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ANNOUNCEMENTS

Hot Topics in Chemical & Biotech Patent Practice Web Series

On April 2-3, 2025, the Chemical Practice and Biotechnology Committees provided a highly successful two-day CLE web series moderated by Committee Chair Ali Anoff and Professional Programs Subcommittee Co-Chair Tom Irving.

2025 Spring Meeting

The 2025 AIPLA Spring Meeting will be held May 13-15, 2025 in Minneapolis, Minnesota at the Hilton Minneapolis Hotel. Meeting Registration can be found here. Book your hotel room by May 6 to receive the discounted rate here.

Joint Cocktail Reception at the 2025 Spring Meeting

During the Spring Meeting, the Chemical Practice Committee, Biotechnology Committee and Food & Drug Committee are co-sponsoring a cocktail reception on Wednesday, May 14 from 5 to 6:00 pm at the Hilton Minneapolis, Marquette IX, 2nd Floor. Come and have a few drinks and get to know your fellow members! Please RVSP to lsmalley@harrisbeachmurtha.com.

Committee Quarterly Calls

The next Committee calls are scheduled for July and September 2025. Details on dates, times, and agendas will be shared via the Chemical Practice Committee microsite prior to the events.

2025 Annual Meeting

The 2025 AIPLA Annual Meeting moves back to the heart of Washington, DC. This year's Meeting will be held October 30 to November 1, 2025 at the Westin Hotel between Gallery Place, City Center and the Convention Center. Hotel reservations can be made here.

2026 Advanced Chemical Practice Institute

In conjunction with the 2026 Spring Meeting in San Francisco, the Chemical Practice and Biotech Committees will hold an Advanced Chemical & Biotech Patent Practice Institute. The Committee is seeking volunteers to present on chemical practice topics and help plan the event. If you are interested in volunteering, contact Vice-Chair Josh Goldberg at JGoldberg@Nathlaw.com.

The 'long-arm' of the Unified Patent Court – New developments in European cross-border patent litigation

By: Ulrike Herr and Heike Röder-Hitschke[1]

Abstract

The jurisdictional reach of the Unified Patent Court (UPC) was a widely and controversially discussed topic from the outset. Some practitioners took the view that the UPC also benefits from the so-called 'long-arm' jurisdiction, meaning the court being able to impose remedies relating to acts of infringement of the national parts of European patents in countries that are not in the European Union (EU) but are members of the European Patent Convention (EPC). This could apply for example to countries such as Norway, Switzerland, Turkey and the UK. In its landmark decision Fujifilm v Kodak, the Düsseldorf Local Division of the UPC ruled that it also has jurisdiction over infringement actions concerning the UK part of a European patent. In this article, we explain the background to and potential impact of this judgment and will comment on the most recent decision from the Court of Justice of the European Union (CJEU) in BSH Hausgeräte vs. Electrolux, which 'confirms' the Düsseldorf approach and thus the greater powers of the UPC, but also expands on it with respect to national courts and patents in non-EU countries.

I. The jurisdictional regime of the Brussels I*bis* Regulation

The so-called 'Brussels I*bis*' Regulation[2] (hereinafter also 'the Regulation') is one of the most notable and significant pillars of European law of international civil procedure containing, inter alia, a comprehensive jurisdictional regime. It becomes relevant for cross-border cases in the EU having a link to more than one EU Member State (EU-MS), although it is not limited solely to intra-EU cases.[3]

The general rule:
'There must be a connection between proceedings to which this Regulation applies and the territory of the Member States. Accordingly, common rules of jurisdiction should, in principle, apply when the defendant is domiciled in a Member State.' (Recital (13) of the Brussels Ibis Regulation)

According to Article 4(1) of the Brussels I*bis* Regulation, a defendant domiciled in an EU-MS shall be sued in the courts of that MS. It also applies to patent infringement proceedings and allows the patent proprietor to sue an EU-domiciled defendant for multistate infringement of

[1] Ulrike Herr, German and European patent attorney and UPC representative, and Heike Röder-Hitschke, attorney-at-law and UPC representative, are with the intellectual property law firm of Maiwald in Munich, Germany (https://www.maiwald.eu/).
[2] REGULATION (EU) No 1215/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2012, on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (recast), OJ L 351 20.12.2012, p. 1, recast of 26.02.2015.
[3] CJEU of 01.03.2005 – C-281/02 – *Owusu*, marginal no. 31; see also Kalden (presiding judge of the second panel of the UPC Court of Appeal), GRUR Patent 2023, 178, 182, marginal no. 48.

the proprietor's patents, thus enabling it to bring all infringement claims before a single court and to obtain comprehensive relief from a single forum.

This universal jurisdiction is, however, subject to other provisions of the same Regulation: Article 24(4) of the Regulation grants exclusive jurisdiction over patent validity to the national courts of the EU-MS in which the patent is registered or validated, irrespective of whether the issue is raised by way of an action or as a defense and regardless of the domicile of the parties. The same applies to European patents validated in an EU-MS (Article 24(4) subpara. 2).

With respect to non-EU-MS (third countries), Articles 33 and 34 of the Brussel I*bis* Regulation determine the conditions under which the EU court seized (having jurisdiction based on Article 4) may stay, dismiss or even continue the infringement proceedings in case of *lis pendens*, i.e., if revocation proceedings regarding the same patent and parties or otherwise related proceedings are already pending before the courts of a third country at the time a court of an EU-MS is seized.

The UPC – a 'common court' to several EU-MS

The same jurisdictional regime applies to the UPC: the international competence of the UPC is defined in Art. 31 UPC Agreement (UPCA), which refers to the Brussels I*bis* Regulation and the Lugano Convention[4]. In addition, according to Article 71a(2)(a) of the Brussels I*bis* Regulation, the UPC is a 'common court' and shall be deemed to be a court of an EU-MS with the result that it has jurisdiction where the court of a Contracting Member State of the UPCA (UPC-CMS) would have jurisdiction under the Brussels I*bis* Regulation in a matter governed by the UPCA (Article 71b(1) of the Regulation).

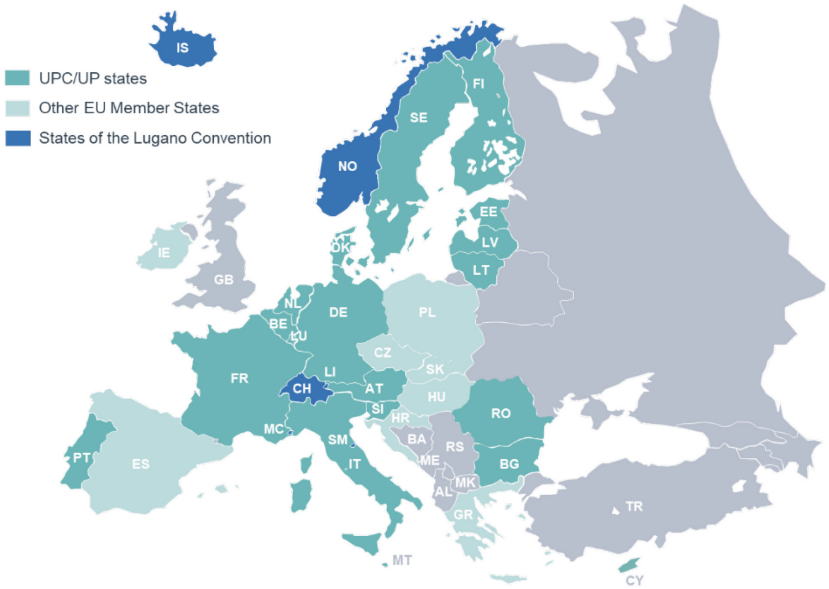


Fig. 1 – States applying the Brussels I*bis* Regulation Regime as of March 31, 2025.

However, the application of these – in themselves quite clear – rules of jurisdiction has raised several further questions in practice, particularly with regard to the jurisdiction of the

[4] Convention on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, done at Lugano on 30.10.2007, including any subsequent amendments; signed by Denmark, Island, Norway and Switzerland.

European courts when (1) a validity defense is raised in patent infringement proceedings and (2) when the subject matter of the infringement proceedings is also a patent also granted in third countries. These questions were answered in the first few months of this year in landmark decisions by both the UPC and, in particular, the CJEU.

II. The UPC's decision of January 28, 2025, case UPC_CFI_355/2023 *(Fujifilm Corporation vs. Kodak GmbH et al.)*[5]

On January 28, 2025 – and thus shortly before the CJEU decision in *BSH Hausgeräte v. Electrolux* (which we will discuss in the next chapter) – the Düsseldorf Local Division of the UPC issued a widely debated decision as regards jurisdiction of the UPC over infringement actions concerning countries with validated national parts of a European patent, which countries, however, are not Contracting Member States of the UPCA (UPC-CMS).

Background: FUJIFILM Corporation (plaintiff) sued three German entities of Kodak (defendants) for infringement of EP 3 594 009 directed to lithographic printing plate precursors; the patent was still in force in Germany and the United Kingdom. No opposition was filed at the EPO, nor was any national revocation action pending at the time the infringement action was filed. The defendants sought revocation of the German part of the patent by means of a UPC counterclaim for revocation. However, revocation (on a national basis) was not sought for the UK part of the patent at the time of the decision. Regarding the UK, the defendants lodged a preliminary objection against the jurisdiction of the Court. The Court decided to handle this objection as part of the main proceedings so that it would have the Advocate General's opinion(s) in the CJEU case *BSH Hausgeräte v. Electrolux* at hand.

Key findings: The Düsseldorf Local Division ruled that it has jurisdiction on infringement of the UK part of a European patent, at least if the defendant is domiciled in a UPC-CMS. Moreover, the court assessed the validity of this patent as a preliminary issue to the infringement – and rejected it on the basis of EPC law – although no objection of invalidity was raised with regard to the UK part, nor, as the court itself stated, would it have jurisdiction to make a final decision on the legal validity of the UK part. The Court found that '*even if the Court cannot decide on the validity of the UK part of the patent in suit, and certainly cannot revoke that part, the infringement action cannot be successful in such a factual and legal situation*'. The Court further assumed that the result of the validity assessment for the German part of the European patent in suit, e.g. the ground for invalidity, also applies to the UK part and stated that '*it would have been up to the Claimant to comment specifically on the differences between Contracting Member States and the UK and to explain why these (possibly) lead to a different assessment of the validity of the UK part of the patent in suit. The Claimant has not done so.*'

Differences in the substantive law between the UPC-CMS and the non-EU-MS that led to a different assessment of the validity of the part of the patent in a non-EU-MS, such as the UK

[5] LD Düsseldorf, UPC_CFI_355/2023 ACT_578607/2023 of 28.01.2025 (https://www.unified-patent-court.org/sites/default/files/files/api_order/CC5DDB59B23C4060B18ADA327BFB5640_en.pdf).

part, the UPC assumes that the result of the validity assessment, e.g. the ground for invalidity, also applies to the parts of the patent in non-EU-MS, such as the UK part.

Takeaway:

The UPC's long-arm jurisdiction extends to all EPC Member States. Provided the defendant is domiciled in a UPC-CMS, the UPC is also competent to rule on infringement of a European patent in a non-EU-MS, such as the UK.

