

Chemical Practice Chronicles

Newsletter of the AIPLA Chemical Practice Committee

Fall 2026

Volume 14 Issue 2

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Dear Members of the Chemical Practice Committee,

As I conclude my term as Chair, thank you to everyone who attended our meetings and events, spoke at our programs, or sponsored our activities. The level of involvement in this committee is outstanding, and your contributions make it such a strong community.

I'm especially grateful to our subcommittee chairs: Sommer Zimmerman and Kimberlee Raley, newsletter co-editors-in-chief; Chloe Holloway and Tom Irving, who lead professional programs culminating in the Advanced Chemical Practice Institute in San Francisco; Ethan Ung and Andrew Chipouras, monthly legal updates; Warren Zitlau and Robert Sovesky, communications; Matt Barton and Mark Pidkowich, international; and Yingling Lai, Eleda Plouch, Jason Wang, and Kei Webber, new practitioner & law students.

Thank you to Rivka Jungreis, our board liaison, for her continued support and for connecting us with the AIPLA Board. I'm also grateful to everyone who helped coordinate Institute sessions. Josh, a special thank-you for your dedication, support, and friendship over the past two years. I've valued working with you, and I'm delighted to pass the chair role to you. I'm excited to see the committee move forward under your leadership, with Sommer as vice chair.

Leading this committee has been an honor and a highlight of my professional career. I hope to see you at the Annual Meeting, next month's virtual CLE program, and our next committee call.

Warm regards,
Ali Anoff, Outgoing Chair, Chemical Practice Committee

Dear Members of the Chemical Practice Committee,

I am humbled and honored to step into the role of Chemical Practice Committee chair and to advance our committee's mission. From educating members on the latest developments in law and technology to fostering networking opportunities, we are one of AIPLA's most active committees, which is due in no small part to all your collective efforts. I look forward to working with Sommer, Debora, the subcommittee chairs, and all of you.

A special thank you to Ali for her exceptional leadership and guidance over the past several years. The Chemical Practice Committee thrived during her highly successful term, due in no small part to Ali's dedication, vision, and inspiration. Prior to her role as chair, she served as vice chair and, during her tenure, has been instrumental in developing and implementing the highly popular Chemical Practice Chronicles and Advanced Chemical & Biotech Practice Institute. Thank you, Ali! I am excited to have you continue your involvement with the committee and AIPLA.

I look forward to seeing everyone at the Annual Meeting and at our next committee call.

With best regards,

Josh Goldberg, Incoming Chair, Chemical Practice Committee

ANNOUNCEMENTS

2026 Annual Meeting

The 2026 AIPLA Annual Meeting will be held **October 29-30, 2026** at the Westin Washington, DC Downtown. More information can be found [here](#).

Joint Cocktail Reception at the 2026 Annual Meeting

The Biotechnology, Chemical Practice, and Food & Drug Committees are co-hosting a cocktail reception at the AIPLA Annual Meeting. The reception will be held on **Thursday, October 29th from 5:00 to 6:00 PM at The Westin DC Downtown, Anacostia Ballroom, Salon F**. Come and have a few drinks and get to know your fellow members!

November CLE Programming

An AIPLA CLE Webinar is scheduled for **November 19, 2026 at 10:30 to 12:00 PM** entitled “Data and Market Exclusivity: An Update on China’s New Law and Comparisons to the US and Europe.” More information can be found [here](#).

Committee Quarterly Calls

The next Committee call is scheduled for **January 12, 2027 at 1:00 PM**. Additional details will be shared via the Chemical Practice Committee microsite prior to the events.

2027 Spring Meeting

The 2027 AIPLA Spring Meeting will be held **May 6-8, 2027** in Denver, Colorado at the Hyatt Regency Denver at the Convention Center. More information can be found [here](#).”

The ARP's Decision in *In re Baurin* and the Continuing Controversy Over OTDP

By Leia Dingott¹

In a decision issued on August 6, 2026, an Appeals Review Panel (ARP) *sua sponte* took up *In re Baurin* in what appears to be an effort to encourage the Federal Circuit to provide clearer guidance regarding the role of the anti-harassment rationale in non-statutory, or obviousness-type, double patenting (OTDP). The opinion, authored by the Director of the USPTO, reversed the prior PTAB decision in *In re Baurin* and reinstated the Examiner's original rejection.

The central issue in the case was whether a later-filed patent may serve as the reference patent in an OTDP rejection against an earlier-filed patent. The Director revived the view that such a later-filed patent can serve as the reference by characterizing *Allergan* as having a narrower holding limited to actual filing dates rather than priority dates or effective filing dates. *Allergan USA, Inc. v. MSN Laboratories Private Ltd.*, 111 F.4th at 1369. (Fed. Cir. 2024).

The application at issue, U.S. Application No. 17/135,529 (the "'529 application"), was filed on December 28, 2020. The '529 application claimed priority to an application filed on March 28, 2012, and therefore would be expected to expire in 2032, based on that earlier priority date. Although six OTDP rejections were raised against the '529 application, both the appeal and the ARP focused on U.S. Patent No. 10,882,922 B2 (the "'922 patent") in view of U.S. Patent Application Publication No. 2009/0162359 A1 ("Klein").

The '922 patent was filed on April 13, 2017, and is scheduled to expire in 2037, including a 70-day patent term adjustment. The Examiner contended that claims 1-18 of the '529 application would have been obvious over claims 1-39 of the '922 patent in view of Klein. The applicant did not directly contest that obviousness analysis. Instead, the applicant argued that the claims of the '922 patent would not have been obvious over the disclosure of the '529 application. The Examiner acknowledged that argument.

Under the reasoning of *Allergan*, the '529 application's priority claim reaches back to a filing date that predates and expires before the '922 patent. Consequently, the applicant would not be obtaining any extension of patent term beyond that of the '922 patent, and a terminal disclaimer would seemingly be unnecessary. However, that reasoning relies on the effective filing date of the '529 application rather than its actual filing date. Because the '529 application was actually filed after the application that matured into the '922 patent, the ARP concluded that *Allergan* did not control.

The ARP opinion devoted substantial attention to the historical development of OTDP. The panel began with the basic principle that the Patent Act does not permit multiple patents covering merely obvious variations of the same invention. The opinion then traced the development of exceptions to that principle.

¹ Leia Dingott is with the law firm of Nath, Goldberg & Meyer (<https://nathlaw.com/>).

In 1952, Congress enacted what is now the statutory basis for terminal disclaimers. By 1964, the Court of Customs and Patent Appeals (CCPA) had permitted terminal disclaimers to overcome certain double patenting rejections. The CCPA reasoned that terminal disclaimers preserved the fundamental objective of limiting patentees to a defined period of exclusivity covering both an invention and its obvious variants.

The decision also reviewed the changes brought about by the Uruguay Round Agreements Act (URAA) in 1994. Prior to the URAA, patents generally expired seventeen years from issuance. Under that regime, the original OTDP doctrine focused on preventing later-issued patents from extending exclusivity through later expiration dates. Following the URAA, patents generally expire twenty years from their filing date, or effective filing date, making an issuance date a less reliable indicator of patent term. Nevertheless, an expiration date remains central to OTDP analysis because the doctrine continues to seek to prevent patent owners from obtaining additional patent term for obvious variations of their own inventions.

According to the ARP, contemporary OTDP doctrine rests on two rationales. The first is the well-established rationale of preventing unjustified extensions of patent exclusivity. The second is the more controversial anti-harassment rationale, which seeks to prevent an accused infringer from facing multiple lawsuits brought by different owners of closely related patents.

The ARP acknowledged that courts have noted the availability of procedural mechanisms for addressing such concerns and observed that, despite nearly two decades of reliance on the anti-harassment rationale, there appears to be little evidence that the feared scenario of harassment by multiple patent owners has actually materialized. Nevertheless, the ARP emphasized that the rationale remains part of Federal Circuit precedent.

The anti-harassment rationale first appeared in *In re Fallaux*, 564 F.3d 1313, 1319 (Fed. Cir. 2009), and was later applied in *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013). The ARP explained that examiners are instructed to consider both rationales when evaluating OTDP rejections. As a result, the panel concluded that the anti-harassment rationale cannot simply be disregarded, even though its continuing significance has been questioned by commentators and courts alike.

At the same time, the opinion appears conflicted. The ARP repeatedly suggested that it was merely following Federal Circuit precedent, yet the opinion reads as an invitation for the Federal Circuit to revisit and clarify the doctrine. The panel's analysis arguably departs from prior decisions, including *Ex Parte Corteva*, in which the Board interpreted *Allergan* as preventing "a first-filed, first-issued, later-expiring claim [from being invalidated] by a later-filed, later-issued, earlier-expiring reference claim having a common priority date." *Ex Parte Corteva* (PTAB June 9, 2026). The Board in *Ex Parte Mates* addressed the harassment rationale head-on describing it as a secondary consideration after a valid OTDP rejection has been made. *Ex Parte Mates* (PTAB Dec. 23, 2025).

If the ARP's objective was to reduce uncertainty surrounding OTDP or diminish the influence of the anti-harassment rationale, it could have allowed existing Board precedent to remain in place while awaiting guidance from pending Federal Circuit cases addressing similar issues. One such

case is *In re Ablynx N.V.*, No. 26-1333 (Fed. Cir.), which arose from *Ex Parte Baumeister*, 2025 WL 3515282 (PTAB Nov. 20, 2025).

