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Newsletter of the AIPLA Chemical Practice Committee

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Dear Members of the Chemical Practice Committee,

As we gear up for the 2024 AIPLA Annual Meeting, I'm pleased to share the 2024 Fall edition of the AIPLA Chemical Practice Chronicles, which explores key issues in Chemical Patent Practice globally. Thank you to Andrew Freistein and Sommer Zimmerman, our co-Editors-in-Chief, for their exceptional dedication in curating this newsletter.

At the Annual Meeting, our committee has co-organized with the Biotechnology Committee a CLE panel on "March-In Rights Under the Bayh-Dole Act" moderated by Brian Stanton, featuring Angela Kujak from The Broad Institute of MIT and Harvard, former USPTO Director David Kappos, and David Korn from PhRMA. If you are attending the AIPLA Annual Meeting, please join us on Friday, October 25, 2024 at 2:15 PM for this timely discussion regarding government-funded inventions. We are also co-hosting a social event with the Biotechnology Committee on Thursday, October 24, from 5 to 6 PM in National Harbor 6-7.

This meeting will also mark a transition in leadership for the Chemical Practice Committee. I want to thank Jeremy McKown, our board liaison, for his continued support in connecting our committee with the AIPLA Board. A big thank you to all subcommittee chairs for their hard work in providing outstanding educational and networking opportunities. Last but not least, I want to thank Ali Anoff for her continued dedication, support, and friendship over the past several years in leading this wonderful committee.

As I step down as committee chair, it is my pleasure to transition this role to Ali Anoff as your new committee chair. I am excited for this new chapter for the Chemical Practice Committee under Ali's leadership. Additionally, I am pleased to announce that Josh Goldberg will serve as the new vice chair and Ann Mueting will be our new board liaison.

I hope to see all of you at the Annual Meeting and on our next committee call.

Warm regards,

Jenny Lee, Outgoing Chair, Chemical Practice Committee

Dear Members of the Chemical Practice Committee,

I am honored to step into the role of chair and to advance our committee's mission of educating members on the latest developments in law and technology, while fostering networking opportunities. I look forward to working with Josh, Ann, the subcommittee chairs, and all of you.

A special thank you to Jenny for her exceptional leadership over the past several years. Her legal expertise, vision, and inspiring approach have made her term highly successful. Prior to her role as chair, she served as vice chair and subcommittee chair, where she played a pivotal role in developing our best-in-class microsite and was instrumental in the publication of the Chemical Practice Chronicles. Thank you, Jenny! 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 on our next committee call.

Warm regards,

Ali Anoff, Incoming Chair, Chemical Practice Committee

Year Two – The Unitary Patent and the Unified Patent Court at a Glance

By Ulrike Herr and Heike Röder-Hitschke[1]

Abstract

We can now look back on a quite successful first year of the new European patent and court system. Now well into its second year, the Unitary Patent (UP) continues to grow in popularity and the Unified Patent Court (UPC) is proving itself to be a truly pan-European court. Both the UP and the UPC are increasingly appreciated by users across all technology areas. The Court is clearly making its mark in terms of speed and efficiency. Several UPC divisions have already signaled how they intend to handle key issues such as claim interpretation, the "same invention test" for claiming a priority right, and assessment of inventive step. Regarding chemistry and pharma, activity before the UPC was sluggish in year one, although it ranked first in terms of value in dispute. But this now looks set to change. In this article we provide some facts and figures and look at the trends vis-à-vis the UP and the UPC, the latter focused on revocation actions.

I. The new European patent and court system – a success story

The Unitary Patent – status quo:

Thanks to the daily updated figures made available by the European Patent Office (EPO) on its website[2], it is very easy to track the development of the UP and its level of acceptance by patent applicants.