Validity can be considered incidentally even if not challenged. Validity is a prerequisite for any order for relief resulting from the infringement of the patent in suit. Although the UPC has no jurisdiction to rule on validity of third country patents, validity of such patents under EPC law can and needs to be discussed also regarding third countries in this regard, which ultimately could be seen as an assessment on validity. However, such 'assessment" for the purpose of the decision on infringement will only have effect *inter partes*.

The burden of proof for different validity considerations lies with the plaintiff. It is up to the claimant to explain that there are differences as regards validity assessment of different parts of a European patent between UPC-CMS and third countries, such as the UK.

III. The CJEU's decision of February 25, 2025, case C-339/22 *(BSH Hausgeräte GmbH vs. Electrolux AB)*[6]

On February 25, 2025, the CJEU issued its much-anticipated decision on the international jurisdiction of EU courts covering two aspects: whether an EU court seized has jurisdiction on validity of a patent registered for another EU-MS, and whether Article 24(4) of the Brussels I*bis* Regulation is to be interpreted to the effect that an EU court has jurisdiction over disputes concerning patents granted for third countries.

Background: BSH Hausgeräte GmbH (BSH), a company incorporated under German law, filed an infringement action for alleged infringement of all national parts (Germany, Greece, Spain, France, Italy, the Netherlands, Austria, Sweden, the United Kingdom and Turkey) of European patent EP 1 434 512, which related to vacuum cleaners, against Electrolux AB, a company incorporated under Swedish law, before the competent Court in Sweden. BSH sought an order requiring Electrolux to cease using the patented invention in all countries in which the same European patent had been validated and for Electrolux to be ordered to pay equitable remuneration and damages for the allegedly unlawful use of that invention. Electrolux counterclaimed against the validity of the patent and argued that the Swedish court lacked jurisdiction over infringement and validity of the non-Swedish parts of the patent in suit.

In the first instance decision, the Swedish court declared that based on Article 24(4) of the Brussels I*bis* Regulation it did not have jurisdiction to hear the action alleging an infringement of patents validated in EU-MS other than the Kingdom of Sweden brought by BSH. It also declared that it did not have jurisdiction to hear the action alleging infringement of the patent validated in Turkey ('the Turkish patent') on the ground that Article 24(4) is the expression of a principle of jurisdiction recognized at international level. Following the appeal of BSH

[6] CJEU (Grand Chamber), C-339/22 of 25.02.2025 (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62022CJ0339).

against this decision, the Swedish Court of Appeal decided to stay the proceedings and to refer three questions to the CJEU for a preliminary ruling:

> (1) Is Article 24(4) of the Brussels I bis Regulation to be interpreted as meaning that the expression '*proceedings concerned with the registration or validity of patents … irrespective of whether the issue is raised by way of an action or as a defence*' implies that a national court, which, pursuant to Article 4(1) of that regulation, has declared that it has jurisdiction to hear a patent infringement dispute, no longer has jurisdiction to consider the issue of infringement if a defence is raised that alleges that the patent at issue is invalid, or is the provision to be interpreted as meaning that the national court only lacks jurisdiction to hear the defence of invalidity?
>
> (2) Is the answer to Question 1 affected by whether national law contains provisions, …, which means that, for a defence of invalidity raised in an infringement case to be heard, the defendant must bring a separate action for a declaration of invalidity?
>
> (3) Is Article 24(4) of the Brussels I bis Regulation to be interpreted as being applicable to a court of a third State, that is to say, in the present case, as also conferring exclusive jurisdiction on a court in Turkey in respect of the part of the European patent which has been validated there?

In the course of the referral proceedings, the Advocate General provided two key opinions, on 22 February 2024 and on 5 September 2024. In his first opinion, the Advocate General addressed the question of the jurisdiction of EU courts over patents within EU-MS (questions 1 and 2) and suggested a narrow interpretation of Article 24(4), allowing the courts to decide on infringement actions while not determining validity, but with an option to stay the infringement proceedings if the validity defense turns out to be serious, pending a decision on validity in the EU-MS where the patent is valid.

In his second opinion (referring to question 3), the Advocate General addressed jurisdictional issues of patents registered in third countries, and discussed three potential solutions: a) EU courts in the defendant's domicile are allowed to rule on validity of third country patents (not preferred); b) Article 24(4) is not applicable to third countries, but in consideration of international law principles that one state cannot interfere with public acts granted by another state, the courts could either decline jurisdiction on validity or stay the infringement proceedings and await a ruling of the third country on validity; c) EU courts can decide on validity of third country patents as an incidental question to determine infringement with *inter partes* effect.

Key findings: In short, the answer of the CJEU to all three referral questions was 'No'.

The CJEU ruled that Article 24(4) of the Brussels I*bis* Regulation must be interpreted as

- meaning that a court of the Member State of domicile of the defendant which is seized pursuant to Article 4(1) of that regulation of an action alleging infringement of a patent granted in another Member State, still has jurisdiction to hear that action where, in the context of that action, the defendant challenges, as its defense, the validity of that

patent, whereas the courts of that other Member State have exclusive jurisdiction to rule on that validity (regarding the first and – at least implicitly – the second question).

- not applying to a court of a third State and, consequently, as not conferring any jurisdiction, whether exclusive or otherwise, on such a court as regards the assessment of the validity of a patent granted or validated by that State. If a court of a Member State is seized, on the basis of Article 4(1) of that regulation, of an action alleging infringement of a patent granted or validated in a third State in which the question of the validity of that patent is raised, as a defense, that court has jurisdiction, pursuant to Article 4(1), to rule on that defense, its decision in that regard not being such as to affect the existence or content of that patent in that third State or to cause the national register of that State to be amended (regarding the third question).

The Court thus followed the Advocate General's recommendation regarding the jurisdiction of the courts over EU-MS patents and confirmed that the exclusive jurisdiction rule of Article 24(4) of the Regulation applies only to questions of validity, but not to infringement. As far as third countries are concerned, the Court follows the third approach discussed by the Advocate General in his second opinion, the implications of which, however, are quite brutal, according to which the EU courts have jurisdiction over infringement actions for patents in third countries and may not make a final decision on the validity of these patents when it is asserted as a defence, but may examine it incidentally as a preliminary matter to the infringement examination and with limited effect only between the parties to the dispute.

Takeaway:

Long-arm jurisdiction of EU courts in cross-border patent litigation affirmed. The individual courts of the EU have jurisdiction over infringement of patents designated to other EU-MS, but also to third countries, provided the defendant is domiciled in the EU, even if validity of the respective patent is challenged.

Global scope of long-arm jurisdiction. The long-arm jurisdiction over infringement cases relates to both European patents and national patents, the latter not being limited to EU designations.

No jurisdiction with respect to validity of patents granted by other EU-MS. In the case of patents designated to other EU-MS, the courts of that EU-MS have exclusive jurisdiction over validity of such patents (Article 24(4) of the Regulation). However, a challenge to validity does not prevent the court seized for patent infringement from continuing with the infringement proceedings – with an *option* to stay the proceedings.

Article 24(4) of the Brussels I*bis* Regulation does not apply to third countries. Subject to other provisions of the Regulation (Article 33 and 34 (*lis pendens*), Article 73 (application of other instruments such as the Lugano Convention or bilateral agreements)), the EU court seized with an infringement action may assess the validity of a third country patent – applying the local law of that country – as a prerequisite to determining infringement. However, such assessment of validity will only have *inter partes* effect due to the international law principle of non-interference.

Long-arm jurisdiction of the UPC extending to all EPC Member States affirmed. Compared to individual courts of the EU, the UPC is only competent to rule on proceedings

relating to European patents and Unitary patents, but not to national patents. Therefore, the 'geographical' jurisdiction of the UPC is limited to the EU and to those third countries that are Member States of the EPC, provided the defendant is domiciled in one of the currently 18 UPC-CMS.

IV. Post-CJEU case law of the UPC

IMC Crétations v. Multi-T-Lock Deutschland et al., Paris Local Division, case UPC_CFI_702/2024[7]

This new CJEU case law has meanwhile been applied and discussed by the Paris Local Division of the UPC in its procedural order issued on 21 March 2025.

Background: IMC Créations sued the Multi-T-Lock German and Swiss entities for infringement of EP 4 153 830, which is validated, inter alia, in Spain (EU-MS, but non-UPC-MS), Switzerland (MS of the Lugano Convention) and the UK (third country). The defendants lodged a preliminary objection with regard to international jurisdiction and competence of the UPC concerning the Spanish, Swiss and UK designations of the patent. Validity of the patent was not raised, either as a defense or in separate national revocation proceedings.

Key findings: The Court came to the conclusion that, in application of the provisions of the Brussels I*bis* Regulation as interpreted in *BSH v. Electrolux*, it is competent to decide on infringement in all these countries: Concerning Spain, EU-MS, and Switzerland, bound by the Lugano Convention, the UPC is competent to decide on infringement and, if deemed appropriate, can stay the infringement proceedings if national revocation proceedings are pending.

As to the UK, the court is competent to decide on infringement and may also decide on invalidity as a prerequisite to infringement, but with *inter partes* effect only.

Note: Although the ruling in *BSH v. Electrolux* only applies to actions against EU-domiciled defendants, the Paris Local Division did not distinguish between the German defendant and the Swiss defendant, in respect of which the Court also has competence and, with respect to the latter, ultimately confirmed its jurisdiction to decide on infringement of a non-UPC-territory part of a European patent by a non-EU domiciled defendant.

Fujifilm Corporation v. Kodak et al., Mannheim Local Division of the UPC, cases 359/2023 and 365/2023

Besides the Dusseldorf case discussed above, two other infringement proceedings between Fujifilm and Kodak are pending before the Mannheim Local Division, both based on different European patents. In both cases, a permanent injunction for, inter alia, the UK is being sought. In contrast to the Dusseldorf Local Division, Mannheim decided on 30 January 2025 to deal with the questions concerning jurisdiction in separate proceedings and stay the decision on infringement until the CJEU decision in *BSH v. Electrolux* has been issued. The decisions in these cases are expected to be delivered soon, but no surprises are expected.

[7] LD Paris, UPC_CFI_702/2024 ORD_11997/2025 of 21.03.2025, https://www.unified-patent-court.org/sites/default/files/files/api_order/1FE75BEBA1EA7637E166B747B0B7C638_fr.pdf.

V. Summary

The CJEU's decision supports centralized multinational infringement proceedings before the courts of the EU, including (to a limited extent) the UPC. It is definitely a game-changer for cross-border patent litigation, extending the long-arm jurisdiction of the UPC to EPC territory, including non-EU countries, and of the national EU courts to a global playground.

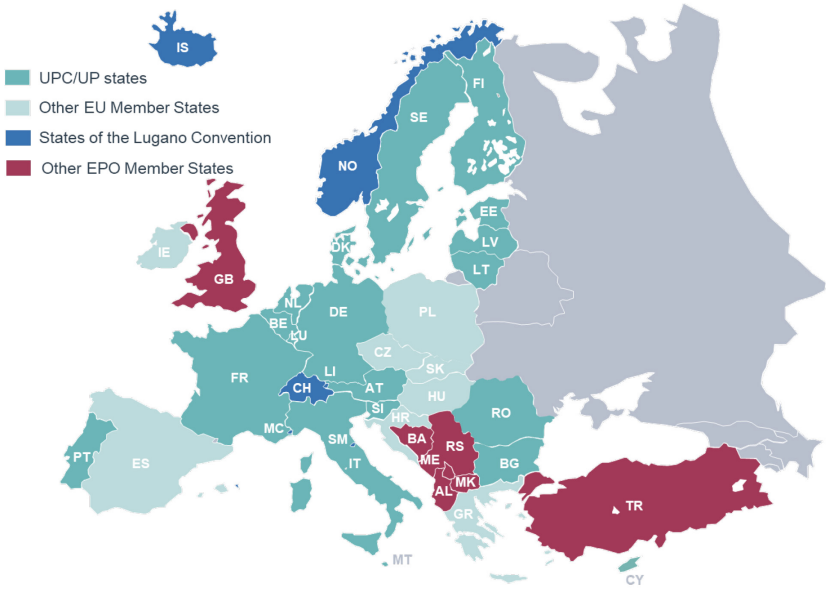


Fig. 2 – States that can be covered by the UPC's long-arm jurisdiction.