Instead, the ARP chose to intervene and issue a comprehensive opinion. As a result, the decision appears less focused on resolving the specific dispute before it and more directed toward expanding the ongoing judicial debate regarding the proper scope and justification of OTDP doctrine.

Wyeth v. AstraZeneca: A Unit Dosage of Enablement

By Sommer Zimmerman, JD, PhD²

Background

On July 9, 2026, the Federal Circuit affirmed a district court's grant of judgment as a matter of law (JMOL) that two Wyeth patents, U.S. Patent Nos. 10,603,314 ("the '314 patent") and 10,596,162 ("the '162 patent"), directed to treating drug-resistant non-small cell lung cancer (NSCLC) were invalid for lack of enablement under 35 U.S.C. § 112(a), wiping out a \$107.5 million jury verdict against AstraZeneca.³ The asserted patents claim methods of treating gefitinib- and/or erlotinib-resistant NSCLC via daily administration of a "unit dosage" of an irreversible epidermal growth factor receptor (EGFR) inhibitor that covalently binds cysteine 773 of EGFR or cysteine 805 of erb-B2.⁴ The decision is a cautionary tale for practitioners drafting and prosecuting method-of-treatment claims, and it shows how a seemingly routine definition in the specification can become the determinative factor to establish (or not establish) patent validity.

The specification explained that the inhibitor "may be any compound which binds to cysteine 773 of EGFR," but described only three compounds (EKB-569, HKI-357, and HKI-272) as exemplary inhibitors with *in vitro* data showing "increased killing of NSCLC cells harboring an EGFR mutation" as to these three compounds. No working examples in patients were provided. Wyeth sued AstraZeneca in September 2021, alleging induced infringement through sales of Tagrisso (osimertinib). After a five-day trial, the jury found the claims not invalid and infringed, and awarded Wyeth \$107,500,000 in damages. The district court then granted AstraZeneca's motion for JMOL post-verdict, concluding that the patents provided "only a starting point, a direction for future research" that would require "an iterative, trial-and-error approach to practice the claimed invention."⁵ Wyeth appealed.

A boilerplate definition of "unit dosage" set the bar for enablement

Claim 1 of the '314 patent recites "administering daily to the patient ... a pharmaceutical composition comprising a unit dosage" of an irreversible EGFR inhibitor. As defined in the specification, the term "unit dosage" means "physically discrete units suitable as unitary dosage for the subject, each unit containing a predetermined quantity of active material calculated to

² [Sommer Zimmerman](#), JD, PhD, is an associate in the Atlanta, Georgia office of Ballard Spahr LLP.

³ *Wyeth LLC v. AstraZeneca Pharms. LP*, 180 F.4th 1371 (Fed. Cir. 2026) (Lourie, J., joined by Linn and Hughes, JJ.), *aff'g* *Wyeth LLC v. Astrazeneca Pharms. LP*, No. 1:21-cv-01338-MFK, 2024 U.S. Dist. LEXIS 144596, 2024 WL 3823006 (D. Del. 2024) (Kennelly, J.).

⁴ The claims at issue were claims 1, 3, and 9 of U.S. Patent No. 10,603,314 and claim 1 of U.S. Patent No. 10,596,162.

⁵ *Wyeth*, 2024 U.S. Dist. LEXIS 144596, [WL] at 15 (quoting *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 939-41 (Fed. Cir. 2010)).

produce the desired therapeutic effect in association with the required diluents.”⁶ The district court adopted that definition at claim construction, and it went unchallenged.⁷

Wyeth argued on appeal that the recited therapeutic effect required nothing more than inhibiting EGFR and killing cancer cells, and that the district court had improperly imported FDA-style clinical safety and efficacy requirements into the claims. While the Federal Circuit agreed that the claims do not require FDA-type safety and efficacy, it noted that the words “administer[ed] daily” to a “patient” must be given meaning, because “[a] claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.”⁸ The claims therefore “necessarily contemplate[d] some repeatable dosing regimen calculated to produce a therapeutic effect *in a patient*,” a requirement that “draws the claims beyond merely requiring ‘killing cancer cells,’ yet constrains them short of requiring full-blown FDA-type clinical safety standards.”⁹

The specification did not provide a basis for translating the *in vitro* data into a daily dosing regimen in a patient

Applying the familiar rule that “the specification must enable the full scope of the invention as defined by its claims,” and that “[t]he more one claims, the more one must enable,”¹⁰ the court held that the specification had to provide some basis for translating *in vitro* activity into a daily dosing regimen in a patient across the full scope of compounds recited in the claimed treatment method. Here, it did not.

The specification stated that dosage “depends on the subject to be treated, capacity of the subject’s system to utilize the active ingredient, and degree of therapeutic effect desired,” as well as “the particular compound employed, the mode of administration and the severity of the condition being treated,” and that “[p]recise amounts of active ingredient . . . depend on the judgment of the practitioner and are peculiar to each individual.”¹¹ It offered that “in general, satisfactory results are obtained . . . at a daily dosage of from about 0.5 to about 1000 mg/kg,” and that the “total daily dosage is projected to be from about 1 to 1000 mg, preferably from about 2 to 500 mg.”¹² Nowhere, however, did the specification provide any description of “how those ranges were derived, how a skilled artisan would select among them for a given compound, or how they relate to the claimed unit dosage calculated to produce a therapeutic effect in a patient.”¹³

Nor could Wyeth fill this gap with the knowledge of one of ordinary skill in the art. The specification asserted that the “skilled artisan is aware of the effective dose for each patient,”¹⁴

⁶ *Wyeth* at 1374.

⁷ *Wyeth* at 1378.

⁸ *Wyeth* at 1378 (quoting *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005)).

⁹ *Id.*

¹⁰ *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610 (2023)). See also *Baxalta Inc. v. Genentech, Inc.*, 81 F.4th 1362 (Fed. Cir. 2023).

¹¹ ‘314 patent at col. 8, lines 55-57; and col. 9, lines 42-46;

¹² ‘314 patent at col. 8, lines 59-66.

¹³ *Wyeth* at 1380.

¹⁴ ‘314 patent at col. 8, lines 57-58.

but otherwise left “dosage determination entirely to the skilled artisan.”¹⁵ The court emphasized that “[i]t is the specification, *not* the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.”¹⁶ The principle that a specification need not disclose what is well known is “merely a rule of supplementation, not a substitute for a basic enabling disclosure.”¹⁷

Inoperative embodiments, and the inventors’ own words, sealed the outcome

The most damaging evidence was unrebutted: for two of the three exemplary compounds, all therapeutically effective doses across the disclosed ranges exceeded the maximum tolerated dose in humans, and Wyeth’s experts opined that the same “may also be true” of the third.¹⁸ Dr. Hausheer, Wyeth’s invalidity expert, agreed that a skilled artisan would seek to avoid toxic doses. Co-inventor Dr. Haber testified that “the drug concentrations in the asserted patents were ‘five times higher’ than what could be administered to patients,” and the inventors’ 2008 publication further acknowledged that “concentrations required in vitro may not be achievable in patients due to drug toxicity.”¹⁹ Inoperative embodiments of this kind only “reinforc[e] the lack of guidance provided by the specification.”²⁰

Notably, the court was explicit that the significance of this evidence was not imposed a toxicity limitation within the claims themselves. Rather, the evidence demonstrated just how little guidance the specification provided as to which dosages were suitable. Again, the court emphasized that one “cannot simply rely on the knowledge of a person of ordinary skill to serve as a substitute for the missing information in the specification,” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.”²¹

Key Takeaways

Practitioners should not read *Wyeth* as condemning method-of-treatment claims generally. The court stated: “We recognize that it is accepted practice in patent law for one to be able to claim a method of treatment disclosing a range of doses to be administered, without showing actual clinical data, and leaving it to the FDA to ensure that approved products are safe and effective.”²² What doomed Wyeth’s patents was the difference between what was claimed and what was disclosed in the specification: “The problem with these patents is that, perhaps because of close prior art, their claims are limited to dosage forms to be administered to patients, yet they disclosed only a broad range of doses some of which were shown to be toxic, and they disclosed

¹⁵ *Wyeth* at 1380.

¹⁶ *Id.* (quoting *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1159 (Fed. Cir. 2019), and *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997)) (emphasis added).

¹⁷ *Wyeth* at 1380 (citing *Genentech* at 1366).

¹⁸ *Wyeth* at 1381.

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.* at 1382 (quoting *ALZA Corp.*, 603 F.3d at 941, 943).

²² *Id.*

no actual dosages for any compound within the scope of the claims, thereby leaving it to a practitioner of the claims to perform undue experimentation.”²³

The central lesson of *Wyeth* is to be careful about reciting a functional result in a patient. A claim that requires administering a unit dosage to a patient, particularly one defined as having been “calculated to produce the desired therapeutic effect,” invites the question of whether the specification actually teaches how to arrive at that dose for every compound within the recited genus. Definitions deserve close review, because a court will adopt them and give operative meaning to every term they touch. Inoperative embodiments can be dangerous, especially where the patentee’s own disclosed compounds fall outside any tolerable dose. And *in vitro* data paired with “general” or “projected” ranges will not carry an *in vivo* dosing limitation unless the *in vitro* data is readily translatable to an *in vivo* method. At the same time, the court’s carve-out confirms that claiming a method of treatment with a disclosed dose range, without clinical data, remains accepted practice when the disclosure provides a genuine basis for that range.

