the date windows for administering the second and subsequent doses made these claims directed to a method of medical treatment. Similarly, Pharmascience argued that dependent claims reciting multiple injection sites (e.g., the deltoid or gluteal muscle) required a physician’s skill or judgment in selecting the site. Further, Pharmascience argued that the different dosage regimen for renally impaired patients requires a physician to exercise skill and judgment, namely, by determining whether the patient is renally impaired. In contrast, Janssen argued that the dosing windows and multiple injection sites were provided merely for convenient administration, and that the claimed dosage regimens needed only to be implemented.

The Federal Court held that the date windows, injection sites, and the different dosage regimen for renally impaired patients did not require skill and judgment. Instead, these claims merely required a physician to implement the claimed dosage regimen. There was no clinical implication resulting from when a dose was administered within the date window or where it was injected, and a patient’s renal impairment status was determined outside the context of the invention. Once the physician chooses to use the product for the claimed purpose, the dosages are fixed. Further, because there was no need for the physician to use clinical judgment when implementing the dosage regimen, the claims were thus not directed to an unpatentable method of medical treatment.⁹⁶

The claims were also all found to be non-obvious, which was not appealed.

⁹⁵ *Ibid.* at para. 163

⁹⁶ *Ibid.* at paras. 168 to 172

On Appeal at the Federal Court of Appeal

Pharmascience appealed the Federal Court's finding that the claims were not directed to methods of medical treatment. The Federal Court of Appeal affirmed that Groups I, III, and IV were directed to vendible products and thus could not be methods of medical treatment.⁹⁷ Notably, the Federal Court of Appeal reaffirmed prior jurisprudence that Swiss-style claims (Group III) were directed to vendible products and thus cannot be methods of medical treatment even when a dosing regimen is an essential element of the claims.⁹⁸

The Federal Court of Appeal also affirmed that the use claims of Group II were permissible use claims and not methods of medical treatment. Specifically, reciting a dosing regimen with inbuilt flexibility did not automatically make the use claim into a method of medical treatment. Rather, the focus of the analysis was on whether the skill and judgment of a physician was implicated. Again, the Federal Court of Appeal agreed that the dosage windows and choice of injection sites did not require the exercise of clinical judgment, and were present merely to provide flexibility in administration.⁹⁹ The Federal Court of Appeal also found that whether a patient is renally impaired or not is an objective distinction, and thus does not implicate a physician's skill and judgment.¹⁰⁰ Thus, the claims of Group II were directed to a patent-eligible medical use.

Leave to Appeal to the Supreme Court of Canada

The hearing of the appeal by the Supreme Court of Canada presents a chance for the Supreme Court to set out a clear test to define an unpatentable method of medical treatment.

Pharmascience has proposed a three-part test¹⁰¹ for determining whether a claim is directed to an unpatentable method of medical treatment:

- (a) Construe the claims;
- (b) Identify whether any of the essential elements as construed are therapeutic or medical; and
- (c) Identify whether any of the therapeutic or medical essential elements relate to how and when a drug or treatment is to be administered by a medical practitioner.

According to Pharmascience, meeting parts (b) and (c) of the test would make a claim unpatentable. Pharmascience submits that this test best suits the public policy rationale for the unpatentability of methods of medical treatment (*i.e.*, that such methods are non-economic and are related to professional fields). Rather conveniently for a generic drug manufacturer, the test also takes a maximalist approach to defining methods of medical treatment and would thus enlarge the scope of unpatentable subject matter.

⁹⁷ Janssen FCA, *supra*, at para. 42

⁹⁸ Janssen FCA, *supra*, at para. 41

⁹⁹ Janssen FCA, *supra*, at paras. 52 and 53

¹⁰⁰ Janssen FCA, *supra*, at para. 56

¹⁰¹ [Factum of the Appellant, Pharmascience Inc.](#), filed December 20, 2024, at para. 7

Janssen,¹⁰² in contrast, seeks to overturn the existing jurisprudence and eliminate the bar to patenting methods of medical treatment. The section of the *Patent Act* that was relied on in the original case¹⁰³ barring methods of medical treatment has been repealed. Janssen argues that subsequent legislative history should be interpreted as removing the bar to patentability. However, Janssen largely does not engage the significant body of case law that has developed even after the section's repeal.

As a fallback position, Janssen argues that the prohibition should be narrow and limited to “non-economic medical activities unrelated to commercial products”.¹⁰⁴ Janssen argues that dosage regimens are complex, expensive, and economically valuable discoveries, and are thus both economic and related to commercial products.¹⁰⁵ While Janssen does not propose a test for patentability, its fallback position would still greatly narrow the definition of unpatentable methods of medical treatment if adopted by the Supreme Court.