The overall picture after 15 months is very positive: expectations for the UP and its take-up figures[3] have been met or exceeded for both 2023 (expected 17%, actual 17.5%) and 2024 (expected 20%, currently 24.7%). From the 17,620 requests for unitary effect filed to date, 16,890 UPs are registered. There is no significant backlog in the processing of applications for unitary effect (4%), and only very few applications (0.1%) have been rejected or withdrawn. Most of the applicants are from Germany, followed by the USA, France and China. The most strongly represented technical fields are so far medical technology (12%), civil engineering (5.6%), measurement technology (5.5%) and digital communication (5.2%), closely followed by pharmaceuticals (3.7%), chemical engineering (3%) and biotechnology (2.3%).[4]

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[1] Ulrike Herr, German and European patent attorney and UPC representative, and Heike Röder-Hitschke, attorney-at-law and UPC representative, are with the intellectual property law firm of Maiwald in Munich, Germany (https://www.maiwald.eu/).

[2] Cf. Unitary Patent Dashboard (https://www.epo.org/en/about-us/statistics/statistics-centre#/unitary-patent), last check August 28, 2024.

[3] Percentage of requests received with respect to European patents granted in the respective year.

[4] Basic materials chemistry 1.9%; organic fine chemistry 2.3%; food chemistry 1%.

Since September 1, 2024, the Unitary Patent comprising 17 EU Member States (first UP generation) has been replaced by the **second UP generation** comprising 18 EU Member States (Romania joined on September 1, 2024; see Fig. 1)[5].

> Note that with each new UPCA participating Member State, there will be a next generation of the UP. Clarity about the territorial scope of protection of the respective UP generation will then only be provided by checking the UP register kept at the EPO. Granted UPs continue unchanged; a later extension of the territorial scope is not possible.

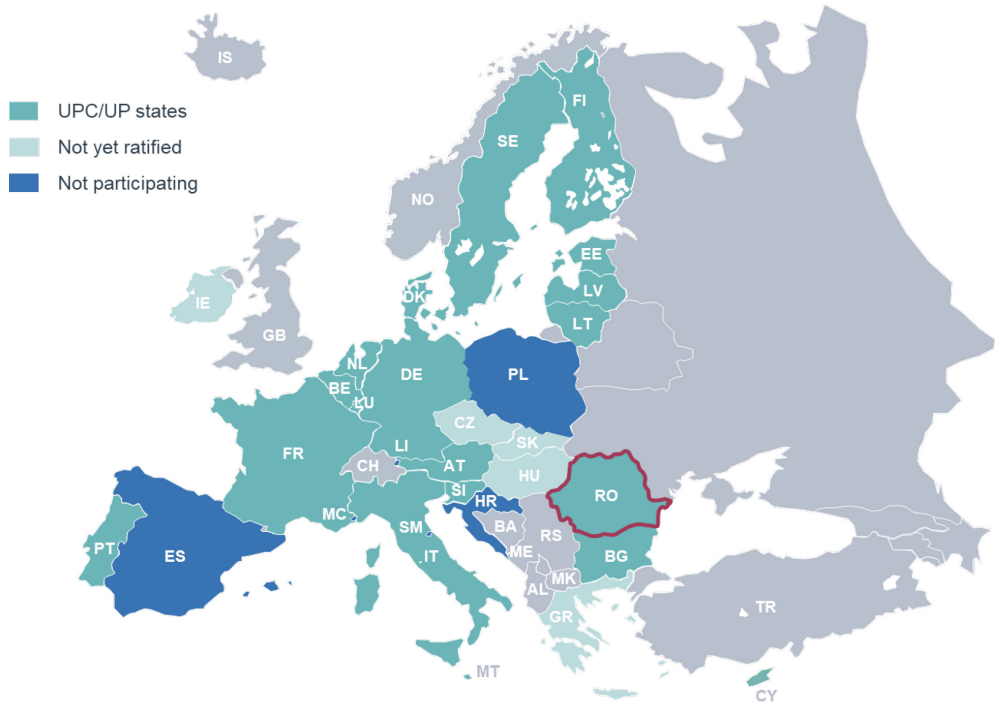

Fig. 1 – UPCA territory as of September 1, 2024.