Practice Tips

At least three strategic recommendations flow from the decision:

First, scrutinize boilerplate. Definitions of commonplace terms such as “unit dosage” may seemingly require little scrutiny, but in *Wyeth* that definition translated into a required claim element of a therapeutically effective dose in a patient. Drafters should consider whether a definition adds a functional result they cannot support, and should use phrases like “administering daily to the patient” only where the specification clearly describes how to do this based on the exemplary data disclosed.

Second, build a bridge from the bench to the bedside. Where claims recite patient dosing, the specification should explain how dosing ranges were derived, for example, by providing a rationale for pharmacokinetic and pharmacodynamic parameters, animal-to-human scaling, or compound-specific ranges tied to the disclosed data. Ranges labeled merely as “general” or “projected,” without an explained basis, invite the criticism the court leveled here, particularly where ranges encompass toxic doses for preferred embodiments (e.g., inoperative embodiments). Likewise, statements that the “skilled artisan is aware of the effective dose” are no substitute for actual guidance and should not be relied upon where a novel feature of the invention is arriving at that effective dose.

Third, align genus breadth with disclosure. A functional genus such as “any compound which binds to cysteine 773” supported by three compounds tested only *in vitro* is particularly vulnerable when paired with an *in vivo* limitation. Consider pursuing method claim sets tailored to the exemplary data in hand, and file new provisional applications to pursue narrower, dose-specific claims as clinical data emerge.

²³ *Id.*

Understanding the Impact of the EPO Enlarged Board Decision G I/24 on European Patent Law

By Ellie Seymour and Andy Nicoll²⁴

On 18 June 2025, the Enlarged Board of Appeal (EBA) issued its much-awaited decision on case [G I/24](#). The EBA is the highest judicial authority within the European Patent Office (EPO) and is responsible for ensuring the uniform application of the European Patent Convention (EPC). The EBA addressed two questions referred by a Board of Appeal, both concerning claim interpretation for the assessment of patentability. In particular, the questions related to the extent to which the description and drawings must be used when construing claims.

Diverging approaches that triggered the referral

Two diverging lines of case law had emerged.

In one approach, the description and drawings were only used to interpret ambiguous terms (sometimes referred to as “primacy of the claims”). In another approach, claims were generally interpreted in light of the description and drawings.

This inconsistency was highlighted in opposition appeal T 439/22, in which the opponent and proprietor advocated for differing approaches. Unable to determine which approach should be applied under the EPC, the Board referred three questions to the EBA.

EBA’s Decision

In short, the EBA held that claims should always be interpreted taking the description and drawings into account when assessing patentability (not only to interpret unclear claim terms).

The EBA’s order reads as follows:

The claims are the starting point and the basis for assessing the patentability of an invention under Articles 52 to 57 EPC. The description and drawings shall always be consulted to interpret the claims when assessing the patentability of an invention under Articles 52 to 57 EPC, and not only if the person skilled in the art finds a claim to be unclear or ambiguous when read in isolation.

Regarding the question of legal basis, the EBA acknowledged that the EPC does not explicitly mandate this approach but found support in established case law for analogous application of the relevant provisions.

²⁴ Ellie Seymour (<https://www.elkfife.com/people/ellie-seymour>) and Andy Nicoll (<https://www.elkfife.com/people/andy-nicoll>) are with the firm of Elkington + Fife (<https://www.elkfife.com/>), a firm of patent and trademark attorneys based in Holborn, central London, and Sevenoaks in Kent.

Possible Repercussions

The decision provides welcome clarity on how the EPO will interpret claims in post-grant proceedings, bringing its approach more closely in line with the courts of many EPC member states. Its impact on examination practice, however, remains less certain. On one hand, applicants may seek to rely more on the description to support claim interpretation and potentially avoid incorporating “essential parameters” directly into the claims when objections are raised. On the other hand, Examining Divisions may feel encouraged to adopt a stricter approach to description amendments, particularly where discrepancies could influence claim interpretation. The result may be a shift toward more rigorous scrutiny of internal consistency during prosecution.

Reasons for the Decision

In its decision, the EBA emphasised the objective of harmonisation. The EBA considered that the EPO should carry out claim interpretation consistently pre- and post-grant. Further, the EBA considered it desirable for the EPO’s approach to be aligned with that of the national courts of the EPC member states and the Unified Patent Court, confirming that its decision was consistent with the current case law of the UPC (referring in particular to [Nanostring Technologies v 10x Genomics](#)).

The EBA considered the notion that the EPO should deliberately adopt a contrary practice to that of the tribunals downstream of its patents (national courts, the UPC) to represent a “most unattractive proposition”.

Drafting strategies in light of G 1/24

- Define potentially ambiguous terms: Continue to include definitions in the description for any claim terms that might be considered ambiguous: the EBA’s decision highlights the “importance of the examining division carrying out a high-quality examination of whether a claim fulfils the clarity requirements of Article 84 EPC” and emphasises that “the correct response to any unclarity in a claim is amendment”.
- Flag intended special meanings: Include definitions in the description for any claim terms that are intended to have a meaning that might differ from the “normal meaning” of that term in the relevant art.
- Draft “claim-ready” definitions: Bearing in mind the EPO’s strict requirement that an amendment be “directly and unambiguously derivable from the application as filed,” ensure definitions included in the description are clear, consistent, and in a form suitable for being introduced into the claim.
- Carefully check boiler-plate text: Ensure routine or AI-generated wording does not contain definitions that unduly narrow or broaden your intended claim scope.

Background: EPO's Assessment of Clarity: Pre- and Post-Grant

The EPC's requirement for clarity is set out in Article 84 EPC. Claims are considered to lack clarity if the exact distinctions which delimit the scope of protection cannot be learnt from them.

According to Article 84 EPC, "The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description".

The EPO's Guidelines for Examination set out that Examining Divisions should read the claims in isolation and give the words of the claim the meaning they usually have in the relevant art, unless the description gives the words a "special meaning" by explicit definition or otherwise. Where a special meaning applies, the Examining Division should raise a clarity objection asking the applicant to amend the claim to make the definition clear from the wording of the claim alone. Of course, any clarifying amendment must meet the EPO's strict requirement that the amended claim defines subject-matter "directly and unambiguously derivable" from the application as filed.

The situation after a patent has been granted is different. Patent claims including "unclear" claim terms (that were present in the granted claims) cannot be opposed on the grounds that the claim lacks clarity. However, it is common for opponents to argue that unclear claim terms should be interpreted very broadly when attacking patentability. While it is possible to amend claims post-grant to clarify the scope, it is preferable to avoid the need to do so (especially bearing in mind the EPO's relatively strict approach to assessing whether amendments result in added subject-matter).

Article 69 EPC, and the Protocol on the Interpretation of Article 69 EPC, set out how claims should be interpreted when determining the extent of protection of European patent claims.

According to Article 69(1) EPC, "The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims."

The Protocol on the Interpretation of Article 69 EPC sets out that Article 69 EPC defines a position between one extreme, in which the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims, and another extreme, in which the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated.

Referring Decision: T 439/22

The patent underlying the referral was directed to an article for a vaping device which contained an aerosol-forming material (tobacco). At issue in the appeal was whether the subject-matter of claim 1 was novel. Central to this question was how the term "gathered sheet" should be interpreted. The patent proprietor-respondent argued that the term should be given its normal meaning in the relevant art. On that basis, claim 1 was novel. The opponent-appellant argued that

the description included a broader definition. On this broader definition, claim 1 encompassed an arrangement disclosed in the prior art and therefore lacked novelty.

The Board of Appeal considered the question as to whether the definition in the description should be applied when interpreting the claim, decisive for the assessment of novelty, and referred three questions to the Enlarged Board of Appeal.

Referred Questions

Question 1:

Are Article 69(1), second sentence EPC, and Article 1 of the Protocol on the Interpretation of Article 69 EPC, to be applied to the interpretation of patent claims when assessing the patentability of an invention under Articles 52 to 57 EPC?

Answer 1:

No single EPC provision provides the legal basis but established case law applying Articles 84 & 69 EPC and the Protocol does.

Question 2:

May the description and figures be consulted when interpreting the claims to assess patentability and, if so, may this be done generally or only if the person skilled in the art finds a claim to be unclear or ambiguous when read in isolation?

Answer 2:

Yes, always.

Question 3:

May a definition or similar information on a term used in the claims which is explicitly given in the description be disregarded when interpreting the claims to assess patentability and, if so, under what conditions?

Answer 3:

Inadmissible. This was covered by the EBA's answer to Question 2.

Judge Rich in *Jentoft* strikes again some 60 years later!

