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ANNOUNCEMENTS

2026 Advanced Chemical Practice Institute

The Chemical Practice and Biotech Committees will hold an Advanced Chemical & Biotech Patent Practice Institute in advance of the 2026 Spring Meeting on May 11-12, 2026 in San Francisco, California. More information can be found here.

2026 Spring Meeting

The 2026 AIPLA Spring Meeting will be held May 13-15, 2026 in San Francisco, California at the Fairmont San Francisco. More information can be found here.

Joint Cocktail Reception at the 2026 Spring Meeting

The Biotechnology Committee, Chemical Practice Committee, and the Food and Drug Law Committee are co-sponsoring a networking reception at the AIPLA Spring Meeting. The reception will be held on **Thursday, Mau 14 from 5:00 to 6:00 PM at the Fairmont San Francisco, Pavillion Room, Lobby Level.** Come and have a few drinks and get to know your fellow members!

Committee Quarterly Calls

The next Committee call is scheduled for July 2026. Details on dates, times, and agendas will be shared via the Chemical Practice Committee microsite prior to the events.

2026 Annual Meeting

The 2026 AIPLA Annual Meeting will be held October 30 to November 1, 2026 at the Westin Washington, DC Downtown. More information can be found here.

A Perfect Storm: The Appeals Review Panel Steps Into The ODP Maelstrom

By Audrey Johnson,[1] Michelle E. O'Brien,[2] Tom Irving[3,4]

Navigating the waters of obviousness-type double patenting ("ODP") has long been a challenge for patent applicants, patentees, and practitioners. This issue has only become more complicated in the past few years since the Federal Circuit's decisions in *Cellect*[5] and *Allergan*[6]. Following issuance of the *Allergan* decision, the USPTO's Patent Trial and Appeal Board ("PTAB") has considered its applicability in reviewing *ex parte* appeals of ODP rejections. Now, the USPTO's Appeals Review Panel ("ARP") is stepping in. The question is whether the ARP will be a lighthouse or will feed the vortex.

I. *Cellect* and *Allergan* Set the Stage for *Baurin*/*Baumeister*

In *Cellect*, the Federal Circuit considered, for the first time, the question of whether an ODP analysis uses the expiration date of a patent that has been awarded patent term adjustment ("PTA") before or after that PTA is added. The court held that ODP is assessed using the patent's expiration date *after* PTA is added. As a result, the award of PTA in various of Cellect's patents made earlier-expiring patents in the same family that had not received any PTA proper ODP reference patents. The court affirmed the PTAB's finding that the claims challenged in reexamination were unpatentable, even though the USPTO had never made an ODP rejection.

Just a year later, however, the same panel in *Allergan* refused to apply *Cellect*. Allergan's drug, eluxadoline (Vibrezi®), was at issue in a Hatch-Waxman proceeding in district court. The first ever patent application for eluxadoline issued as the '356 patent with 467 days of PTA. Defendants argued that claim 40 of the '356 patent was invalid for ODP over claims in Allergan's '011 and '709 patents, both of which claimed priority to the '356 patent. All three patents would expire on the same date but for the 467 days of PTA awarded the '356 patent.

The Federal Circuit noted that the holding in *Cellect* did not require that Allergan's claim 40 be found invalid simply because the '356 patent expires later than the putative ODP reference patents and, in fact, *Cellect* does not address the broader question at issue, *i.e.*, under what circumstances a patent can serve as a proper ODP reference. As the '356 patent was the first ever patent to cover eluxadoline, the *Allergan* court disagreed that the '356 patent improperly extended Allergan's exclusivity of the subject matter claimed in the '011 and '709

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[4] The coauthors are grateful for insights provided by Julie Burke, Ph.D., a world-renowned patent office expert. The coauthors also thank Dr. Victoria Pedanou of Sanofi for calling out attention to *Baurin* and *Baumeister*, both of which are discussed herein, as well as the numerous *Baurin* ARP briefs, found in Patent Center in the *Baurin* file history. Neither Marbury Law Group nor any of the authors represents Sanofi; as such, the views expressed herein are independently and solely our own. Not legal advice; no attorney-client relationship; for entertainment and educational purposes only; does not necessarily represent the views of any past, present, or future client of the Marbury Law Group; liability is disclaimed for any error or omission.

[5] *In re Cellect,* 84 F.4th 1216 (Fed. Cir. 2023).

[6] *Allergan USA, Inc. v. MSN Labs. Priv. Ltd.*, 111 F. 4th 1358 (Fed. Cir. 2024).

patents simply because the '356 patent expires later, which conclusion would be "antithetical to the principles of ODP." Instead, the court said:

> As the first-filed, first-issued patent in its family, it is the patent that sets the maximum period of exclusivity for the claimed subject matter and any patentably indistinct variants. We therefore hold that a first-filed, first-issued, later-expiring claim cannot be invalidated by a later-filed, later-issued, earlier-expiring reference claim having *a common priority date*.[7]

Therefore, since the '356 patent was a first-filed, first-issued, later-expiring patent, which only expires after the later-filed, later-issued, earlier-expiring '011 and '709 patents because of PTA, the *Allergan* court reversed the lower court's finding that claim 40 was invalid for ODP.

II. PTAB After *Allergan*: A Spectacular Electrical Storm

Since *Allergan* was decided in August 2024, PTAB has decided the question of ODP in *ex parte* appeals where the ODP reference patent was a later-filed, later-issued patent. One obvious factual distinction between these *ex parte* appeals and *Allergan* is that *Allergan* considered the question of ODP *vis-à-vis* granted patents, whereas *ex parte* appeals necessarily involve pending applications whose expiration dates may not be known with certainty until grant. A second distinction, however, is that *Allergan* concerned patents in the same family (*i.e.*, having the same priority date)—which has not always been the case in the PTAB decisions that have relied on *Allergan*.

A. Ex Parte Baurin[8]

Baurin appears to have been the first PTAB decision citing *Allergan*. Briefing in the appeal was complete in June 2024, before *Allergan* was decided in August 2024, but the Decision on Appeal issued later in November 2024. A distinction between the facts of *Baurin* and those of *Allergan* is that the reference patents were not in the same family as the application under appeal. Despite this difference, however, the *Baurin* panel reversed the ODP rejections, focusing on similarities of the facts of the case at issue with the facts of *Allergan* and the policy reason behind the ODP doctrine.

1. Decision on Appeal: Reversing the ODP Rejections

In reversing the ODP rejections, the Decision on Appeal first focused on the order in which the application on appeal and the reference patents had been filed, with reference to their priority dates.[9] While the application on appeal was filed in December 2020, the first non-provisional application to which priority was claimed was filed in March 2012, whereas the earliest-expiring alleged reference patent was filed in April 2017. In addition, the Decision noted that, because a terminal disclaimer had been filed in the application on appeal, even if PTA was awarded, any patent issuing thereon would nevertheless expire in March 2032—more than five years before the earliest-expiring reference patent.

[7] *Id.*, 111 F. 4th at 1369 (emphasis added).
[8] Decision on Appeal, Appeal No. 2024-002920 (PTAB Nov. 8, 2024).
[9] *Id.*, pp. 6-7.

The Decision acknowledged that the reference patents and appealed application were not in the same family but considered this to be irrelevant in view of the court's reasoning in *Allergan*.[10] Specifically, the panel considered whether issuance of a patent would be an "unwarranted extension" of patent term. Noting that the claims of the alleged reference patent had been found "non-obvious over the [appealed application]," the Decision concluded that the claims on appeal would issue as the "first patent to cover" the claimed subject matter.[11] Thus, the *Baurin* panel concluded that *Allergan's* underlying reasoning supported reversing the rejections.

2. Examiner's Request for Rehearing

In a rare procedural turn of events, and what may be part of a broader, coordinated effort in the USPTO, the Examiner took the unusual step of requesting that the panel reconsider the decision. The Request for Rehearing ("Request") urged that the panel had misapplied *Allergan*.

The Request asserted that *Allergan's* holding was limited in its effect.[12]

The Request reasoned that because "the instant application is not 'first-filed' as this term is used in *Allergan*," *Allergan* should not control:

> Notably, the *Allergan* court used the term "first-filed" not "earlier-filed," [and] was focused on the first patent of the patent family, and considered the actual filing dates, not the effective filing dates, in its analysis. In *Allergan*, the claims of the challenged patent were "first-filed" because the challenged patent was the first-filed patent in its family and had an actual filing date of March 14, 2005, while the "later-filed" reference patents had actual filing dates of July 19, 2010, and November 30, 2012. The reference patents issued from continuing applications claiming benefit to the challenged patent, and all three patents claimed priority to an earlier provisional application filed on March 15, 2004. In view of the facts in *Allergan*, it is clear that the term "first-filed" refers to the first-filed patent of the patent family and is based on actual filing dates. It would not make sense to read "first-filed" as referring to effective filing dates because the relevant claims in the three patents in *Allergan* appear to all have the same effective filing date.[13]

Next, the Request stated:

> [T]he instant application is not "first-issued" as this term is used in *Allergan*. The instant application has not yet issued. ... Because *Allergan* shields only "first-issued" patent claims from a nonstatutory double patenting challenge, *Allergan* cannot shield the claims of the instant application.[14]

Finally, the Request focused on the issue of common priority date:

> [T]he instant application and the [reference] patent do not have a "common priority date" as this term is used in *Allergan*. The Federal Circuit explained in

[10] *Id*., p. 9.
[11] *Id*.
[12] Request for Rehearing dated Jan. 3, 2025, p. 2.
[13] *Id*., p. 3.
[14] *Id*., p. 4.

> *Allergan* that it was using the term "priority date" to mean the 35 U.S.C. § 154(a)(2) date, which is the date that starts the clock for the 20-year patent term. … Because a shield under *Allergan* applies only when a challenged patent and a reference patent have a "common priority date," *Allergan* does not shield the claims of the instant application from the claims of the [reference] patent.[15]

Separately, the Request argued that (1) the Decision on Appeal ignores the USPTO's guidance in the MPEP regarding ODP rejections, and (2) "that the risk of separate ownership is 'immaterial' is not supported by case law or USPTO guidance."[16]

3. Decision on Rehearing: Denying Request

In a 2-1 split panel, the Request was denied, with Judges Townsend and Schneider who were on the original panel in the majority denying, and Judge Adams, who was added to the panel in view of a judge's unavailability, dissenting.

The Decision on Rehearing rejected all of the reasons set forth in the Request. First, it explained that the initial decision relied on *Allergan's* reasoning, not merely its facts, so any difference between *Allergan* and *Baurin* was not material to the outcome.[17] Instead, the majority explained that both effective filing dates and expiration dates matter in deciding whether a patent is a proper ODP reference, and that *Allergan* is not limited to the first-issued patent in a family.[18] The majority further explained that the MPEP is guidance rather than binding law, and examiners can determine whether a patent is a proper ODP reference by comparing effective filing and expected expiration dates, including the effects of terminal disclaimers and possible PTA.[19] Finally, the majority reiterated that the mere possibility of separate ownership, by itself, does not justify an ODP rejection, distinguishing prior cases such as *Hubbell*, *Van Ornum*, *Fallaux*, and *Griswold*.[20] Judge Adams, excepting the majority's discussion of *Hubbell*, dissented "for the reasons set forth in the Request."[21]

As discussed in **III**, below, the Decision on Rehearing is now positioned squarely in the eye of the ODP storm at the USPTO.

B. Ex Parte Baumeister[22]

After the PTAB's Decision on Appeal in *Baurin*, but before the Decision on the Request for Rehearing, a different PTAB panel decided *Baumeister*. Thus, unlike *Baurin*, *Baumeister* was both briefed *and* decided post-*Allergan*. *Baumeister* was an appeal of ODP rejections by a different Examiner than in *Baurin*, but on very similar facts.

Despite the similarity of the facts of the case before it and those in *Baurin*, the *Baumeister* panel declined to consider the earlier *Baurin* panel's decision, and found that *Allergan* was inapposite because the reference patents at issue do not share a priority date with the

[15] *Id*., pp. 4-5.
[16] *Id*., pp. 6-12.
[17] Decision on Rehearing, Appeal No. 2024-002920, p. 3 (PTAB Dec. 18, 2025).
[18] *Id*., pp. 3-10.
[19] *Id*., pp. 11-16.
[20] *Id*., pp. 16-23.
[21] *Id*., p. 26.
[22] Decision on Appeal No. 2026-000193 (PTAB Nov. 21, 2025).

challenged claims.[23] Instead, the *Baumeister* panel found the facts of *In re Fallaux*[24] to be more on point:

> Like this case, the reference patents in *Fallaux* have later patent term filing dates compared to the application under examination. Because they are post-URAA patents, they would expire twenty years from the patent term filing dates. The application under exam was also filed post-URAA, and thus, any patent issued from the application would expire before the reference patents expired. Yet, the Federal Circuit upheld the Board's decision affirming the [ODP] rejection of the pending claims over the reference patents with later patent term filing dates and later expiration dates because "there is a second justification of obviousness-type double patenting–harassment by multiple assignees."[25]

The *Baumeister* Decision on Appeal therefore affirmed the ODP rejections. To add more complexity to the fun, the PTAB's *Baumeister* decision, appealed to the Federal Circuit in January 2026, is pending.

III. The ARP: Thunder and Lightning Increases

In another highly unusual turn of events, and possibly to cure the USPTO loss on the *Baurin* Request for Rehearing, the USPTO Director issued a March 5, 2026, Order convening an ARP in *Baurin* and *sua sponte* granting further rehearing. The Order authorized briefing by the appellant and *amici* on the following three issues:

> (1) the applicability, if any, of *Allergan USA, Inc. v. MSN Laboratories Private Ltd.*, 111 F.4th 1358 (Fed. Cir. 2024), to the facts of this appeal, and consideration of what constitutes "first-filed" for OTDP purposes under facts different than those presented in *Allergan*; (2) whether examiners should determine projected expiration dates to support OTDP rejections during prosecution; and (3) whether the risk of separate ownership and preventing potential harassment by separate owners of claims to obvious variants of an invention is an independent basis that supports an OTDP rejection during prosecution.[26,27]

The Order does not provide any insight into why this rare procedural step was taken.[28] In view of the substantial overlap in the facts of *Baurin* and *Baumeister*, one could assume that the same issues raised in the ARP's Order will be answered by the USPTO's reviewing court, the Federal Circuit, in the appeal of *Baumeister*. The USPTO could then simply wait for the *Baumeister* decision and follow the court's direction.

The USPTO may have recognized that it may be sometime in early 2028 before there is a decision in *Baumeister*, and even then, if it is affirmed, there could be further proceedings, perhaps culminating in a petition for writ of *certiorari*. Perhaps, the USPTO's goal is simply to

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[23] *Id.*, p. 7.
[24] 64 F.3d 1313 (Fed. Cir. 2009).
[25] Decision on Appeal No. 2026-000193, p. 8 (PTAB Nov. 21, 2025) (internal citations omitted).
[26] Order Convening Appeals Review Panel and Granting *Sua Sponte* Rehearing, dated Mar. 5, 2026, p. 2.
[27] In addition to the brief filed by appellant (Sanofi), numerous *amicus* briefs were filed—all but one argued that the *Baurin* panel decided the case correctly. The exception was a brief filed by two Stanford law professors. As mentioned above, all the briefs can be found in Patent Center in the Baurin file history.
[28] Notably, since the ARP panel was established in 2023, it has been convened only three times. *See* https://www.uspto.gov/patents/ptab/decisions/appeals-review-panel-status.

provide predictability for its customers in the meantime. *But see* PROSSER ARP amicus brief, pp. 5-9 and cases discussed therein.

More likely however, as noted above, it seems reasonable to conclude that the Examining Corps has decided that the holding in *Allergan* should be limited to those instances where the application under examination and the reference patent have "*a common priority date*." This conclusion is supported by the fact that the Request filed in *Baurin*, which was written like a legal brief, required and received approval of the Director of Technology Center 1600 and Deputy Commissioner for Patents. That the positions articulated in the Examiner's Answer in *Baumeister* were almost *verbatim* the positions in the rehearing request filed in *Baurin* (including those regarding the application of *Allergan* reproduced in **II(A)(2)**, above,[29] as well as those regarding the guidance in the MPEP[30] and the "risk of separate ownership"[31]), may suggest a carefully-crafted USPTO policy position, suggesting to us that the ARP Decision will find that *Baurin* was incorrectly decided, notwithstanding the plethora of compelling arguments in the many briefs supporting the panel decision in *Baurin.* And even the Stanford brief extolls the importance of the Federal Circuit. Why not wait for *Baumeister?* Stay tuned.

[29] Compare Request for Rehearing dated Jan. 3, 2025 (Baurin), pp. 2-5, with Examiner's Answer dated Aug. 22, 2025, pp. 13-14 (Baumeister).
[30] Compare Request for Rehearing dated Jan. 3, 2025 (Baurin), pp. 6-9, with Examiner's Answer dated Aug. 22, 2025, pp. 12-13 and 17-18 (Baumeister).
[31] Compare Request for Rehearing dated Jan. 3, 2025 (Baurin), pp. 10-12, with Examiner's Answer dated Aug. 22, 2025, pp. 18-19 (Baumeister).

Preliminary Injunctions in German Pharmaceutical Patent Litigation

By Dr. Marco Stief LLM[*]

Introduction

In German pharmaceutical patent litigation, preliminary injunction proceedings are no longer a peripheral or merely defensive procedural device. They have instead become one of the most effective instruments available to originators seeking to prevent generic or biosimilar entry. This is not because German law formally abandons the traditional caution associated with interim relief. Rather it reflects the reality that, in the pharmaceutical sector, delayed relief is often commercially worthless. Once a generic or biosimilar enters the market, the originator may face immediate price erosion, loss of market share, and longer-term distortive effects that are difficult, and sometimes impossible, to reverse later by damages alone. For that reason, preliminary injunction proceedings have become one of the decisive battlegrounds of German pharmaceutical patent enforcement.

This point warrants explicit emphasis. Germany remains, in practical terms, an injunction jurisdiction. The statutory proportionality language introduced into the Patent Act has not altered the basic position that injunctive relief remains the standard remedy once infringement is established, and commentary continues to describe the German system as an "automatic injunction" jurisdiction in substance, even if that label is, strictly speaking, polemical.[32] In pharmaceutical disputes this matters acutely because patentees do not merely seek eventual success on the merits. They seek to stop launch. German practice provides them with a genuine opportunity to achieve this, and to do so within a very short timeframe.
The attraction of Germany as a forum for pharmaceutical disputes is not merely doctrinal. It is procedural. Current practitioner guidance confirms that preliminary injunctions may, in appropriate cases, be obtained within a very short period, either *ex parte* or following a brief inter partes hearing. Once issued and served, the order is directly enforceable, even if the defendant later challenges it by objection or appeal.[33] In launch-sensitive pharmaceutical cases, that combination of speed and enforceability gives preliminary relief a significance that goes well beyond its formally provisional character.