The Unified Patent Court – status quo:

Since December 2023, the UPC has published monthly updates on its website on the court's workload and case distribution. According to the last update of 31 July 2024[6], a total of 477 proceedings were pending before the UPC in the first year. These included 170 infringement proceedings (85 of which involved counterclaims for revocation), 41 revocation proceedings (two of which involved counterclaims for infringement), 32 applications for provisional measures, six applications for preserving of evidence, one application for an order for inspection, one request for damages and two applications for declarations of non-infringement. The proceedings are divided up among the divisions of the Court of First Instance as follows:

[5] Romania deposited its instrument of ratification for the UPCA on May 31, 2024, and as of September 1, 2024 be the 18th EU Member State to participate in the new system.

[6] Cf. https://www.unified-patent-court.org/sites/default/files/upc_documents/Case%20load%20of%20the%20Court_end%20July_2024_31072024.pdf

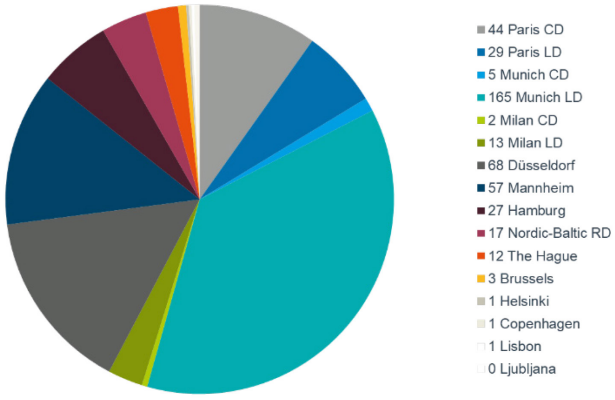

Fig. 2 – Case load of the UPC Court of First Instance at end of July 2024.

Proceedings at the UPC can be conducted in English at all divisions of the Court of First Instance, although until March 2024 German was the predominant language of proceedings. This can be explained by, *inter alia*, the large number of proceedings brought before the German Local Divisions. English has meanwhile taken the lead, currently accounting for 51% of all proceedings (German makes up 43%).

The first year was marked by a large number of procedural orders and interim decisions. Some decisions were also made in proceedings on the merits. By August 28, 2024, 440 orders and decisions had been published by the UPC, of which three decisions were in infringement actions and three in revocation actions. The latter will be discussed in more detail below (section III.).

II. Revocation action and parallel opposition proceedings: UPC vs. EPO?

Of the 41 revocation actions pending, five are directed against UPs; seven of the EPs concerned were returned to the jurisdiction of the UPC by opt-in. In 15 cases, parallel opposition or appeal proceedings are pending before the EPO. This is because the UPC Agreement (UPCA) allows for a revocation action to be filed even if EPO opposition proceedings are pending.

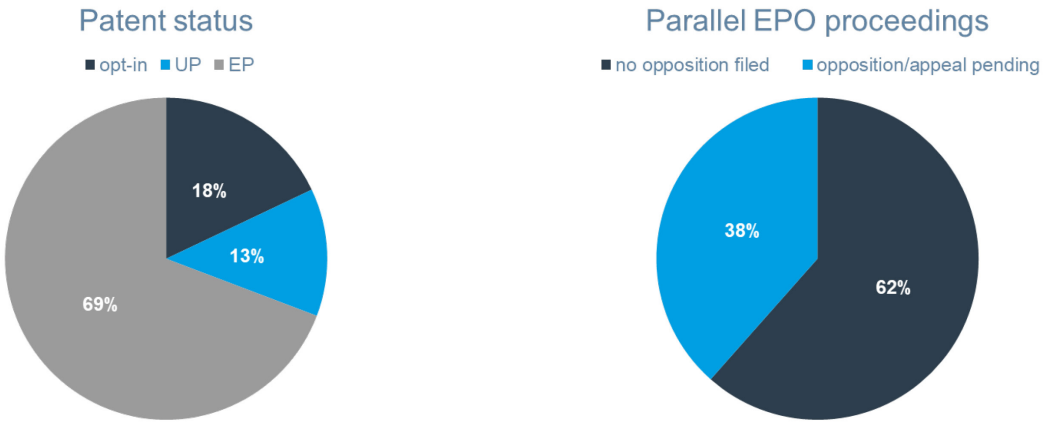

Fig. 3 – Status of patents in dispute and proportion of patents with pending EPO proceedings.