By Michelle O'Brien,²⁵ Audrey Johnson,²⁶ and Tom Irving^{27,28}

Introduction

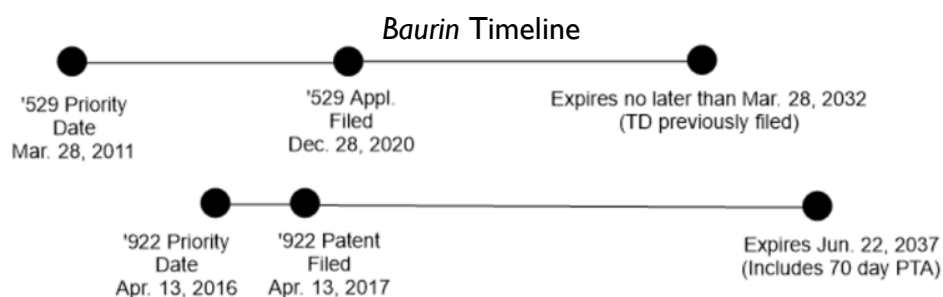
We present herein a new, and, if we are right, a bombshell point of view on why the 1968 *Jentoft* CCPA case mandates reversal by the Federal Circuit of both *Baurin* and *Baumeister*, litigated sub nom *In re Ablynx, Sanofi* (referred to herein as *Baumeister*), and why *Van Ornum* does not perturb *Jentoft*, as urged by at least one brilliant commentator. Let our story begin.

We are perplexed by the *Baurin* ARP, which reverses Judge Townsend solely on the basis of a “possible harassment” ODP theory (in short, a third party can get sued by more than one patentee on patentably indistinct patents), with that same issue now before the Federal Circuit in *Baumeister*.

We respectfully reject that possible harassment theory. As we see it, the Federal Circuit should reverse in both cases in favor of Sanofi.

We rely primarily on *In re Jentoft* (sometimes called *Application of Jentoft*) 392 F.2d 633 (CCPA 1968).²⁹ *Jentoft*, written by Judge Rich, who co-wrote the seminal 1952 Patent Act, makes clear that the harassment rationale is NOT an independent basis to apply ODP in either *Baurin* or *Baumeister*. Ironically, *Jentoft*, raised by the USPTO in the *Baurin* ARP, supports wins for Sanofi in both *Baurin* and *Baumeister*.

In *Jentoft*, the Appeal Board held certain claims invalid for ODP, but the CCPA reversed. A terminal disclaimer had been filed; we note that a terminal disclaimer also had been filed in the *Baurin* and *Baumeister* applications, as shown by the *Baurin* and *Baumeister* timelines below:



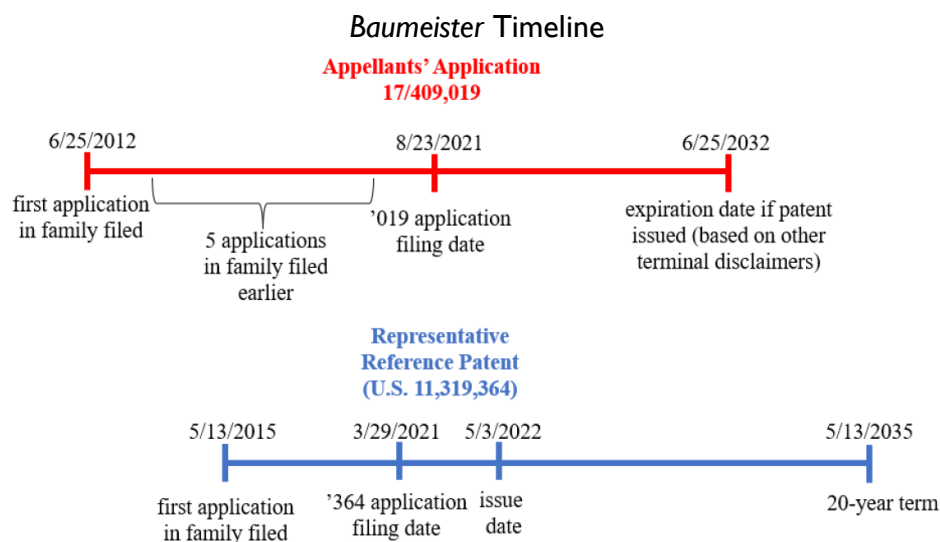
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²⁸ Sanofi is the real party in interest in both *Baurin* and *Baumeister*. None of us coauthors represents Sanofi (at one time Michelle and I did at a former firm, but that representation of Sanofi ended decades ago). Hence the views in this article are ours and are independent of any loyalty to Sanofi.

²⁹ We did not have access to USPQs from 1968, so we found the case on a website called “JUSTIA U.S. Law.”



Note in both *Baurin* and *Baumeister*, the applications containing the rejected claims, when issued, would, because of the terminal disclaimers, expire before each of the reference ODP patents.

In *Jentoft*, the terminal disclaimer (TD) was not considered by the Examiner or the Board to be effective to overcome the ODP rejection. The *Jentoft* opinion ruled that the TD, contrary to the Board's view, was proper and obviated the extension of monopoly objection (I). Similarly, in the *Baurin* ARP, the Director admitted that there was no issue of extension of monopoly. The PTO's August 14, 2026, responsive brief in *Baumeister* admitted the same point: "[T]he '364 reference patent's 20-year patent term would likely expire after the '019 application's 20-year patent term (i.e., there does not appear to be a time-wise extension of the patent right)." BR at 15.

Moving on, the CCPA in *Jentoft* pointed out that *Robeson* 331 F.2d 610 (CCPA 1964) articulated the objections to "double patenting" as (1) extension of monopoly, (2) harassment by multiple assignees, and (3) avoidance of file wrapper estoppel. This article deals only with points (1) and (2). Re point (2), the *Jentoft* CCPA noted that the Board raised another "often voiced presumed problem of harassment." Noting in *Robeson*, the CCPA "**did not approve**" of the harassment rationale, finding it to be insufficient to support the rejection, *Jentoft* included an entire section in the opinion, entitled "Harassment Argument Lacks Substance." Therein, *Jentoft* stated:

"We are further of the belief that a person or corporation obtaining patents on inventions so closely related that they can give rise to double patenting rejections **is most unlikely to divide the ownership of them**. Though the *Robeson* opinion says that we do not 'minimize' the possibility, inter alia, of harassment by 'multiple assignees,' upon further reflection there does not appear to us to be much to minimize on this score. In any event, it should be remembered that **we refused, in *Robeson*, to accept the harassment argument. Yet we do not see the courts bogged down with harassment suits**. In those rare instances where there is a situation which a court can be persuaded amounts to harassment, it has means for dealing with it by inflicting the plaintiff with attorney's fees. This can be a powerful deterrent. See the case relied on by the solicitor in his brief, supposedly as illustrating harassment."

As noted, the *Baurin* ARP actually cited *Jentoft* and doesn't seem to disagree with the above characterization of *Jentoft* as seen at pp. 24-25 of the ARP, the part of the opinion we would call "apologist," basically stating that if not for those meanies at the Federal Circuit, the ARP in *Baurin* would have affirmed Judge Townsend.

"Were the Office not bound by the Federal Circuit's precedents applying the OTDP anti-harassment rationale, this ARP would clarify that the risk of separate ownership and hypothetical harassment generally should not form a standalone basis for OTDP rejections during examination. This is so because, absent evidence that an applicant/patentee has engaged in splitting ownership to patents covering obvious variants of the same invention and that the public has been subject to separate lawsuits on such patent, the Office is just speculating. And such speculation encumbers patents with terminal disclaimers including an anti-alienation and anti-enforcement provision that is premised on contingencies that may never come to be. **As Judge Rich presciently observed nearly sixty-years ago, the anti-harassment rationale is more theory than real. *In re Jentoft*, 392 F.2d 633, 641 (CCPA 1968)** (remarking "we do not see the courts bogged down with harassment suits").

Further, the Office's grant of a patent without an OTDP rejection or terminal disclaimer to overcome the rejection would not immunize that patent from all future challenges. If, in fact, a patentee does split ownership of multiple patents and facilitate harassment lawsuits, the courts are empowered to adjudicate validity under the judge-made OTDP doctrine **or to penalize the offending behavior as appropriate. *Jentoft*, 392 F.2d at 641 ("In those rare instances where there is a situation which a court can be persuaded amounts to harassment, it has means for dealing with it by inflicting the plaintiff with attorney's fees.")**" (emphasis supplied)

In our view, the *Baurin* ARP totally missed the boat on the importance of *Jentoft*. In fact, *Jentoft* controls *Baurin*, and thus the ARP was incorrectly decided, and also controls *Baumeister*, which itself was also incorrectly decided by PTAB.

Why CCPA *Jentoft* Is Binding, Established Precedent at the Federal Circuit

As was its custom, the CCPA always sat en banc. Hence, *Jentoft* was an en banc decision and is not a panel decision like *Gilead*, *Fallaux*, *Hubbell*, or even *Cellect*, relied on in the *Baurin* ARP and in *Baumeister*. It is axiomatic that en banc authority trumps panel decisions disagreeing with the en banc authority.

In particular, in the first appeal decided by the Federal Circuit, *South Corporation*, 690 F.2d 1358 (October 28, 1982), the Federal Circuit sat en banc. The Federal Circuit in *South Corporation* specifically stated that the reason for sitting en banc was to consider what case law, if any, may appropriately serve as established precedent. The en banc Federal Circuit in *South Corporation* reasoned that this appeal is the first to be heard, and this opinion the first to be published by the United States Court of Appeals for the Federal Circuit, established October 1, 1982, by the Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25:

“The court sits en banc to consider what case law, if any, may appropriately serve as established precedent. We hold that the holdings of our predecessor courts, the United States Court of Claims and the United States Court of Customs and Patent Appeals (CCPA), announced by those courts before the close of business September 30, 1982, shall be binding as precedent in this court.” Id. at 1369. (emphasis supplied).