Scope and Speed of Relief

The practical leverage generated by German preliminary injunction practice can be highly significant in pharmaceutical cases. A German preliminary injunction is not merely an abstract judicial warning; it constitutes a coercive order backed by immediate enforceability. In the usual originator-versus-generic scenario, this may mean a market stop at the most commercially sensitive moment, often shortly before or immediately after launch. In appropriate cases, the relief may go beyond a simple cease-and-desist command and include obligations aimed at unwinding the market effects of entry, in particular recall obligations. That makes interim relief in Germany materially different from systems in which provisional measures are slow, hard to obtain, or narrow in scope.

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[32] On Germany's continuing reputation as an injunction jurisdiction and the narrow practical reach of the proportionality defense, see Stief, PharmR 2/2023, 61 (61f.); Stief, PharmR, 3/2023, 152 (158); see also Müller, ZdiW 2021, 407 (407ff.).
[33] Benkard PatG/Grabinski/Zülch/Tochtermann, 12. Aufl. 2023, § 139, Rn. 153.

The recent aflibercept litigation in Munich provides a particularly striking example of how German preliminary injunction practice may be used as a powerful enforcement tool for originators. In January 2026, the Munich Regional Court granted preliminary injunctions in favor of Regeneron and Bayer against several biosimilar entrants. Reporting on the case indicates that the injunctions not only blocked marketing activities but also included recall obligations. One order was even reported as extending beyond Germany.[34] Whatever the precise territorial reach of individual orders, the broader point is unmistakable: in present-day pharmaceutical litigation, German courts are capable of granting interim relief with immediate and serious market consequences.

The Munich courts, in particular, warrant separate consideration. Current commentary frequently characterizes Munich as a patentee-friendly venue that is prepared to proceed expeditiously, to adopt a comparatively assertive approach to interim protection, and to accord considerable weight to existing validity decisions when assessing the availability of broader relief.[35] From the perspective of an originator confronted with an imminent generic or biosimilar launch, that combination is highly attractive. Without resorting to rhetorical exaggeration, it can be stated that Munich is a forum in which patentees may reasonably expect rapid handling of cases and, in suitable constellations, interim measures of considerable remedial force.

This is one reason why Germany has retained, and in some respects strengthened, its strategic importance for pharmaceutical patentees after the advent of the UPC. Even where wider European litigation is conceivable, the prospect of obtaining a rapid German injunction remains an important source of leverage. That is especially true where the threat concerns the German market itself, where pricing and reimbursement dynamics create acute launch pressure, or where a German order can be used to influence settlement dynamics on a broader front.

Urgency and the Threat of First Infringement

A particular feature of pharmaceutical disputes is that the patentee often begins from an unusually advantageous informational position. The pharmaceutical regulatory setting allows the originator to assess the threatened launch comparatively early through product information, SmPCs, listing data, pricing activity, and other market signals. That transparency facilitates rapid enforcement. At the same time, it also supports the courts' expectation that the patentee will proceed quickly and in a focused manner. Therefore, German case law on urgency, though not lax, is commercially realistic. The question is not whether the patentee moved with theoretical maximum speed. The question is whether a patentee acted with sufficient determination to show that it genuinely wanted immediate enforcement and did not delay unnecessarily.

The Duesseldorf Cinacalcet decisions remain especially important here, but they should not be read as signs of special restraint. Their real message is practical: a patentee does not lose urgency merely because it waits for reliable evidence, commissions laboratory work,

[34] *See also* JUVE Patent, Regional Court Munich grants PI to Regeneron against generics in Eylea case (2026)< https://www.juve-patent.com/cases/regional-court-munich-grants-pi-to-regeneron-against-generics-in-eylea-case/> accessed 12 March 2026.

[35] *See* Chambers and Partners, Life Sciences & Pharma IP Litigation 2026 - Germany, Trends and Developments, describing Munich's role in life sciences patent litigation and the current forum landscape.

coordinates across several jurisdictions, or investigates several threatened infringements in parallel.[36] That line of authority benefits serious claimants. It means that a well-organized originator can build a robust evidentiary record without being told later that it waited too long. In pharma launch disputes, that is a major advantage. The system rewards thorough preparation while at the same time enabling rapid enforcement.

At the same time, German courts insist that urgency does not arise in a vacuum. The applicant must still establish a sufficiently concrete threat of infringement. In pharmaceutical cases, that often raises the question whether a marketing authorization, a listing, a price notification, or other preparatory act already makes launch sufficiently imminent. The courts have traditionally resisted the idea that mere market anxiety is enough. The fact that the pharmaceutical market is comparatively transparent cuts both ways: it enables early enforcement, but it also underpins the expectation that the claimant will identify and articulate concrete launch facts rather than rely on broad assumptions.[37]

The possibility of *ex parte* relief further intensifies the analysis of urgency. German practice recognizes protective briefs precisely because defendants know that, in truly urgent matters, courts may still proceed without first hearing them. Current German practice materials confirm that protective briefs remain a central defensive instrument in industries, such as pharma, where the claimant may attempt to block a launch at very short notice. The existence of that mechanism itself is telling: *ex parte* injunctions are not a historical curiosity, but continue to form a significant element of strategic planning.

Secured Validity and the Generics/Biosimilars Problem

If urgency is one foundation of interim relief, secured validity is the other. Traditionally, German patent injunction case law, especially in Duesseldorf, insisted that a patent should normally have survived first-instance adversarial validity proceedings before interim relief would issue. That basic position was rooted in a structural concern rather than in doctrinal formalism. Summary proceedings are ill-suited to resolve technically difficult validity disputes with the degree of certainty that a market-excluding order may require. The classic authorities therefore demanded a legal situation to be clear enough that a materially erroneous decision was not seriously to be expected.[38]

In pharmaceutical disputes, however, the secured validity requirement has long been softened where imminent generic entry threatens to destroy the remaining practical value of the right. The *Flupirtine*, *Maleate*, and *Desogestre*l litigations are the classic examples of this.[39] Their central insight was straightforward: where generic entry is imminent and the likely harm to the originator is severe, insisting on the ordinary validity timetable may deprive the patent of any meaningful commercial residue. In those circumstances, the balance may justify interim enforcement even before validity has been secured in the usual sequence.

[36] OLG Duesseldorf, judgment of 15 Feb. 2021, 2 W 3/21 - Cinacalcet I; OLG Duesseldorf, judgment of 9 July 2021, 2 U 4/21 - Cinacalcet III.
[37] OLG Duesseldorf, judgment of 20 Sept. 2012, I-2 U 44/12 - HIV-Drug; on market transparency and Lauer-Taxe, see also the discussion in the injunction chapter of the handbook.
[38] OLG Duesseldorf, judgment of 29 Apr. 2010, I-2 U 126/09 - Urinary Catheter Set; OLG Duesseldorf, judgment of 9 July 2021, 2 U 4/21 - Cinacalcet III.
[39] OLG Duesseldorf, judgment of 17 Jan. 2013, I-2 U 87/12 - Flupirtine Maleate; OLG Duesseldorf, judgment of 7 Nov. 2013, I-2 U 94/12 - Desogestrel.

This generics-specific logic has, if anything, become more significant in current practice. The commercial asymmetry is obvious. If a generic or biosimilar launch goes ahead and the patent is later upheld, the originator may suffer immediate and lasting harm. If, by contrast, the defendant is wrongly restrained for a limited period, the system proceeds on the basis that the resulting loss is, at least in principle, compensable. German courts have been prepared to work with that asymmetry, and it is one of the central reasons why preliminary injunctions have become so powerful in originator-versus-generic and biosimilar disputes. This is not a sector in which interim relief merely preserves the status quo; in many cases it effectively determines which party will control the market during the decisive launch window.

That said, one should not overstate the point. The case law has never meant that every pharmaceutical dispute automatically warrants an injunction. Nor has the mere fact that the defendant is a generic company been treated as sufficient in itself to grant the injunction. The *Rivastigmine* litigation remains a useful reminder that the nature of the right the patentee asserts still matters. An unexamined utility model is not automatically treated like a fully examined patent merely because the defendant is a generic manufacturer.[40] More broadly, the pharmaceutical context influences the balancing exercise; it does not abolish the need for a persuasive infringement case and a serious showing on legal status.

The issue becomes even more acute in biosimilar litigation. Biosimilars are expensive to launch, commercially significant from the first day, and often embedded in wider European rollout strategies. In that setting, the availability of a fast German preliminary injunction can exert pressure far beyond the immediate German market. Recent Munich practice confirms that, where the patentee presents a strong rights position and a clear launch threat, German courts are prepared to grant relief with immediate strategic consequences for biosimilar entrants.[41]

Phoenix Contact, Forum Practice and Present-Day Reality

The Court of Justice of the European Union ("CJEU")'s decision in *Phoenix Contact* reinforced the broader movement toward preliminary injunctions in pharmaceutical patent cases. It rejected a rigid national practice under which preliminary patent injunctions would, in principle, be unavailable until validity had been confirmed in first-instance opposition or invalidity proceedings.[42] The decision did not abolish the requirement of secured validity, but it did remove the conceptual foundation for any categorical refusal to protect newly granted patents on an interim basis. For pharmaceutical patentees, that matters because it strengthens the argument that the court must look at the actual circumstances of the case, including the apparent strength of the patent, the quality of the attacks raised, and the market consequences of withholding relief.

Even after *Phoenix Contact*, the practical difference between the main German fora remains highly important. Duesseldorf continues to be associated with a more structured and, at least rhetorically, more cautious approach to secured validity. Munich, by contrast, has acquired a reputation for speed and practical willingness to protect patentees in strong cases. Current commentary describing Munich as prepared to move quickly and to grant powerful interim

[40] LG Duesseldorf, judgment of 12 Sep. 2013, 4b O 43/13 U – Rivastigmine.
[41] LG Munich, judgment of 25. Sep. 2025, 7 O 16055/24 – Formycon.
[42] CJEU, judgment of 28 Apr. 2022, C-44/21, ECLI:EU:C:2022:309 - Phoenix Contact.

relief in high-stakes life sciences cases is therefore not merely journalistic color. It reflects a real and perceived feature of forum practice.[4]

This, in turn, explains why German preliminary injunction practice in pharmaceutical litigation often appears more far-reaching than the formal doctrinal vocabulary might suggest. The law still speaks in the language of exception, urgency, and careful balancing. In practice however, especially in originator-versus-generic or biosimilar cases, the approach is frequently markedly robust. Orders can issue quickly, they are directly enforceable, and the commercial effect of even a short-lived injunction may be decisive. German preliminary injunction practice therefore operates as a system of highly effective interim enforcement rather than as a merely symbolic preservation mechanism.

A 2022 PharmR article already captured an essential part of this development: pharmaceutical patent disputes have to be understood in the tension field between formal procedural caution and the commercial necessity of immediate enforcement.[43] What has become even clearer since then is the extent to which German practice - above all in Munich - has moved toward a distinctively patentee-effective model. That is not the same as saying that patentees always win. It is, however, a fair description of a system in which a well-prepared rights holder has a serious opportunity to stop launch quickly and decisively.

Conclusion

The broader lesson is clear: in German pharmaceutical patent litigation, preliminary injunctions are not merely available in theory. They are fast, directly enforceable, and capable of producing consequences that go well beyond a simple cease-and-desist order. In suitable cases they may stop launch, force recall, and reshape competitive conditions before the merits have been finally decided. Germany therefore remains one of the most attractive European jurisdictions for originators seeking rapid patent enforcement, and Munich in particular stands out as a venue in which patentees can expect both speed and serious remedial force.

That is why it remains fair, at least as a practical characterization, to describe Germany as an injunction jurisdiction and, in some commentary, even as an automatic injunction jurisdiction.[44]The legal framework still speaks in the language of proportionality, urgency, and secured validity. But in present-day pharmaceutical practice, especially in disputes involving generics and biosimilars, the system is markedly more assertive than that restrained language might imply. The result is a model of interim enforcement that is commercially highly effective and strategically central to modern pharmaceutical patent litigation.

A fuller treatment of these questions is contained in Pharmaceutical, Biological and Chemical Patents by Marco Stief, Maximilian Haedicke, and Annelie Wünsche. The handbook places preliminary injunctions in the wider context of German pharmaceutical patent litigation and complements that discussion with detailed analysis of validity, infringement, enforcement and compulsory licensing in chemical, biological, pharmaceutical and life sciences patent law. Beyond this specific topic, the handbook offers a highly comprehensive overview of German patent law as it applies to pharmaceutical, chemical, biological, and life sciences inventions. It covers the full range of substantive and procedural issues that arise in practice, from

[43] Stief/Meyer, Originator vs. Generika - Pharmapatente im Spannungsfeld des einstweiligen Verfugungsverfahrens, PharmR 2022, 425 ff.; id., PharmR 2022, 509 ff.
[44] See also Samer, The new PatR/Samer, § 1 Rn. 3; Stierle, GRUR 2019, 873 (873); Hofmann, NJW 2018, 1290 (1292).

patentability and validity to infringement, enforcement and compulsory licensing, and does so in a structure that is particularly useful for the reader. The relevant statutory provisions and guiding principles are presented first, followed by concise case summaries and English translations of the principal decisions. The result is a reference work that provides a clear map of the leading German case law in this field and a highly practical guide to one of the most dynamic areas of European patent litigation.

This article is but an excerpt from the book entitled "Handbook Pharmaceutical, Biological and Chemical Patents." *See https://www.maiwald.eu/de/publikationen/handbook-patents/*. Please contact Dr. Marco Stief at stief@maiwald.eu for more information.

Drafting and Defending Chemical Subgenus Claims After *Duke Univ. v. Sandoz*: Written Description "Blaze Marks" in the U.S. and Beyond

By Robert J. Sovesky,[45] Matthew Barton,[46] and David Huang[47]

Disclaimer

This article is provided for general informational purposes only and does not constitute legal advice or a legal opinion. Reading or relying on this article does not create an attorney-client relationship. You should consult qualified legal counsel regarding your specific circumstances.

I. Overview

The Federal Circuit's decision in *Duke University v. Sandoz Inc.*, No. 24-1078, slip op. (Fed. Cir. Nov. 18, 2025), provides clear, cautionary guidance for drafting and defending chemical genus and subgenus claims. The court held that a specification describing an enormous chemical universe does not satisfy the written description requirement when the asserted claims target a much narrower subgenus that is neither exemplified nor meaningfully guided by structural "blaze marks." This article focuses on the guidance from the court on how to create specifications that support a later-claimed subgenus. The article includes a broad international context, comparing the Federal Circuit's approach to written description with European and Chinese disclosure standards and highlighting where global practices converge and diverge.

II. Review of Written Description Under U.S. Patent Law in view of *Duke University v. Sandoz*

In *Duke University*, the Federal Circuit reversed a $39 million jury verdict and held claim 30 of U.S. Patent No. 9,579,270 (the '270 Patent) invalid for lack of written description under 35 U.S.C. § 112(a). The Federal Circuit concluded that the specification of the '270 Patent disclosed a "universe of billions" of prostaglandin F (PGF) analogs, while the asserted claim 30 of the '270 Patent ultimately targeted a far narrower subgenus (on the order of ~1,620–4,230 compounds). In this article, "genus" refers to the broader class of PGF analogs disclosed by permitting multiple alternative substituents at several variable positions (*i.e.*, a Markush-style disclosure across variable positions), while "subgenus" refers to a narrower subset carved out by selecting particular alternatives at one or more of those positions. Put differently, the written description question here is whether the specification's variable-position/Markush framework provides enough guidance to support the later-asserted, more specific combination of selections recited in claim 30. The Federal Circuit held that the "specification [of the '270 Patent] fails to provide the relevant artisan with sufficient blaze marks or structural commonalities among the claimed compounds to lead her to conclude that the inventor actually possessed the claimed invention." *Duke Univ.*, No. 24-1078, slip op. at 17. In so doing, the court reaffirmed that the written description requirement "reflects the basic premise of the patent system[:] an inventor may 'obtain[] a patent' only if she 'discloses [the]

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invention' to the public, in sufficient enough detail that a person of ordinary skill in the art will understand that the inventor truly 'possessed the invention as claimed.'" *Id.*

By way of background, the '270 Patent is owned by Duke University and is licensed to Allergan. The '270 Patent concerns topical application of PGF analogs to stimulate hair growth, which relates to a well-known commercial product named Latisse® marketed by Allergan for treatment of eyelash hair loss by stimulating hair growth. Sandoz manufactured and sold a generic version of Latisse®. In 2018, Allergan sued Sandoz for infringement of claim 30 of the '270 Patent. In district court, Sandoz stipulated to infringement of claim 30 but challenged the validity of the claim. A jury rejected Sandoz's defenses and awarded $39 million to Allergan. On appeal, the Federal Circuit reversed on written description grounds and entered judgment as a matter of law for Sandoz that claim 30 of the '270 Patent was invalid.

The specification of the '270 Patent enumerated a PGF structure with various substitutable positions, each with many alternatives. Further expanding the structure, the '270 Patent included salts, hydrates, amides, esters, imides, optical isomers, diastereomers, enantiomers, and epimers, which the court recognized as leading to a vast "universe of billions of compounds." In contrast, claim 30 (read with its dependencies on claims 17, 24, and 25) defined a subgenus of ~1,620–4,230 PGF analogs bounded by particular structural limits, including (i) the characteristic prostaglandin hairpin, (ii) amides at the C1 position, and (iii) connected to the unsubstituted phenyl ring at the omega end. The Federal Circuit found nothing in the '270 Patent that would guide the skilled artisan from the initial "universe of billions of compounds" to the ~1,620–4,230 analogs captured by claim 30.

The Federal Circuit reiterated the well-known standard for a genus of chemical compounds that requires "a representative number of members of the genus or structural features common to the members of the genus, in either case with enough precision that a relevant artisan can visualize or recognize the members of the genus." *Id.* at 8. As "the '270 [P]atent does not expressly disclose even a single embodiment of claim 30[,]" the analysis focused mainly on factors to determine if there are structural features common to the members of the genus. *Id.*

III. Lessons from the Court on Identifying Common Structural Features

To satisfy written description for a subgenus, the '270 Patent must "'provide sufficient blaze marks' to direct a skilled artisan to the claimed subgenus." *Id.* at 9 (quoting *Regents of the Univ. of Minn. v. Gilead Scis., Inc.*, 61 F.4th 1350, 1356–58 (Fed. Cir. 2023)). Allergan argued that the [i] hairpin feature was a common structural feature of the members of the genus recited in claim 30. However, the Federal Circuit found that Allergan failed to identify how this common structural feature was unique to the claimed subgenus in claim 30, as opposed to the entire genus described in the specification of the '270 Patent. *Id.* Thus, under U.S. Patent Law, to support the argument that a structural feature is common to the members of the subgenus, the Federal Circuit discussed that common structural feature should also be discriminative from the broad genus from which it is selected.