The new case law raises strategic considerations and has implications for both claimants and potential defendants:

On the one hand, the UPC is strengthened by the new case law in that it will have comprehensive jurisdiction over the entire territorial scope of a European patent for infringement proceedings. On the other hand, patent owners may wish to reconsider their previous litigation strategy with regard to the UPC if they now have the option of also bringing in effect 'worldwide infringement proceedings' before a single national European court if the infringer is domiciled in the EU. This is because, unlike before the UPC, the national courts of the EU could also assert the infringement of non-European patents, for example from the USA, Brazil, China or India, and thus of entire patent families. This could intensify the already existing competition between the UPC and the national courts.

Patent holders would be well advised to review their European (and probably also worldwide) patent portfolios and, if necessary, also to rethink their patent prosecution strategy. In view of the new possibilities, it could make sense to file several national patents in addition to (if permissible) or even instead of a European patent in order to enforce these (possibly together with the entire patent family) within the framework of the long-arm jurisdiction of the national EU courts.

For potential defendants domiciled in the EU, it will be extremely important to develop (and pay for!) a broad defence strategy if they want to ensure that invalidity arguments are heard and, ideally, lead to a suspension of the infringement proceedings. Ultimately, in particularly important cases, it could come down to filing a corresponding number of revocation counterclaims (with the UPC) or filing separate revocation actions, depending on the number of patents involved in the litigation.

It remains to be seen how these and other, as yet still unanswered, follow-up questions will be judged by the courts. For example, it is still unclear whether, in the case of multiple defendants, the long-arm jurisdiction of the UPC or the EU courts also applies to defendants based outside the EU if one of the other defendants is domiciled in the EU. Furthermore, whether and how judgments for patent infringement in which a decision on validity was made with effect *inter partes* can be enforced and recognized in third countries, whether there is a risk of a new wave of anti-suit injunctions, etc.

For the moment, however, one thing is certain: the latest case law on the jurisdiction of the European courts has also strengthened the UPC, making it a forum for centralized infringement proceedings concerning European patents.

Beijing IP Court Reverses CNIPA Decision and Upholds Ozempic® semaglutide patent in China as VALID based on Novo Nordisk's Post Filing Data

By: Jennifer Che[8]

Recently, all eyes have been on China as the fundamental patent covering semaglutide, the active ingredient in Ozempic® and Wegovy®, will expire on March 20, 2026. It goes without saying that generics are ramping up bigtime in China (and also around the world), preparing to manufacture and sell this blockbuster drug to one of the biggest markets in the world. Any shortening of the patent term for this key semaglutide patent in China could cause an immediately shift in the Chinese Ozempic market (not to mention directly impacting Novo Nordisk).

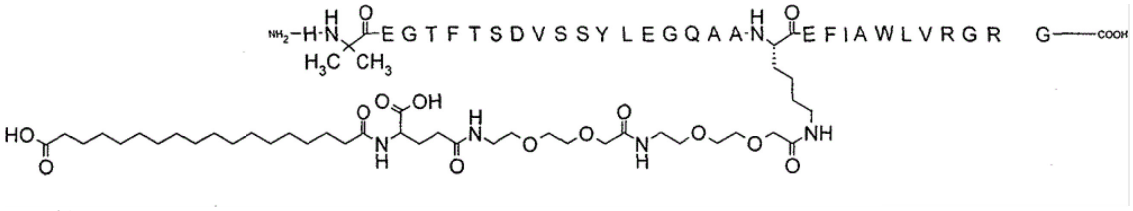
Novo Nordisk's Semaglutide Patent in China

On September 5, 2022, the China National Intellectual Property Association (China's patent administrative office, hereinafter "CNIPA") declared Novo Nordisk's key semaglutide patent in China[9] to be invalid.[10]

The petitioner was Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. ("Huadong"), a Chinese drug manufacturer that currently already sells a generic version of liraglutide, another GLP-1 receptor agonist originally developed by Novo Nordisk. The CNIPA indicated that Novo Nordisk's patent disclosure did not contain any actual experimental data, making it difficult to confirm that all the compounds possessed the surprising technical effects asserted in the specification.
The amended claims at issue[11] claimed a single compound (semaglutide), compositions comprising the compound, and preparations of a medicament comprising the compound for treating a variety of different medical conditions (e.g., hyperglycemia, diabetes, IBD, etc.).

Translation of amended claim 1 (which refers to semaglutide)

1. A compound, wherein said compound is



N-ε[26]-[2-(2-[2-(2-[2-(2-(2-[4-(17-carboxyheptadecanoylamino)-4(S)-carboxybutanoylamino]ethoxy)ethoxy]acetylamino)ethoxy]ethoxy)acetyl][Aib8, Arg34]GLP-1-(7-37) peptide.

[8] Jennifer Che is a Principal at Eagle IP
[9] ZL 200680006674.6
[10] Invalidation Decision No. 57950
[11] Based on the amended claims from an earlier invalidation case brought by Hangzhou Jiuyuan Gene Engineering Co., Ltd and decided on 8 Apr 2022, which were ruled to be partially invalid by the CNIPA.

Novo Nordisk submitted significant evidence in the form of post-filing experimental data showing that semaglutide had increased half-life and a longer duration of action when compared with liraglutide, the closest prior art.

Nevertheless, despite the amended claim scope and post-filing data, the panel of 3 judges concluded that the patent was entirely invalid. The data itself was compelling and showed improvement over the closest prior art (liraglutide). However, the CNIPA argued that the technical effect about the longer duration of action "could not be obtained from the specification as originally filed."

Novo Nordisk appealed to the Beijing IP Court, which reversed the CNIPA's invalidation and upheld the patent.

In order to fully understand the nuance of the Beijing IP Court's decision and rationale, we provide first a brief "primer" about post-filing data in the patent world.

Post-Filing Supplemental Data: why this is such a hot topic

One of the biggest concerns amongst life science patent attorneys with regards to China has been **post-filing data**; more specifically, about China's lack of flexibility in accepting it. In general, China is notoriously strict about experimental data requirements in patents, especially in fields that are "unpredictable", such as biology, chemistry, and the like. Patent applicants typically can only obtain a scope of protection tightly around aspects of their invention that they have "proven" through working examples.

Contrast this to other jurisdictions, like the US and Europe, which usually allow broader scopes of protection based on less number of working examples. Furthermore, jurisdictions like the US and Europe are more lenient when it comes to allowing patent applicants to rely on data generated *after the patent filing* to help support a broader claim scope after-the-fact. As a result of this difference, most patentees get much narrower patents in China compared to the US and Europe, at least in "unpredictable" fields such as the life sciences.

In 2021 the United States and China signed Phase One of the US China Economic and Trade Agreement. Under this agreement[12], China agreed to update its patent laws to "permit pharmaceutical patent applicants to rely on supplemental data to satisfy relevant requirements for patentability, including sufficiency of disclosure and inventive step."

While China had been accepting post-filing data under certain circumstances prior to 2021, in the 2021 Examination Guidelines, China further solidified the instructions for Examiners to consider post-filing supplemental data. Specifically, Part 2 Chapter 10 Section 3.5.1 of the

[12] Article 1.10: **Consideration of Supplemental Data**
1. China shall permit pharmaceutical patent applicants to rely on supplemental data to satisfy relevant requirements for patentability, including sufficiency of disclosure and inventive step, during patent examination proceedings, patent review proceedings, and judicial proceedings.

current Examination Guidelines stipulates that Examiners shall consider post-filing supplemental data when considering inventive step[13] and sufficiency[14]
if the technical effect demonstrated by the supplemental data could undoubtedly be obtained by a skilled person in the art from the disclosure as **originally filed.**

The Examination guidelines provided several helpful examples to demonstrate how Examiners should treat post-filing data (we've written a more extensive article about these examples in the blog post available here: https://chinapatentstrategy.com/chinas-newest-examination-guidelines-post-filing-supplemental-data-for-compounds-part-i/).

Novo Nordisk's Post-Filing Data

As we saw from above, Novo Nordisk had mountains of data on semaglutide, most of it probably generated after the original patent application was filed. The Beijing IP Court had to decide whether to accept this data. The key question centered upon: what is the standard for "could undoubtedly be obtained by a skilled person in the art from the disclosure as originally filed"?

What was in the Disclosure as Originally Filed?

The patent disclosure described a genus of compounds that were effective as GLP-1 receptor agonists. Notably, there were 22 actual example compounds that were described specifically with their preparation methods and characterization data, including semaglutide. The patent disclosure described screening studies using db/db mice and minipigs. However, it did not specify which GLP-1 compound(s) were used in these screening studies.

Semaglutide Patent in China Rejected for Lack of Inventive Step

During the invalidation, all claims were rejected for lack of inventive step (Article 22.3), in view of the closest prior art, liraglutide. Although the two compounds were not identical, they shared a lot of common molecular structures. The CNIPA argued that one of skill in the art would expect that semaglutide would behave similarly to liraglutide, given their similar structure and their similar mechanisms of action.

Nova Nordisk argued that semaglutide had surprising technical effects that were markedly improved over liraglutide, pointing to post-filing comparison data showing semaglutide's significantly improved half-life (60-70 hours in minipigs) and long duration of action (48 hours in db/db mice) compared to liraglutide (24 hours).

As the original specification did not specify which compounds possessed the above-mentioned surprising effects, (and thus no mention of **semaglutide** specifically having such technical effects), the CNIPA opined that the effects demonstrated by the supplemental data "could

[13] Article 22.3 of the Chinese Patent Law: Inventiveness means that, as compared with the prior art, the invention has prominent substantive features and represents an obvious progress, and that the utility model has substantive features and represents a progress.
[14] Article 26.3 of the Chinese Patent Law: The description shall contain a clear and comprehensive description of the invention or utility model so as to enable a person skilled in the relevant field of technology to carry it out; where necessary, drawings shall be attached to it. The abstract shall state briefly the main technical points of the invention or utility model.

not be undoubtedly obtained by a skilled person in the art from the disclosure as originally filed".

The Beijing IP Court's Reasoning

Long Duration of Action

However, the Beijing IP Court sided with Novo Nordisk, agreeing that the patent disclosure as originally filed did possess sufficient support for the idea that semaglutide had a long duration of action. Specifically, the Beijing IP Court pointed to paragraph [0534] in the specification, which stated:

> [0534] In one aspect of the invention, the GLP-1 agonist has a duration of action of at least 24 hours after administration to db/db mice at a dose of 30 nmol/kg.