Overturning en banc CCPA holdings, such as *Jentoft*, should, therefore, require either a decision by an en banc Federal Circuit or a decision by the CCPA overruling earlier CCPA precedent. The last chance the CCPA had to overrule one of its decisions was in 1982, some 44 years ago. *Jentoft* has never been overruled by the CCPA or by an en banc Federal Circuit decision. Hence, *Jentoft* remains as established, binding precedent in the Federal Circuit.

The *Baurin* ARP, obviously not an en banc Federal Circuit decision, had no authority to overrule *Jentoft*. In fact, the *Baurin* ARP made no effort to overrule or even distinguish *Jentoft*, instead noting *Jentoft* and stating that if the ARP were not bound by such binding Federal Circuit precedent as *Gilead*, *Fallaux*, *Hubbell*, and *Collect* (panel decisions *all*), the ARP would have affirmed PTAB.

Possibly, the Federal Circuit could sit en banc in one of *Baurin* or *Baumeister* and overrule *Jentoft*. We have no reason to think that will occur, but we shall see. Certainly, as of now, the en banc *Jentoft* case is binding authority at the Federal Circuit. In our view, it controls both *Baurin* and *Baumeister* and should lead to victory in both for Sanofi.

Why CCPA *Van Ornum* did not overrule *Jentoft* sub silentio

In *Van Ornum*, the application serial No. 821,360, under rejection, inter alia, for ODP, was rejected over the '893 patent and the '799 patent. Unlike *Jentoft*, where the documents involved in the ODP rejection were commonly owned, in *Van Ornum*, the '893 patent issued to General Motors Corporation, but the rejected application and the '799 patent were owned by Rockcor.

The Federal Circuit in *Van Ornum* made a two-part analysis; **first** the court determined that there was improper extension of the patent term and **only then** proceeded to discuss possible harassment. In particular, the appellant not only admitted but urged that the claims on appeal are generic to—that is, to say, they dominate—the inventions claimed in both ODP reference patents. Hence, Judge Rich easily found in *Van Ornum* that in the absence of a terminal disclaimer, there would be unjustified patent term extension, or in the language of *Jentoft* and *Robeson*, extension of monopoly.

Therefore, *Van Ornum* is easily factually distinguished from *Jentoft*, *Baumeister*, and *Baurin*, where there was common ownership and there were terminal disclaimers in place, thus resulting in no improper timewise extension, i.e. no extension of monopoly. Hence, *Van Ornum* in no way controls *Baurin* and *Baumeister* and does not overrule sub silentio *Jentoft*.

Panel decisions relied on by the USPTO, such as *Fallaux*, *Hubbell*, *Gilead*, and *Collect* in no way trump en banc *Jentoft* and fall by the wayside. But what effect might en banc *Van Ornum* have on

Baumeister, where the documents involved in the ODP rejection were not, as they were not in *Van Ornum*, commonly owned?

The answer should be absolutely no effect. That is because, as explained above, in *Baumeister*, there is no possible improper timewise extension because of the TD, just as in *Baurin*. In *Van Ornum*, Judge Rich did not even look at “possible harassment” until **after Judge Rich was satisfied there was improper timewise extension**. Hence, *Van Ornum*, although admittedly en banc, is distinguishable from and does not control *Baumeister*, **where there was no improper timewise extension, i.e. no extension of monopoly** (emphasis supplied).³⁰

Conclusion

For all these reasons, *Jentoft* controls both *Baurin* and *Baumeister* and *Van Ornum* is of no Import. Hence, the Federal Circuit should reverse in both cases.

³⁰ **Disclaimer:** Not legal advice, no attorney client privilege, solely for information and entertainment purposes, does not necessarily reflect the view of past, present, or future clients of the Marbury Law Group; liability is disclaimed for any error or omission

UPC opt-outs: act early or risk being locked in

By Christopher King, Jimmy Nicholls, Hiro Shimazaki, and Martin Jackson³¹

In [Omnia v Sidel, UPC_CFI_799/2026, 7 May 2026](#), it was held in a first instance order of the Paris seat of the Central Division that a UPC action may be brought in respect of a pending European patent application as it approaches grant, and that such an action can render a later-filed UPC opt-out ineffective, locking the resulting patent into the jurisdiction of the UPC. The Court of Appeal has recently confirmed that the UPC is *competent* to hear such actions and that their commencement renders subsequently filed opt-outs ineffective ([Sidel v Omnia, UPC_COA_90/2026, 21 September 2026](#)). However, the Court of Appeal left open the question of whether such an action is *admissible* in view of its timing.

Grant procedure at the EPO

As a European patent application approaches grant, the procedure involves (i) the issuance of a communication under Rule 71(3) EPC notifying the applicant of the intention to grant the application; (ii) the applicant performing various acts to progress the application to grant, including approving the text that is proposed for grant; (iii) the issuance of a communication notifying the applicant of a decision to grant the application under Article 97(1) EPC; and (iv) publication of the mention of grant in the European Patent Bulletin. The publication of the mention of grant typically occurs around a month after the decision to grant communication on a date that is specified in the decision to grant communication. Article 97(3) EPC states that the decision to grant takes effect when the mention of grant is published in the European Patent Bulletin.

Opt-out legal framework

Article 83(3) UPCA provides that a conventional (i.e. non-Unitary) European patent may be opted out of the jurisdiction of the UPC during a transitional period. However, this is possible only if an action has not already been brought before the UPC (Article 83(3) UPCA, Rule 5.6 RoP). As things stand, the transitional period will run until the end of May 2030, but it may be extended.

Article 32(1) UPCA provides that, absent an opt-out, the UPC has exclusive competence over various actions involving patents, including actions relating to declarations of non-infringement (DNI). The UPCA clearly distinguishes between *patents* and patent *applications* (see e.g. Article 3(c)-(d) UPCA). Thus, upon the UPC's inception, one reading of the statute was that the actions listed in Article 32(1) UPCA involving patents could not be initiated until a pending European patent application had reached grant to become a granted European patent.

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The facts

On 3 March 2026, an action was brought before the Paris seat of the Central Division for a DNI concerning EP4594194 and EP4624351. As of 3 March 2026, both EP '194 and EP '351 were pending European patent applications.

After the filing of the action, the patentee filed opt-outs for EP '194 and EP '351 on 2 and 8 April 2026, respectively. It then challenged the UPC's competence in respect of the DNI action in a preliminary objection lodged on 9 April 2026.

At the time at which the action was brought, the communication under Rule 71(3) EPC had been issued for EP '194, but the patentee had not yet taken the action necessary for the application to proceed to grant. For EP '351, at the time at which the action was brought, the communication under Rule 71(3) EPC had not yet been issued.

Prior to the Central Division issuing its order, the patentee had taken the necessary action for grant of EP '194, and the mention of grant had been published in the European Patent Bulletin (on 22 April 2026). For EP '351, the communication under Rule 71(3) EPC had been issued, the applicant had taken the necessary action for grant, and the decision to grant under Article 97(1) EPC had been issued, with a date for the publication of the mention of grant set as 20 May 2026 (shortly after the date of the order).

The DNI action

At first instance, the Central Division acknowledged that a patent application is not a “patent” for the purposes of the UPCA. Despite this, it held that the UPC is competent to hear actions seeking a DNI if the patent has been granted pursuant to Article 97(1) EPC before the statement of defence is submitted (two months from service of the statement of claim for the DNI, i.e. 19 May 2026 in this case). Since, for both EP '194 and EP '351, the communication regarding the decision to grant under Article 97(1) EPC had already been issued, the UPC was competent to consider the DNI action.

In coming to this conclusion, the Central Division noted that, by the time of its order, the granted claim scope for both EP '194 and EP '351 was settled because EP '194 was formally granted and EP '351 was soon to grant. It was also stated that allowing the filing of actions prior to grant is in the interest of procedural efficiency, because it avoids the situation in which a new action is filed by the claimant immediately after (or in the case of EP '351, a couple of weeks after) the UPC declares its lack of competence.

The Court of Appeal came to a similar conclusion, noting that while EP '194 and EP '351 were patent applications at the time of the filing of the DNI action, the DNI action is clearly in respect of the patents to arise from the applications after grant, and so the action falls under Article 32(1) UPCA. The Court of Appeal did not mention that the relative timing of the grant date and the date on which the statement of defence is submitted is relevant.

However, while the Court of Appeal held that the UPC is *competent* to hear the DNI action, it noted that there is also a question as to whether the DNI action is *admissible* in view of the fact that the action was brought before the grant of the relevant patent applications. As such questions of admissibility cannot be raised as a preliminary objection under Rule 19 RoP, this issue will be considered in later proceedings.

The effect on the opt-out

As the Central Division considered itself competent to consider the DNI action, it further held that the opt-outs filed were ineffective because an action in respect of the patents had already been brought before the UPC at the time of the opt-outs (Article 83(3) UPCA). The Court of Appeal agreed.