Leave to intervene was granted to three physicians, a patient group, two pharmaceutical-innovator industry groups, one generic-pharmaceutical industry group, and FICPI. As of this writing, the intervenors' factums have not been published by the Supreme Court.

As of this writing, the Supreme Court of Canada also has not posted a hearing date. A hearing is likely to occur in late Spring or Fall 2025, with reasons for judgment generally taking six to twelve months to be released after the hearing.

As a further note, the Supreme Court's granting of leave in a patent case is quite rare, with the Court not having issued a patent-related decision since *Nova Chemicals Corp. v. Dow Chemical Co.*¹⁰⁶ in November 2022.

Conclusion

The Supreme Court of Canada's upcoming decision in *Pharmascience Inc. v. Janssen Inc.* has the potential to significantly change Canadian case law regarding the patentability of methods of medical treatment. By addressing the distinction between unpatentable methods of medical treatment, patentable medical uses, and vendible products, the Supreme Court will hopefully provide much-needed clarity on the boundaries of patent-ineligible methods of medical treatment. The Supreme Court of Canada may also take the opportunity to revisit whether methods of medical treatment are unpatentable under Canadian law.

¹⁰² [Factum of the Respondent, Janssen Inc.](#), filed February 24, 2025, at para. 38

¹⁰³ *Tennessee Eastman*, *supra*.

¹⁰⁴ Factum of the Respondent, *supra*, at para. 58

¹⁰⁵ *Ibid.* at para. 59

¹⁰⁶ [Nova Chemicals Corp. v. Dow Chemical Co.](#), 2022 SCC 43

Patent Prosecution in Latin America: Challenges, Delays, and Acceleration Mechanisms

By: Mariana Bullrich¹⁰⁷

In most Latin American countries, patents are granted for a non-extendable period of 20 years from the application filing date, in line with the minimum protection established under the TRIPS Agreement. The aim of this provision was to prevent counterproductive delays in patent prosecution, especially in cases where the term was counted from the grant date rather than the filing date.

For many years, Brazil was the exception. Until 2021, Article 40 of Law 9279 was in force, which established that patents would be granted either 20 years from filing or a minimum of 10 years from grant, ensuring at least 10 years of protection for applicants. In 2021, the Supreme Court ruled that Article 40 was unconstitutional, aligning Brazil's legislation with the general 20-year term from filing.

The TRIPS Agreement also establishes that patents must be granted within a "reasonable period" to ensure that the effective duration of protection is not unduly shortened. However, in many countries of the Latin America region, patent offices have backlogs and patent prosecution times often exceed desirable limits, reducing the effective protection available to patent holders. This backlog is particularly relevant for inventions in certain technical fields such as pharma and biotech.

Some countries in the region, such as Chile, Costa Rica, Guatemala, the Dominican Republic, El Salvador, Honduras, and Nicaragua, have incorporated provisions into their legislation that allow for patent term adjustment when prosecution delays are attributable to the Patent Office (e.g., when the process exceeds five years from the application date or three years from the examination request).

In Colombia and Peru, although their legal frameworks also allow for the adjustment of patent terms, pharmaceutical patents are explicitly excluded from this benefit.

It has been observed that in countries where patent term adjustments are permitted, such as Chile and Colombia, patent offices have implemented measures to accelerate prosecution and prevent extended patent protections. The result has been a significant reduction in prosecution times, to the point that the grant of term adjustments has become increasingly rare.

Several factors affect the duration of the patent examination process. Perhaps the most significant is the lack of sufficient examiners. While some countries, such as Chile, have taken steps to improve staffing by hiring external examiners, the problem is difficult to resolve in the short term. This is not only due to financial constraints, but also because training new examiners is a complex and time-consuming process.

Other factors contributing to prosecution delays include unclear rules, frequent changes in examination criteria, and the absence of limits on the number of office actions that examiners

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are allowed to issue. For example, in Dominican Republic and Peru, restricting the number of office actions has helped to speed up prosecution times.

The implementation of clear examination guidelines, such as those adopted in Chile (2013 and 2022) and the Andean Community (Andean Manual 2022), facilitates better adaptation of claims to local requirements. This reduces the number of office actions and adverse decisions, which often force applicants to challenge them through lengthy and costly legal procedures.

Changes in patentability criteria have also hindered the ability to obtain timely final decisions. An example of this was seen in Argentina after the publication of Joint Ministerial Resolution 118/2012, 546/2012, and 107/2012, which introduced new guidelines for examining chemical and pharmaceutical applications. These guidelines significantly altered previously established examination criteria in this particular technical field. As a result, not only were prosecution times extended, but applications that would have been granted before 2012 were instead rejected, forcing applicants into lengthy litigation. These legal proceedings often concluded only when the patent had little time left before expiration or had already expired.