The Federal Circuit also held that the '270 Patent does not provide sufficient guidance to account for the variation at the R^1 and Z positions. *Id.* at 11. The Federal Circuit further held that "one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say 'here is my invention.'" *Id.* at 13 (quoting *Purdue Pharma L.P. v. Faulding Inc.*,

230 F.3d 1320, 1326 (Fed. Cir. 2000)). Instead, the patent must provide sufficient "blaze marks directing the skilled artisan to that tree." *Id.* Under U.S. Patent Law, to support an argument that a structural feature is common to members of the subgenus, the Federal Circuit discussed that it can be beneficial to describe the subgenus as a selection.

The use of "preferable" and "more preferred" can be a double-edged sword under U.S. Patent Law. For example, under U.S. Patent Law, using the terms "preferable" and "more preferred" can be seen as blaze marks for elements following that language. *Id.* However, by the same token, the Federal Circuit considered groups not included within the "preferable" and "more preferred" language as non-preferred groups and considered the patent to point the skilled artisan away from those non-preferred blaze marks.

The blaze marks must be continuous. In *Duke University*, for the Z position, the specification presented an initial menu of eight broad substituent categories, one of which was "aromatic." Allergan pointed to language indicating that, within the aromatic category, phenyl was most preferred, and the Federal Circuit agreed that phenyl was the most preferred aromatic substituent disclosed. *Id.* at 15. But the Federal Circuit found a missing step. Namely, the Federal Circuit found that the specification did not first guide the skilled artisan to choose the aromatic category from the initial eight-category menu. Therefore, to make multitier narrowing of a genus defensible, the patent should provide blaze marks at each tier.

IV. European Law

At the European Patent Office (EPO) the equivalent provision to 35 U.S.C. § 112(a) is Article 83 EPC which simply states that "The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art." While Article 83 EPC is directed to an "application," the same provision is fully applicable to granted European patents in EPO opposition proceedings. Typically, examiners and practitioners refer to "sufficiency (of disclosure)" when referencing Article 83 EPC.

While on the face of it the legal definition of sufficiency is short and simple, in practice the EPO Boards of Appeal have developed a wealth of case law on the subject, and this case law is reflected by the Guidelines for Examination which explain to examiners and practitioners how Article 83 EPC should be applied in practice.

In principle, an application or patent must include a detailed description of "at least one way" of carrying out the invention, which must include all essential inventive features (well-known ancillary features do not need to be included). If the patent claims are broad, more than one example may well be needed to extend across the scope protected by the claim. The burden of proof for a sufficiency attack normally rests with the party raising the attack, who must produce serious doubts, substantiated by verifiable facts, that the skilled person would not be able to work the invention.

Like in the US, an application or patent must contain sufficient information for the skilled person to be able to carry out the claimed invention across the entire claimed scope without undue burden, including without undue experimentation. It is noteworthy that an invention defined by its function, for example a composition claim in the field of chemistry, is not sufficient if the patent discloses only isolated examples. Rather, the patent must teach the skilled person a technical concept fit for generalization, which would enable the skilled person to achieve the envisaged result without undue difficulty within the whole ambit of the claim

containing the functional definition. This situation may be akin to the "blaze marks" described above in relation to USPTO practice: the application or patent at the EPO must show the way to the skilled person, starting from an isolated example, how the teaching from that example should be modified to achieve the same function in other areas of the claim.

In *Duke Univ.*, described above. the Federal Circuit found no guidance in the '270 Patent from the initial, "universe of billions of compounds" in claim 1 to the ~1,620–4,230 analogs captured by claim 30. The Court affirmed that a patent holder seeking to claim a genus or subgenus of chemical compounds must disclose either 1) a representative number of species within that genus or subgenus or 2) common structural features that would guide a person of skill in the art to the claimed genus or subgenus. This approach appears to translate directly into the EPO's approach of the requirement for 1) "at least one way," or multiple ways for a broad claim, or 2) a concept fit for generalization – which may include structural similarities.

The *Duke Univ.* decision also seems to touch on the concept of added subject matter at the EPO, under Article 123(2) EPC: "The European patent application or European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed." In the case of chemical compounds defined by Markush groups, starting from a broad genus and amending to produce a narrower subgenus can add matter if the narrower group is not directly and unambiguously derivable from the original application. While shrinking a generic group may not always be objectionable, such shrinking must not lead to "singling out" specific compounds or groups of compounds. In decision T 98/09 of the Boards of Appeal, which concerned this "singling out" of combinations of active ingredients not originally disclosed from lists, the board held that a deletion from a list could constitute added matter if the singling out of one individual ingredient led to a selection of combinations, which, even if conceivably covered by the application as filed, had not been specifically disclosed.

On the other hand, if the application contains a "pointer" to what is claimed in the narrower subgenus, then the amendment may be allowable. Pointers include indications in the description that moieties or structures are "preferred," or the use of such moieties or structures in the worked examples. These pointers may be seen as somewhat equivalent to "blaze marks" under US practice.

A recent decision of the Unified Patent Court (UPC) Court of Appeal, case number UPC_CoA_528/2024 ("*Amgen v. Sanofi*") illustrates that the UPC tends to follow the EPO's practice when considering validity in the light of sufficiency of disclosure and in view of added matter. The case involved medical use format claims, directed to compositions for therapeutic use, specifically a monoclonal antibody or an antigen-binding fragment thereof for use in treating or preventing *inter alia* hypocholesterolemia. In terms of sufficiency, Headnote 6 of the decision provides that "[a]n invention is sufficiently disclosed if the patent specification shows the skilled person at least one way – and in case of functional features: one technical concept – of performing the claimed invention." This fully matches the EPO approach explained above. The patent was deemed sufficiently disclosed and the respondent had not shown that the skilled person would be unable to obtain further antibodies with the claimed functional properties in a reliable manner with a reasonable amount of trial and error and without undue burden (Decision at paragraph 121). Therefore, even broad functional claims may survive a sufficiency attack at the UPC if the patent contains a workable teaching and the opponent does not provide substantiated evidence of failure.

Concerning added matter in *Amgen v. Sanofi*, the respondents argued that certain granted claims added matter to the application as filed because the application is used as a reservoir to make arbitrary selections and artificially create new combinations in the granted claims. According to the Court at paragraph 55 of the Decision, "[t]he underlying rationale for this requirement [no added matter] is that the patentee cannot claim more than he actually contributed to the state of the art at the priority date. Therefore, an amendment that is made after the priority date should not provide the skilled person with additional technically relevant information which [*sic*] was not derivable from the original application."

The UPC closely followed the EPO's approach to added matter and found that the granted claims did not contravene the requirement. The Court of Appeal looked for "pointers" to what was claimed in combination in granted claim 1 and was satisfied that even if literal support was not provided, the skilled person could derive the claimed invention from the application as a whole due to preferred features and links between the preferred features. For example, in paragraph 68 of the Decision concerning the claim integer "monoclonal antibody" the Court found that "[w]hen reading the application, and the clear emphasis therein on monoclonal antibodies, the skilled person would without doubt understand that the monoclonal antibody is the preferred one."

The takeaway for added matter at the UPC is that literal basis for amendments is not required, but there must be clear technical pointers in the original disclosure.

Finally, it is interesting to note that in the corresponding US proceeding to this UPC case (*Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023)) the Supreme Court came to a totally different conclusion, that Amgen's patent was invalid for lack of enablement under 35 U.S.C. §112(a) in view of required trial and error screening across a vast number of antibodies to reach the claimed invention, which was seen as a research assignment and not an enabling disclosure. This highlights the much more patent-friendly approach taken by the UPC and EPO, for the same type of antibody claim defined by function.

V. Chinese Law

If an Examiner at the China National Intellectual Property Administration (CNIPA) or judge is considering whether a broad genus supports a subgenus, he will primarily consider whether a subgenus is supported by specific examples/embodiments and data disclosed in the specification, while whether the specification has disclosed a wider genus is of only a secondary significance. The "examples/embodiments" and "data" relate to both the molecular formula/structures and the medical efficacy as a stated purpose of the patent.

The above position is best reflected in a paragraph of Section 3.2.1, Chapter 2, Part 2 of CNIPA's Patent Examination Guidelines on the requirement of support for a claim by the specification. This paragraph essentially introduces two relevant concepts, "nominal support" and "true support." That is, even if a feature in the claim in dispute has a literal mention in the specification, this only provides nominal support for the feature and may not be enough. Particularly for chemical, biological and pharmaceutical inventions, only if the specification provides sufficient details/data making persons in the art reasonably expect that the feature would work as intended can it be said that the feature has true support in the specification.

In the *Duke Univ.* decision, there is a focus on whether the specification of the '270 patent "provides the relevant artisan with sufficient blaze marks or structural commonalities among the claimed compounds to lead her to conclude that the inventor actually possessed the claimed invention." This concept relates to whether "the inventor actually possessed the claimed invention" and if "the inventor actually found that compounds sufficiently pointed to by certain blaze marks or represented by certain structural commonalities would work as intended." In this sense, the *Duke Univ.* decision is largely in line with China.

Regarding the use of "preferable/y" in the specification, a Chinese examiner/judge would also consider such language in the specification, but what is more important is data/result of specific test/experiment, which would be the foundation of the Chinese examiner/judge's analysis. "Preferable/y" may not be sufficient to convince a Chinese examiner/judge as he could think that that word is only the patent attorney's drafting trick. Instead, he would focus on actual technical connections between a claimed structure and what is actually tested in the specification, mostly in terms of structural commonalities or similarities.

The patent owner may try to introduce data from a new test/experiment (so-called "additional data") to support its position. But when the issue is about support by the specification/enablement, the bar is high to persuade a Chinese examiner/judge to admit the additional data, particularly when none of the existing examples in the specification provides sufficient blaze marks or structural commonalities.

VI. Conclusion

Disclosing a sprawling chemical genus may not be enough to support a later-asserted subgenus, without representative species or clear, continuous "blaze marks" that discriminate the claimed selection from the broader universe. For U.S. practice, drafters may want to consider an intentional narrowing path through exemplified compounds, tier-by-tier preferences, and articulated structural commonalities so that a skilled artisan can recognize the claimed subgenus as actually possessed. The EPO's sufficiency and added-matter analyses likewise turn on whether the application teaches at least one workable way (or a concept fit for generalization) and contains pointers that avoid impermissible singling out. China similarly looks beyond nominal textual support to "true support," placing particular weight on concrete embodiments and data that tie structure to the asserted technical effect. Taken together, these regimes reward patent specifications that pair breadth with guidance, linking preferred features and examples to the claim scope that applicants ultimately intend to defend.

Biosimilar Patent Litigation in India: The Delhi High Court's Emerging Playbook

By Vidisha Garg[48]

India's biosimilar patent litigation landscape has matured significantly over the last decade. What began as disputes entangled in regulatory positioning and market entry strategies has now evolved into technically rigorous patent litigation governed by structured claim construction and disciplined evidentiary standards.

The Delhi High Court's recent decisions in E.R. Squibb & Ors. v. Zydus Lifesciences Ltd. (Single Judge, 18 July 2025) and the subsequent Division Bench ruling (12th January 2026) provide perhaps the clearest articulation yet of how Indian courts intend to adjudicate biosimilar disputes: biosimilarity is not infringement.

Why does biosimilar litigation "feel different" in India?

Biosimilar disputes sit at an awkward intersection of (a) patent infringement standards and (b) drug-regulatory similarity standards. In India, this tension is sharpened by a well-settled premise: there is no patent linkage, *i.e.* regulatory approval does not automatically determine patent infringement, and patent rights do not automatically block CDSCO/DCGI processes. This theme is explicit in the Delhi High Court's approach in recent biosimilar matters, where courts insist on claim-to-product mapping rather than "biosimilarity."

At the same time, patentees routinely seek *quia timet* and launch-blocking injunctions, while biosimilar entrants position themselves around:

- Section 107A (Bolar exemption / research & regulatory submissions),
- Non-infringement (different structure/function or process),
- Validity challenges (opposition/counterclaim/revocation), and
- Public interest / access arguments (often most persuasive near patent expiry).

A short timeline of "headline" Delhi High Court biosimilar disputes

A. The Trastuzumab saga: where the court first wrestled with "biosimilar" positioning:

The Roche v. biosimilar manufacturers litigation around trastuzumab (Herceptin) became the earliest large-scale Indian template, less about classic "molecule infringement" and more about how biosimilars are presented/labelled/represented and whether approvals followed applicable biosimilar pathways.

Practical takeaway: Trastuzumab litigation taught the market that biosimilar disputes in India often involve parallel narratives, regulatory conduct, and market representations running alongside patent and passing-off style arguments.

B. Nivolumab (BMS / E.R. Squibb v. Zydus): the modern "claim-mapping vs biosimilarity" clash:

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This dispute has become the most instructive recent Delhi High Court case study for biosimilars because it squarely addresses whether courts can infer infringement merely because a product is positioned as a biosimilar.

(i) Single Judge (18 July 2025): interim restraint

In E.R. Squibb v. Zydus (18 July 2025), the Delhi High Court granted interim restraints against launch, with discussion around the suit patent (IN 340060) for "Human Monoclonal Antibodies to PD-1" and the patented antibody (nivolumab) and the litigation being framed as a *quia timet* action to prevent market entry during patent term.

The decision engaged with Section 107A questions and the alleged "stockpiling/launch readiness" anxieties that patentees raise as patent expiry approaches.

(ii) Division Bench (12 Jan 2026): "biosimilarity is not infringement"

The Division Bench decision (FAO(OS)(COMM) 120/2025, 12 Jan 2026) is the real doctrinal inflection point. The DB dissects the error of equating "biosimilar to nivolumab" with "falls within every element of the patent claim." It notes, pointedly, that mapping to the INN name and biosimilarity cannot substitute for rigorous claim-element analysis especially where parts of the claim were allegedly not mapped (*e.g.*, "isolated" and "binds specifically to PD-1").

In other words, product-to-product similarity (regulatory) is not equal to claim-to-product infringement (patent). The DB also addresses the patentee's own prosecution positions and the defendant's non-infringement stance, including arguments akin to a Gillette-style defense (*i.e.*, "we do what prior art does").

(iii) Beyond the High Court: the access signal

The dispute continued into higher fora, with access/public interest and patient pricing featuring prominently in public narratives.

Practical takeaway: If you are suing/defending a biosimilar in Delhi, you cannot avoid the "homework":

- For Patentee: clean, element-by-element claim chart, plus credible evidence for each element.

- For Defendant: show what *exactly* breaks equivalence (structure/function/binding profile), and why biosimilarity claims are not admissions of infringement.

C. Pertuzumab (Roche v. Zydus): process, disclosure, and Section 104A pressure-points:

Biologics frequently shift the fight from "what's the molecule" to "how was it made" and "what's inside the black box." Here, process patent strategies and burden shifting under Section 104A become important.

- Delhi High Court orders in the Roche–Zydus pertuzumab dispute have engaged with requests for manufacturing/process disclosure and how far a patentee can push discovery at an interim stage.

- Delhi High Court order (dated 23 Feb 2024) in F. Hoffmann-La Roche v. Zydus is part of this larger thread of how Indian courts manage interim relief and evidentiary asymmetry in biologics.

Practical takeaway: In India, biologics plaintiffs often try to use Section 104A and targeted discovery to bridge information gaps, but courts remain careful about forcing premature disclosure without a strong foundational showing.

Procedural realism: the Delhi High Court Patent Suit Rules, 2022

The Delhi High Court's IPD ecosystem is not just "substantive law," it's also procedure that forces discipline. The Rules Governing Patent Suits, 2022 are frequently invoked in modern orders and commentary to insist on:

- structured pleadings,
- claim charts / mapping, and
- litigation that is engineered for faster, cleaner resolution (especially in technical disputes).

The recent orders explicitly tie biosimilar disputes to this procedural requirement and prove infringement with claim mapping, not with rhetoric about similarity.

What's the "Indian standard" for interim injunctions in biosimilars?

Indian interim injunction analysis remains the familiar triad:

1. Prima facie case
2. Balance of convenience
3. Irreparable injury

But in biosimilars, "prima facie" is increasingly evidence-heavy:

- What is the claim construction?
- What are the essential elements?
- Do we have lab/analytical data? (or do we just have inference?)
- Is the product launched or still in regulatory pipeline?

The DB in the Nivolumab appeal underscores that courts cannot skip the claim-element analysis merely because the defendant calls its product a biosimilar.

A notable remedial trend (when courts allow entry but want to protect the patentee) is account-keeping / sales accounts / undertakings, which functions like an "equitable pressure valve" in high-stakes access cases.

Strategy notes for innovators and biosimilar entrants

For innovators (patentees)

- Don't litigate "biosimilarity." Litigate the claims. Your plaint and interim record must read like a claim chart with evidence, not like a regulatory critique.
- Anticipate Section 107A: courts understand the regulatory pathway; target the line where "regulatory" allegedly turns into commercial stockpiling / launch prep.

- Own your prosecution history: Delhi HC is increasingly sensitive to what was said to secure grant (e.g., specificity, binding thresholds), and defendants will weaponize it.

For biosimilar defendants

- Treat "biosimilar" as a regulatory label, not a litigation admission, rather, say it early, say it clearly, and support it with technical material.
- Where the patentee's case is inference-driven, push the court back to:
  - "show me the element-by-element mapping," and
  - "show me evidence, not assumption."
- If you're close to expiry, public interest and patient access arguments land better, but only if you also look responsible (accounts, undertakings, transparency).

The forward view: where Indian biosimilar litigation is headed

Three trends look durable:

1. Evidence will become the battleground: Courts will increasingly insist on reliable technical proof (analytical testing, binding assays, expert affidavits) and will calibrate discovery accordingly.
2. Process patents and Section 104A will matter more: As molecule claims narrow or expire, process claims and confidential manufacturing details will take center stage—forcing courts to continually balance fairness vs confidentiality.
3. The IPD procedural framework will keep tightening the discipline: Patent Suit Rules and structured case management will reduce "loose injunctions" and push both sides to litigate on the merits early.