The effect of a subsequent inadmissibility ruling on the opt-outs remains unresolved: the Court of Appeal gave no indication that the opt-out could potentially be deemed retroactively to have been effective if the DNI action is later found to be inadmissible. In this regard, it is noted that it is no longer possible to validly file an opt-out once an action has been *brought* at the UPC (Article 83(3) UPCA), and this is irrespective of whether the action is pending or has been concluded (Rule 5.6 RoP). Thus, for the opt-out to have been validly filed, it would seem that the inadmissibility finding would need to have the effect that the DNI action is considered never to have been brought for the purposes of Article 83(3) UPCA.

Both the Central Division and the Court of Appeal limited their findings to DNIs, but it seems that the same reasoning could be applied to other types of action, e.g. revocation actions.

Could delaying grant assist the applicant?

Delaying grant so that the application remains pending as the UPC proceedings progress might strengthen an argument that a pre-grant action is inadmissible because it was brought prematurely. There are various mechanisms by which grant of a European patent application can be delayed after a communication under Rule 71(3) EPC has been issued, e.g. by using the EPO's "further processing" provisions or by requesting amendments to the text proposed for grant.

However, it cannot be assumed that delaying grant would restore the ability to opt the patent application out of the jurisdiction of the UPC, even if the UPC action is found to be inadmissible.

Implications for opt-out strategy

For applicants wishing to opt an application out of the jurisdiction of the UPC, it is advisable not to treat the date of the publication of the mention of grant as a final available deadline for filing the opt-out request. As this case shows, doing so may, in some circumstances, allow the UPC to be seized of an action, locking the patent into the jurisdiction of the UPC.

It is possible to opt European patent applications out of the jurisdiction of the UPC from the date of publication of the application, i.e. at an early stage in prosecution, before examination. Given the potential risks involved in delaying an opt-out until around the time of grant, it is prudent for

applicants keen to avoid the jurisdiction of the UPC to consider filing an opt-out at an earlier stage.

In this regard, it is worth noting that an early decision to opt out is not necessarily irreversible: opt-outs can be subsequently withdrawn, provided that an action has not been brought before a national court.

The Fall of the Atomic Bar: Section 4, SHANTI and India's Nuclear Patents

The history and jurisprudence of Section 4 of the Patents Act, 1970, the SHANTI Act, 2025, and the lessons of Huntington Alloys v. Union of India

By Vidisha Garg³²

I. Introduction

For fifty-five years, Section 4 of the Patents Act, 1970 stood as the only provision in Indian patent law that extinguished an invention rather than examined it. Where Section 3 tells the applicant, ‘what is not an invention,’ and Chapter VII merely silences defence-relevant applications while keeping them alive, Section 4 declared an entire technological field of atomic energy to be beyond the reach of the patent system altogether. No amendment, no argument, no appeal: if the invention related to atomic energy, the application died.

That era has now ended. The Sustainable Harnessing and Advancement of Nuclear Energy for Transforming India Act, 2025 (the “SHANTI Act”), officially received Presidential assent on December 20, 2025, has repealed the Atomic Energy Act, 1962 and substituted Section 4 of the Patents Act, replacing the absolute bar with a regime of conditional patentability for peaceful nuclear inventions. Almost in the same breath, the Bombay High Court in *Huntington Alloys Corporation v. Union of India & Ors.* (Writ Petition No. 2086 of 2021) has delivered the latest and most emphatic instalment in a decade-long judicial campaign against the manner in which the old bar was administered, holding that even a final and absolute power of refusal must be exercised through a reasoned order. This article traces the history of Section 4, weighs its merits and demerits, surveys the case law it generated, examines the new SHANTI architecture and what it demands of applicants, and closes with practical guidance for foreign applicants whose inventions involve radioactive materials.

II. Section 4 As It Stood: Text and Machinery

Prior to its substitution, Section 4 read simply: “No patent shall be granted in respect of an invention relating to atomic energy falling within sub-section (1) of section 20 of the Atomic Energy Act, 1962.” The brevity was deceptive, for the operative content lay in the cross-referenced provision. Section 20(1) of the Atomic Energy Act denied patents for inventions which, *in the opinion of the Central Government*, were useful for or related to the production, control, use or disposal of atomic energy, or the prospecting, mining, extraction, production, physical and chemical treatment, fabrication, enrichment, canning or use of any prescribed substance or radioactive substance, or the ensuring of safety in atomic energy operations. “Atomic energy” itself meant energy released from atomic nuclei by fission, fusion or like processes; and the schedule of “prescribed substances” most recently notified by the Department of Atomic Energy on 28 April 2016 swept in not only uranium, plutonium and thorium but

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beryllium, deuterium, zirconium, hafnium, niobium, tantalum and a long catalogue of radioisotopes with entirely civilian uses.

The machinery was equally distinctive. Where an examiner suspected that an application attracted the bar, the Controller referred it to the Central Government in practice the Department of Atomic Energy (DAE) under Section 20(6) of the Atomic Energy Act. By Section 20(8), the DAE's determination bound the Controller absolutely: the Patent Office had no independent authority to form its own view, and if the DAE certified that the invention related to atomic energy, refusal followed as a matter of course, with no statutory appeal. Even after grant, Section 65 of the Patents Act empowered the Central Government to direct revocation of a patent subsequently found to relate to atomic energy. The numbers show the bar was no dead letter: the IPO's Annual Report for 2023–24 records 134 applications referred to the DAE, of which 44 roughly one in three were certified as relating to atomic energy and consequently refused.

III. The History: Why India Sealed the Atom

Section 4 was not an accident of drafting but a deliberate act of policy, and its roots pre-date the Patents Act itself. Independent India's first Parliament enacted the Atomic Energy Act, 1948, modelled on the United Kingdom's Atomic Energy Act, 1946 within a year of independence, reflecting the Nehru–Bhabha conviction that atomic energy was too consequential, strategically and developmentally, to be left to private hands. The 1948 Act gave way to the more elaborate Atomic Energy Act, 1962, which entrenched a complete State monopoly over the nuclear fuel cycle and, through Section 20, over nuclear invention itself: not merely could private actors not operate reactors, they could not even own exclusive rights in nuclear knowledge.

When Justice N. Rajagopala Ayyangar's 1959 Report and the ensuing Patents Bill culminated in the Act of 1970, Section 4 was the patent-law expression of that settlement, folding the Section 20 bar into the patent statute by reference. The surrounding history explains its severity: a fledgling three-stage nuclear programme built on scarce thorium and uranium resources, a non-signatory's position outside the NPT framework, the 1974 Pokhran test and the technology-denial regimes that followed all reinforced a culture in which nuclear knowledge was treated as sovereign property.

For decades the settlement held, because civilian nuclear-adjacent innovation was largely confined to State laboratories in any event. It began to fray only when the private economy caught up with the atom: nuclear medicine, radiopharmaceuticals, industrial radiography, radiation sensors, advanced alloys and, latterly, small modular reactors placed a growing volume of genuinely commercial technology within the literal sweep of “prescribed substances” and the bar, drafted for bombs and reactors, began refusing hospital equipment and boiler pipes.

IV. The Balance Sheet: Pros and Cons of the Old Section 4

In its favour, Section 4 had a coherent logic. It gave statutory primacy to national security in a domain where the cost of error is existential; it kept sensitive fuel-cycle knowledge out of the published patent record, which is, after all, a global disclosure instrument; it avoided the awkwardness of the State granting private monopolies over technology it alone was permitted to

practise; and, by locating the decisive opinion in the Central Government rather than the Patent Office, it ensured that the assessment of nuclear sensitivity was made by the department technically competent to make it. It was also honest: unlike secrecy regimes that leave applications in indefinite limbo, Section 4 delivered a definitive answer.

Against it stood objections that grew heavier with each passing decade. First, over-breadth: the bar turned on whether an invention “related to” atomic energy or employed a prescribed substance, not on whether it was strategically sensitive so a zirconium dental alloy, a deuterated pharmaceutical or a ceramic fuel-cell coating stood, in principle, in the same position as an enrichment cascade. Secondly, opacity: DAE determinations were routinely one-line conclusions, unreasoned and unappealable, leaving applicants unable to understand, contest or design around the objection. Thirdly, the absence of any amendment pathway in practice: applicants were rarely told which claim or feature attracted the bar, and so could not excise it. Fourthly, the chilling effect: investors and foreign filers simply avoided India for anything nuclear-adjacent, exporting R&D and filings elsewhere, a self-inflicted wound for a country simultaneously courting nuclear medicine and clean-energy investment. Fifthly, incongruity with comparative practice: major patent systems handle nuclear sensitivity through screening and secrecy orders while preserving patentability of civilian technology; India alone maintained a subject-matter extinction. The provision, in short, protected the State’s monopoly long after the monopoly had ceased to serve the State’s interests.

V. The Jurisprudence: How the Courts Disciplined the Bar

If Parliament was slow to reform Section 4, the constitutional courts were not idle. A consistent line of authority, spanning three High Courts and a decade, converged on a single principle: however absolute the power, its exercise without reasons cannot survive.