Where a revocation action and an EPO opposition are running in parallel, Art. 33(10) UPCA states:

> *"[…] The Court **may stay** its proceedings when a **rapid decision** may be expected from the European Patent Office."*

In two proceedings to date, the Central Division of the UPC, which has exclusive jurisdiction over revocation actions, decided not to make use of the possibility of staying revocation proceedings in favor of parallel opposition proceedings, as a rapid decision by the EPO was not to be expected in either case. At the time of the decisions, the oral hearing on the opposition in one case (Munich) was scheduled for about 4 months later[7] and in the other case (Paris) the date was not yet fixed[8]. In the Paris case, the Court of Appeal confirmed the decision not to stay the revocation action, as the date of the oral hearing on the opposition, which had in the meantime been fixed, would not have taken place until more than four months after the oral hearing on the revocation action.[9] In this context, the Court of Appeal made some significant statements:

- as a general principle, the Court will not stay revocation proceedings;
- the mere fact that the patent is also subject of opposition proceedings is not a sufficient reason to allow an exception; and
- the mere fact that the EPO has granted a request to accelerate the opposition proceedings is not a sufficient reason to stay the revocation action.

Anticipating the inevitable question of whether this might lead to conflicting decisions by the UPC and the EPO, the Court of Appeal stated:

- where one body upholds the patent and the other revokes it, the latter decision will prevail; and
- it should be ensured that the body that decides last can take the decision of the body that decides first into account when making its decision.

Takeaway:
No stay of revocation action. If the UPC has jurisdiction, it will most likely decide first on the validity of a newly granted patent or a patent that is only in the early stages of opposition proceedings. It remains to be seen whether and how the EPO will then consider the UPC's arguments and decision.

III. The Unified Patent Court's first decisions on revocation actions

The Munich and Paris sections of the Central Division have delivered the first judgements in a revocation action (and parallel counterclaim(s) for revocation) on July 16, 2024, July 19, 2024 and July 29, 2024. In all cases, the decisions were handed down approximately one year after the action was filed. The decisions are a rough indicator of how the UPC will handle key issues such as claim interpretation, the "same invention test" for claiming a priority right, the applicability of the EPO's "problem-solution approach" at the UPC and the reasonable number of (auxiliary) requests.

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[7] CD Munich, UPC_CFI_80/2023 ORD_579547/2023 APP_577540/2023 of 20 November 2023.
[8] CD Paris, UPC_CFI_263/2023 ORD_591040/2023 APP_590707/2023 of January 8, 2024.
[9] CoA, UPC_CoA_22/2024 APL_3507/2024 of May 28, 2024.

Central Division Munich, Decision of July 16, 2024, case UPC_CFI_1/2023 (*Sanofi Aventis et al. vs. Amgen, Inc.*)[10]

Decision: The proceedings concerned European patent EP 3 666 797 ("the '797 patent") which related to antigen binding proteins to proprotein convertase subtilisin kexin type 9 ("PCKS9"). The Central Division revoked the '797 patent in its entirety due to lack of inventive step. Auxiliary Requests 1-17 lack inventive step for the same reasons.

Background: Regarding the validity of the '797 patent, there was a situation of concurrent pendency before different divisions of the UPC: Regeneron Pharmaceuticals Inc. ("Regeneron") and Amgen, Inc. both market cholesterol-lowering antibody drugs which are biotechnologically produced PCSK9 inhibitors. Amgen filed an infringement action related to the '797 patent at the Munich Local Division against Regeneron and three other parties. In return, Regeneron filed a counterclaim for revocation of the '797 patent. The Munich Local Division, with the agreement of the parties, referred the counterclaim to the Central Division which decided on this together with Sanofi's separately filed "stand-alone" revocation action.

Takeaway:
Parallel proceedings before different UPC divisions, Art. 33 (3) UPCA:
The situation of concurrent pendency before different UPC divisions can occur in two different scenarios: first, as in the present case, when the patent proprietor files an infringement action and the defendant responds with a counterclaim for revocation, while a third party challenges the same patent with a separate revocation action, and second, when a party files a revocation action and then a counterclaim for revocation of the same patent in response to an infringement action is subsequently brought against it.