Conclusion

The Delhi High Court's January 2026 Division Bench decision marks a doctrinal turning point. It firmly establishes that Indian biosimilar patent litigation will hinge on disciplined claim construction and evidentiary proof, not regulatory positioning.

For foreign practitioners observing the Indian market, the message is clear: *"while India lacks patent linkage and follows its own statutory framework, its courts are developing a sophisticated and structured approach to biologics patent enforcement."*

The era of inference-driven biosimilar injunctions appears to be giving way to technically grounded adjudication.

The Crystal-Ball Problem: Early-Stage University Filings and Written Description

By Kim Vines[49]

Introduction

The written description requirement of 35 U.S.C. § 112(a) poses an enduring challenge for universities and academic research institutions. Universities file patent applications at the earliest stages of scientific discovery—when mechanistic understanding is preliminary, optimization has not begun, and the commercially relevant molecular species remain unknown. Patent law, however, requires applicants to provide structural specificity at filing, years before downstream developers, whether established biopharmaceutical companies or university-affiliated startups, identify the actual embodiments that will eventually matter.

Although companies also file early, they typically have the financial resources to file new PCT applications as incremental improvements emerge, capturing additional structural details and narrowing the invention as development progresses. Universities, by contrast, often lack the budget to pursue serial follow-on filings, making that initial early-stage disclosure carry a disproportionate burden under § 112(a).

The Federal Circuit's decision in *Seagen v. Daiichi Sankyo* underscores this structural mismatch. There, Seagen's early-stage filing attempted to claim a broad conceptual genus of peptide linkers; a decade later, Daiichi developed a specific tetrapeptide sequence that proved clinically valuable. Unable to show possession of that narrower species in its original application, Seagen lost priority—and ultimately its claim.

This Article argues that while universities cannot eliminate the inherent timing asymmetry of early-stage research, they can significantly improve written-description outcomes through institutional reform. Technology transfer offices (TTOs) can adopt practices that better capture the tacit scientific knowledge inventors already have but often fail to articulate—knowledge that frequently constitutes the very "blaze marks" § 112(a) demands. Modern AI tools can further assist TTOs in eliciting that information in a systematic, economically feasible way.

I. *Seagen v. Daiichi* and the Demands of Written Description

A. Enhertu and ADC Innovation

The dispute in *Seagen* involved Enhertu, a next-generation HER2-targeted antibody–drug conjugate (ADC). Enhertu includes several technical innovations: a potent DXd topoisomerase I inhibitor payload, a high drug-to-antibody ratio of approximately eight, and a specifically engineered tetrapeptide linker—Gly–Gly–Phe–Gly—designed for intracellular protease cleavage. The precision of its conjugation chemistry and its pronounced bystander effect distinguish it from earlier ADC platforms.

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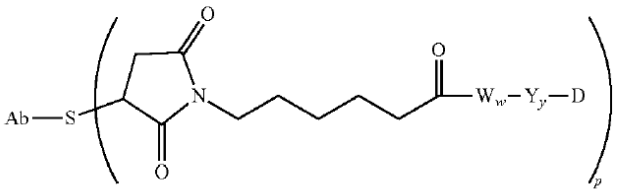
Crucially, the Enhertu linker sequence emerged from Daiichi's work and was publicly disclosed in 2015—more than a decade after Seagen's 2004 priority application.

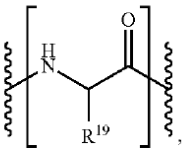
B. The Priority Problem

Seagen sought claims in a 2019 continuation (resulting in U.S. Patent No. 10,808,039 ("the '039 patent")) to encompass the Enhertu linker that claimed priority to a 2004 application.

Claim 1 of the '039 patent was directed to an antibody-drug conjugate having the formula:



each —W_w— unit is a tetrapeptide; wherein each —W— unit is independently an Amino Acid unit having the formula denoted below in the square bracket:



wherein R^{19} is hydrogen or benzyl,

wherein Y is a spacer unit; y is 0, 1 or 2; D is a drug moiety, and; p ranges from 1 to about 20, wherein the S is a sulfur atom on a cysteine residue of the antibody, and wherein the drug moiety is intracellularly cleaved in a patient from the antibody of the antibody-drug conjugate or an intracellular metabolite of the antibody-drug conjugate.

Daiichi's Enhertu uses trastuzumab (as the HER2-targeting antibody), a topoisomerase I inhibitor payload (DXd), a y value of 0, and a W_w region consisting of the tetrapeptide Gly-Gly-Phe-Gly.

Since Enhertu's 2015 disclosure would be prior art absent a valid 2004 priority date, the Federal Circuit scrutinized whether Seagen's 2004 application adequately described the specific tetrapeptide subgenus later claimed.

The 2004 application did identify peptide linkers of various lengths—including tetrapeptides—as potential embodiments within the broad W_w formulation. However, the only tetrapeptide sequences exemplified or hinted at in the filing consisted of combinations of neutral residues that did not include the glycine/phenylalanine motif that later proved crucial. Nothing in the 2004 specification suggested glycine-rich sequences, phenylalanine motifs, or any structural principle directing a skilled artisan toward the Enhertu-type tetrapeptide.

Because the priority application lacked blaze marks pointing to the claimed subgenus, Seagen was denied the 2004 priority date; Enhertu then became prior art, rendering the claim invalid as a matter of law and reversing a jury award to Seagen for more than $41 million.

C. The Structural Mismatch

The problem was not the absence of tetrapeptides from the 2004 disclosure, but the absence of directional structural information that would have signaled which tetrapeptide subclasses mattered. The case exemplifies a broader phenomenon: early-stage academic filings must satisfy a doctrine that demands structural specificity typically generated only after years of medicinal chemistry—not at the point of initial discovery.

II. The Combinatorial Explosion Problem

A theoretical solution would be to disclose every possible peptide sequence within a genus—and modern AI systems could, in principle, generate such exhaustive lists. Yet even tetrapeptides alone encompass 20^4 (160,000) combinations (and that figure counts only the twenty canonical amino acids). Enumerating this vast combinatorial space would be scientifically meaningless, economically prohibitive, and doctrinally insufficient. Written description jurisprudence does not reward brute-force disclosure; it demands blaze marks that direct a skilled artisan toward the specific subgenera the inventors actually possessed. An AI-generated wall of sequences, no matter how comprehensive, cannot substitute for the structurally meaningful guidance that § 112(a) requires.

III. The Institutional Dimension: What University TTOs Must Do

A. Correcting the Most Harmful Misconception

Inventors often mistakenly believe they may disclose only compounds they have synthesized or tested. This misconception excludes the very information § 112(a) treats as evidence of possession: predicted structures, planned variants, mechanistic explanations, and design constraints. These "in-between" embodiments frequently become critical blaze marks years later.

B. Systematically Capturing the "In-Between" Structural Space

Academic specifications routinely describe a broad genus and a handful of examples, omitting the intermediate structural territory. Yet courts increasingly look to that "in-between" zone to determine possession.

1. Example: Peptide Linkers (as in Seagen)

TTOs should elicit:

- preferred linker lengths (*e.g.*, 3–6 residues),
- amino acid preferences or exclusions,
- residue-specific functional roles (*e.g.*, glycine for flexibility),
- protease-recognition logic (*e.g.*, aromatic residues),
- non-preferred charged motifs,
- planned linker sequences yet to be synthesized.

2. Example: Broad-Structure Small-Molecule Chemistry

TTOs should elicit:

- preferred core scaffolds,
- substituent pattern rationales (*para* vs. *meta*),
- steric/electronic constraints,
- SAR hypotheses,
- preferred chain lengths or heteroatoms,
- disfavored motifs,

- planned analogs or next-generation variants.

These insights often exist in the inventor's mind but remain unstated unless intentionally elicited.

C. Budget Constraints and the Limits of Attorney-Driven Elicitation

Although patent attorneys are trained to probe for missing technical details, universities cannot depend on counsel to reconstruct the full scope of an invention's conceptual architecture. Attorney involvement typically occurs under tight deadlines, and universities—especially public institutions and smaller research organizations—operate with limited patent budgets that restrict the depth and frequency of attorney interviews. As a result, attorney-driven elicitation often captures only a fraction of the design logic, mechanistic reasoning, and predicted subgenera that inventors understood contemporaneously.

The more effective—and economically sustainable—approach is for inventors and research groups to document their reasoning at the moment of invention and communicate it to the TTO before drafting begins, ensuring the disclosure reflects their full scientific understanding rather than a compressed reconstruction.

D. Post-Draft Review Sessions as a Mechanism for Eliciting Intermediate Structural Insight

Even when patent counsel prepares the initial draft application, the disclosure almost always improves if the TTO and the inventors reconvene to review that draft together. A first-pass specification gives inventors a concrete text to react to, making omissions far more visible than during abstract questioning. When presented with draft claim sets, subgenera, or structural definitions, inventors frequently identify missing preferred linkers, disfavored residues, scaffold constraints, or mechanistic explanations they had assumed were too obvious to state. This second-stage review—conducted either before the provisional is filed or, if a provisional has already been submitted, before the non-provisional application is prepared—often surfaces the "in-between" structural knowledge that written-description doctrine treats as evidence of possession. It is also highly cost-effective: a focused session centered on an actual draft typically elicits more § 112(a)-critical detail than a lengthy open-ended interview at the outset.

The value of these post-draft discussions is underscored by cases like *Duke v. Sandoz*, where the university ultimately held a patent family that failed to disclose the specific commercial embodiment at issue—the active ingredient later marketed as Latisse. Over the course of multiple continuation applications, the specification never evolved to capture the structure of the product that eventually drove the dispute. At some point between the original provisional filing and the nth continuation, a careful post-draft review could have revealed that the commercially significant embodiment fell outside the written description, allowing the specification to be updated before any public disclosure. A structured post-draft review process is precisely the type of institutional safeguard that can prevent such omissions.

E. Requiring Structural Rationales

Even brief explanations of *why* certain motifs, ranges, or residues are preferred serve as powerful blaze marks. Courts treat mechanistic reasoning as evidence of possession and tend to discount disclosures that merely enumerate possibilities without direction.

F. AI as a Support Tool (Not a Substitute for Inventor Insight)

AI can explore structural neighborhoods, generate variants, surface patterns, identify gaps, and standardize intake interviews. But AI cannot, by itself, generate legally sufficient blaze marks. Written description requires evidence of the inventors' actual possession, and AI-generated suggestions remain inferential, not evidentiary. While emerging generative models may someday propose plausible narrowing rationales or subgenera, their contributions are ultimately conjectural. Direct conversations with inventors remain the most reliable method for uncovering mechanistic understanding, feasibility constraints, and design intent—insight that § 112(a) uniquely privileges. AI can scaffold the elicitation process, but only inventors can supply the blaze marks that withstand judicial scrutiny.

IV. How AI Can Help TTOs Elicit Inventor Knowledge

Although AI cannot satisfy the written description requirement on its own, it can substantially improve the *elicitation* of inventor knowledge—the stage where most § 112(a) failures originate. Modern generative tools can analyze draft disclosures, slide decks, or laboratory materials and produce targeted, domain-specific questions that prompt inventors to articulate preferences, constraints, mechanistic rationales, and plausible subgenera they would not otherwise verbalize.

AI can also identify doctrinally relevant gaps, such as unexplained ranges or overly broad Markush groups, and can generate hypothetical structural variants that help inventors clarify which designs are preferred, disfavored, or mechanistically implausible. By mining lab notebooks, emails, and presentations, AI can surface implicit reasoning that inventors assumed was obvious or did not think to include, and it can produce structured interview guides to ensure consistent, technically adequate elicitation across TTO staff with varying scientific backgrounds.

Yet AI's role remains supportive rather than substantive. While future models may propose narrowing rationales or subgenera that resemble blaze marks, such inferences cannot replace the legally meaningful evidence of possession that comes from the inventors' own descriptions of their understanding at the time of filing. AI can help uncover blaze marks, but only inventors can supply the ones that withstand judicial scrutiny; and in all cases, universities must ensure that confidential research information is never entered into unsanctioned public AI tools, but handled only within secure, institutionally approved environments that preserve confidentiality and privilege.

Conclusion

Seagen v. Daiichi highlights the structural mismatch between early-stage academic research and the Federal Circuit's increasingly demanding written description jurisprudence. Universities cannot anticipate which specific embodiments downstream developers—or their own startups—will ultimately adopt. But they can capture far more of the design logic, mechanistic insight, and "in-between" structural knowledge that inventors already possess.

By dispelling misconceptions, eliciting intermediate structural understanding, recognizing budget constraints, conducting post-draft review sessions, and using AI to surface tacit knowledge, university TTOs can materially strengthen their § 112(a) position. Applications with richer intermediate disclosure not only fare better under written-description scrutiny but also present more credible and commercially attractive patent assets.

These reforms cannot eliminate § 112(a)'s crystal-ball problem, but they can substantially improve the durability and value of university patents in an era of increasingly exacting written-description doctrine.

Thin Disclosure but "Bulletproof" Protection: How a Salt Form Patent was Upheld in China Despite Minimal Data

By Jennifer Che[50]

In China, innovative drug companies typically rely on their initial composition of matter patents to block out competitors. Other "follow-on" IP, such as those directed towards formulations, polymorphs, and salt forms, are often regarded as less likely to survive invalidation challenges, especially in China where the standard of "person skilled in the art" is so high.

Having said that, we share below today a positive counter example case in which a salt form of a JAK inhibitor survived invalidation. This case is one of CNIPA's Top Ten Patent Re-examination and Invalidation Cases for 2024 (published in the 2025 list). These cases are meant to be guiding cases, showcasing exemplary real-world decisions that clarify certain aspects of the law.

Background

Incyte Corporation is owner of Chinese patent ZL200880102903.3 ('033 patent) which claims three salt forms of Ruxolitinib ((R)-3-(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl)-3-cyclopentylpropanenitrile). Ruxolitinib is a Janus Kinase (JAK) inhibitor used to treat certain blood cancers and was disclosed in an earlier Incyte patent application (US 11/637,545, hereinafter the '545 application).

Petitioner Chongqing Pharscin filed an invalidation request based on Articles 26.3, 26.4, (29) and 22.3 of the Chinese Patent Law. The petitioner argued that the '033 patent was invalid for lack of inventiveness and insufficient disclosure, alleging that the patent had an invalid priority claim and thus was not inventive in view of its own earlier Ruxolitinib prior art. If Incyte could not establish a valid claim to priority, its earlier US application directed towards Ruxolitinib would become the closest (and likely destructive) prior art.

After detailed analysis of a variety of issues, the CNIPA Patent Reexamination and Invalidation Department (PRD) upheld all claims as valid (Decision No. 4W117594).

What happened? How did this patent survive the allegations of insufficient disclosure?

This case highlights how invention patents in the chemical and pharmaceutical arts are examined in three key aspects:

1. Priority entitlement and "same subject matter" in highly unpredictable fields
2. Cited foreign documents "incorporated" into a priority application's specification
3. Sufficiency of disclosure for salt-form inventions

A Seemingly Faulty Specification

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At first glance, the '033 specification appeared to be missing a lot of important details, such as the compounds' abilities to inhibit JAK activity and treat JAK-related diseases. For example, when describing the results of Example A (an in vitro JAK kinase inhibition assay), the specification only stated "[b]oth the phosphoric acid[(phosphate)] salt of the invention, and the corresponding free base compound, were found to have IC_{50} values of less than 50 nM for each of JAKI, JAK2, and JAK3." However, the specification failed to explain what technical effects were associated with IC_{50} values of less than 50 nM. Furthermore, out of the three salt forms (maleic acid, sulfuric acid and phosphate salts), only the phosphate salt had associated data. There were also no clinical data regarding the diseases that could be treated.

The priority document US 60/943,705 (filed on 13 Jun 2007) did not recite Example A either, making it questionable whether the priority claim was valid.

In short, this '033 Chinese patent appeared to be missing a lot of key information:

- Only the phosphate salt's JAK1/2/3 IC_{50} values (<50 nM) were reported (Example A)
- No IC_{50} data for maleate or sulfate salts
- No in vivo or clinical data
- Example A was absent from the earliest US provisional priority document (60/943,705, filed 13 June 2007)

Priority Claiming in China

In order to properly claim priority in China, inventions need to have the "same subject matter of invention" as those in the priority application. The definition of the "same subject matter of invention" is similar to the standard for novelty: the same technical field, the same technical solution, the same technical problem to be solved, and the same expected technical effect.

As Example A was not present in the priority document, one could not directly determine whether the priority document shared the same expected technical effect with the '033 patent. At the same time, the advantageous properties of the salt forms over the free base form were clearly stated in the specification.

What ultimately saved the priority claim was a statement in the priority application's background section that cited an even earlier patent US 11/637,545. This, together with the common knowledge in field of JAK research, made it such that the priority document included the same subject matter as the invention.

Cited Foreign Document Treated as Part of the Priority Document

This decision recognizes that an earlier foreign patent application (US 11/637,54) merely cited in the priority application's specification is treated as part of the priority document itself, sort of as if it were incorporated by reference. Despite earlier Examination Guidelines requiring cited documents to be published before the priority date, the PRD applied the 2023 Guidelines retroactively in light of legislative intent and interest balancing, holding that the cited US application forms part of the priority document itself for assessing technical effects (despite the US application publishing after the Chinese application was filed).

"Same Subject Matter" Established via Common General Knowledge

In order to determine whether a priority claim is valid, the priority document and the present application must share "the same subject matter," and "the same subject matter" is defined by having the same technical field, the same technical problem to be solved, the same technical solution and the same technical effects. As summarized in the invalidation decision:

> In the field of chemistry and pharmaceuticals, due to the high degree of unpredictability of technical effects, it is generally necessary to include in the specification sufficient qualitative or quantitative experimental data to demonstrate the achievement of the stated purpose and/or expected effect, so as to assure those skilled in the art that the invention can achieve the stated purpose or effect. Accordingly, in the determination of "the same subject matter" in the field and possess the same technical effect [for determining whether priority claim is valid], there is a high degree of reliance on experimental data.

With the high standard on experimental data, even without Example A in the priority document, a person skilled in the art could reproduce the JAK assay from the cited US 11/637,545 and would immediately recognize that the phosphate (and other) salts retain the same potent JAK-inhibitory profile as the free base. Therefore, a person skilled in the art would understand that the priority document and the present application have the same technical effects and share "the same subject matter," making the priority claim valid.

Sufficiency of Disclosure Upheld

The PRD rejected the insufficiency attack on three independent grounds, all rooted in the low predictability threshold required when the invention is a pharmaceutically acceptable salt of a well-characterized active compound.

First, salt formation and characterization are routine operations. As no special conditions or unexpected difficulties were provided as evidence by the petitioner, the preparation methods and structural confirmation of the salts were deemed sufficiently enabled by a person skilled in the art.