In *ER Squibb & Sons, LLC v. Union of India* [W.P.(C) 2879/2016, decided 4 April 2016], the Delhi High Court set aside a refusal founded on a bare DAE communication, holding that an applicant visited with the extinction of its application is entitled to know why. The Kolkata Patent Office’s 2016 refusal of *Merck Eprova AG*’s application again resting on nothing more than a DAE letter concluding that “the invention relates to atomic energy and the application be refused” met the same fate before the Calcutta High Court, which reaffirmed that the atomic energy bar does not dilute the obligation to pass a reasoned order. The Bombay High Court then joined the chorus in *Ceres Intellectual Property Company Limited v. Controller of Patents* [W.P. No. 2257 of 2018, decided 6 October 2022]: Ceres’ application for a “Method for Deposition of Ceramic Films” for solid oxide fuel cells had been refused solely on the DAE’s direction, and a Division Bench held that the Controller cannot refuse an application merely on such a direction, reasons must accompany the refusal, remitting the matter for reconsideration on merits.

Huntington Alloys completes, and crowns, this line. Huntington, a US corporation, had entered the national phase with an application for an “Ultra Supercritical Boiler Header Alloy and Method of Preparation”, a nickel-cobalt-chromium alloy, containing niobium and tantalum, for ultra-supercritical boiler headers operating between 538 and 816 degrees Celsius in conventional power generation. A request for examination was filed in 2012; the application then sat unexamined for eight years. In November 2020 the Deputy Controller referred it to the DAE

under Section 20(6) with a prima facie view that Section 4 barred the grant, and in April 2021 the DAE directed refusal in a single sentence: the invention “does relate to Atomic Energy.” A Division Bench of Justices Bharati Dangre and Manjusha Deshpande set aside both the reference and the refusal. The Court accepted that the Central Government’s determination is final; what it would not accept is that finality excuses silence. Reasons, the Bench held, are the precondition of judicial scrutiny and of the applicant’s ability to amend its specification so as to take the invention outside the prohibited field, an opportunity the Court anchored in the scheme of Section 65(2) of the Patents Act, reasoning that if the government may revoke a granted patent after affording amendment, an applicant facing pre-grant refusal can scarcely be worse placed. The matter was remitted for fresh consideration. Commentators have fairly questioned the transplantation of Section 65, a post-grant revocation provision into the pre-grant context; but the core holding is orthodox administrative law of unimpeachable pedigree, and its practical effect is that the *ipse dixit* era of Section 4 refusals is over. Fittingly, Huntington’s reconsideration will now occur under the SHANTI framework, where a boiler alloy for civilian power generation should face a very different reception.

VI. The SHANTI Act, 2025: The New Architecture

The SHANTI Act does far more than amend a patent provision: it repeals the Atomic Energy Act, 1962, opens reactor operation, equipment manufacture and fuel fabrication to private participation, confers statutory status on the Atomic Energy Regulatory Board, and restructures civil nuclear liability into a tiered framework designed to bring international suppliers back to the Indian market. But for patent practitioners, its centre of gravity is the substitution of Section 4, which now provides that patents *may* be granted for inventions relating to nuclear energy, subject to the provisions of the Patents Act and to Section 38 of the SHANTI Act.

Section 38 is the new gatekeeper, and its scheme rests on four pillars. **First**, the Central Government may grant patents for inventions which, in its opinion, are for the peaceful uses of nuclear energy and radiation, the affirmative opening that Section 4 never contained. **Secondly**, inventions relating to activities reserved exclusively to the Central Government under Section 3(5) of the SHANTI Act, the strategic fuel cycle, including enrichment and reprocessing or which the Government considers sensitive or attended by national security implications, remain non-patentable; and by the proviso to Section 38(1), such sensitive inventions are deemed to have been made or conceived by the Central Government, vesting the rights in the State itself. **Thirdly**, where the character of an invention is unclear, the Controller must seek and act upon the instructions of the Central Government, preserving, in attenuated form, the referral reflex of the old regime. **Fourthly**, Section 38(5) imposes a novel pre-disclosure duty: any person with reason to believe that an invention relates to nuclear energy must inform the Central Government *before* disclosing it to any third party. Complementing these, Section 9 confers an express freedom to conduct research, development and innovation in nuclear energy for peaceful purposes, and Section 39 of the SHANTI Act creates a “restricted information” regime for material whose disclosure would harm national security.

What, then, must an applicant now establish? Three things, in substance:

- that the invention satisfies the ordinary patentability requirements of the Patents Act;

- that it falls on the peaceful, civilian side of the Section 38 line i.e. nuclear medicine and radiopharmaceuticals, radiation-based diagnostics, food irradiation, safety instrumentation, reactor-environment materials, SMR components and comparable non-strategic technology; and
- that the pre-disclosure and procedural duties under the SHANTI Act have been discharged.

The gains for applicants are substantial:

- a field closed for half a century now carries enforceable commercial value in India;
- the operative question has shifted from the crude “does it relate to atomic energy?” to the calibrated “is it strategically sensitive?”; and
- the *Huntington* line of authority guarantees that adverse determinations must be reasoned and are amenable to writ review.

Two caveats temper the celebration, “peaceful uses” is nowhere defined, leaving a margin of executive appreciation that only administrative practice and jurisprudence will discipline; and the deeming provision for sensitive inventions is a vesting mechanism of real severity. It also bears emphasis that the general controls of the Patents Act survive untouched: Section 35 secrecy directions, Section 39’s foreign-filing licence for Indian residents, and Section 157A all continue to apply to nuclear subject matter. The bar has fallen; the watchtower remains.

VII. Advisory: Foreign Applicants with Inventions Involving Radioactive Materials

For foreign applicants particularly in radiopharmaceuticals and nuclear medicine, isotope production, radiation instrumentation and imaging, shielding and reactor materials, and SMR technology, the following course is recommended.

1. Re-open India in the filing strategy. Patent families historically kept out of India because of Section 4 should be reviewed. National phase entries and Paris Convention filings for peaceful-use nuclear inventions are now viable; and pending applications previously referred to the DAE or refused on unreasoned orders deserve a fresh look in light of the amended Section 4 and the *ER Squibb–Ceres–Huntington* line of authority.

2. Audit claims against the prescribed-substance legacy and the Section 3(5) reserve. The old refusals were most often triggered mechanically by the presence of prescribed substances, zirconium, hafnium, niobium, tantalum, deuterium, radioisotopes in the claims. Draft to make the civilian context explicit on the face of the specification, keep claims well clear of the reserved strategic fuel cycle (enrichment, reprocessing and allied activities), and build in fallback amendments capable of excising any element susceptible of a sensitive reading. *Huntington* confirms that the opportunity to amend is part of the fairness the law now demands, draft so that you can use it.

3. Discharge the Section 38(5) pre-disclosure duty. Before disclosing a nuclear-related invention to any third party in India, a prospective licensee, joint-venture partner or contract manufacturer, even under NDA, the Central Government must be informed. Integrate this into

invention-disclosure and deal-clearance workflows; it is a statutory duty with no counterpart in ordinary patent practice.

4. Respect the surviving controls. Section 35 secrecy directions and Section 157A remain available for nuclear subject matter, and Section 39 of the Patents Act continues to require a foreign-filing licence where any inventor is resident in India, a recurring hazard for multinationals with Indian R&D teams and global first-filing policies. Obtain permissions as a matter of routine.

5. Price the sensitivity risk in transactions. If the Government forms the opinion that an invention is sensitive, it is not merely unpatentable, by the proviso to Section 38(1) it is deemed made or conceived by the Central Government. India-bound licences, collaborations and assignments involving nuclear technology should address this vesting risk expressly through representations, severability and consequence clauses.

6. Insist on reasons; use the writ courts. If a reference or refusal issues, demand a reasoned order. The settled position after *ER Squibb*, *Merck Eprova*, *Ceres* and *Huntington* is that a bare conclusion will not survive challenge, finality clauses notwithstanding, the writ jurisdiction of the High Courts under Article 226 remains fully available. Engage Indian counsel at the drafting stage, not the refusal stage; and where the character of the invention is arguable, consider proactively placing material before the authorities demonstrating its peaceful character rather than awaiting an adverse *prima facie* view.

VIII. Conclusion

Section 4 was the patent system's tribute to a particular moment in India's history, a moment when the atom was synonymous with sovereignty and every nuclear invention was presumptively a State secret. That the provision outlived its moment by several decades is evident from the case law it generated: four High Court interventions were required merely to establish that its invocation must be explained. The SHANTI Act retires the absolute bar and replaces it with what may fairly be called supervised inclusion, patents for the peaceful atom, State ownership of the sensitive one, and a government first-look over everything in between. *Huntington Alloys* supplies the accompanying constitutional discipline: sovereign power over nuclear inventions must henceforth speak in reasons, not conclusions. For applicants, Indian and foreign alike, the message is one of genuine but vigilant optimism, the atomic gate is open at last, but it is a gate with a keeper, and those who approach it with disciplined drafting, statutory compliance and a readiness to hold the administration to its duty of reasoned decision-making will pass through it.

Supreme Court of Canada Affirms Law on Methods of Medical Treatment

By Yael Bienenstock³³, Teresa Reguly³⁴, and Andrew Shaughnessy³⁵

Earlier this year, on July 17, 2026, the Supreme Court of Canada released a highly anticipated decision on the issue of the patenting of methods of medical treatment. That decision, *Pharmascience Inc. v. Janssen Inc.*, 2026 SCC 26, upheld the validity of a patent to a long-acting dosing regimen for the treatment of schizophrenia. While the both parties to the appeal asked the court to do a major overhaul of the prohibition on patenting methods of medical treatment (MoMT), a seven-judge majority left the law essentially intact: claims to methods of medical treatment are impermissible, but this prohibition is narrow, and only applies to those claims that seek to monopolize “professional skill and judgement.” Two judges, in a concurring decision, would also have upheld Janssen’s patent but would have gone further and erased the prohibition against MoMT.