Interviews with examiners have proven to be a useful tool for expediting patent prosecution. Unfortunately, this option is not available in all countries. Expanding this option to more jurisdictions would be highly beneficial.

Another effective mechanism for reducing delays is the adoption of patent acceleration programs known as the Patent Prosecution Highway (PPH). This mechanism enables national examiners to leverage search and examination results from other offices. By starting their examination with pre-existing reports from foreign jurisdictions, they can avoid duplicating efforts and can significantly reduce prosecution times.

While each office has different requirements and criteria, in general, PPH programs require that the claims under review have the same or narrower scope than those deemed patentable in the corresponding foreign jurisdiction.

It should be noted that applying for PPH does not guarantee a direct patent grant, but does significantly shorten the examination process. The Patent Office will still conduct a substantive examination to ensure that the claims comply with local legislation and do not cover non-patentable subject matter (e.g., therapeutic treatment methods, which are excluded from patentability in the region). If the Patent Office determines that objections persist despite modifications, an office action will be issued; otherwise, the patent will proceed to grant.

In addition to amending the claims to align them with those accepted in other offices, applicants must also submit copies of prior examination reports, search results, and responses, along with translations into the local language when required.

The optimal time to request PPH participation is when filing the substantive examination request. Once the examiner has begun the substantive review, it is no longer possible to opt for this route.

Several PPH programs are currently available, including PPH-PCT, Global PPH, PPH-Mottainai, PPH-PROSUR, and Pacific Alliance PPH, as well as bilateral agreements between various patent offices.

For example, Brazil, Chile, Colombia, and Peru are part of the Global PPH, which allows applicants to base their PPH requests on a broad range of jurisdictions.

Brazil has a particular limitation in that it imposes an annual cap on PPH requests. In 2024, this cap was increased to 3,200 total applications, with a maximum of 1,000 applications within the same section of the International Patent Classification. Brazil has also implemented special priority programs based on applicant type, application status, and technology field.

In Argentina, Resolution 56/2016 has proven to be a very useful tool for shortening prosecution times. According to this resolution, when an application has been granted in a country with substantive examination standards aligned with those of Argentina, the applicant may modify the claims to have the same or narrower scope and request the application be prosecuted under the provisions of Resolution 56 based on the elected granted patent. The Argentine Patent Office then only conducts an internal search for local prior art and must issue a decision within 60 days. If no objections remain, the patent is granted; otherwise, an office action is issued. The advantage of this system over conventional PPH programs is that it significantly reduces prosecution times by imposing a deadline on examiners and does not require applicants to submit full documentation of the foreign case, except for a translation of the granted claims if not available online in Spanish or English.

Uruguay introduced the Prompt Resolution Program (PRP) through Resolution 11/2021, which has been instrumental in addressing the significant backlog at the patent office. However, local pharmaceutical companies have challenged this resolution, seeking its annulment along with the patents granted under this framework. This lawsuit is pending resolution. Recently, the State Attorney for Administrative Litigation issued a non-binding favorable opinion, stating that Resolution 11/2021 complies with the requirements of Law No. 17.164 and recommending the Administrative Litigation Tribunal (TCA) to dismiss the lawsuit and uphold the PRP. The TCA is expected to rule on the matter later this year.

Unfortunately, many countries in the region, such as for example Bolivia, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Honduras, Nicaragua, Panama, Paraguay, and Venezuela, do not have effective PPH programs. In these cases, applicants are recommended to adapt the claims to those granted, for example, by the European Patent Office (EPO) or the United States Patent and Trademark Office (USPTO) before the examiner begins the substantive examination so that the application is in an acceptable format at that stage. Decisions of other jurisdictions are not binding for local examiners but are usually a favorable antecedent when having to decide on a case.

In the case of Costa Rica, it is important to highlight that a recent agreement was signed between the Costa Rican Patent Office and the European Patent Office, allowing patents granted by the EPO to be validated in Costa Rica. However, this agreement has not yet been implemented, as significant administrative and regulatory adjustments are required for it to come into force. The criteria of the Costa Rica PTO are significantly more restrictive than those applied by European examiners, particularly for pharmaceutical and biotech inventions. This raises concerns about how the agreement will function once fully implemented.

Delays in granting a patent in countries without term adjustment seriously affect innovation and technological advancement, as they reduce or even eliminate the effective time during which the patent holders can exclusively exploit their invention, thereby discouraging investment in research and development.