Regarding the point that only the phosphate salt's result was disclosed: Because the three claimed salts share the same cationic core, the activity of the other two salts is predictable to a person skilled in the art and can be tested by the experimental methods cited in the specification. Therefore, the disclosure of only the phosphate salt's result was sufficient to enable the others without undue experimentation.

Most importantly, regarding the claimed therapeutic use/use in manufacture of therapeutic drugs: The specification and the priority document cited multiple references in the background to show that researchers in this art have long focused on and studied the relationship between JAK and various diseases. Although the '033 patent discloses no experimental data or clinical results specifically linking the three salts to disease treatment, a person skilled in the art would still understand that the claimed salts, which possess the similar JAK-inhibitory activity, have potential therapeutic use for those diseases.

EIP Thoughts

Being the first ever JAK inhibitor approved, Ruxolitinib remains highly significant in the pharmaceutical market due to its inhibition of a fundamental pathway. Numerous clinical trials are ongoing to expand its indications. Several other companies have petitioned to invalidate this salt form patent, and one of the petitions challenging disclosure sufficiency was rejected under the "一事不再理原则" (*ne bis in idem* principle).

This patent remains robust in China, likely due to its narrow scope limited to the specific salt form compounds, which have different structures than the prior art compounds at that time. Furthermore, the surprising technical effects of the salts are clearly stated in the specification. While the specific patent strategy used to protect these Ruxolitinib salt forms might not be 100% applicable in other cases, this invalidation decision still provides some useful insights regarding priority entitlement, the determination of "the same subject matter," the role of cited foreign documents, and sufficient disclosure. It provides a positive example of how technical effects can still be fully considered even when the priority document and the later application are not identical.

Further, as seen in this decision, the determination of whether two applications include the same subject matter in this particular field involves more common knowledge in the art, including the effect of Ruxolitinib itself and importantly, the common knowledge that salt formation does not change the property or effect of the drug. A person skilled in the art would recognize the claimed salt as a direct, foreseeable improvement derived from the parent compound.

Our general practice is <u>not</u> to leave out certain disclosures and rely solely on incorporation by reference. While the Examination Guidelines permit examiners to consult cited documents when necessary, Part II, Chapter 2, Section 2.2.6 also explicitly cautions that content essential for meeting Article 26(3) (sufficiency/enablement) "should not be written by citing other documents, but should be specifically included in the specification." Omitting comparative examples, characterization data, or key technical effects and expecting examiners to retrieve them from prior applications or literature carries unnecessary risk of rejection for insufficient disclosure.

Therefore, the safest and most examiner-friendly approach is to incorporate all enabling and distinguishing technical information directly into the Chinese specification itself.

Much Ado About Skinny Labels

By Genevieve M. Halpenny, Ph.D.[51]

Introduction

On April 29, 2026, the Supreme Court will hear oral argument in *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.*, No. 24-889. This case invokes Congress's attempt in the Hatch-Waxman Act to balance the public interest in research and regulatory approval of new uses for known drugs with the public interest in bringing generic versions of those drugs to market for unpatented uses as soon as possible. This case has also renewed the debate concerning whether a label approved by the FDA via the section viii pathway and unqualified or "vague" but otherwise true statements made by generic pharmaceutical companies can support induced infringement claims against those companies in certain circumstances.

This case comes on the heels of the Federal Circuit's high-profile decision in *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021) (per curiam) ("*GSK*") which presented some similar facts and legal issues. In *GSK*, the jury returned a verdict of infringement and awarded damages. The district court granted Teva's renewed motion for judgment as a matter of law on infringement. The Federal Circuit vacated the grant of JMOL, reinstated the jury's verdict and damages award, and remanded for further proceedings. Judge Prost dissented.

In *GSK*, the FDA approved GSK's Coreg® carvedilol for three indications: treatment of hypertension, treatment of congestive heart failure (CHF), and reduction of cardiovascular mortality in patients suffering from left ventricular dysfunction following a myocardial infarction (post-MI LVD). Teva filed an Abbreviated New Drug Application (ANDA) seeking FDA approval of its generic carvedilol for all three indications. It certified that it would not launch its product until U.S. Patent No. 4,503,067, directed to the carvedilol compound, expired under Paragraph III of the Hatch-Waxman Act. Teva also certified under Paragraph IV that GSK's U.S. Patent No. 5,760,069, directed to a method of administering carvedilol and an ACE inhibitor, a diuretic, or digoxin to decrease mortality cause by CHF (the CHF indication) was invalid, unenforceable, or not infringed. Teva gave a Paragraph IV notice to GSK that the claims of the patent directed to the CHF indication were anticipated or would have been obvious. GSK did not sue but applied for reissue of the '069 patent.

The FDA tentatively approved Teva's ANDA for the treatment of heart failure and hypertension. Such approval would become effective upon expiration of the '067 patent in 2007. Shortly before Teva launched its carvedilol product, it certified to the FDA that its label would not include the CHF indication until expiration of the '069 patent. Consequently, Teva's label included only two indications: the post-MI LVD indication and the hypertension indication. However, Teva's press releases and marketing materials promoted its carvedilol product as "indicated for treatment of heart failure and hypertension," as the "Generic version of [GSK's] cardiovascular agent Coreg®," and as an "AB-rated generic equivalent of [GSK's] Coreg® Tablets." These statements did not specify that Teva's product was not approved for the CHF indication.

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In 2008, the PTO issued Reissue Patent No. RE40,000, and GSK promptly notified the FDA. In 2011, GSK delisted the '069 patent and U.S. Patent No. 5,902,821. In view of these changes, the FDA instructed Teva to revise its label to include the information associated with the '821 patent from GSK's Coreg® label. The FDA also asked Teva to provide information regarding its position on the '000 patent. Accordingly, Teva amended its label to include the indication for treating patients with chronic heart failure by administering carvedilol to increase survival and reduce the risk of hospitalization. Teva also responded that it did not need to provide certification to the '000 patent because it received final approval of its ANDA before the '000 patent issued. In 2014, GSK sued Teva, alleging that it had induced infringement of the '000 patent.

The district court instructed the jury to evaluate whether Teva induced infringement during two periods: the "partial label period" (during which Teva's label included only the post-MI LVD and hypertension indications) and the "full label period." The jury found the '000 patent was not invalid, that Teva induced infringement of claims 1-3 during the partial label period, and that Teva induced infringement of claims 1-3 and 6-9 during the full label period. The jury based its damages award on a combination of lost profits and a reasonable royalty and found willful infringement.

The district court granted Teva's renewed motion for JMOL because GSK did not prove that Teva's alleged inducement, as opposed to other factors, caused physicians to directly infringe by prescribing carvedilol to treat CHF. As such, the district court decided that substantial evidence did not support the verdict. Additionally, the district court found that no reasonable juror could have found induced infringement based on the post-MI LVD indication in Teva's label.

At the Federal Circuit, the panel majority disagreed. It found that the jury was entitled to credit GSK's expert testimony regarding how a physician would read Teva's partial label in view of patient overlap between the post-MI LVD and CHF patient populations, and as such "was not a skinny label."[52] The panel majority also cited Teva's product catalogs, advertising and promotional activities, Monthly Prescribing References for doctors, and testimony from Teva's own company witnesses, as evidence that the jury could have relied on to find the requisite intent to encourage, recommend, or promote infringement.
Judge Prost's dissent argued that in coming to market with its "skinny" label, Teva "played by the rules, exactly as Congress intended."[53] The dissent further faulted the majority's willingness "to see culpable intent behind a generic's describing its product as the 'equivalent' of a brand drug—in a system that requires generic drugs to be equivalent, and in which everyone understands that generic drugs are equivalent."[54] Judge Prost cautioned that confusion would be created, because "the difference is indiscernible between this case and one in which the generic is safe. Indeed, it's unclear what Teva even did wrong—or, put another way, what another generic in its shoes should do differently."[55]

Although generic companies need not discourage infringing uses under existing law,[56] one alternative to abandoning the section viii pathway is to state the scope of FDA approval in

[52] *GSK* at 1328.
[53] *Id.* at 1342.
[54] *Id.* at 1343.
[55] *Id.* at 1359-60.
[56] *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 632 n.4 (Fed. Cir. 2015).

public statements and marketing materials when omitting this information would imply that a generic drug is approved for more indications than its approval covers.

Indeed, despite the dissent's warnings, the pleas of amici, and ample commentary that *GSK* would eviscerate section viii and chill filings, generics continue to obtain FDA approval via the section viii pathway.[57]

In response to *GSK*, Sen. Hickenlooper introduced the Skinny Labels, Big Savings Act, which would exclude certain acts from infringement including: submitting or seeking approval of a skinny label for a generic or biosimilar drug, promoting or commercially marketing a drug with skinny labeling approved by the FDA, or describing a drug product approved by the FDA as a generic of, or therapeutically equivalent to, the branded drug.

Against this backdrop, the fate of Amarin's complaint alleging that Hikma induced infringement of its patents has similarly ping-ponged as this case has progressed to the Supreme Court.

The Parties and Factual Background

Amarin sells Vascepa® icosapent ethyl for the treatment of severe hypertriglyceridemia (SH indication) and cardiovascular risk reduction (CV indication). Initially icosapent ethyl was only approved for the SH indication. Hikma filed an ANDA seeking approval of its icosapent ethyl product for the SH indication and successfully invalidated Amarin's patents as obvious via the Paragraph IV pathway.[58]

After Amarin's Vascepa® icosapent ethyl was approved for the CV indication, Hikma certified under section viii and carved that indication out of its label. The FDA approved Hikma's ANDA and its proposed skinny label.

Leading up to approval and product launch, Hikma issued press releases that referred to Hikma's product as the "generic version" of Vascepa, which it also described as "medicine that is indicated, in part, [to treat] severe (≥ 500 mg/dL) hypertriglyceridemia." Hikma also provided sales data for Vascepa, stating that sales of the product in the United States "were approximately $919 million in the 12 months ending February 2020." After receiving FDA approval, a press release stated that Hikma had received FDA approval for its icosapent ethyl tablets, "the generic equivalent to Vascepa®" and quoted Hikma's President of Generics as saying that "[t]he approval for our generic version of Vascepa® is an important milestone towards bringing this product to market." After its win in the appeal of the litigation over the patents directed to the SH indication, Hikma's press release stated:

> Vascepa® is a prescription medicine that is indicated, in part, as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. According to IQVIA, US sales of Vascepa® were approximately $1.1 billion in the 12 months ending July 2020.

[57] *See, e.g.*, Krista Hessler Carver et al., "Call Off Chicken Little: The Sky is Not Falling for Skinny Labeling After GSK v. Teva" (available at https://ipwatchdog.com/2024/07/25/call-off-chicken-little-sky-not-falling-skinny-labeling-gsk-v-teva/).
[58] *See Amarin Pharma, Inc.* v. *Hikma Pharm. USA*, 449 F. Supp. 3d 967 (D. Nev. 2020), *aff'd*, 819 F. App'x 932 (Fed. Cir. 2020).

Hikma knew from this litigation that more than 75% of Amarin's Vascepa® sales were attributable to the CV indication but did not include this detail in its press release. Upon launch, Hikma issued a press release stating:

> Hikma's FDA-approved Icosapent Ethyl Capsule product is indicated for the following indication: as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. Hikma's product is not approved for any other indication for the reference listed drug VASCEPA®.

Unlike the previous press releases, this one clearly explained the scope of the FDA approval of Hikma's icosapent ethyl, *i.e.*, that it was only approved for the SH indication.

Amarin sued Hikma and alleged induced infringement of U.S. Patent 9,700,537 and U.S. Patent 10,568,861 based on purported flaws with Hikma's skinny label and these press releases.

Procedural History

Hikma filed a motion to dismiss Amarin's amended complaint which was referred to a magistrate judge for report and recommendation. The magistrate judge issued its recommendation to deny Hikma's motion to dismiss two days before the Federal Circuit issued its decision in *GSK*.[59]

The district court divided its analysis between the allegations directed to the skinny label and the press releases. In regard to the label, the district court agreed with Hikma that neither the warning concerning side effects in people who have cardiovascular disease nor the absence of a CV limitation on the label constitute recommending, encouraging, or promoting an infringing use.

Turning to the press releases and advertising, the district court found that describing Hikma's icosapent ethyl as the "generic equivalent" of Vascepa did not subject it to liability under its interpretation of *GSK*. The district court further found that Hikma's press releases might be relevant to intent, but they did not support inducement. In accordance with its analysis, the district court found that Amarin failed to plead inducement and granted Hikma's motion to dismiss.[60]

The Federal Circuit reversed.[61] The Federal Circuit opened by explaining that this case is neither a Paragraph IV ANDA case, nor a section viii case in which the patent owner's allegations are based solely on the premise that the generic company's proposed label is "not skinny enough."[62] Rather, "it is nothing more than a run-of-the-mill induced infringement case arising under 35 U.S.C. § 271(b). In such a case, we review the allegations of inducement as a whole, not piecemeal. Accordingly, we must consider whether the *totality* of the allegations, taken as true, plausibly plead that Hikma induced infringement."[63] Unlike *GSK*, which was decided after post trial motions, this case reached appeal "at its most nascent stage: on a

[59] *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, No. 20-1630, 2021 WL 3396199 (D. Del. Aug. 3, 2021).
[60] *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 578 F. Supp. 3d 642, 648 (D. Del. 2022).
[61] *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 104 F.4th 1370 (Fed. Cir. 2024) (rehearing denied unpublished).
[62] *Id.* at 1376-77.
[63] *Id.* at 1377.

motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), where we are tasked with reviewing *allegations*, not findings, for *plausibility*, not probability."[64]

Under 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." To clear this hurdle, "a patent owner must plausibly allege facts establishing that there has been direct infringement by a third party and that the alleged infringer affirmatively induced that infringement with knowledge that the induced acts constituted patent infringement."[65] Because direct infringement and intent were not disputed, the Federal Circuit focused on whether Amarin plausibly pleaded that "Hikma 'actively' induced healthcare providers' direct infringement, *i.e.*, that Hikma encouraged, recommended, or promoted infringement."[66] The Federal Circuit agreed with the magistrate judge that "many of the allegations depend on what Hikma's label and public statements would communicate to physicians and the marketplace. … As we observed in *GSK*, that is a question of fact—not law—and is therefore not proper for resolution on a motion to dismiss."[67]

In response to Hikma's pleas that reversal would "effectively eviscerate section viii carve-outs," the Federal Circuit advised "[w]hat we can also say is that clarity and consistency in a generic manufacturer's communications regarding a drug marketed under a skinny label may be essential in avoiding liability for induced infringement."[68]

Issues Presented

Hikma now asks the Supreme Court to decide the following two questions:

1. When a generic drug label fully carves out a patented use, are allegations that the generic drugmaker calls its product a "generic version" and cites public information about the branded drug (*e.g.*, sales) enough to plead induced infringement of the patented use?

2. Does a complaint state a claim for induced infringement of a patented method if it does not allege any instruction or other statement by the defendant that encourages, or even mentions, the patented use?

Amarin frames the issue as follows:

> Whether the court of appeals correctly found that, on the particular constellation of facts pleaded in respondents' complaint, respondents have plausibly alleged petitioners' active inducement to infringe patented uses of respondents' innovative pharmaceutical product.

Hikma's Positions

Hikma argues that it is undisputed that its skinny label alone does not induce infringement and that its prelaunch press releases are accurate. Hikma further argues that none of the accused statements mention the patented CV indication, co-administration of a statin, or reducing the

[64] *Id.*
[65] *Id.*
[66] *Id.* at 1378 (cleaned up).
[67] *Id.* at 1379.
[68] *Id.* at 1381.

risk of CV events or death as claimed. Hikma characterizes Amarin's allegations as a "theory of passive inducement." Finally, Hikma repeats the argument that allowing Amarin's complaint to proceed would "effectively nullify section viii." As evidence of the chilling effect of *GSK* and the decision below, Hikma argues that launch of generic drugs eligible for label carve outs decreased from "approximately half" in 2021 and 2021 to one fifth in 2023.[69]

Amarin's Positions

Amarin argues that its Vascepa® icosapent ethyl became well known for its success in treating the patented CV indication, which accounted for most of its sales. Under these circumstances, Amarin argues intentionally broad statements would lead prescribers and pharmacists to think that Hikma's product was approved for this indication. Amarin notes that it does not take issue with the marketing practices of the several other generic manufacturers of icosapent ethyl that are also approved only for the SH indication. Amarin responds to Hikma's argument that chilling has been observed by citing the same article as Hikma. Amarin explains that although the overall number of section viii approvals was 20%, only five new generics were eligible for skinny labeling and that even if the number fluctuates, the rate has remained about the same.

In response to the government's argument that generic substitution laws explain at least some instances of infringement, Amarin argues that this argument was not raised below, and as such, was waived. Even if the argument were not waived, Amarin argues that generic prescriptions in compliance with such substitution laws would support its allegations of Hikma's intent.

Amarin also offers the Supreme Court the option to dismiss the writ of certiorari in view of Hikma's failure to develop the argument from its petition that there is a circuit split over whether induced infringement is proper for resolution on a motion to dismiss.

Lasty, even if the Court were to conclude that the amended complaint did not meet pleading standards, Amarin argues that it would be entitled to leave to amend, especially in view of evidence collected during discovery.

Concluding Remarks

This case can be decided on its facts without creating new law. If the Court were to answer Hikma's questions presented in the negative, a new safe harbor for generic companies to market their drugs for patented indications would effectively be created. Although the many amici in support of Hikma argue that such a brightline rule would be consistent with Congress's intent, such rule making should be left to Congress. One such bill has already been referred to the Committee on the Judiciary. Additionally, the incentives required by companies to investigate new uses of known drugs should not be forgotten. Finally, in line with the abrogation of Form 18, any decision should not create patent- or pharmaceutical-specific pleading standards.

[69] Pet.Br. at 46 (citing Therese J. Ziaks et al., *Frequency of First Generic Drugs Approved Through "Skinny Labeling," 2021 to 2023*, 31 J. MANAG. CARE SPEC. PHARM. 343, 346 (2025).)

Recombinant Realities: *REGENXBIO* Reinvigorates § 101

By Usayd Siddiqi[70]

Background

A. Overview

Patent-eligibility challenges under 35 U.S.C. § 101 remain a recurring feature of biotechnology litigation—particularly where claims touch naturally occurring DNA, proteins, or other biological building blocks. In *REGENXBIO Inc. v. Sarepta Therapeutics, Inc.*, the Federal Circuit delivered a notable decision reversing a summary judgment that invalidated gene-therapy manufacturing claims as allegedly directed to a natural phenomenon.