According to the Beijing IP Court, the statement "the GLP-1 agonist" was referring to the entire genus of compounds, and thus was asserting that all the compounds (or at least the 22 examples in the specification) had a duration of action at least 24 hours after administration. The Beijing IP Court judge wrote in a follow up statement about this case, "[a]lthough this technical effect is not specifically described as a technical effect of semaglutide, it can be reasonably inferred that semaglutide has this technical effect since it is a specific compound within the scope of protection of the general formula compound."

In essence, the general statement in paragraph [0534] was strong enough that the technical effect demonstrated by the supplemental data (duration of action after 24 hours) could undoubtedly be obtained by a skilled person in the art. The court emphasized that if a patentee has already demonstrated that a general formula has a particular effect, then it can be presumed that all the compounds within the general formula have this effect. In this case, the patentee should have the right to submit post-filing data to confirm the effects of a specific compound within the general formula. Otherwise, if this was not allowed, the patentee would need to recite the results of each specific compound in the original specification, which would not be reasonable nor practical.

Prolonged Half Life

The Beijing IP Court contrasted the above case to the other study using minipigs on prolonged plasma half-life. Below is an English translation of two other paragraphs from the specification (emphasis added):

> [0543] One aspect of the present invention is the preparation of GLP-1 analogues/derivatives with prolonged plasma half-life suitable for weekly administration. Pharmacokinetic properties can be assessed in minipigs, or domestic pigs as described below.
>
> [0550] A second part of the pharmacokinetic screening was conducted on those compounds with an initial terminal half-life of 60-70 hours or more. This screening consisted of a single dose intravenous and subcutaneous administration of 2 nmol/kg to six minipigs for each route of administration. […]

The Beijing IP Court argued that in the study using minipigs, the specification did not clearly indicate *which* GLP-1 analogs have the technical effect of having a longer half-life. Instead, the property of having "an initial terminal half-life of 60-70 hours or more" was recited ***as the conditions required*** for a second screening rather than recited **as technical effects** in paragraph [0550]. The judges argued that, based on the conditions stated in paragraph [0550], one of skill the art would not be able to infer that semaglutide could be suitable for the second part of the screening, and there was no way for one of skill in the art to know undoubtedly that semaglutide would possess the technical effects of having a half-life of 60-70 hours or more. As a result, the post-filing supplemental data regarding increased half-life was not accepted by the court.

Since Novo Nordisk only needed to demonstrate that semaglutide had improved properties over liraglutide with respect to one aspect (duration of action > 24 hours), the patent was upheld based on the admissibility of the post-filing data.

Eagle IP Thoughts: semaglutide patent in China

This is a HUGE case for so many reasons. The sheer importance of the product, the economic and legal impact of the decision, and the fine line the Court ultimately drew to clarify China's position on post-filing supplemental data make this a fascinating case to study.

At a minimum, this case broadens the standard for what types of statements in a specification could be sufficient to demonstrate that an idea can be "undoubtedly obtained" from the disclosure as filed. Importantly, in this case semaglutide was never specifically called out as having significantly good PK properties. Instead, the specification held a general position that the compounds (*implicitly all the compounds*) had a >24 hour duration of action.

Drafting Strategies

For patent practitioners, the ability to have this additional "hook" based on generic language could be a lifesaver in a lot of situations. Astute patent drafters should consider carefully what types of general statements asserting technical effect they wish to add. A general statement that's not entirely true (and unsupported by data) could be fatal, while a general statement that is true could literally save the life of a patent (as it did in this case). Be careful making statements that imply only a subset of compounds have a certain technical effect (unless it's true and supported by data).

To hedge against future inventive step challenges, consider adding "hooks" describing as many different and unique properties of a lead molecule as possible. For example, one could add physical properties, PK properties, efficacy data in various models, and more. For any of these unique features that may help distinguish the to-be-patented product from the prior art, try to provide at least one method of testing that feature. It's hard to know what type of data is needed to overcome unexpected prior art. Having the "hooks" makes it much easier to submit post-filing data to demonstrate inventiveness over the cited reference.

What If . . .

It begs the question, though. What would happen if Huadong were able to show that some of the compounds in the group of 22 examples did not have such property? Would that negate the statement entirely? In the case above, would the other compounds showing negative

results negate the general statement, and thus remove the support for the surprising effects of semaglutide? Would the court still accept semaglutide's good post-filing data in this case?

This case isn't completely over yet. Huadong has appealed to the Supreme People's IP Court. March 20, 2026 is still some time away, but we expected to hear a final decision before the patent expiration date. As always, we are watching this case closely and will report updates as soon as we hear more.

European Patent Office Requirement to "adapt" description to allowable claim set (and to potentially rewrite the entire description) may be history

EPO BoA T 56/21 (F. Hoffmann-La Roche AG) of October 4, 2024

By: Dr. Holger Tostmann[15]

In a requirement unique to the European Patent Office (EPO), the EPO Examining Divisions regularly require that the applicant *"adapts"* the description to an allowable claim set. In recent years, in particular based on amendments to the EPO's *Guidelines for Examination*, this has led to lengthy and costly exercises of rewriting significant parts of the description, unnecessary rounds of discussions with Examiners, and to a string of contradictory case law.

No other relevant jurisdiction known to the author forces the applicant to comprehensively rewrite the description (i.e. the originally filed disclosure) once an allowable claim set has been agreed upon. While the requirement for the *claims* to be clear and concise (or to not be *"indefinite"*) can be found in all major jurisdictions, a requirement that the *description* needs to be amended, prior to grant, in order to remove supposed "inconsistencies" between the claims and the description is exclusive to the EPO. Supposedly, this requirement is meant to *"help"* first instance courts that have to decide on infringement of the granted EP patent.

In fact, the fact that the description of an EP patent may be quite different from the description of an US counterpart (in the same patent family) may lead to unnecessary inconsistencies in post-grant proceedings in the US when interpreting claims based on the description.

Without going into the details of the case law controversy that has ensued, one aspect that is particularly annoying to applicants shall be highlighted: Examiners often introduce language from their end (or request that the applicant introduces language into the description) that explicitly states that certain embodiments are *"not part of the invention"*.

Obviously, making such a statement, if even possible, is risky for the applicant and the applicant will either push against this requirement or obviate the problem by simply cancelling the respective passage of the description.

In good news, EPO Board of Appeal Decision **T 56/21** of October 4, 2024 may signal the beginning of the end of this strict practice.

The case underlying T 56/21 was subject to anticipatory discussions by the IP community interested in European Patent Law since

(a) the Board had initially indicated to refer the question of whether it can be required from the applicant to *"adapt"* the description to allowable claims to the **Enlarged** Board of Appeal, i.e. the highest EPO instance, and

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(b) some commentators had expected that the question in this Decision may be combined with the more fundamental questions underlying the referral **G 1/24,** i.e. the question whether it is (even) allowable to resort to the description to *"interpret"* claims that in themselves are perfectly clear.

In the end, the Board 3.3.04 has decided to not refer any questions to the Enlarged Board of Appeal, but rather concluded on its own that there simply is no basis in the EPC to request that the applicant somehow *"adapts"* the description to an allowable claim set. The Board also has provided extensive *(orbiter dictum)* comments in regard to the question of whether or not the description should play a significant role in interpreting the claims, highlighting the *"primacy of the claims"* and generally stating *"reservations"* about using the description to interpret the claims for the purpose of *examining* an application.

Irrespective of the fact that no referral has been made and that this Decision has not been combined with the broader referral question G 1/24, the Decision is important and carries weight, not the least because an extensive discussion of the existing case law in regard to the questions regarding claim interpretation outlined above is provided, which cannot be easily ignored (however, the EPO is just doing that: Seemingly, according to an internal directive, the EPO Examiners are advised to not take this Decision into account when requesting that the description is amended to allowable claims).

The IP Commentariat and the IP Blogosphere have eagerly taken up the Decision and generally express the hope that this Decision will eventually lead to the demise of the current strict EPO requirements to *"adapt"* the description to an allowable claim set.

The Reasons for the Decision T 56/21 are essentially divided into two separate segments. Under items # 1 to 52 of the Reasons for the Decision, the Board of Appeal more fundamentally examines whether **Art. 69 EPC** [essentially stating that the description must be considered when interpreting the claim and setting limits how far this (re)interpretation of the wording may go] has any role to play in examination (before grant) and comes to the conclusion that there is no need or purpose to determine (or worry about) the *scope protection* of the claims during examination.

In fact, according to the Board, for the **examination** of patentability of an application, the *reference point* is the *prior art* and no determination of the scope of protection is required while, when assessing **infringement** of a patent after grant, the *"extent of protection"* conferred by the claims is relevant, which is then determined *in view of the infringing subject-matter*, which, in the Board's view, is an entirely different question (see item # 15 on page 10 of the Decision referring, among others, to G 1/98)[16].

The Board of Appeal's conclusions in regard to this question can be summarized as follows (see Reasons, # 52; highlighting added):

> *(a)* […].
>
> *(b)* *The assessment of clarity and of support of the claimed subject-matter by the description* [i.e. examining the requirements of Art. 84 EPC] *before grant of a*

[16] In fact, the practice of the national European courts and of the Unified Patent Court (UPC) is to <u>always</u> consider the description for claim interpretation, even if the claims are clear in themselves.

patent is a matter distinct from determining the extent of protection conferred by granted claims after grant. It is the purpose of the assessment of Article 84 EPC as part of the examination of patentability to arrive at a definition of the patentable subject-matter in terms of distinctive technical ***features distinguishing it from the prior art****.*

(c) […].

(d) ***Article 69 EPC and the Protocol are not concerned with the "interpretation" of claims in the sense of claim construction****, i.e. determining the meaning of the terms of a claim and its subject-matter for the purpose of assessing patentability. These provisions do not therefore provide a general methodology for determining the subject-matter claimed for assessing patentability in examination.*

(e) Relying on the description to resolve ambiguities or contradictions in claims of an application ***before*** *assessing their compliance with clarity and support requirements under Article 84 EPC deprives claims of their function as defined by Article 84, first sentence, EPC, and affects the assessment of Article 84 EPC and further requirements for patentability.*

(f) It is not ***the purpose of the examination*** *of European patent applications* ***to anticipate equivalent matter*** *potentially relevant to infringement. Construing claims in a way that extends the subject-matter claimed beyond the strict wording of the claims* ***when assessing patentability*** *distorts this assessment.*

(g) […]*, claims should be construed objectively (not subjectively) based on the* ***usual technical understanding of the features in the context of the claim as a whole*** *(see T 10/22,* […]*).* […]*, the understanding of the disclosure should not replace or add to the definition of the subject-matter in the claims by way of implicit features, but allow for a definition of patentable subject-matter in the claims.*

As mentioned above, these more fundamental questions will be taken up some time later this year in the likely very relevant G 1/24 Decision by the Enlarged Board of Appeal, which may answer some of these questions differently.

The second part of the Decision T 56/21 (items # 53 to 99) then more specifically deals with the question whether the Examining Division can *require* that the applicant *must* adapt the description to allowable claims based on Art. 84 EPC and/or Rule 48(1)(c) EPC. The Board quite summarily answers this question in the negative (see Reasons, # 99, highlighting added):

(a) […]

(b) Article 84 EPC and Rule 43 EPC are not a corollary of Article 69 EPC even though claims are the main determinant of the extent of protection. Consequently, the requirements of Article 84 EPC and Rule 43 EPC are to be assessed separately and independently of considerations of extent of protection when examining a patent application.