It is essential for governments and patent offices in the region to recognize the importance of these challenges and implement measures to ensure that proceedings are completed within reasonable time frames. They should enable and promote procedural efficiency tools, which have proven to be highly effective in reducing prosecution times, to ensure a fair patent term and to encourage applicants/inventors to continue with the virtuous cycle of research and development.

The Delicate Balance: Pharmaceutical Patents, Public Health, and the Quest for Innovation

By: Sharad Vadehra¹⁰⁸

Over the years, India has emerged as a global leader in the production of generic drugs, playing a crucial role in providing affordable medicines across the world. A significant portion of these generics is exported to both the developed and developing nations, contributing to global healthcare affordability.

Pharmaceutical patents are intended to incentivize innovation by rewarding pharmaceutical companies that invest in developing new and better drugs. However, when patents are granted for minor modifications of the existing drugs without genuine improvement, it can lead to extended monopolies, inflated drug prices, and limited access for the general public. To prevent such misuse, while still encouraging meaningful innovation, India has implemented robust safeguards within its patent framework.

Section 3(d): India's Firewall against Evergreening

To address the risk of evergreening - where patent holders attempt to prolong exclusivity by making incremental, non-substantive changes to existing drugs - India introduced a unique provision: Section 3(d) of the Patents Act, 1970. This section states: *"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus [is not patentable], unless such known process results in a new product or employs at least one new reactant."* The explanation to Section 3(d) further clarifies that salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of a known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

India's stance on evergreening was firmly reinforced in the Supreme Court's landmark decision in *Novartis AG v. Union of India*¹⁰⁹. Novartis had applied for a patent on the β -crystalline form of Imatinib Mesylate, the active ingredient in its cancer drug Glivec. The Court ruled that the new form did not show a significant improvement in therapeutic efficacy over the known substance. By rejecting the application under Section 3(d), the Court emphasized that mere improvements in bioavailability or physical properties such as flow or stability do not meet the threshold. The decision became a defining moment in India's IP regime, balancing patent rights with the right to health and setting a global example of access-oriented IP policy. Since then, it is understood that to combat Section 3(d), significant enhancement of therapeutic efficacy must be shown to receive protection for new forms of known substances.

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¹⁰⁹ AIR 2013 SUPREME COURT 1311

India's Higher Threshold Compared to other Jurisdictions

It may be said that the Indian Patent Office seems to apply a dual test for pharmaceutical patentability. In addition to the global standards of novelty and inventive step, India requires that new forms of known substances must also demonstrate enhanced therapeutic efficacy under Section 3(d).

In contrast, the United States Patent and Trademark Office (USPTO) allows patents on new forms of known substances (e.g., polymorphs or salts) if they are non-obvious, without mandating therapeutic efficacy. The European Patent Office (EPO) assesses inventive step and plausibility, but lacks an equivalent provision to Section 3(d).

This clause has become a cornerstone of India's pharmaceutical patent regime and reflects the country's commitment to maintaining a high threshold for pharmaceutical inventions.

The Role of Courts in Balancing Rigour with Procedural Fairness

While the Indian Patent Office has adopted strict scrutiny under Section 3(d), Indian courts have often taken a more flexible, procedural fairness-oriented stance. Courts have emphasized that rejection orders must be well-reasoned and must take into account all data and arguments presented by the applicant, including additional data submitted at later stages, provided it supports the original disclosure. The Courts have remanded numerous cases for reconsideration where the Indian Patent Office had issued rejections. For example, here are a few cases where the courts' opinions differed from that of the Indian Patent Office.

In *D.S. Biopharma v. Controller of Patents and Designs*¹¹⁰, the Delhi High Court set aside the rejection of a composition comprising 15-oxo-epa or 15-oxo-dgla, which was denied by the Patent Office under, *inter alia*, Section 3(d). The rejection was primarily based on a hearing notice that simply cited Section 3(d) without identifying the specific known substance or explaining how the claimed compound was a new form of it. The court held that a valid objection under Section 3(d) requires at least a brief identification of the known substance and the basis for its comparison. As the Patent Office failed to provide this and gave the applicant insufficient time to respond meaningfully, the Court remanded the matter for reconsideration.

In *Novozymes v. Assistant Controller of Patents & Designs*¹¹¹, the Madras High Court clarified that Section 3(d) applies not only to pharmaceutical substances but also to biochemical substances such as enzymes, including phytase. The court held that efficacy need not be narrowly defined and can include properties such as thermostability, provided such enhancements meaningfully improve the product's utility.