The asserted patent, U.S. Patent No. 10,526,617 (the "'617 patent"), relates to engineered materials used in producing adeno-associated virus (AAV) gene therapy vectors. AAVs are naturally occurring viruses that can be adapted as delivery vehicles for therapeutic genes. The '617 patent focuses on host cells engineered to contain AAV-related sequences—specifically AAVrh.10 capsid sequences—along with non-AAV genetic material.

The representative claim (Claim 1) recites:

> 1. A cultured host cell containing a recombinant nucleic acid molecule
>
> encoding an AAV vp1 capsid protein having a sequence comprising amino acids 1 to 738 of SEQ ID NO: 81 (AAVrh.10) or a sequence at least 95% identical to the full length of amino acids 1 to 738 of SEQ ID NO: 81, wherein the recombinant nucleic acid molecule further comprises a heterologous non-AAV sequence.

Critically, the parties did not dispute that the claimed host cells are human-made and do not exist in nature, and that the recombinant nucleic acid molecule is created by splicing together sequences from two different organisms.

B. Procedural History

REGENXBIO sued Sarepta in the District of Delaware alleging infringement based on Sarepta's use of an AAV variant (rh.74) in cultured host cells to manufacture its Duchenne muscular dystrophy gene therapy product. Both sides moved for summary judgment on § 101.

The district court granted Sarepta's motion and held the claims ineligible, reasoning that the claim components were natural (AAV sequences + non-AAV sequences) and that combining them in a host cell did not supply the "change" required for eligibility. The district court analogized the claims to *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), characterizing the invention as a non-inventive mixture of natural products. REGENXBIO appealed to the Federal Circuit.

Federal Circuit Recenters the Inquiry

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After laying out the gene-therapy backdrop and the parties' undisputed premise—that the claimed host cells and recombinant constructs do not exist in nature—the Federal Circuit framed the case as a composition-of-matter "product of nature" dispute governed principally by the *Chakrabarty* "markedly different characteristics" test.

REGENXBIO thus reads like a course-correction: when the claim is to an engineered biological composition, the court asks whether the claimed composition, viewed as a whole, is non-naturally occurring and markedly different from what is found in nature.

A. "Recombinant" and "Heterologous" Are Not Labels

A key feature of the opinion is that it treats "recombinant" and "heterologous" as workhorse limitations that *force* the non-natural conclusion, rather than mere descriptors:

- "**Recombinant**" was understood as requiring human-mediated splicing or artificial joining of nucleic-acid segments.
- "**Heterologous**" was understood to require genetic material from a different species.

Read together, these two limitations mean the claim is not merely "AAV DNA + other DNA," but rather a single recombinant nucleic acid molecule assembled through human intervention which is then incorporated into a cultured host cell. That is why the court could say it was "uncontested" the claimed host cells include a recombinant molecule that "does not and cannot exist in nature."

This is where the court aligned the claims with the eligible side of *Myriad*. Like cDNA in *Myriad*, even if portions of the sequence are "dictated by nature," the lab technician "unquestionably creates something new" when he constructs the non-naturally occurring molecule. *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 594-95 (2013).

B. The Comparison Is Composition-by-Composition, Not Component-by-Component

The Federal Circuit noted that the district court's mistake was methodological because the district court evaluated whether each naturally occurring component was individually changed. That approach effectively presumes ineligibility whenever a claimed biotechnology composition is built from natural building blocks.

The Federal Circuit rejected that framing, and emphasized that the "markedly different" inquiry is directed to the claimed composition as a whole—including how the components are integrated and configured—and whether that whole is "not naturally occurring." This framing is consistent with the broader anti-dissection principle in § 101: it is "inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements." *Diamond v. Diehr*, 450 U.S. 175, 188 (1981).

Why *Funk Brothers* Didn't Fit and Why "Conventionality" Didn't Carry Step One

A. Integration vs. Aggregation

The district court analogized the claims to *Funk Brothers* reasoning that putting two natural DNA sequences together was no different than mixing two natural bacterial strains. The Federal Circuit called the analogy "flawed" and inconsistent with the scientific record.

The panel's distinction is instructive.

- In *Funk Brothers*, the claimed composition was an **aggregate**: each bacterial species remained unchanged and "perform[ed] in [its] natural way." 333 U.S. 127, 131 (1948). The combination produced no new bacteria and did not change how the bacteria functioned—commercial convenience (one package instead of six) was not enough. *Id.*

- In *REGENXBIO*, the claim required **integration**: "genetically engineering two nucleic acid sequences from separate species into a single molecule" and "transforming a host cell" to incorporate that molecule which created "a cell containing a molecule that could not form in nature on its own."

That difference—**a new integrated construct versus a mixture of unchanged natural actors**—does much of the work in the opinion.

It also explains why the panel viewed *Chakrabarty* as the more analogous case. In *Chakraborty*, the inventors inserted multiple plasmids into a bacterium and created a nonnaturally occurring composition with markedly different characteristics and significant utility.

B. The Court Refused to "Read Out" Conventional Limitations at Step One

Sarepta attempted to reframe the claim as one that focused on the naturally occurring AAV sequence and dismiss the remaining limitations regarding host cells, recombinant assembly, and heterologous sequence as conventional.

The Federal Circuit rejected that approach and refused to disregard limitations simply because they might be routine, known, or appear in the prior art. The panel noted that "[c]ontrolling precedent does not direct us to disregard conventional limitations when considering whether claims are 'markedly different' from products of nature."

C. Positioning Relative to *Myriad* and *ChromaDex*

The opinion also helps define what kinds of biotech claims remain vulnerable by discussing *Myriad* and *ChromaDex*.
In *Myriad*, the Supreme Court found claims to isolated genomic DNA ineligible because isolation did not change the relevant thing the claims were about: the naturally occurring genetic information that already existed in nature. Sarepta tried to pull *REGENXBIO* into that same bucket by reframing the case as effectively directed to isolating the AAVrh.10 sequence. However, this characterization failed because the claim explicitly required a cultured host cell and a recombinant molecule encoding both an AAV capsid protein and a heterologous non-AAV sequence.

In *ChromaDex*, the only structural difference was isolation of a naturally occurring vitamin from milk, which the court found insufficient to create markedly different characteristics. Here, the key difference was creation of a recombinant construct and engineered cell that cannot occur naturally.

Practical Implications and Takeaways

1. Eligibility Can Be Engineered Into the Claim Language

The decision gives real weight to structural terms like "recombinant" and "heterologous" when those terms are tethered to a non-natural requirement. For patent prosecutors, this is a reminder to ensure the claim language compels the conclusion that the claimed composition cannot occur in nature, rather than leaving that point to attorney argument.

2. Describe the Human Intervention Clearly, Not Just the Result

The opinion drew support from the undisputed scientific record describing recombinant DNA creation and cell transformation. While the claim need not recite every lab step, a specification that explains how the construct is made, why it is not naturally occurring, and what it is useful for can materially improve the patentee's ability to frame eligibility early.

3. Push Back On "Conventional Limitations"

Defendants will often try to describe a claim as directed to a natural phenomenon and treat the engineered context as mere environment. *REGENXBIO* provides authority to resist that reframing and insist on evaluating the actual claimed composition, including limitations a defendant labels "conventional."

Conclusion

REGENXBIO is not a magic words holding. The court's logic depends on understanding that the asserted claim reveals a technical impossibility in nature. When drafting or litigating, the goal is to ensure the claim limitations *compel* that inference. Additionally, this "whole-claim" lens that *REGENXBIO* applies is significant because most commercially meaningful biologics are assemblies of natural components arranged in non-natural ways. This case serves as a reminder that eligibility does not turn on whether each piece is "natural," but whether the claimed engineered whole exists in nature.

How Long Are the Arms of the European Courts? The Reach of Cross-Border Injunctions in Europe after *BSH Hausgeräte v Electrolux*

By Chris King, John Hornby, and Thomas Compton[71]

In February 2025, the Court of Justice of the European Union (CJEU) handed down a landmark judgment that opened the door to "long-arm" jurisdiction in infringement proceedings, allowing courts to rule on infringement actions in respect of patents granted by states outside their ordinary jurisdiction (*C-339/22, BSH Hausgeräte v Electrolux, 25 February 2025*). The judgment came in what was already an interesting time for European patent litigation, with the Unified Patent Court (UPC) having opened its doors in 2023. Now, over a year on from *BSH Hausgeräte v Electrolux*, we are seeing more clearly how the judgment is being interpreted by the UPC and the national courts, and what it means for patent enforcement strategies in Europe and beyond.

Jurisdictional Framework and Terminology

Before turning to the law, it is helpful to set out some definitions. States that are party to the European Patent Convention (EPC) are "EPC Contracting States". A European patent may be granted for any or all of the EPC Contracting States.

In this article, EU Member States (such as Germany, France, Italy and Spain) and states that are party to the Lugano Convention (such as Norway and Switzerland) will often be referred to together as "EU/Lugano States" because the same jurisdictional framework broadly applies to both: for EU Member States, jurisdiction in civil matters is governed by the Brussels I bis Regulation (Recast), and the Lugano Convention applies similar rules. The Brussels I bis Regulation (Recast) will be referred to by the abbreviation "BR".

"UPC Member States" refers to the EU Member States that participate in the UPC, including France, Germany and Italy. The UPC is a common court which has jurisdiction over actions where the courts of a UPC Member State would have jurisdiction (Articles 71a and 71b BR). Notably, the UPC Agreement (UPCA) expressly limits the UPC's jurisdiction to European patents, whereas some national courts may face no such limitation.

Straightforwardly, "non-UPC states" refers to all states which do not participate in the UPC, while "non-UPC EU/Lugano States" refers to a subset of the non-UPC states which are EU/Lugano States. Examples of non-UPC EU/Lugano States are Spain, Norway and Switzerland. "Third states" refers to states that are neither EU Member States (and therefore cannot be UPC Member States) nor parties to the Lugano Convention. Examples of third states include EPC Contracting States such as the UK and Türkiye, as well as states outside the European patent framework, such as the US and Japan.

The Situation Before *BSH Hausgeräte v Electrolux*

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Article 4(1) BR provides that parties can be sued in the courts of the EU Member State in which they are domiciled. However, following a decision of the CJEU in 2006 (*GAT v LuK, C-4/03, 13 July 2006*) the common understanding was that a court of an EU Member State hearing an action relating to infringement of a patent granted by another EU Member State could not proceed once invalidity had been raised (either as a defence or a counterclaim). This is because the Brussels Regulation provides that the state in which a patent was granted has "exclusive jurisdiction" as to the validity of the patent.

That said, cross-border preliminary injunctions have nonetheless been possible, because courts may grant provisional measures without jurisdiction as to the substance of the matter (Article 35 BR). Also, in *Solvay v Honeywell, C-616/10, 12 July 2012*, the CJEU held that the exclusive jurisdiction provisions do not necessarily preclude the granting of provisional measures. After *Solvay v Honeywell*, some European courts (such as the Dutch courts) became well known for issuing cross-border preliminary injunctions, but many others adopted a much more cautious approach.

BSH Hausgeräte v Electrolux

In *BSH Hausgeräte v Electrolux*, the CJEU considered again the "exclusive jurisdiction" of the court of the state in which a patent was granted as to the validity of a patent (Article 24(4) BR). The judgment distinguishes between EU/Lugano States and third states, such as the UK.

For the national part of a European patent in an EU/Lugano State, the CJEU held that the "exclusive jurisdiction" relates only to the part of the dispute relating to the validity of the patent. Accordingly, a court of an EU Member State (or the UPC) with jurisdiction over an infringement action regarding a national part of a European patent in an EU/Lugano State by virtue of the defendant's domicile does not lose jurisdiction where the defendant raises invalidity. However, the CJEU noted that the infringement court may stay proceedings if it considers that there is a reasonable, non-negligible possibility of the relevant patent being declared invalid by the court of the state in which the patent was granted.

For patents granted in a third state, the CJEU held that Article 24(4) BR does not apply at all. Thus, Article 24(4) BR does not preclude a court of an EU Member State (or the UPC) from considering the validity of patents granted in third states in an infringement action brought against defendants under the jurisdiction of the court by virtue of their domicile. However, this consideration of validity will not affect the existence or content of the patents in the third state, or cause its national register to be amended. As such, the decision only has *inter partes* effect.

Thus, *BSH Hausgeräte v Electrolux* substantially altered the position following *GAT v LuK* and set the stage for long-arm jurisdiction in infringement proceedings in Europe.

A Straightforward Case: *HL Display v Black Sheep*

The application of *BSH Hausgeräte v Electrolux* is most straightforward when the patent as granted is found to be valid, as it was in *HL Display v Black Sheep, UPC_CFI_386/2024 and 610/2024, 10 October 2025*. An infringement action was brought against a company domiciled in the Netherlands at The Hague Local Division of the UPC. As the Netherlands is a UPC Member State, the UPC had jurisdiction over the infringement action by virtue of the domicile of the defendant (Article 4(1) BR). The infringement action encompassed UPC Member States,

non-UPC EU/Lugano States (e.g. Poland, Switzerland and Norway) and a third state (the UK). Invalidity was raised by the defendant, as a revocation counterclaim in respect of the UPC Member States, and an invalidity defence in respect of the non-UPC states.

The Hague Local Division substantively examined validity and found the patent as granted to be valid. There were several implications of this. First, the counterclaim for revocation in respect of the UPC Member States was dismissed. Next, applying *BSH Hausgeräte v Electrolux* for the non-UPC EU/Lugano States, the court found that there was no serious, non-negligible chance of the patent being revoked by the competent national courts. Finally, applying *BSH Hausgeräte v Electrolux* for the third state (the UK), the court held that the patent was valid *inter partes*. Consequently, the court granted an injunction in respect of all of the states.

Partial Validity and Injunctions in Non-UPC EU/Lugano States: *Mul-T-Lock v IMC Creations*

The situation becomes more complex when, as in *Mul-T-Lock v IMC Creations, UPC_CFI_702/2024 and 369/2025, 16 January 2026*, the patent is found to be valid in amended form. In this case, an infringement action was brought against a French defendant at the Paris Local Division of the UPC. Jurisdiction was established by virtue of the domicile of the defendant (Article 4(1) BR). By the time of the hearing, the action concerned the UPC Member States and Switzerland (a non-UPC EU/Lugano State).

During proceedings, the patentee requested (as its main request) an amendment to the claims for the UPC Member States to improve their inventive step position. The amended claim was found to be valid and infringed. This amendment in the UPC proceedings had no effect in Switzerland, and the patentee did not initiate amendment proceedings in Switzerland. Applying *BSH Hausgeräte v Electrolux*, the court held there was a serious doubt as to the validity of the unamended Swiss part of the patent, resulting in a reasonable, non-negligible risk of invalidation by the Swiss courts. Consequently, the court dismissed the infringement claim insofar as it related to Switzerland. This suggests that initiating local amendment proceedings may be required to obtain long-arm injunctions in non-UPC EU/Lugano States.

Partial Validity and Injunctions in Third States: *Kodak v Fujifilm*

In *Kodak v Fujifilm, UPC_CFI_365/2023, 18 July 2025*, an infringement action was brought against three German entities at the Mannheim Local Division of the UPC. Jurisdiction was established on the basis of the domicile of the defendant (Article 4(1) BR). The action was in respect of acts performed in Germany and the UK. The court applied *BSH Hausgeräte v Electrolux* and held that the UPC has jurisdiction to decide upon the infringement in the UK, and to consider the validity of the UK part of the European patent on an *inter partes* basis.

During the proceedings, the patentee requested (as its main request) an amendment to claim 1, and the amended claim was found to be valid and infringed. The German patent register was updated to reflect this amendment. However, for the UK part of the patent, the court stated that the amendment only had *inter partes* effect, and the amended claim was held to be valid *inter partes*. Thus, the patent on the UK register remained unchanged. The court went on to grant a UK injunction without requiring any limitation of the UK part of the patent. This outcome should be compared to that in *Mul-T-Lock v IMC Creations* discussed above.

One can see that a curious situation arises here, where the patent in respect of which the UK injunction has been issued (*i.e.* the patent as amended during the proceedings) is different to the patent that is actually in force in the UK. This leads to some questions. For example, could Kodak bring proceedings in respect of the patent against a different party at the UPC or at the UK courts, and amend the patent in a different way (*e.g.* in order to cover a different infringement) during those proceedings?

Also, how would the matter proceed if, in the future, the UK courts were to revoke the UK part of the patent? Kodak may need to request that the UPC rescind the UK injunction ordered by the Mannheim Local Division on the basis that the UK part of the patent never existed. The Mannheim Local Division did not provide for this eventuality. However, Rule 354(2) of the UPC Rules of Procedure gives the UPC a discretion to order that an order is no longer enforceable, *e.g.* to lift an injunction. Another question raised is that of whether the infringement defendant would be permitted to bring a revocation action in the UK. While the Mannheim Local Division suggested that any validity declaration it made would not be binding between the same parties in revocation proceedings in the UK, the patentee may argue that the defendant should be estopped from bringing a revocation action in the UK on the grounds that doing so would amount to a re-litigation of the same cause of action between the same parties.

The UK injunction is to be enforced by the imposition of a penalty payment. Since issuing the UK injunction in July 2025, the Mannheim Local Division has commented on the enforcement of the UK injunction (*Kodak v Fujifilm, UPC_CFI_365/2023, 30 January 2026*). In the opinion of the Mannheim Local Division, for an order of the UPC in respect of a non-UPC state to be enforceable, and in the absence of a relevant treaty, the order of the UPC must be recognised by the courts of the non-UPC state. The comments of the Mannheim Local Division seem to suggest that this applies both (i) to the injunction being enforced by the UPC itself (*e.g.* by imposing penalty payments) and (ii) to the injunction being enforced locally in the UK by the UK courts. If this reasoning is followed by other Local Divisions and the UPC Court of Appeal, it may limit significantly the practical reach of the UPC's long arm.

The *Kodak* case is currently under appeal, with a decision of the Court of Appeal being expected in mid-2026.

The Role of Anchor Defendants and a CJEU Referral: *Dyson v Dreame*

So far, all of the cases discussed have been infringement actions brought against a defendant domiciled in a UPC Member State, allowing the UPC straightforwardly to claim jurisdiction over the defendant under Article 4(1) BR. However, in the *Dyson v Dreame* dispute, we see *BSH Hausgeräte v Electrolux* applied by the UPC to consider infringement in a non-UPC state (Spain) by a non-UPC-domiciled defendant – in this case a Hong Kong-based manufacturer ("HK manufacturer"). The HK manufacturer offers to supply allegedly infringing products throughout Europe (including in Spain) via its website. A co-defendant in the proceedings was the HK manufacturer's EU authorised representative ("authorised representative"). In many cases, it is a legal requirement that non-EU manufacturers have an authorised representative in the EU.