> *(c)* ***Article 84 and Rules 43 EPC set forth requirements for the claims. They do not provide a legal basis for a mandatory adaptation of the description to claims of more limited subject-matter.*** *Within the limits of Article 123 EPC, an applicant may, however, amend the description on its own volition.*
>
> *(d) Rule 48 EPC is concerned with the publication of an application and the avoidance of expressions which are contrary to public morality or public order, or certain disparaging or irrelevant statements.* ***Rule 48 EPC does not provide for a ground for refusal based on the inclusion of merely "irrelevant or unnecessary" matter in the description*** *intended for grant and even less for "discrepancies" between the subject-matter claimed and that disclosed in the description.*

The point raised under (d) addresses a specific requirement often put forward by Examining Divisions, which is that *numbered embodiments* sometimes presented at the end of the description must be removed since they are *"superfluous"* or can be confused with the claims. The Board concludes that there simply is no basis in the EPC for such a requirement.

Another important conclusion can be taken from item 102 on page 83 of the Decision, where the Board addresses the argument that harmonization of the practice of the national courts *"requires"* that the description is brought in accordance with the claims. In that respect, the Board holds:

> *However, such harmonisation of the practice of national courts by way of interpreting Article 84 EPC contrary to its wording, is outside of the powers of the EPO (see T 712/10, point 8.2 of the Reasons). If the legislator considers it justified to require that the description be aligned with the subject-matter of claims held allowable, the legislator should provide for the respective legal basis by way of amendment of the EPC.*

Notably, in T 56/21, the Board of Appeal also discusses the landmark Decision by the new European Unified Patent Court (UPC), *NanoString Technologies Inc. et al. vs. 10x Genomics Inc. et al.* which is (among others) concerned about preventing any discrepancy between the subject-matter of the *same patent* in infringement and in nullity proceedings. While this may be sensible or even essential in proceedings before a court dealing with infringement, where both questions of infringement and validity are at issue in parallel, for examination of patentability only, the Board of Appeal has *"reservations"* about interpreting claims in grant proceedings with the intention to determine the *"extent of protection"*, instead of determining the content and meaning of the claims, independently of considerations which scope of protection may be adequate (see item # 51 on page 36 of the Decision). Again, the Board points out that the *"point of reference"* is different for assessing patentability and infringement.

Now turning to **practical advice** to applicants, it will certainly take a while before this Decision and others will be incorporated into the Guidelines for Examination and then into the practice of the Examining Divisions. Also, the outcome of G 1/24 needs to be awaited. However, the catchword of the Decision T 56/21 is so succinct that it seems useful to confront a particularly obstinate Examiner with the same:

> *In examination of a patent application, neither Article 84 nor Rules 42, 43 and 48 EPC provide a legal basis for requiring that the description be adapted to match allowable claims of more limited subject-matter.*

Pragmatically and in order to allow the Examiner to *"save face"*, it is nevertheless recommended to introduce boiler plate sentences into the description that only state the obvious, for example *"the invention is as defined in the appended claims"* or "*examples/embodiments not falling under the claims are provided for reference"*. It is also recommended to copy the wording of claim 1 into the summary of the invention (if that is not already the case from the onset) and to fulfill the other formal requirements that are typically brought forward by the Examiners in regard to the description, such as briefly discussing relevant prior art in the background section or removing any instances of *"incorporation by reference"*. On the other hand, Applicants should resist proposals made by the Examining Division to add statements to the description that certain embodiments are *"not part of the invention"*. If still necessary or if the quick grant of a patent is important, particularly *"offensive"* passages of the description may simply be cancelled.

Arguing Unexpected Results Supported by a Rule 132 Declaration: A "Deep Dive" with *Ex Parte Eidschun*

By: Kimberly Vines[17]

Introduction

Evidence of unexpected results may be used to overcome a 103 rejection. In order to successfully make an unexpected results argument, Applicants must show that differences in properties between the claimed invention and the cited art differ to such an extent that the difference is really unexpected (*see* MPEP § 716.02). Greater than expected results, a superior shared property, the presence of an unexpected property, and the absence of an expected property may constitute an unexpected result.

Because arguments of counsel cannot take the place of evidence in the record, unexpected results arguments submitted to the U.S. Patent and Trademark Office (USPTO) must be supported by the record. Evidence of unexpected results may be included in the Examples of the application as filed. However, because Applicants can only guess, but do not know what prior art the Examiner may cite during prosecution, the examples in the patent application may not be relevant to the references cited in the rejection.

In the absence of evidence of unexpected results being present in the application, a Rule 132 Declaration is the only way to submit experimental data not included in the application as filed for consideration by the Examiner. Specifically, 37 CFR 1.132 provides: "When any claim of an application or a patent under reexamination is rejected or objected to, any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for **must** be by way of an oath or declaration under this section."

Despite the fact that an unexpected results argument supported by a Rule 132 Declaration can overcome a 103 rejection, patent practitioners are sometimes hesitant to use them to advance prosecution for fear that expert or inventor testimonial statements[18] in a Rule 132 Declaration could potentially be used against the patent owner during a future litigation. That danger is much less when submitting post-filing data because the Declaration need only describe the experiments and results. As an added advantage, a Declaration can help establish a legally and factually strong record of patentability (*e.g.*, non-obviousness) during prosecution and can potentially help in avoiding the institution of an inter partes review (IPR) or a post grant review (PGR).

The USPTO released training materials on "Declaration practice under 37 CFR 1.132 (Rule 132),"[19] which can be a useful tool for applicants and practitioners considering filing a Rule 132 declaration. In addition to the basic requirements that a declaration must be timely filed, signed, and include a "willful false statement" clause, the declaration should include the following: a description of what was tested, a description of the test conditions, the test results, and analysis of test results. Regarding the description of what was tested, the declarant must compare the claimed invention with the closest prior art identified by the Examiner, or

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[18] Factual evidence is preferable to opinion testimony during prosecution as well. *See* MPEP 716.01(c), Sec. III
[19] See https://www.uspto.gov/sites/default/files/documents/declaration_practice_under_37_cfr_1_132_.pdf.

prior art that is more closely related to the invention than the art cited by the Examiner. "The test results must include the results of the test performed on the claimed invention and on the closest prior art. Precisely what was done should be recited in the declaration (*e.g.*, the actual steps carried out, the materials employed, and the results obtained). Conclusory statements such as 'the prior art did not perform well,' without a showing of the actual results of the test performed on the prior art and the claimed invention is insufficient."[20]

Ex Parte Eidschun

The Rule 132 Declaration at issue in *Ex Parte Eidschun*[21] is illustrative of a Declaration deemed insufficient to overcome a 103 rejection. In affirming the Examiner's rejection, the Patent Trial and Appeal Board's (PTAB's) reasoning was as follows: (1) the showing of unexpected results was not a comparison to the closest prior art because Windsor Bowen was not sufficiently specific for comparison to the claimed method; (2) it was not explained how the results were unexpected; and (3) the evidence of unexpected results was not commensurate in scope with the claims.

The '133 Application

Application No. 17/161,133 ('133 application) was directed to metal finishing (*i.e.*, anodizing) methods. Simply put, anodizing is a way to protect metallic substrates from corrosion and wear. Unlike a coating that can be applied to the surface, anodization is an electrochemical process used to increase the thickness of the natural oxide layer on the surface of the metal, where the metal (*e.g.*, aluminum) chemically reacts with oxygen to form the oxide layer (*e.g.*, aluminum oxide). The claimed anodizing process includes a combination of an acid and an oxidizing agent.

The anodizing solution of the method of claim 1 includes:

> an acid solution formed from at least one acid selected from the group consisting of sulfuric acid, nitric acid, phosphoric acid, hydrochloric acid, citric acid, boric acid, carboxylic acid, carbonic acid and combinations thereof diluted with deionized water; and
>
> at least one oxidizing agent selected from the group consisting of potassium permanganate, sodium permanganate, hydrogen permanganate, lithium permanganate, sodium orthovanadate and combinations thereof;
>
> wherein the at least one acid is present in the anodizing solution at a concentration of between about 10% w/v to about 20% w/v;
>
> wherein the at least one oxidizing agent is present in the anodizing solution at a concentration of between about 0.01% w/v to about 0.05% w/v.

[20] *Id.* at page 22.
[21] Appeal 2023-003437

The 103 Rejection

The Examiner rejected the claims over Windsor Bowen (GB 396,743) in view of Liao (US 2006/0141751) and/or Yang (US 2011/0171600), in view of Haga (JP H07-074055).

The claims were rejected by the Examiner as being obvious over Windsor-Bowen, which disclosed an anodizing process using an anodizing solution containing sulfuric acid and crystallized sodium sulfate in addition to optionally containing less than 1% of an oxidizing agent that can be sodium nitrate or potassium nitrate, in view of Liao and/or Yang for teaching the use of deionized water, in view of Haga, which disclosed an anodizing process using an anodizing solution comprising about 5–35 wt% sulfuric acid and an oxidizing agent that includes potassium permanganate.

The Examiner concluded that it would have been obvious for a person having ordinary skill in the art before the effective filing date of the claimed invention to have substituted the oxidizing agent of Windsor Bowen with Haga's potassium permanganate.

The Rule 132 Declaration

As highlighted in the training materials, Declarant must compare the claimed invention with the closest prior art identified by the Examiner, or prior art that is more closely related to the invention than the art cited by the Examiner. A Rule 132 Declaration was needed because the examples of the '133 application were not relevant to the rejection of record. The acid solution of Windsor Bowen was an aqueous solution of sulfuric acid and sodium sulfate at a concentration ranging from 22-55% and the sulfuric acid and sodium sulfate were present in a 1 to 3.2 weight ratio. Although the '133 application was supported by numerous examples, the examples of the '133 application are not a comparison with the closest prior art, when the closest prior art is Windsor Bowen. The anodizing solutions of the examples included sulfuric acid, but not a combination of sulfuric acid and sodium sulfate in a 1 to 3.2 weight ratio. To be a proper comparison with Windsor Bowen, the examples must include a combination of sulfuric acid and sodium sulfate in a 1 to 3.2 weight ratio.

In finding that the Rule 132 Declaration was insufficient to overcome the Examiner's rejection, the PTAB concluded that the showing of unexpected results was not a comparison to the closest prior art because Windsor Bowen was not sufficiently specific to allow for a comparison to be drawn to the claimed method.

This was an interesting finding, given that the Rule 132 Declaration did not include an example using the claimed method with which to compare Experiment I, which was performed using the method of Windsor Bowen. As illustrated below, Table 1 of the Rule 132 Declaration only includes Experiment 1 as a comparative example. Rather than provide a showing of unexpected results, Table 1 attempts to show that Windsor Bowen is not enabled, as set-forth in the Appeal Brief.[22]

[22] Appeal Brief, filed on January 23, 2023 (available on the USPTO's Patent Center).