In case of concurrently pending invalidity attacks by different parties against the same patent before different divisions (here: revocation action before Central Division and counterclaims for revocation before Local Division) the Local Division has the discretion either (a) to proceed with both the action for infringement and the counterclaim for revocation, (b) refer the counterclaim for revocation to the Central Division for decision, or (c), with the agreement of the parties, refer the entire case to the Central Division for decision, Art. 33 (3) UPCA.

Claim interpretation:
This case illustrates how important a consistent description is for the interpretation of the claims. The features of claim 1 of the '797 patent required interpretation. The Court set out that a patent claim is not only the starting point, but the decisive basis for determining the scope of protection of a European patent according to Art. 69 EPC and the Protocol on its interpretation. The Central Division Munich additionally stipulated that a patent claim is to be interpreted from the point of view of the skilled person who does not apply a philological understanding when interpreting a patent claim, but determines the technical meaning of the terms used with the aid of the description. From the function of the individual features in the context of the patent claim as a whole, it must be deduced which technical function these features actually have individually and

[10] CD Munich, UPC_CFI_1/2023 ORD_598362/2023 ACT_459505/2023 of 16 July 2024 (https://www.unified-patent-court.org/sites/default/files/files/api_order/7BD3093D60CBD34C06940FCA0C598CEE_en.pdf).

as a whole. Ultimately, the meaning of the terms resulting from the patent specification may be authoritative. In applying these principles, the Court's aim is to combine adequate protection for the patent proprietor with sufficient legal certainty for third parties.

Assessment of 'same invention' for material validity of priority
A claimed invention is to be considered as "the same invention" as the invention in a previous application (see Article 87 EPC) if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole. This means that the Court uses the same standard for assessment as the EPO (see G 2/98).

Assessment of inventive step at the UPC
The Central Division Munich explained the Court's approach when assessing inventive step. The Court considers it to be sufficient to start assessment of inventive step from a **realistic starting point** in the prior art. There can be several realistic starting points. It is not necessary to identify the "most promising starting point." In this regard, the Court's approach differs slightly from the EPO's approach.

(Non-)Obviousness of a claimed solution
The Court considers a claimed solution to be obvious if the skilled person would be **motivated**, i.e. have an incentive, to consider the claimed solution and would **implement it as a next step** in developing the prior art, although it may be relevant whether the skilled person would have expected any particular difficulties in taking any next step(s). The absence of a reasonable expectation of success (or in more general terms non-obviousness) does not follow from the mere fact that other ways of solving the underlying problem are also suggested in the prior art and/or (would) have been pursued by others. The decisive question that must be answered is whether the claimed solution is non-obvious. To justify a denial of inventive step it is sufficient that the skilled person would without inventive contribution arrive at a result that is covered by a claim. Here, the Court's approach seems to be based on the approach of the German Federal Court of Justice.

The importance of a technical effect
The Court outlined that a technical effect or advantage achieved by the claimed subject matter compared to the prior art may be an indication for inventive step. The Court emphasized that a feature that is selected in an **arbitrary** way out of several possibilities cannot generally contribute to inventive step.

Central Division Paris, Decision of July 19, 2024, case UPC_CFI_255/2023 (*Meril Italy Srl et al. vs. Edwards Lifesciences Corp.*)[11]

Decision: The proceedings concerned European patent EP 3 646 825 ("the '825 patent"), which related to a prosthetic heart valve having a sealing mechanism to prevent or minimize perivalvular leakage. The Court ruled that the proposed amendments to the patents were suitable to address

[11] CD Paris, UPC_CFI_255/2023 ORD_598365/2023 ACT_551308/2023 of 19 July 2024 (https://www.unified-patent-court.org/sites/default/files/files/api_order/010422A1E32BDD20F2248FE73E2D447D_en.pdf).

the plaintiffs' objections regarding mainly, added matter, lack of novelty and lack of inventive step and upheld the '825 patent in amended form.