Dyson filed an application for a preliminary injunction at the Hamburg Local Division against, amongst others, the HK manufacturer and the authorised representative (*UPC_CFI_387/2025, 14 August 2025)*. The court noted that provisional measures may be granted even if the courts

of another EU Member State have jurisdiction over the substance of the matter (Articles 35 BR and 71b(2) BR). However, the court did go on to consider the underlying jurisdictional principles substantively, and this is discussed below.

A first finding of the Hamburg Local Division was that the authorised representative can be subject to a preliminary injunction. This was because the authorised representative is an intermediary whose services are being used to infringe a patent within the meaning of Enforcement Directive 2004/48/EC, which is incorporated into the UPCA in Article 63(1) and into the Spanish Patent Act. The UPC has jurisdiction over the authorised representative because of its domicile in Germany (a UPC Member State), and so granted a preliminary injunction against the authorised representative extending across the UPC Member States and to Spain.

Jurisdiction over the HK manufacturer in respect of the UPC Member States was established based on Article 7(2) BR (with Article 71b(2) BR), which provides that parties can be sued in the courts of the state where the harmful event occurred or may occur. More interestingly, the Hamburg Local Division also held that the authorised representative acts as an anchor defendant within the meaning of Article 8(1) BR, and thus the UPC has jurisdiction over the HK manufacturer in respect of Spain. Article 8(1) BR states the following, and Article 71b(2) BR opens this up to defendants domiciled outside of the EU for proceedings at the UPC.

> *A person domiciled in a Member State may also be sued… where he is one of a number of defendants, in the courts for the place where any one of them is domiciled, provided the claims are so closely connected that it is expedient to hear and determine them together to avoid the risk of irreconcilable judgments resulting from separate proceedings.*

The Hamburg Local Division went on to issue preliminary injunctions against the HK manufacturer and the authorised representative in respect of the UPC Member States and Spain.

This is not the first time that the UPC has applied Article 8(1) BR to establish jurisdiction over defendants domiciled in non-UPC states performing acts outside of the UPC Member States: in *Moderna v Genevant & Arbutus, UPC_CFI_191/2025 and 192/2025, 23 May 2025*, The Hague Local Division established jurisdiction over three Moderna entities domiciled in non-UPC EU/Lugano States (Norway, Spain and Poland) and performing acts in their respective states. This was on the basis that a Dutch Moderna entity was an anchor defendant, because it played a central role in the sales and supply across Europe, including in Norway, Spain and Poland.

Also, in February 2026, we saw another example of a UPC first instance court (The Hague Local Division) granting a long-arm preliminary injunction covering a non-UPC state (Spain) against a manufacturer domiciled outside of Europe (China) on the basis of an EU authorised representative acting as an anchor defendant (*Abbott v MicroTech, UPC_CFI_830/2025, 6 February 2026*).

Back to the *Dyson v Dreame* dispute, on appeal the UPC Court of Appeal stayed proceedings to the extent that they concern the action against the HK manufacturer in respect of Spain and the action against the authorised representative in respect of all states, and referred four questions to the CJEU (*UPC_CoA_789/2025 and 813/2025, 6 March 2026*).

The first question asks: is a situation in which (i) a first company from a non-EU state (*e.g.* Hong Kong) is alleged to have infringed a European patent in a non-UPC EU/Lugano state (*e.g.* Spain), and (ii) a second company from a UPC Member State (*e.g.* Germany) is alleged to be an intermediary whose services are used by the first company for the infringement (*e.g.* a European authorised representative) capable of leading to "irreconcilable judgments" resulting from separate proceedings, as referred to in Article 8(1) BR?

The second question asks whether, for provisional measures, a common court (*e.g.* the UPC) has jurisdiction over a company from a non-EU state (*e.g.* Hong Kong) that is alleged to infringe a patent in both (i) a UPC Member State, such as Germany, and (ii) a non-UPC EU/Lugano State, such as Spain, if the company is offering the same product through identical websites in both (i) and (ii). This question does not require that the company uses the services of an intermediary in a UPC Member State, and is therefore quite broad. The third question builds on the second question, asking whether the fact that the company uses the services of an intermediary (*e.g.* a European authorised representative) in a UPC Member State is relevant.

The fourth question asks whether preliminary injunctions can be granted against authorised representatives to prevent or prohibit infringement by other parties. The referral of these questions to the CJEU is far from a request for the CJEU to provide clarification of the general principle of long-arm jurisdiction. Rather, the questions are mainly focused on the specific situation that has arisen in the present case, involving a non-EU manufacturer working with a European service provider (though question 2 is slightly broader). Thus, the answers provided by the CJEU will not be relevant to every case involving long-arm jurisdiction. However, proceedings involving non-European manufacturers and EU authorised representatives are not uncommon. It is worth mentioning that CJEU preliminary rulings can take 15-24 months to be handed down, so we will not get answers to the questions for some time.

No Long-Arm Jurisdiction Based on Place of Infringement: *Adobe v KeeeX*

In all of the cases discussed above, long-arm jurisdiction has been established on the basis of the domicile of at least one of the defendants. However, a court can also establish jurisdiction in an infringement action if the harmful event (*e.g.* the infringement) occurs in the court's territory (Article 7(2) BR). But can Article 7(2) BR be used to establish long-arm jurisdiction over defendants domiciled outside of the UPC Member States?

The UPC Court of Appeal considered this question in *Adobe v KeeeX, UPC_COA_922/2025, 923/2025, 924/2025 and 925/2025, 13 March 2026,* in which none of the defendants was domiciled in a UPC Member State, and the action involved UPC Member States, non-UPC EU/Lugano States, and a third state. The court noted that the CJEU has previously ruled that, where jurisdiction is established under Article 7(2) BR, the court of the place where the harmful events occurred or threaten to occur has jurisdiction only to hear cases concerning the harmful events that have occurred or threaten to occur in the territory of the court. Thus, in *Adobe v KeeeX*, under Article 7(2) BR, the UPC could consider infringement actions in respect of the alleged infringements in the UPC Member States, but not in non-UPC states.

There is another provision which might allow the courts of EU Member States and the UPC to exert long-arm jurisdiction when jurisdiction is established on the basis of where the harmful event occurred. Article 71b(3) BR provides that, where the UPC has jurisdiction over a defendant in a dispute concerning infringement of a European patent that gives rise to damage within the EU, it may also exercise jurisdiction over damage arising outside the EU

from the infringement. The Court of Appeal left open the question of whether "damage arising outside the EU" could in theory be interpreted to mean infringement of parts of a European patent in non-UPC states.

The Court was able to leave open this question because KeeeX had not properly substantiated its arguments supporting the UPC's jurisdiction based on Article 71b(3) BR. On this, the first headnote of the Court of Appeal order states that *"[a]s a rule, the Statement of claim should contain the facts and legal arguments necessary to justify the jurisdiction of the Court."* This should be borne in mind by patentees looking to seek long-arm injunctions in cases where the jurisdictional situation is not straightforward.

Long-Arm Jurisdiction is Not Just For the UPC: *Regeneron v Formycon*

BSH Hausgeräte v Electrolux is not just for the UPC. This is shown by *Regeneron/Bayer v Formycon, 7O9382/25, 7O9383/25, 25 September 2025*, in which the Munich Regional Court I granted, on the basis of a nationally validated European patent, a preliminary injunction in respect of twenty-two of the EU Member States.

The defendants were domiciled in Germany, and so jurisdiction was established on the basis of Article 4(1) BR. Interpreting *BSH Hausgeräte v Electrolux*, the Munich Regional Court set out that it is not always necessary to suspend pending infringement proceedings in response to invalidity proceedings in another EU Member State or to the raising of an invalidity defence by the defendant; rather, it will depend on whether the court seised of the infringement proceedings considers validity to be "sufficiently secured." In earlier invalidity proceedings before the German Federal Patent Court, the patent-in-suit was held to be valid in amended form. Based on the decision of the German Federal Patent Court, it was assumed that the corresponding patents in the other EU Member States would be valid in the same amended form. Thus, validity was considered to be sufficiently secured.

Interestingly, the issuance of the preliminary injunction for the other EU Member States was not contingent on the amendment of the patents in those other EU Member States. This should be compared to the outcomes in *Kodak v Fujifilm* and *Mul-T-Lock v IMC Creations*.

This case shows that it is possible to obtain geographically broad injunctive relief in Europe without using the UPC. This is an important consideration for those considering bringing infringement proceedings in Europe. In some cases, the national courts of an EU Member State may be more attractive than the UPC, for example because of the types of relief available or procedural aspects of proceedings before the court.

Can Long Arms Reach the US: *BMW v Onesta*

Whereas the UPC is limited to disputes concerning European patents, the national courts of EU Member States are not restricted in the same way. In a dispute between BMW and Onesta, we have seen an attempt to use *BSH Hausgeräte v Electrolux* to assert US patents at a European court. In October 2025, Onesta (a non-practising entity) filed three infringement actions against BMW at the Munich Regional Court I, two of which were based on US patents. BMW is domiciled in Germany, and so would come under the jurisdiction of the Munich Regional Court under Article 4(1) BR. Under *BSH Hausgeräte v Electrolux*, the US is a third state, and so Article 24(4) BR seems not to preclude a court of an EU Member State (or the UPC) from

considering the validity of US patents if the court has jurisdiction over infringement because of the defendant's domicile.

BMW responded in the US, filing a declaratory judgment action and seeking an anti-suit injunction (ASI) preventing Onesta from pursuing the infringement actions in Germany. This action was filed at the US District Court for the Western District of Texas. Hearing the case, Judge Albright granted a temporary restraining order (TRO), and then later issued the anti-suit injunction (*Bayerische Motoren Werke Aktiengesellschaft (BMW) v. Onesta IP, LLC, No. 6:25-cv-00581, 2026 WL 474871 (W.D. Tex. 13 February 2026*)).

In granting the anti-suit injunction, Judge Albright noted that the German proceedings threatened to frustrate US policy that disputes over US patents should be adjudicated in US courts, and that the German proceedings would prejudice BMW by depriving it of procedural protections available under US law, including discovery and the right to a jury trial.

Onesta has now withdrawn all of the German infringement actions and, according to some reports, has irrevocably waived any substantive claims against BMW arising from the patents in suit. The actions were withdrawn before the Munich Regional Court issued any judgment or reasoned order, so we have no indication of how the German court would have responded to the assertion of the patents in jurisdictions outside of the EPC Contracting States, such as the US and Japan. Accordingly, whether courts of EU Member States will in fact seek to exercise long-arm jurisdiction over US patents remains to be seen.

The *BMW v Onesta* dispute suggests that, for infringement actions concerning US patents, anti-suit relief granted by a US court may offer an effective means of resisting the reach of the long arms of European courts. However, this option may not always be available, since it depends on the party bringing the European action being under the jurisdiction of a US court. Moreover, although Judge Albright of the Western District of Texas was willing to grant an anti-suit injunction in this case, the law governing such relief differs across the federal circuits, and other US courts may not necessarily take the same approach.

It remains to be seen whether the courts of other non-UPC states will be amenable to granting anti-suit relief to restrain proceedings before the UPC.

Concluding Thoughts

Both the UPC and the national courts of EU Member States are, in appropriate circumstances, willing to apply *BSH Hausgeräte v Electrolux* to establish long-arm jurisdiction, hearing infringement actions extending beyond their ordinary jurisdiction. However, the case law is still developing, and we are yet to see complete clarity on issues such as the effect of validity challenges, the effect of claim amendments, the nature of the anchor defendant, and the enforcement of long-arm injunctions. We are also yet to see whether *BSH Hausgeräte v Electrolux* will allow European courts to establish jurisdiction over patents outside of the EPC Contracting States, such as in the US. What is clear, though, is that *BSH Hausgeräte v Electrolux* has expanded the strategic options available to patentees in Europe, and so it is now even more important that questions of forum and territorial reach are considered in detail by all parties that are, or may become, engaged in infringement proceedings in Europe.

Enablement for Validity Versus Enablement for Anticipation: Lessons from *Agilent Technologies, Inc. v. Synthego Corp.*

By Clint South[72]

In June 2025, the Federal Circuit affirmed the PTAB's invalidation of two CRISPR-Cas gene editing patents in *Agilent Technologies, Inc. v. Synthego Corp*.[73] The decision is noteworthy not for breaking new doctrinal ground, but for its clear articulation of a distinction that chemical and biotech practitioners encounter regularly: the difference between enablement under 35 U.S.C. § 112 and enablement for prior art anticipation under 35 U.S.C. § 102. For practitioners drafting specifications, challenging patents in IPR, or defending against anticipation, *Agilent* offers a practical roadmap, and a reminder that a modest prior art disclosure can topple broad claims even where the patentee's own specification might survive a § 112 challenge.

I. The Case at a Glance

Synthego filed IPR petitions challenging Agilent's U.S. Patent Nos. 10,337,001 and 10,900,034, both directed to chemically modified guide RNAs ("gRNAs") for use in CRISPR-Cas systems. The patents claim priority to December 3, 2014 provisional applications. Representative claims recite a synthetic gRNA with chemical modifications near its 5′ or 3′ ends, wherein the gRNA retains "gRNA functionality comprising associating with a Cas protein and targeting the gRNA:Cas protein complex to a target polynucleotide."[74] Dependent claims narrow the modifications to specific types, including phosphonoacetate ("PACE") and thiophosphonoacetate ("thioPACE") groups.[75]

The Board found all claims unpatentable, holding that Pioneer Hi-Bred (an international patent application filed August 20, 2014, titled "Genome Modification Using Guide Polynucleotide/Cas Endonuclease Systems and Methods of Use") anticipated most claims and that certain dependent claims were obvious over Pioneer Hi-Bred when combined with other references.[76] The Federal Circuit affirmed in a unanimous opinion.

II. The Core Distinction: § 112 Versus § 102 Enablement

The heart of the decision is the court's treatment of enablement. The Federal Circuit drew a clear line between two inquiries that patent practitioners must keep separate.

Section 112 enablement requires a patent specification to teach a skilled artisan to both "make" and "use" the claimed invention across the full scope of the claims.[77] As the Supreme Court emphasized in *Amgen Inc. v. Sanofi*, "the more a party claims, the broader the monopoly it demands, the more it must enable."[78] Section 112 enforces the patent system's quid pro quo: exclusive rights in exchange for meaningful public disclosure.

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[73] 139 F.4th 1319 (Fed. Cir. 2025), *cert. denied*, No. 25-570, 2026 WL 858431 (U.S. Mar. 30, 2026).
[74] *Id.* at 1322.
[75] *Id.* at 1321-22.
[76] *Id.* at 1323.
[77] 35 U.S.C. § 112(a).
[78] 598 U.S. 594, 613 (2023).

Section 102 enablement demands less. The anticipation statute contains no requirement that a prior art reference enable the "use" of an invention; it requires only that the reference enable a skilled artisan to "make" the claimed subject matter.[79] As the *Agilent* court stated: "The reason for this distinction 'is that [§] 112 provides that the specification must enable one skilled in the art to "use" the invention whereas [35 U.S.C. §] 102 makes no such requirement as to an anticipatory disclosure.'"[80]

The seminal articulation of this principle appeared in *In re Hafner*, where the Court of Customs and Patent Appeals held that a disclosure lacking utility teaching is "entirely adequate to anticipate a claim" yet "entirely inadequate to support the allowance of such a claim."[81] The *Agilent* court reaffirmed this line of authority, stating plainly that § 112 and § 102 enablement "are two separate inquiries."[82]

This divergence reflects the different purposes of the two provisions. Section 112 ensures that patentees earn the scope of their monopoly through adequate disclosure. Section 102 prevents the patenting of subject matter the public could already practice. Requiring prior art to meet the same rigorous standard as patent specifications would improperly extend monopolies over subject matter already technically accessible to skilled artisans.

A. Principles of Prior Art Enablement

Agilent reaffirmed several established principles that, taken together, make prior art enablement a significantly lower bar than § 112 enablement.

No actual reduction to practice required. Anticipation "does not require the actual creation or reduction to practice of the prior art subject matter; anticipation requires only an enabling disclosure."[83] A reference need not prove that anyone actually made or tested the disclosed invention.

No proof of efficacy. The Federal Circuit has consistently held that "proof of efficacy is not required in order for a reference to be enabled for purposes of anticipation."[84] The reference need only show that a skilled artisan *could* practice the disclosure, not that it actually works or works well.

A single enabled embodiment suffices. This is perhaps the most consequential distinction. For § 102 purposes, "a prior-art reference to be enabling . . . need not enable the [challenged] claim in its entirety, but instead the reference need only enable a single embodiment of the claim."[85] Contrast this with § 112, which requires enabling "the full scope of the invention as defined by its claims."[86] The *Agilent* court invoked this distinction directly: "In the § 112 context, enablement ensures the patentee does not obtain a broader monopoly than the specification teaches. That is not a concern in the enabling anticipatory prior art context."[87]

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[79] *In re Hafner*, 410 F.2d 1403, 1405 (C.C.P.A. 1969)
[80] *Agilent*, 139 F.4th at 1329 (quoting *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1325 (Fed. Cir. 2005)).
[81] *In re Hafner*, 410 F.2d at 1405.
[82] *Agilent*, 139 F.4th at 1328-29.
[83] *Id.* at 1327 (quoting *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1380 (Fed. Cir. 2003)).
[84] *Id.* (quoting *Rasmusson*, 413 F.3d at 1326).
[85] *In re Morsa*, 803 F.3d 1374, 1377 (Fed. Cir. 2015).
[86] *Amgen*, 598 U.S. at 610.
[87] *Agilent*, 139 F.4th at 1329 n.10.

Presumption of enablement. Prior art patents and printed publications are presumptively enabled.[88] The burden falls on the patent holder to affirmatively demonstrate that undue experimentation would be required to practice the reference, a burden that proved insurmountable in *Agilent*.[89]

These principles combine to create significant exposure for broad functional claims common in chemical and biotech patents. A genus claim that encompasses millions of embodiments falls if prior art enables just one species within the genus, even if that species was never actually made or tested.

B. How the Court Applied These Principles

The Board's enablement analysis centered on whether a person of ordinary skill in the art, as of December 2014, could practice Pioneer Hi-Bred's disclosures without undue experimentation. While acknowledging that "the use of gRNA in a CRISPR/Cas system was a relatively new discovery first published in mid-2012," the Board found that by December 2014 the art "was far from a blank slate."[90] A POSITA would have understood how CRISPR-Cas components function together, which chemical modifications reduce RNA degradation while preserving functionality, and standard synthesis techniques for making the disclosed modified gRNAs.[91]
The Federal Circuit rejected each of Agilent's challenges to this finding.