TABLE 1

	Windsor	Experiment 1
Solution concentration	Between 25% to 55%	40%
Solution composition	Ratio of 1:3.2 of sulfuric acid to sodium sulfate	Sulfuric acid 400 g/L Sodium sulfate 1280 g/L Ratio 1:3.2
Oxidizing agent concentration	≤1%	0.1%
Oxidizing agent composition	Na or K nitrate Na or K persulfate Na or K perborate	Na persulfate
Voltage	>80 V DC	90 V DC
Amps	1-5 amps/sq. ft.	Unable to measure due to safety concerns
Temperature	Not given Known in the art to use between 62°F to 68°F	65°F
Substrate type	Aluminum and Al alloys	Aluminum
Processing time	Not given	< 1 minute due to safety concerns

In the Appeal Brief, Appellant argued that Windsor Bowen was not enabled because it does not disclose the temperature or the equipment used for anodization. Given that Windsor Bowen was published in 1933, the type of machinery used for anodizing is different from what is used today. Using modern day anodizing equipment with the parameters (*e.g.*, voltage) disclosed in Windsor Bowen, Experiment 1 failed to produce a coating. In fact, the solution of Experiment 1 boiled within 15 seconds and the wires began to melt! Appellants explained in the Rule 132 Declaration that "the type of equipment used to anodize aluminum in the 1930's was substantially different from that available today, particularly given the current rectifiers used for anodizing aluminum today run at a much lower voltage of around 10-15V DC."[23]

Although the PTAB did not address the non-enablement arguments,[24] Experiment 1 of the Declaration may have served to persuade the PTAB that Windsor Bowen was not properly asserted as the primary reference.

The PTAB only referenced Table 3. What is wrong with Tables 2 and 4?

Appellants asserted unexpected results with respect to conventional anodizing systems currently used to anodize metal substrates. As stated in the application as filed, conventional anodizing systems use sulfuric acid.

[23] Appeal Brief, page 3.

[24] A common losing argument at the PTAB is that a reference used in an obviousness combination is non-enabling. Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, **when filed**, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. MPEP 2164.01. The issue is whether one of ordinary skill in the art in 1933 would have been able to make and use the invention without undue experimentation.

As emphasized in the training materials, post-filing data must include the results of the test performed on the claimed invention (*i.e.*, examples) and on the closest prior art (*i.e.*, comparative examples). **Examples should be encompassed by the claims, whereas comparative examples should not be encompassed by the claims.** Examples and comparative examples should be proper side-by-side comparisons, so that the unexpected result is attributable to the difference between the example and the comparative example.

Table 2 of the Eidschun Rule 132 Declaration includes a proper side-by-side comparison. The "control" represents conventional anodizing and resulted in no coating formation on the surface of the aluminum. Advantageously, the "permanganate additive" example resulted in the formation of a coating. The only difference between the "control" and the "permanganate additive" is the presence of potassium permanganate, so comparison of "control" with "permanganate additive" is a proper side-by-side comparison.

TABLE 2

	Windsor	**Control**	**Persulfate additive**	**Permanganate additive**
Solution concentration	Between 25% to 55%	10%	10%	10%
Solution composition	Ratio of 1:3.2 of sulfuric acid to sodium sulfate	Sulfuric acid	Sulfuric acid	Sulfuric acid
Oxidizing agent concentration	≤ 1%	N/A	0.1%	0.1%
Oxidizing agent composition	Na or K nitrate Na or K persulfate Na or K perborate	N/A	Na persulfate	K permanganate

The PTAB did not address Table 2 in the opinion. This may be because the "permanganate additive" example is not encompassed by the claims. "Permanganate additive" includes 0.1% potassium permanganate, which is outside of the claimed range of 0.01 to 0.05%.

Table 3

In the opinion, the PTAB only referred to Table 3 of the Declaration, and asserted that the Applicant did not explain how the results were unexpected. Table 3 summarized the differences between the claimed methods and the conventional methods. Table 3 did not include any experimental results at all, so no explanation as to why the results were unexpected was needed.

	Current Conventional Anodizing	Claimed System
Solution Concentration	10% to 15%	10% to 20%
Solution Composition	Sulfuric acid	Sulfuric acid

Oxidizing Concentration	N/A	0.01% to 0.05%
Oxidizing Composition	N/A	K permanganate
Voltage	10-15 V DC	10-15 V DC
Amps	18-40 amps/ft^2 (dependent on total surface of substrate)	10-50 amps/ft^2 (dependent on total surface of substrate)
Temperature	Between 62 °F to 68 °F	Between 62 °F to 68 °F
Substrate type	2024, 6061, or 7075 Aluminum	2024, 6061, or 7075 Aluminum

Table 4

Table 4 is a summary of results (processing time, dimensional change, corrosion resistance, abrasive wear, weight of coating, and pore formation/microstructures) for examples prepared by "current conventional anodizing" and the "claimed system" in the application as filed. Table 4 does not include new examples or comparative examples.

As briefly summarized in Table 4, discussed in the application as filed, and discussed in the Appeal Brief (*see* p. 33-34), the examples of the application demonstrate unexpected results as compared with conventional anodizing. Described in more detail below, the examples of the application demonstrate that the claimed methods (*i.e.*, 13.84% sulfuric acid and 0.01-0.02% potassium permanganate) produce coatings having "type III" performance for a "type II" (*i.e.*, thinner) coating – this is the unexpected result. Type II anodizing is often used in general-purpose applications, whereas type III (also referred to as "hardcoat anodizing") uses a more concentrated sulfuric acid solution (*i.e.*, 16-20% for type III versus 8-12% for type II), and a much higher current is applied,[25] resulting in a thicker and harder oxide later. Type III is used in high-performance applications where extra wear resistance is required.

Example 6 describes the salt spray analysis test, where the test specimen (0.0003 in. thickness, "type II") demonstrated superior "type III" corrosion resistance (*i.e.*, 800 h, no pit formation) as compared with a conventionally anodized specimen. In general, test specimens using the conventional anodizing method will have at least 2-3 pits at 336 hours in the salt spray chamber.[26]

Example 7 describes a particularly impressive result in the abrasive wear test. Typically, the taber abrasion test requires a type III coating having ≥ 0.002 in. thickness to pass the test.[27] Two specimens of different thicknesses (*i.e.*, 0.008 in. and 0.0012 in.) were tested. Both test specimens passed, each having around half the coating thickness that is usually required to pass. Applicant went a step further, subjecting both test specimens to a second test. Both test specimens passed the second test, with the wear index of each sample unchanged between the first and second taber abrasion tests.

Example 8 describes a coating weight analysis of type II test specimens having a thickness of 0.0003 in. The average coating weight for the test specimens was 2639.52 mg/ft^2, which is about five times the upper limit required for coatings of that thickness.[28]

[25] US 20210147998 A1, at [0005]-[0006].
[26] *Id.* at [0182].
[27] *Id.* at [0183].
[28] *Id.* at [0191].

The anodic coatings of Example 12 did not show any signs of pore formation or microfractures when examined using scanning electron microscope (SEM). This is in contrast to a standard aluminum oxide coating "that is currently being used in the industry today."[29]

Despite these impressive results, the PTAB did not address Table 4 in the opinion. It is possible that the PTAB may have been confused and believed that the results for "current conventional anodizing" and "claimed system" of Table 4 correspond to the "current conventional anodizing" and "claimed system" of Table 3.

In either the Rule 132 Declaration or the Appeal Brief, there should have been a description of the examples. For instance, how the examples were prepared (*i.e.*, 13.86% sulfuric acid and 0.01-0.02% potassium permanganate) and thickness of the coatings should have been included. In some instances, the comparative example is not tested, but the typical test result is described. For example, as stated in Example 6, samples prepared using conventional anodizing "will have at least 2-3 pits at 336 hours in the salt spray chamber," indicating that the test was not performed for the comparative example. Pursuant to the training materials, in a Declaration, "conclusory statements such as 'the prior art did not perform well,' without a showing of the actual results of the test performed on the prior art and the claimed invention is insufficient." The same may also be true for examples included in the application as filed. Furthermore, the Rule 132 Declaration or the Appeal Brief should have explained why the results were unexpected, restating the explanations included in the examples of the application as filed.

The evidence of unexpected results is not commensurate in scope with the claims

The PTAB alleged that claim 1 encompasses "eight acids alone or in combination and five oxidizing agents alone or in combination, but Table 3 includes only one acid (sulfuric acid) and one oxidizing agent (potassium permanganate)."[30] Practitioners might be tempted to advise the client to either submit additional data or to narrow the claims. However, evidence of unexpected results need only be commensurate in scope with the claims in light of the cited references. If the prior art does not disclose a claimed element, then additional data is not needed because the Examiner has not established a *prima facie* case with respect to the non-disclosed element. Similarly, narrowing claim amendments are not needed.

For example, had Windsor Bowen been considered the closest prior art, there would be no need to need to limit the acids because Windsor Bowen only disclosed sulfuric acid and did not disclose any of the other recited acids. Similarly, regarding Haga, which was cited for teaching that oxidizing agents for anodizing methods may include potassium permanganate, Haga failed to disclose any other recited oxidizing agents, so there would be no need to need to limit the oxidizing agents of claim 1. If Haga is applied as the primary reference, additional examples and/or narrowing amendments would likely be required because Haga discloses other acids.[31]

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[29] *Id.* at [0231].

[30] *Ex Parte Eidschun*, page 6 of the opinion. Table 3 does not describe the anodizing solutions of Table 4, the examples of the application do. Examples 6-8 and 12 include a combination of sulfuric acid and potassium permanganate.

[31] Haga discloses the following acids: H_2SO_4, H_3PO_4, $CH_2(COOH)_2$, oxalic acid, malonic acid, H_2CrO_4, and $Si(OH)_4$, overlapping in some respects with the claimed acids.

Regarding the sufficiency of the examples to claim the ranges, the PTAB also stated that claim 1 includes an acid concentration range of 10-20% and an oxidizing agent range of 0.01-0.05%, but Table 3 does not include any specific concentrations for the acid and oxidizing agent. "Thus, no specific composition within the scope of Appellant's claim 1, particularly, a composition containing 0.01% w/v oxidizing agent, is compared to prior art."[32] The results of the examples are summarized in Table 4, but the compositions are summarized in the application as filed. The PTAB would have a point, if this was correct. As discussed above, Examples 6-8 and 12 all include 13.86% sulfuric acid and 0.01-0.02% potassium permanganate.

Conclusion

Arguing unexpected results supported by either the examples of the application as filed or a Rule 132 Declaration can be effective in overcoming a 103 rejection. The PTAB's decision in *Ex Parte Eidschun* coupled with the Rule 132 Declaration training materials for examiners together provide guidance as to information that should be provided to support an unexpected results argument.

[32] *Id.*

Crystal Clear? Patentability of Polymorphs in Europe and the U.S.

By: Dr. Adam Lacy and Michelle E. O'Brien[33]

I. Introduction

Many of the molecules which make up pharmaceutical agents exist as solids. The relative arrangement of the molecules in these solids can vary significantly. The molecules can be arranged in a disordered manner, in which case the solid is amorphous. Alternatively, they can be arranged in an ordered manner based on a repeating pattern, in which case the solid is crystalline. For some crystals, several different repeating patterns are possible. This is known as polymorphism, and the crystalline solids with different patterns are known as polymorphs, as demonstrated in the diagram below.

Amorphous disordered structure **Ordered crystalline structures**
Polymorph I **Polymorph II**

The phenomenon of polymorphism is highly unpredictable, and it is generally not possible to know whether a particular compound will exist in more than one form:

> "It is sometimes difficult to comprehend why and how new polymorphs still emerge (while others disappear) long after crystal form screens presumably have been completed. ... The point is that it can never be stated with certainty that the most stable form has been found; at best it can be determined which of the known forms is the most stable. ... A new (and most often more stable) form can appear at any stage in the history of a compound (or life-cycle of a drug)."[34]

These various possible polymorphic forms may have different properties and behavior to each other, both during the formulation of the pharmaceutical product, and when it is administered to patients. Many patent applications have been filed to new polymorphs of existing pharmaceutical agents, seeking to rely on these different properties to establish novelty and inventive step or non-obviousness.