In *Oyster Point Pharma Inc. v. Controller of Patents and Designs*¹¹², while setting aside the rejection order, the Calcutta High Court held that the Controller should have considered the details of the experiments conducted, comparative studies made, and their conclusive results to determine efficacy, which was submitted at a later stage of the prosecution. This decision was

¹¹⁰ C.A. (COMM.IPD-PAT) 6/2021

¹¹¹ (T) CMA (PT) No.33 of 2023

¹¹² AID NO.10 of 2022

upheld by the Delhi High Court in *Ischemix LLC v. Controller of Patents and Designs*¹¹³, wherein the court held that in the pharmaceutical industry, a drug could be undergoing clinical trials for a new form at the time of filing of the patent application. Given the complexities and lengthy nature of the process for drug development, empirical evidence may not be readily available to the applicant at the time of filing a patent application. Therefore, additional data submitted at later stage should be accepted.

In *Mr. Tony Mon George Constituted Attorney of ABBVIE Inc. v. Deputy Controller of Patents & Designs*¹¹⁴, the Madras High Court held that the claimed invention, which relates to polymorphic forms of a parent compound (RTA-408), which was made known to the public after the priority date of the claimed invention, does not qualify as a 'known substance' for purposes of Section 3(d).

In *Frito-Lay Trading Company-Gmbh v. Assistant Controller of Patents & Designs*¹¹⁵, the Madras High Court held that the Controller misdirected himself in concluding that the claimed formulation is only a combination of two types of salts with a varied degree of primary particle sizes, with the particles exhibiting their own properties. The court believed that the Controller had failed to see that the Appellant had clearly exhibited considerable sodium level reduction, and thereby a synergistic effect, and remanded the matter for reconsideration.

Recent Patent Office Trends

Recently, judicial guidance seems to have influenced how the Controllers at the Indian Patent Office assess chemical and pharmaceutical patent applications. Some Controllers have started adopting a more reasoned and balanced approach in line with judicial standards, particularly when evaluating objections under Section 3(d).

One such example is the patent for "Solid Oral Formulation of Utidelone" (IN 555915), which faced a pre-grant opposition from the Indian Pharmaceutical Alliance. The opponents raised objections under Section 2(1)(ja) (lack of inventive step), Section 3(e) (mere admixture), and Section 3(d). The claimed invention related to a solid oral formulation comprising Utidelone and pharmaceutically acceptable excipients. After a detailed examination, the Patent Office concluded that the claims were novel, involved an inventive step, and were not barred by Sections 3(d) or 3(e). The Controller also observed that the formulation demonstrated improved drug release and increased bioavailability, which constituted a technical advancement over prior art. It was further held that the claimed formulation was not a known substance under Section 3(d), exhibited a synergistic effect, and was not a mere admixture. Thus, the Controller defeated the pre-grant opposition and allowed the patent.

In 2419/DELNP/2011, the Indian Pharmaceutical Alliance again filed a pre-grant opposition on grounds including lack of inventive step and non-patentability under Sections 3(d) and 3(e). The claims pertained to diethyl-[6-(4-hydroxycarbamoyl-phenylcarbamoyloxymethyl)-naphthalen-2-yl-methyl]-ammonium chloride, or its pharmaceutically acceptable salts and/or solvates, proposed for treating Philadelphia-negative myeloproliferative syndromes, at a daily dosage of 50 to 150 mg. The Patent Office held that the claimed subject matter was a product

¹¹³ C.A.(COMM.IPD-PAT) 33/2022&I.A.23186/2023

¹¹⁴ (T) CMA (PT) No.150 of 2023

¹¹⁵ (T) CMA (PT) No. 202 of 2023

per se and thus fell outside the scope of Section 3(e), thus rejecting the associated ground of opposition. Additionally, it was found that prior art references failed to teach or suggest the claimed compound at such a therapeutically effective and significantly lower dosage. Based on the efficacy data and improved tolerability compared to that of the prior art, the Controller concluded that the objection under Section 3(d) was not maintainable, and the patent was accordingly granted.

These examples reflect a positive trend toward merit-based, balanced examination at the Patent Office, in line with judicial reasoning and India's public health commitments.

Conclusion

India's approach to chemical and pharmaceutical patent applications reflects a delicate equilibrium in fostering innovation and addressing public health requirements. Through provisions like Section 3(d), India has crafted a distinctive legal standard that prevents unjustified patent extensions while still leaving room for novel drug discoveries to receive protection. Recent judicial decisions and evolving trends at the Patent Office indicate a growing emphasis on transparency, procedural fairness, and scientific evidence. Going forward, the real challenge will be to maintain this delicate equilibrium: encouraging pharmaceutical research and attracting global investment, without compromising affordable access to essential medicines.

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