Prophetic examples. Agilent argued that the prophetic nature of certain Examples in Pioneer Hi-Bred undermined the enablement presumption. The court disagreed, holding that "that fact alone does not undermine the presumption that Pioneer Hi-Bred is enabled."[92]

Non-working examples. The court held that "the disclosure of some non-working examples in Pioneer Hi-Bred does not undermine the disclosure of other examples that were disclosed as functional."[93] One enabled embodiment is sufficient.

Theoretical breadth. Most notably, Agilent argued that Pioneer Hi-Bred theoretically encompassed "over a quadrillion quadrillion" possible combinations. The court found this framing "not consistent with our case law."[94] The relevant question is whether undue experimentation is required "to make and use a gRNA with the claimed chemical modifications and functionality given the relevant disclosures in Pioneer Hi-Bred"; the question is not whether the reference mathematically encompasses a vast number of permutations.[95]

Distinguishing *Impax*. The court distinguished *Impax Laboratories, Inc. v. Aventis Pharmaceuticals*, where the prior art disclosed "hundreds or thousands of compounds and

[88] *Impax Lab'ys, Inc. v. Aventis Pharms., Inc.*, 545 F.3d 1312, 1316 (Fed. Cir. 2008); *In re Antor Media Corp.*, 689 F.3d 1282, 1288 (Fed. Cir. 2012).
[89] 139 F.4th at 1327.
[90] *Id.* at 1327.
[91] *Id.*
[92] *Id.*
[93] *Id.* at 1326.
[94] *Id.* at 1329 n.11.
[95] *Id.*

several diseases" without sufficient guidance.[96] Pioneer Hi-Bred, by contrast, "exemplifies particular crRNA sequences having the recited chemical modifications at the recited locations" in its Tables 7 and 8, providing specific examples of modified crRNAs.[97]

Distinguishing *Amgen*. The court identified two grounds for distinguishing the Supreme Court's 2023 decision. First, *Amgen* addressed § 112 enablement, "not whether a prior-art reference was enabling and could thus support anticipation."[98] Second, unlike *Amgen*, where the patents required "painstaking experimentation to see what works," here the Board found that skilled artisans understood how CRISPR-Cas elements function together.[99] *Amgen*'s rigorous full-scope analysis applies to the patentee's own specification, not to the prior art.

III. Practical Lessons for Chemical and Biotech Practitioners

Agilent offers actionable guidance at every stage of patent practice.

A. Drafting and Prosecution

Practitioners must ensure that specifications enable the full scope of the claims, recognizing that *Amgen* demands correspondingly broad enablement for broad claims. Including multiple working examples that span the claim scope remains essential. At the same time, practitioners should be mindful that prior art references will be judged under a more forgiving standard. Comprehensive prior art searches should account for references that disclose relevant subject matter even without demonstrating utility or efficacy. Such references may anticipate claims under § 102 even if they could never support a patent under § 112.

Practitioners should also consider whether narrowing functional claim language may reduce exposure. In *Agilent*, the broad "gRNA functionality" limitation swept in embodiments disclosed in Pioneer Hi-Bred. More specific structural limitations might have avoided anticipation, though at the cost of narrower coverage. This trade-off is inherent in claim drafting, but *Agilent* reminds us that functional breadth comes with anticipation risk.

B. IPR Petition Strategy

Petitioners benefit from the enablement asymmetry in several ways. They can rely on relatively sparse disclosures that plausibly enable one embodiment. They need not show the prior art actually worked or was reduced to practice. And the presumption of enablement shifts the burden to the patent owner.

Expert testimony is critical. In *Agilent*, Synthego's expert explained what a skilled artisan would have understood about CRISPR-Cas systems, RNA modifications, and synthesis techniques as of December 2014.[100] This testimony supported the Board's conclusion that practicing Pioneer Hi-Bred's disclosures would not require undue experimentation. Petitioners should anticipate the need for expert declarations addressing the *Wands* factors and explaining why the prior art is enabling in light of contemporaneous knowledge.

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[96] *Agilent*, 139 F.4th at 1328 (quoting *Impax*, 545 F.3d at 1315).
[97] *Id.*
[98] *Id.*
[99] *Id.*
[100] *See id.* at 1331-32.

C. Defending Against Anticipation

Patent owners face a steep climb. Overcoming the presumption of enablement requires affirmative evidence of true impossibility or undue experimentation, not arguments about theoretical breadth. *Agilent* illustrates several unsuccessful strategies: invoking vast numbers of theoretical combinations, pointing to prophetic examples, and highlighting non-working embodiments. None succeeded when the reference also disclosed functional embodiments with specific guidance.[101]

Successful defenses likely require demonstrating that the state of the art was genuinely nascent, meaning that skilled artisans lacked the foundational knowledge to practice the prior art's disclosures. In *Agilent*, the Board found the art "was far from a blank slate" by December 2014.[102] Patent owners must present robust expert testimony and contemporaneous evidence establishing that the field truly lacked the knowledge necessary to practice the reference.

D. Litigation Considerations

In district court, challengers should ensure that jury instructions clearly convey the enablement asymmetry. Fact-finders may assume that prior art must meet the same standard as patent specifications, a misconception that disadvantages the challenger. Clear instructions explaining that anticipation requires only an enabling disclosure of a single embodiment, without proof of efficacy or commercial viability, are essential.

E. Broader Significance

Agilent arrives at a moment of heightened attention to enablement doctrine. The Supreme Court's 2023 *Amgen* decision reinvigorated § 112 enablement as a meaningful constraint on claim scope, particularly for functionally defined genus claims. *Agilent* complements *Amgen* by clarifying what it does *not* hold: its rigorous enablement analysis applies to § 112, not to anticipation under § 102. A reference that would fail *Amgen*'s full-scope requirement may nonetheless anticipate claims because § 102 demands only that the reference enable a single embodiment.

For CRISPR-related disputes, the decision suggests that early prior art disclosures, even prophetic ones lacking experimental validation, may prove potent tools for challenging later-filed patents. The court found that by December 2014, "substantial research into such systems had been published" sufficient to enable practice of references like Pioneer Hi-Bred.[103] Patent owners in this space should carefully evaluate their exposure to early-filed references, particularly given the rapid development of CRISPR technology between 2012 and 2015.

More broadly, *Agilent* confirms a durable feature of patent law that chemical and biotech practitioners must account for: the enablement asymmetry between § 112 and § 102 is doctrinally sound and well-entrenched. Practitioners should structure their prosecution, IPR, and litigation strategies accordingly.

IV. Key Takeaways

[101] *Id.* at 1326.
[102] *Id.* at 1327.
[103] *Id.*

The core lessons from *Agilent* for chemical IP practitioners are straightforward:

1. **Section 112 and § 102 enablement are distinct inquiries.** Section 112 requires enabling a skilled artisan to "make and use" the invention across the full claim scope. Section 102 requires only enabling one to "make" a single embodiment.

2. **Prior art need not demonstrate utility, efficacy, or actual reduction to practice.** Prophetic disclosures and theoretical teachings can anticipate claims if they enable a skilled artisan to make the invention.

3. **Prior art is presumptively enabled.** The burden falls on the patent owner to show otherwise, and arguments based on theoretical breadth or non-working examples are unlikely to carry that burden.

4. ***Amgen*'s rigorous full-scope analysis applies to § 112, not § 102.** Practitioners should not assume that *Amgen* raised the bar for prior art enablement.

5. **Broad functional claims are especially vulnerable.** Claims defining inventions by function rather than structure encompass vast numbers of embodiments, any one of which can be anticipated by an enabling prior art reference.

Agilent does not rewrite the rules, but its thorough application of established principles to a high-profile CRISPR dispute, and its express distinction of *Amgen*, provides valuable clarity. As gene editing technology advances and patent disputes intensify, the enablement asymmetry will remain a critical battleground. *Agilent* offers practitioners on both sides a clear roadmap for navigating the terrain.

Polymorph Patent Applications in Latin America

By Iván Milic[104]

Abstract

This article outlines the current situation of patent applications related to chemical polymorphism in the Latin American context. It gives fundamental concepts of polymorphs and covers the criteria laid down by Latin American Patent Offices when evaluating these patent applications.

First Look: Polymorph

Scientific research and development contribute significantly to the development of drugs, where innovators find value in the science, polymorphism being a prime example. Polymorphs are essential tools in pharmaceutical development used to enhance bioavailability, stability, and manufacturability, among others.

In the pharmaceutical context, polymorphism refers to different solid forms (such as crystalline polymorphs, solvates, hydrates, and amorphous forms) of a chemical compound, which can differ in stability, solubility, and bioavailability, among others. Particularly, it is defined as the ability of a solid material to exist in more than one form or crystal structure. While the chemical formula remains identical, the arrangement of these molecules in the crystal lattice differs.

According to a quick search, evidence shows that by the 1980s, patent applications with polymorphism-based claims in solid-state (crystalline) drugs were filed. However, chemical polymorphism has become an issue since it gained relevance in the international framework. Obtaining an improved polymorph of a drug may sound simpler than it actually is. The creation of a polymorph is far from accidental. Even though the history of science records accidental breakthroughs, the development of polymorphs is generally the result of deliberate and informed action. Such achievements are manifestations of the systematic application of skills and cumulative knowledge. Technically, inventors need to force the obtainment of polymorphs through specific conditions, not only thermodynamic and kinetic conditions, but also solvents, temperature, etc. Hence, the outcome leans towards an invention rather than a simple discovery. Nevertheless, patent legislation provides legal requirements (novelty, inventive step, and industrial application) for an invention to be granted a patent, and polymorphs are not exempt from complying with these requirements.

The prevailing patent regimes operate under a dual framework of incentivized reward and public disclosure. The latter is fundamental to support the quid pro quo on which the system is based. Anyone seeking patent protection should describe the prospective invention comprehensively in order to obtain exclusivity on the product or procedure. With innovation as a primary objective, inventors seek to solve technical problems, thereby generating a positive impact on the quality of life for society.

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Research and development require significant time and a substantial capital investment. To compensate for these costs, the patent system grants inventors temporary exclusivity in exchange for fostering public knowledge through disclosure.

The Latin American Landscape

Polymorphism is treated inconsistently across Latin America. In some cases, jurisdictions have adopted specific rules within their patentability guidelines; in others, there is no specific legislation addressing polymorphs. What is certain is that each PTO established its own approach to handle the increasing focus on these patent applications.

Quite recently, in Argentina the Government has implemented a regulatory shift that broke a decade of precedent. The well-known Joint Ministerial Resolution has been repealed; said resolution was issued in 2012 with restrictive guidelines for pharmaceutical patent applications. It is worth recalling that the resolution indicated that polymorphs were considered inherent properties of solid-state substances rather than man-made inventions and viewed as mere discoveries of known substances. Consequently, claims directed to polymorphs of known compounds were not patentable, even if they exhibited unexpected, improved properties. Furthermore, the processes to obtain them were considered routine practice and obvious under conventional methods, failing to meet the requirement of an inventive step.

This decade-long framework no longer applies when examining polymorph applications. While this could have been an opportunity to formulate new rules governing the treatment of polymorphism, current reality shows a return to the status quo prior to the resolution. Now, polymorph applications will be examined on a case-by-case basis, applying the legal requisites of novelty, inventive step, and industrial applicability. Prior to the application of the Joint Resolution the Argentine Patent Office granted many patents for new crystalline forms of known compounds. It remains to be seen how examiners will react to this change, and it may take some time to ascertain the new criteria.

Colombia, Peru, Ecuador, and Bolivia are the members of the Andean Community, and they all are governed by Decision 486 -Common Provisions on Industrial Property- dated in 2000. Even though polymorphs are not mentioned in the Decision, member states have a different approach towards polymorph patent applications.

Both Colombian and Peruvian practice dictates that polymorph applications have been granted when an unexpected technical effect or significant technical advantages over the known form are demonstrated. Examiners usually apply the Andean Manual for Patent Examination which contains specific guidelines for the examination of polymorph patent applications regarding inventive step, clarity, or sufficiency of disclosure, including specific examples.

A different scenario for polymorphs unfolds in Ecuador, where local policy limits its patentability. Ecuadorian PTO has adopted a strict criterion in respect to the inventive step when dealing with polymorphs. While polymorphs are not explicitly excluded from patentability in Ecuadorian legislation, articles 268 and 273 of the Organic Code on the Social Economy of Knowledge, Creativity and Innovation indicate that polymorphs are not patentable subject matter. Although the legality of these articles could be challenged, in practice these applications are rejected.

The Chilean Patent Law does not refer to polymorphism. These patent applications are considered as chemical-pharmaceutical inventions subject to patentability requirements. In 2022, the PTO issued Guidelines specifying how polymorphs should be addressed during the examination stage. Their patentability depends on the unexpected advantages that can be evidenced, such as better stability, solubility or bioavailability compared to known structures. The problem-solution approach is applied for the assessment of inventive step. Moreover, claims should be clear and preferably limited to the particular polymorph and its advantageous properties, excluding salts or solvates without proper support in the specification.

After years of uncertainty, Brazil has unified its criteria based on technical merit, moving away from categorical prohibitions. Polymorphs are patentable subject matter as long as the requirements of novelty and inventive step are met. It is worth noting that the burden of evidence is substantial. Beyond being novel, the polymorph must demonstrate a non-obvious technical advantage.

In Mexico, the governing legal framework is the Federal Law on the Protection of Industrial Property (LFPPI) published in 2020. Unlike other countries that have issued resolutions to restrict the protection of polymorphs, Mexico has kept a broad definition of patentable subject matter. Articles 45 and 47 of the Federal Law determine the scope of an invention without excluding new forms of known substances. As a result, polymorphs are, in principle, patentable subject matter. However, satisfying the requirements of inventive step and sufficient disclosure poses a challenge involving a demanding evidentiary standard. Mexican PTO applies rigid examination criteria, generally requesting applicants to demonstrate an unexpected technical effect and a clear advantage.

The Bottom Line

Polymorphism contributes to the development of inventions that provide significant societal benefits. Subject to meeting legal patentability criteria, a patent may be granted. In the Latin American context, Patent Offices apply divergent criteria. A shift in the regional legislation is vital to align with international standards on this subject (as seen in the recent shift in Argentina).

High Court of Australia to determine the future of patent term extensions for pharmaceutical formulation patents

By Candace Wu and Michael Christie[105]

In late 2025, the Full Court of the Federal Court of Australia issued a landmark decision in *Otsuka Pharmaceutical Co Ltd v Sun Pharma ANZ Pty Ltd* [2025] FCAFC 161 (Otsuka v Sun Pharma), finding that Otsuka's patent to controlled release aripiprazole formulations is not eligible for a patent term extension (PTE).

The decision diverged from several first instance decisions of the Federal Court and the longstanding practice of the Australian Patent Office to allow PTEs for formulation patents. Otsuka appealed the decision to the High Court of Australia – Australia's highest appellate court. The High Court has granted special leave to appeal, and we can expect a decision to be handed down within the next 12 months.

Criteria for patent term extensions in Australia

Australia's Patents Act provides an extension of up to five years beyond the standard 20-year term for certain pharmaceutical patents, provided the following criteria are met:

1. one or more pharmaceutical substances *per se* (or one or more pharmaceutical substances when produced by a process that involves the use of recombinant DNA technology) is in substance disclosed in the patent specification and in substance falls within the scope of the claims;
2. goods containing, or consisting of, the substance must be included in the Australian Register of Therapeutic Goods (ARTG);
3. the period beginning on the effective filing date of the patent and ending on the first regulatory approval date of the pharmaceutical substance must be more than five years; and
4. the term of the patent must not have been previously extended.

The Patents Act defines a 'pharmaceutical substance' as:

> a substance (including a mixture or compound of substances) for therapeutic use whose application (or one of whose applications) involves:
>
> a. *a chemical interaction, or physico-chemical interaction, with a human physiological system; or*
> b. *action on an infectious agent, or on a toxin or other poison, in a human body;*
>
> but does not include a substance that is solely for use in in vitro diagnosis or in vitro testing.

The Australian Patent Office has long taken the view that this definition encompasses pharmaceutical formulations comprising an active pharmaceutical ingredient (**API**) and excipients, and that patents claiming pharmaceutical formulations are therefore eligible for a PTE, subject to other requirements being met. This position has been supported by several first instance decisions of the Federal Court of Australia.

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Background to the dispute

Otsuka Pharmaceutical Co., Ltd (**Otsuka**) is the patentee of an Australian Patent No. 2004285448, entitled 'Controlled release sterile injectable aripiprazole formulation and method.' The patent claims are to controlled release aripiprazole formulations and its standard 20-year term expired on 18 October 2024.

Otsuka obtained a PTE based on the ARTG listing of Abilify Maintena, used for the treatment of schizophrenia and bipolar disorder, and the patent's term was extended to 25 July 2029.

Sun Pharma contended that the PTE was wrongly granted. Otsuka cross-claimed for threatened infringement of its patent.

The "pharmaceutical substance"

The Full Court considered that only an active ingredient is capable of interacting with a human physiological system (or acting on an infectious agent, toxin or poison) in the manner contemplated by the statutory definition of "pharmaceutical substance."

In examining the legislative history of the PTE regime, the Full Court found that the Parliament's intention was for the definition of 'pharmaceutical substance' to be limited to APIs. Specifically, the Full Court noted that the legislative purpose of the PTE regime is to compensate patentees for delays encountered when seeking regulatory approval for new and inventive substances, but not for improvements in delivery systems or dosage forms (i.e., new formulations), which, the Court found, do not face the same regulatory delays.

Consequently, the PTE granted on Otsuka's controlled-release formulation patent was found to be invalid.

Consequences of Otsuka's High Court Appeal

Although Otsuka v Sun Pharma concerns a specific pharmaceutical formulation, the case has potential consequences for patents to pharmaceutical formulations more broadly.

The Full Court's decision, if upheld by the High Court, will significantly narrow the range of patents that are eligible for a PTE under Australian law, and many existing PTEs granted on the basis of pharmaceutical formulations will be vulnerable to challenge.

Until a decision of the High Court is handed down, there will be a degree of uncertainty surrounding the PTE eligibility of patents to pharmaceutical formulations in Australia. The Australian Patent Office has issued a statement that it will pause processing PTE applications which may relate to formulations.

While this much-anticipated decision of the High Court is expected within the next 12 months, the precise timing will depend on the availability of counsel and the Court's workload.

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