II. Validity of polymorph claims in Europe

An analysis of some EPO Board of Appeal decisions in this field show that while many polymorph claims are upheld, it can be difficult to predict whether a given polymorph will be found patentable.

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[33] Dr. Adam Lacy is a European patent attorney with Hoffmann Eitle. Michelle E. O'Brien is a U.S. patent attorney with the Marbury Law Group.
[34] Bučar, D.K.; Lancaster, R.W.; Bernstein, J. Disappearing Polymorphs Revisited. Angew. Chem. 2015, 54, 6972–6993.

A. T 777/08 Atorvastatin

T 777/08 is the landmark case in this field, and is partly responsible for the EPO's reputation for a strict approach on polymorph patentability. During opposition proceedings, the EPO problem solution approach was formulated in the following manner:

- **Closest prior art** was identified as the amorphous form of atorvastatin;
- **Distinguishing feature** was selected as form IV of atorvastatin;
- **Technical effect** of this distinguishing feature was acknowledged as the improved filterability and drying properties of form IV compared to the amorphous form, as demonstrated by comparative evidence on file;
- **Objective technical problem** was formulated as the provision of atorvastatin in a form with improved filterability and drying characteristics.

The only question before the Board was therefore whether, starting from the amorphous form, it would have been obvious to the skilled person to use form IV to achieve these improved filterability and drying properties. At first sight, one might assume that inventive step would be acknowledged. After all, when the objective technical problem is formulated as the provision of an improved property, the EPO would normally reason that obviousness is established only where the prior art motivates the skilled person to select the specific claimed invention to achieve said improved property. In this case, form IV was not even known, so there was no motivation in the prior art to use this polymorph of atorvastatin, and certainly no indication that this form would deliver improved filterability and drying properties.

However, the Board did not follow this line of reasoning. Instead, they based their decision more heavily on the common general knowledge and the likely behaviour of the skilled person with regard to polymorphs. Evidence on file established that the skilled person understood that polymorphism is a common phenomenon affecting pharmaceutical agents. Furthermore, the numerous strict regulations concerning pharmaceuticals actually require manufacturers to investigate whether their pharmaceutical agents exist in polymorphic forms in order to gain marketing approval. The evidence also suggested that the skilled person had several routine methods at their disposal in order to isolate and identify such polymorphic forms, and that it was generally considered advisable in the industry to screen for these early on in product development. Regarding the improved filterability and drying properties relied upon in the objective technical problem, the common general knowledge on file also identified that "*Crystalline products are generally the easiest to isolate, purify, dry and, in a batch process, handle and formulate*" (emphasis added).

Based on this common general knowledge, the Board concluded that "*the skilled person, starting from the amorphous form of a pharmaceutically active compound as closest prior art, would have a clear expectation that a crystalline form thereof would provide a solution to the problem*". Therefore, even though the prior art doesn't specifically teach the skilled person to use form IV, the Board felt that it would have been obvious for the skilled person to investigate this form with a reasonable expectation of success.

Regarding the motivation to select form IV in particular, it was stated that: *The board does not deny that there may be other options for solving the problem posed... However, an arbitrary selection from a group of equally suitable candidates cannot be viewed as involving an inventive step* (emphasis added). Put simply, since the effects of improved filterability and drying might reasonably be

expected to be attained by any crystalline form relative to the amorphous form, form IV was obvious for the same reason that any other crystalline form was obvious.

This landmark decision has been followed multiple times, and sends a clear signal. It is difficult to establish inventive step in the selection of a specific polymorphic form **when the relevant effects are exhibited by all crystalline forms of the pharmaceutical agent**.

B. T 2114/13 Febuxostat

This more recent decision shows how the Board of Appeal is willing to accept that the polymorphic form confers inventive step in some circumstances. The following problem-solution approach was relied upon in the decision:

- **Closest prior art** was an 80:20 mixture of polymorphs A:C obtained when the prior art method was carried out;
- **Distinguishing feature** was that claim 1 is restricted only to polymorph C of Febuxostat;
- **Technical effect** of this distinguishing feature was demonstrated by evidence on file showing that stirring the prior art 80:20 mixture of A:C in the common solvent acetone delivers pure polymorph C, while pure C remains stable in the same conditions;
- **Objective technical problem** was formulated as the provision of Febuxostat with improved stability in the presence of acetone. The patentee persuaded the Board that this leads to the additional effects of improved quality and reliability during the formulation of Febuxostat, on the basis that some formulation processes may involve contact with common solvents such as acetone.

The question before the Board was again whether the use of polymorph C would have been an obvious solution to this objective technical problem. Similar common general knowledge was on file to that in the landmark T 777/08 case above: i.e. that polymorphism is commonplace, regulations already require an investigation of the crystal form used, and routine methods are available for doing so.

At first sight, one might assume that inventive step would not be acknowledged for similar reasons to T 777/08: the skilled person would reasonably expect that one of the polymorphs would be the most stable and screen the various available options to find it. However, the Board did not follow this line of reasoning, instead finding the claims non-obvious because *No guidance can be found in any of the documents as to how a particular crystalline form with **desirable properties** can be obtained in a **targeted manner**.* Here, the approach of the Board is much closer to the usual reasoning applied by the EPO where the objective technical problem is formulated as the provision of an improved property: obviousness is established only where the prior art motivates the skilled person to select the specific claimed invention to achieve the specific improved property.

Why then does this case diverge from T 777/08? In their decision, the Board explains that in the landmark decision *the specific polymorph claimed was found to be an **arbitrary choice from equally suitable candidates**, in view of the skilled person's clear expectation that a crystalline form would have improved filterability and drying properties compared to the known amorphous form. In the present case, the board has **no doubt that not all crystalline forms of febuxostat are equally suitable candidates** to solve the problem of providing a crystalline form with improved*

polymorphic stability. Indeed, the patent in suit also mentions crystalline forms, which are not polymorphically stable… (emphasis added).

Therefore, for the Board the key difference seems to be that the technical effect relied upon in T 777/08 applies to all polymorphs relative to the amorphous prior art, while the technical effect in T 2114/13 is rather restricted to polymorph C, and does not apply to other polymorphs. However, as discussed with respect to T 41/17 in the following section, this principle does not reliably determine inventive step.

C. T 41/17 Sorafenib tosylate

T 41/17 demonstrates that relying on stability effects to establish inventive step is no sure path to success. It was based on the following problem solution analysis:

- **Closest prior art** was amorphous sorafenib tosylate;
- **Distinguishing feature** was polymorph I of sorafenib tosylate;
- **Technical effect** of this distinguishing feature was demonstrated by evidence on file showing that polymorph I was more stable during grinding than polymorphs II and III. Grinding of crystals is often used in drug formulation;
- **Objective technical problem** was formulated as the provision of a stable crystalline form of sorafenib tosylate suitable for tablet formation.

Once again, the only question before the Board was whether polymorph I was an obvious solution to this problem. Similar common general knowledge was on file to the cases above. A further document was filed, with general advice to screen polymorphs to find their most thermodynamically stable form. Although the technical effect relied upon in formulating the objective technical problem was not thermodynamic stability but stability to milling, the Board noted that polymorph I also happened to be the most thermodynamically stable form. They went on to find polymorph I obvious on the basis that:

Faced with the objective technical problem and starting from the sorafenib tosylate of D1, the skilled person would ***therefore have performed a screening*** *of the different polymorphs of sorafenib tosylate which could exist in order to* ***isolate and identify the thermodynamically most stable form*** *thereof. By doing so, he would have arrived at polymorph I of sorafenib tosylate, which is the thermodynamically most stable form and which is, for this reason, expected not to convert to other forms under mechanical stress (emphasis added)*

This conclusion is difficult to reconcile with T 2114/13 above. After all, improved stability had been found for the specific claimed polymorph, and there was no doubt that not all polymorphs of sorafenib tosylate deliver the same improved stability. The patentee had cited T 2114/13 in their defence, but the Board did not follow this precedent, noting that in the earlier case the exact type of "solvent" stability was different, and the closest prior art was also different in that it related to a polymorphic mixture and not an amorphous mixture. No further explanation was given for why these factors were considered important, and it is not immediately obvious to us why they should lead to a different conclusion on inventive step.

Nevertheless, it is worth bearing in mind that inventive step of polymorphs may be more difficult to establish where the closest prior art is the amorphous form, and where the stability effect relied upon is accompanied by higher thermodynamic stability: the unusual finding of

stability to acetone in T 2114/13 may have contributed to the finding of inventive step in that case.

D. T 1684/16 Bosutinib

T 1684/16 shows how inventive step can still be established for polymorphs based on stability effects. The following problem solution approach was used:

- **Closest prior art** was other solid/crystalline forms of bosutinib;
- **Distinguishing feature** was crystalline form I;
- **Technical effect** was demonstrated by evidence on file showing improved appearance/purity/water content/crystallinity of form I after heating at 75°C relative to the other forms of bosutinib;
- **Objective technical problem** was therefore formulated as the provision of a form of bosutinib which is more stable.

Again, similar evidence of the common general knowledge was on file. The basic facts of the case were therefore like those of T 41/17 and a finding of obviousness might have been expected on the basis that the skilled person could screen the possible polymorphs to find the most stable form. However, the Board in this case adopted reasoning more in line with T 2114/13, concluding that the claims are non-obvious:

*Only if the prior art contains a **clear pointer** that it is the claimed subject-matter that solves this problem or where it at least creates a **reasonable expectation that a suggested investigation will be successful**, can inventive step be denied. In this case, however, there is no clear pointer in any of D4, D5 or D7 that it **is the specific crystalline Form I** as defined in claim 1 that is the most stable form. (emphasis)*

Although T 41/17 is not discussed, it is possible that a different conclusion was reached in this particular case since the claimed polymorph of bosutinib was present as a hydrate: meaning that a water molecule was present in the crystal together with the bosutinib. Evidence on file suggested that it is more difficult to screen for different polymorphs in such hydrates, which might perhaps explain the positive assessment of inventive step in contrast to the conclusion in T 41/17.

E. Sub-conclusion – Europe

The various decisions cited above show that while patentability is often acknowledged, it is difficult to predict when a polymorphic form will confer inventive step in Europe. Some general points do however emerge.

Firstly, in view of the landmark T 777/08 decision, a polymorphic form is unlikely to support inventive step if the technical effect is not specific only to the claimed form, but applies to all crystal forms.

Secondly, by comparing the outcomes in T 2114/13 and T 41/17, it seems that inventive step is more likely to be found if the effect of the polymorphic form is unusual.

Thirdly, it seems from comparing T 1684/16 and T 41/17 that inventive step is more likely where the polymorph claimed is a hydrate or solvate form of the pharmaceutical agent.

Finally, it seems that inventive step is more likely to be found when the closest prior art is an existing polymorph as in T 2114/13 and T 1684/16 rather than when the closest prior art is an amorphous or unspecified form as in T 777/08 and T 41/17.

Although it is far from being crystal clear whether any given polymorphic form will be found inventive in Europe, there are several pointers in the decisions discussed above which might be useful in determining the likely outcome.