Background: Also in this case, there was a situation of concurrent pendency before different divisions of the UPC. Meril Italy Srl filed a revocation action against Edwards Lifesciences Corporation concerning the '825 patent before the Central Division Paris arguing that the '825 patent is not valid for added matter, lack of enabling disclosure, lack of novelty and lack of inventive step. Edwards Lifesciences lodged a statement of defense to amend the '825 patent based on 9 conditional amendments and a considerable number [84!) of auxiliary requests. Two subsequent requests to amend the '825 patent were filed. In parallel, counterclaims for revocation of the same patent in the infringement action were pending before the Munich Local Division.

Takeaway:

Criteria for exercising the Court's discretion in case of parallel proceedings, Art. 33 (3) UPCA:

In the present case of concurrent pendency before different UPC divisions where a party files a revocation action and then a counterclaim for revocation of the same patent in response to an infringement action is subsequently brought against it, the Central Division Paris stated that the Local Division's decision should be taken on a "case-by-case basis" (see item 19 of the decision). In exercising its discretionary power, the Court must take into account the principle of efficiency. This can be undermined by unnecessary procedural activities, duplication of these activities, and by irreconcilable decisions. Additionally, the Court must weigh up the interest in issuing expeditious decisions, which are important for enhancing legal certainty regarding the validity and enforcement of the patents. It may be relevant that there is likely to be a significant time difference between the decisions of the Divisions involved. Further, the similarity of grounds for invalidity in both proceedings and the multiplicity of infringement actions in which counterclaims against the same patent are filed play a role (see item 20).

Amendments and "subsequent" request(s) to amend the patent:

The Court noted that the defendant in a revocation action is entitled to amend the patent, provided that the relevant application is included in the statement of defense (Rules 30 and 50 RoP) and includes an explanation why the amendments satisfy the requirements of clarity (Art. 84) and Art. 123(2)(3) EPC and why the amended claims are valid. **Rule 30.2 RoP allows for a "subsequent" request(s) to amend the patent.** This presupposes that the first request to amend the patent is found to be admissible. If this is not the case, any "subsequent" request(s) must also be considered inadmissible (see items 29-34).

Number of (Auxiliary) Requests:

The panel considered the number of Auxiliary Requests (84) to be "extremely high" and "potentially hindering the efficiency of the UPC proceedings." Nevertheless, in this case, this number was not considered to be "unreasonable" in view of the complexity of the case and the importance of the patent (see item 33). Hence, the admissible number of Auxiliary Requests depends on the case.

Applicability of the EPO's "problem-solution approach" at the UPC to assess inventive step:
Under the EPO's "problem-solution approach," the judge determines the "closest prior art," then defines the "objective technical problem" to be solved and finally considers whether or not the claimed invention would have been obvious to the skilled person. The Court emphasized that the EPO's "problem-solution approach" is not mandatory under the EPC and also not at the UPC (see items 153 to 155 of the decision).

Central Division Paris, Decision of July 29, 2024, case UPC_CFI_263/2023 (*Bitzer Electronics A/S vs. Carrier Corp.*)[12]

Decision: The proceedings concerned European patent EP 3 414 708 ("the '708 patent"), which related to an apparatus and a method for cold chain monitoring of perishable goods. The Central Division rejected the revocation action and maintained claim 1 as amended by auxiliary request.

Background: Bitzer Electronics filed a revocation action against Carrier Corp. concerning the '708 patent, arguing that the patent is not valid on account of added matter, lack of enabling disclosure, lack of novelty and lack of inventive step of claim 1. In its statement of defense, Carrier lodged an application to amend the patent including a main conditional request and 12 auxiliary requests related to the attacked claim 1 as well as to non-attacked claims. In the reply to the statement of defense, Bitzer Electronics presented further attacks on the patent. During the written procedure, Carrier requested that the Court stay the proceedings pending the outcome of opposition proceedings before the EPO. The request was rejected (see II. above).

Takeaway:
Admissibility of amendment of the patent:
The request to amend the patent which concerns both claims challenged by the revocation action and claims not challenged by it is inadmissible with respect to the latter claims.

In a situation in which the patent is not attacked in its entirety, the patent proprietor is entitled to propose amendments to the challenged claims also by inserting features that were omitted in the original claims but were mentioned in the non-attacked claims.