Background

Janssen owns Canadian Patent No. 2,655,335 (“335 Patent”) protecting its drug product, INVEGA SUSTENNA, a long-acting injection of paliperidone palmitate used to treat schizophrenia and related disorders. The 335 Patent claims a dosing regimen designed to achieve an optimal blood plasma concentration of paliperidone over time. Pharmascience sought approval to market a generic version of Janssen’s drug and claimed that the 335 Patent was unpatentable as claiming a MoMT. Both the Federal Court and the Federal Court of Appeal rejected this argument.³⁶ The Court of Appeal concluded that the question of whether a claim constitutes an unpatentable method of medical treatment turns on whether using the invention requires professional skill and judgment.

Trial and Appeal Decisions – abandoning fixed versus variable distinction

At the time of these decisions, the law in Canada was that “claims restricted to particular dosages and specific administration schedules...where the amounts and timing are fixed” were patentable, whereas “claims to dosages or schedules with ranges within which the physician must exercise skill and judgment” were not.³⁷ The trial judge held that a “drug is arguably no less a vendible product simply because its dosage or interval of administration is not fixed.”³⁸ The Federal Court of Appeal approved the departure from the ‘fixed’ versus ‘variable’ standard: “whether or not a patent claim to a dosing regimen relates to a method of medical treatment cannot be based exclusively on whether its dosing and schedule is fixed or not.”³⁹ Rather, acknowledging that “[i]t

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³⁶ 2022 FC 1218, aff’d 2024 FCA 23.

³⁷ *supra* note 1, at para. 164.

³⁸ *supra* note 1, at para. 166, citing *Hospira Healthcare Corp. v. Kennedy Trust for Rheumatology Research*, 2020 FCA 30, at para. 52.

³⁹ *supra* note 2, at para. 37.

is difficult to provide more detailed guidance than this,”⁴⁰ the Federal Court of Appeal shifted the inquiry to “whether use of the invention (i.e., how to use it, not whether to use it) requires the exercise of skill and judgment.”⁴¹

Supreme Court of Canada

Pharmascience was granted leave to appeal to the Supreme Court of Canada where both parties asked the top court to clarify the law on MoMTs.

Pharmascience proposed a test for MoMT that would invalidate any patent claim directed to “how and when” a medical practitioner administers a drug or treatment. On the other hand, Janssen argued that the prohibition on MoMTs should be abolished altogether, since it was premised on a provision of the Patent Act that has now been repealed.⁴² The Supreme Court upheld the validity of Janssen’s 335 Patent, but did not accept either party’s invitation to modify the law. It held that the claimed dosage regimen was valid because it did not require professional skill and judgment to implement.

The Majority: MoMTs remain unpatentable

The majority decision confirmed the prohibition on MoMT, noting that this prohibition derives from the definition of “invention” in s. 2 of the *Patent Act*,⁴³ a point confirmed by *Tennessee Eastman Co.* where the Supreme Court of Canada also discussed the now-repealed prohibition contained in s. 41(1). The prohibition on patenting methods of medical treatment is, according to the Court, distinct from s. 41, and relates to a specific application of the broader principle flowing from the definition of “invention” that professional skills unrelated to trade, industry, or commerce are not patentable subject matter.

The Court confirmed that the existing law (used by the Court of Appeal) for determining when a patent impermissibly claims a method of medical treatment remained sound. The Court confirmed that dosing regimens may, but not necessarily, constitute patentable subject matter. It did not impose categorical restrictions, including the distinction between fixed and variable dosages. This categorization continues to be not dispositive. The ‘ultimate question’ is whether the claimed subject matter amounts to professional skill and judgment: “[t]he inquiry is whether the claim seeks to ‘fence in’ an area of medical practice.”⁴⁴ The Court held that determining the patentability of a dosing regimen claim is a “factually suffused exercise that depends on the evidence as to how the dosing regimen is intended to be applied”⁴⁵ and, perhaps recognizing the

⁴⁰ *supra* note 2, at para. 35.

⁴¹ *supra* note 2, at para. 37.

⁴² *Patent Act*, s. 41(1) precluded claims to medicines other than as process or product-by-process claims: “In the case of inventions relating to substances prepared or produced by chemical processes and intended for food or medicine, the specification shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents.” Section 41(1) was repealed in 1993.

⁴³ *Janssen*, at para 55.

⁴⁴ *Janssen*, at paras 88-89.

⁴⁵ *Janssen*, at para 106.

Federal Court of Appeal's *cri de coeur* about the difficulty in applying this test, the Court offered three non-exhaustive guidelines:

1. Whether the subject matter of the claim amounts to professional skill and judgment—and not whether such judgment is exercised in *selecting* the claimed invention for a particular patient.
2. The more the claim involves tailoring treatment to individual patients, the more likely it is to be a method of medical treatment.
3. The application of the test must remain focused on the purpose of the prohibition: “The more a medical professional would already be incentivized to develop or improve a given subject matter in the course of their professional practice, the more likely it is that the subject matter amounts to a method of medical treatment.”

As a result of this decision, methods of medical treatment remain unpatentable subject matter in Canada on the basis that they seek to monopolize professional skill and judgment, inconsistent with the purpose the *Patent Act*. Whether a claim covers an unpatentable method of medical treatment will turn on whether the claimed subject matter amounts to professional skill and judgment. There are no ‘bright lines’ or categorical rules about when such subject matter will be unpatentable: the analysis is inherently fact-specific. In the context of dosing, a claim is more likely to be valid where flexibility in timing, dose, or administration does not require the application of clinical judgment—for example, to a class of patients without the need for individualized adjustment.

The Concurrence: MoMTs are not inherently unpatentable

Justices O’Bonsawin and Moreau agreed that the 335 Patent is valid, but arrived at that conclusion with different reasoning. They would have abolished the prohibition on MoMTs, accepting Janssen’s argument that the repeal of former subsection 41(1) of the *Patent Act*, did away with it.

It is worth noting that neither side argued for the maintenance of the *status quo*—which is, in effect, the result of the majority decision. The parties to the appeal, and the Courts below, in this case and others, had criticized the current state of the law. That current state, according to the Minority, wound its way back to the decision of the Exchequer Court in *Tennessee Eastman*, where it was stated that the idea of skill and judgment were unpatentable. However, according to concurring decision, the *Tennessee Eastman* decision was “inextricably linked to the statutory language of s. 41(1).”⁴⁶ And so, with the repeal of s. 41(1), the minority reasoned that the “precedential value of *Tennessee Eastman* is doubtful.”⁴⁷ Moreover, they refused to uphold the MoMT doctrine on the basis of policy concerns alone. The minority explained that, although the balancing of policy concerns is “integral to the interpretation of the legislation,” the “role of policy has its limits.”⁴⁸ In particular, it is “not for the courts to use policy as a tool to prevent certain subject matters from obtaining patent protection absent guidance from the legislature, especially when such express guidance was removed from the statute.”⁴⁹

⁴⁶ Janssen, para. 160.

⁴⁷ Janssen, para. 162.

⁴⁸ Janssen, para. 216.

⁴⁹ Janssen, para. 216.

With *Tennessee Eastman* and policy out of the way, the Minority went back to the definition of “invention” in s. 2 of the Patent Act to determine whether MoMT may be patentable. Looking at its text, context and purpose, the minority concluded that there is no basis for prohibiting the patenting of MoMTs. (Coming full circle, the Minority pointed again to the repeal of s. 41(1) in saying that Parliament must have intended MoMTs to have the full benefit of the patent bargain.)

In arriving at this conclusion, the minority noted that the *Patent Act* already has safeguards that would alleviate the policy concerns against patenting MoMTs. In its view, the utility requirement was particularly suited to this role.

Frankly, this final part of the decision would tend to move patent attacks from one basis to another—a moving of the ‘goalposts’ as it were. Instead of professional skill and judgement being unpatentable subject matter, we would be arguing whether professional skill and judgement lacked utility. Fortunately, this issue is one which we will not have to be decided in future cases.

Implications

This decision does little to clarify the law. The lower courts had held that claims to a specific dosing regimen would be patentable, while claims to dosing ranges were unpatentable as MoMTs. This was never satisfactory in theory, but it was a distinction that the industry could follow. The Supreme Court has re-affirmed the prohibition on MoMTs, but clearly did not impose categorical restrictions, throwing some doubt on how to apply the test.

For patentees, the decision confirms that dosing regimen patents remain available in Canada, and careful claim drafting and evidentiary support will be critical. Claims will be stronger where: (a) the dosing regimen can be applied generally to a class of patients without the need for adjustment at the individual patient level, and (b) where any flexibility in timing, dose, or administration can be shown not to involve clinical judgment. For patent challengers, the decision preserves a viable invalidity argument where a claim, in substance, requires or monopolizes professional medical skill and judgment. However, the decision also makes clear that a challenger cannot rely categorically on the fact that a claim involves dosing, timing, or administration instructions.

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