III. Patentability of polymorphs in the U.S.

New polymorphic forms of a compound are patentable in the U.S. as long as all statutory requirements are met by the claims. However, meeting these requirements for polymorphs presents unique challenges, particularly in view of their unpredictability.

A. Novelty

Challenges to novelty of polymorph patents have primarily been based on inherent disclosures in a prior art reference that, when practiced, necessarily results in production of the claimed crystal form. This is particularly true when the most stable form of the compound is formed spontaneously by conversion of a less stable form. Thus, inherent anticipation is of particular concern when it comes to patenting polymorphs.

Anticipation requires the presence in a single prior art disclosure of all elements of a claimed invention arranged as in the claim.[35] However, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference, and that it would be recognized by a skilled artisan.[36] Importantly, inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient."[37] Inherent anticipation does not require that a skilled artisan recognized the inherent disclosure in the prior art at the time the prior art is created.[38] Rather, to inherently anticipate, a prior art reference must simply enable the subject matter sought to be claimed.[39]

In *SmithKline Beecham Corp. v. Apotex Corp*., the patentee was using a method described in U.S. Patent No. 4,007,196, issued February 8, 1977, to make paroxetine hydrochloride.[40] In 1985, it was discovered that a new polymorphic form of paroxetine hydrochloride was being produced—a hemihydrate—rather than the previous anhydrate form.[41] SmithKline obtained a new patent that claimed the hemihydrate form of the compound, U.S. Patent No. 4,721,723,

[35] *Connell v. Sears, Roebuck & Co*., 722 F. 2d 1542 (Fed. Cir. 1983).
[36] *Continental Can Co. v. Monsanto Co*., 948 F.2d 1264, 1268 (Fed. Cir. 1991).
[37] *Id.* at 1269 (citations omitted).
[38] *Schering Corp. v. Geneva Pharm. Inc*., 339 F.3d 1373 (Fed. Cir. 2003).
[39] *Id.* at 1381.
[40] 403 F.3d 1331 (Fed. Cir. 2005).
[41] *Id.* at 1334.

issued January 26, 1988, with claim 1 reciting simply: Crystalline paroxetine hydrochloride hemihydrate.

In its infringement arguments, SmithKline took the position that Apotex's process of making anhydrous paroxetine hydrochloride necessarily produced some amount of hemihydrate form. However, because the infringement theory rested on inherency, the Federal Circuit found that the claim was invalid for inherent anticipation: because a process for making the anhydrate form was described in the prior art, practicing that prior art method would inevitably contain trace amounts of the claimed hemihydrate polymorph.[42]

SmithKline, therefore, demonstrates the level of uncertainty that exists when a patent on a new polymorphic form of a compound is sought, particularly when the new form is the most stable and therefore most likely to be found in the prior art inherently.

B. Obviousness

In view of the unpredictability of polymorphs, U.S. district and appeals courts have generally considered them to be non-obvious. However, at least one recent case has called this general proposition into question.

1. *Grünenthal GmbH v. Alkem Labs. Ltd.*, 919 F.3d 1333 (Fed. Cir. 2019)

The patent at issue in *Grünenthal GmbH v. Alkem Labs. Ltd*, U.S. Patent No. 7,994,364, covered Form A of tapentadol hydrochloride.[43] Claim 1 recited:

> A crystalline Form A of (−)-(1R,2R)-3-(3-dimethylamino-1-ethyl-2-methylpropyl)-phenol hydrochloride exhibiting at least X-ray lines (2-theta values) in a powder diffraction pattern when measured using Cu Kα radiation at 15.1±0.2, 16.0±0.2, 18.9±0.2, 20.4±0.2, 22.5±0.2, 27.3±0.2, 29.3±0.2 and 30.4±0.2.

The prior art relied on by Alkem was a patent disclosing the earlier-in-time Form B of the compound and a 1995 article describing processes for screening for polymorphs of a compound by Byrn.[44] Example 25 of the Form B patent described preparing tapentadol hydrochloride and reported that the resulting product was crystalline–no further details related to the structure of the crystal were provided, and made no mention of polymorphs.[45] Byrn described a "conceptual approach" to identifying different forms of compounds, including a flow chart describing steps to be taken to determine potential polymorphism of a compound, and described how certain variables can affect polymorph formation and characterization.[46]

The Federal Circuit affirmed the district court's finding that Alkem failed to prove that a skilled person would have reasonably expected a polymorph screening of Form B disclosed in the Form B patent to result in Form A because there was (1) no known or expected polymorphism of tapentadol; (2) no evidence that the synthesis of Example 25 results in Form

[42] *Id.* at 1344-45.
[43] 919 F.3d 1333 (Fed. Cir. 2019).
[44] *Id.* at 1337.
[45] *Id.*
[46] *Id.*

A; and (3) no guidance as to what particular solvents, temperatures, agitation rates, etc., were likely to result in Form A.[47] The court specifically pointed to the unpredictability of polymorphs, stating "[t]his lack of knowledge in the field shows there was little to no basis from which a [skilled artisan] could expect a probability of success in producing Form A."[48] However, the court cautioned that "[o]ur decision today does not rule out the possibility that polymorph patents could be found obvious. But on the record here, the district court did not clearly err in finding a failure to prove that a POSA would have had a reasonable expectation of success at arriving at the claimed invention based on the prior art."[49]

Thus, after *Grünenthal*, it appeared that U.S. courts generally considered discovery of a new polymorph to be non-obvious.

2. *Pharmacyclics LLC v. Alvogen, Inc.,* No. 2021-2270, 2022 WL 16943006 (Fed. Cir. Nov. 15, 2022) (nonprecedential)

Similar to the outcome in *Grünenthal*, the Federal Circuit affirmed the district court's finding that claims to a polymorphic form of ibrutinib were not shown to be obvious in *Pharmacyclics LLC v. Alvogen, Inc.*[50] In that case, U.S. Patent No. 9,725,455 claimed form A, the most stable form of ibrutinib, with claims 1 and 5 reciting, respectively:

> A crystalline form A of [ibrutinib] that has an X-ray powder diffraction (XRPD) pattern comprising 2-Theta peaks at 5.7±0.1°, 18.9±0.1°, and 21.3±0.1°.
>
> The crystalline form of claim 1, wherein the X-ray powder diffraction (XRPD) pattern further comprises 2-Theta peaks at 13.6±0.1°, 16.1±0.1°, and 21.6±0.1°.

While the parties agreed that a skilled artisan would have been motivated to find **a** crystalline form of ibrutinib, Alvogen argued that that person would have been motivated to find **the most stable** crystalline form.[51] The Federal Circuit held that the district court's finding that "given the lack of teaching in the art regarding crystalline forms of ibrutinib and the expert testimony that polymorph screening can produce unpredictable results, a skilled artisan would not have reasonably expected success in producing Form A of ibrutinib" was not clearly erroneous.[52]

3. *Salix Pharm. Ltd. v. Norwich Pharm. Inc.*, 98 F.4th 1056 (Fed. Cir. 2024)

In *Salix*, the district court rejected the defendant's argument that the prior art (Cannata) inherently anticipated claims covering a particular polymorph of rifaximin (Form β), but

[47] *Id.* at 1344.
[48] *Id.*
[49] *Id.* at 1344-45.
[50] No. 2021-2270, 2022 WL 16943006 (Fed. Cir. Nov. 15, 2022).
[51] *Id.* at *11-*12.
[52] *Id.* at *12.

nevertheless found those claims were invalid for obviousness.[53] Claim 4 of U.S. Patent No. 7,612,199 recited:

> Rifaximin in polymorphic Form β, wherein the rifaximin has x-ray powder diffraction pattern peaks at about 5.4°; 9.0°; and 20.9°2θ and wherein the rifaximin has a water content of greater than 5%.

The court found that Cannata's methods of preparing the compound and solvent systems that it used would have naturally resulted in the claimed β form, based on the expert testimony presented.[54] The court also found that a skilled artisan would have been motivated to characterize the product produced by following Cannata's processes, because the reference disclosed that rifaximin had strong antibacterial properties and low bioavailability, in view of FDA requirements that properties such as solubility, stability, and bioavailability be determined.[55]

Although Cannata did not explicitly define the crystal structure of rifaximin produced by the disclosed methods, the Federal Circuit upheld the lower court's finding that "routine characterization" experiments, conducted within a day, could have identified rifaximin in its β form.[56] The court also noted that Salix did not contest the existence of a motivation to look for potential rifaximin polymorphs, given that rifaximin was a known compound with established utility, and emphasized that form β is the most stable polymorph.[57]
In affirming the obviousness determination, the court took care to distinguish this case from the earlier *Grünenthal* and *Pharmacyclics* decisions. The court pointed out that the key issue in those cases was whether a skilled artisan would have had a reasonable expectation of success in **producing** a crystalline form of the compound, while this case centered on the **characterization of** the crystalline form resulting from the prior art process.[58]

Notably, however, the court explained that "we do not hold that there is always a reasonable expectation of success in accessing or characterizing polymorphs. We are simply reviewing the district court's decision before us as to its factual finding of a reasonable expectation of success, and in so doing, have not been left with a definite and firm conviction that a mistake was made in reaching that finding."[59]

C. Sub-conclusion – U.S.

While the unpredictability of polymorphs provides an opportunity for obtaining patent protection on novel forms of a compound, the spontaneous conversion of a less-stable form to a more-stable form of a compound presents novelty challenges. It should also be kept in mind that this unpredictability also has the potential to pose challenges for enablement, and practitioners should take care to provide reproducible methods for preparing a particular form of a compound, as well as sufficient characterization thereof, when pursuing patent protection for a polymorph.

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[53] *Salix Pharm., Ltd. v. Norwich Pharm., Inc.*, No. 20-430-RGA, 2022 BL 277908 (D. Del. Aug. 10, 2022).
[54] *Id.* at *7.
[55] *Id.*
[56] *Salix Pharm. Ltd. v. Norwich Pharm. Inc.*, 98 F.4th 1056, 1066 (Fed. Cir. 2024).
[57] *Id.*
[58] *Id.*
[59] *Id.* at 1066-67.

IV. Conclusion

In view of current case law, it is not "crystal clear" in either Europe or the U.S. to what extent a new polymorphic form of a compound is patentable. However, in both jurisdictions what is clear is that the specific facts of each case will impact the outcome, and the cases discussed above provide helpful guidance for practitioners to evaluate how to proceed when seeking patent protection for polymorphs.

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

By: Dr. Marco Stief, LL.M[60]

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 exemption[61] and the Bolar exemption[62].

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 uncodified 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 proceeding[66] 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.[65], Inc.*, 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. Polish[69] and German courts had already dealt with this issue in 2012 and 2013 in *Polpharma v. Astellas Pharma*. In 2012, the Düsseldorf Regional Court[70] 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 Düsseldorf[71] 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 proposal[76] 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> 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.

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[80] Cf. Meyer/Grabow, Managing IP, EU seeks harmonisation of privilege for generic market entry, 9 January 2025, <https://www.managingip.com/article/2e9idap95k1fotg86i1vk/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 Dingott[83]

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

By: Christopher Chiavatti, BSc, MSc, JD[84]

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 appeal[85] 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. 2,655,355[92] 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]

1. 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 ±2 days after the first loading dose; and

[89] Axcan 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 test[101] 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.

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[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 case[103] 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 Bullrich[107]

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 Vadehra[108]

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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