Inadmissibility of late-filed grounds for invalidity:
Grounds for revocation that could have been included in the initial statement to request for revocation are inadmissible if they do not relate to the content of the defense raised by the opposing party or to the application to amend the patent and, therefore, do not constitute a legitimate response to them.

[12] CD Paris, UPC_CFI_263/2023 ORD_598395/2023 ACT_555899/2023 of 29 July 2024 (https://www.unified-patent-court.org/sites/default/files/files/api_order/03E6FFB4899351 12BBC9A1AE34083C04_en.pdf).

IV. Summary

Around 60 first instance decisions on infringement actions and around 20 decisions on revocation actions are expected by the end of 2024; in addition, important decisions are expected from the Court of Appeal.

The first revocation decisions from the UPC indicate that it is developing its own standards for dealing with key issues based on a mixture of standards applied by the EPO and by national Courts such as the German Federal Court of Justice. The standard for assessing inventive step applied by the UPC appears to be high. There are certainly still many opportunities to shape these initial standards and case law.

In terms of speed, the Central Division of the UPC is so far meeting the aimed-for duration of first instance revocation proceedings of only one year from filing to decision and is adhering to the strict timetable stipulated in the UPCA and the Rules of Procedure. The general approach not to stay revocation proceedings is only one indicator that the Court is not only capable of meeting this very ambitious target, but also fully focused on doing so.

Consultations Continue for the New Patented Medicine Prices Review Board (PMPRB) Regulatory Framework

By Eileen McMahon and Teresa Reguly[13]

Background

The Patented Medicine Prices Review Board (PMPRB) is a quasi-judicial body created under the *Patent Act,* that regulates the prices of patented medicines in Canada. The PMPRB regulates factory-gate sales (first sale) from a manufacturer to a wholesaler, distributor, hospital, or pharmacy; it does not regulate the retail prices of drugs. If the price of a patented medicine is deemed excessive, the PMPRB can order a patentee (typically the manufacturer or distributor of a patented medicine) to lower the price of the medicine and offset excess revenues. The PMPRB can hold public hearings on the question of whether a price of a patented medicine is excessive if a voluntary agreement on price is not reached with the patentee.

Amendments to the Patented Medicines Regulations (PMR) came into force on July 1, 2022 after multiple delays due to legal challenges to the scope of the proposed PMR amendments and the scope of the PMPRB's authority. As of July 1, 2022, there is a new set of 11 comparator countries for the PMPRB to reference (referred to as the PMPRB11) when assessing whether a proposed list price in Canada is excessive. The PMPRB11 consists of the following countries: Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the United

[13] Eileen McMahon and Teresa Reguly are partners at Torys LLP (https://www.torys.com/en). They practice in the Toronto, Ontario, Canada office and specialize in intellectual property, and food and drug regulatory matters.

Kingdom. Notably, the PMPRB11 does not include the United States or Switzerland, which were comparators prior to the PMR amendments.

Consultations - Discussion Guide

The specific price tests used by the PMPRB when assessing whether a patented medicine's price is excessive are set out in non-binding guidelines. The guidelines are intended to provide transparency and predictability to patentees and are heavily relied upon by PMPRB staff during price investigations. An updated version of the guidelines is required due to the introduction of the PMPRB11 and in response to various judicial decisions over the last few years. The PMPRB is in the midst of consultations with stakeholders on its new regulatory framework.

To support the development of new guidelines, the PMPRB has published a consultation document outlining its proposed approach for price regulation, titled: Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines.

Proposed Framework

The discussion guide describes the basic structure of price review as consisting of four main sections: Section A: Initial Price Review; Section B: Post-Initial Price Review; Section C: Special Provisions; and Section D: In-Depth Review.

A. All patented medicines would undergo an initial price review, where the goal is to identify medicines that are at a greater risk of being excessively priced, which would then prompt an in-depth review. The initial price review would be based on comparing the list price in Canada with the list price of the PMPRB11 countries. The discussion guide is not settled on the price level within the PMPRB11 that will be used – the suggested choices are the median international price (MIP), highest international price (HIP), or midpoint between the MIP and HIP.

B. The post-initial price review framework proposes continuous monitoring of a medicine's price throughout the lifetime of the patent. This monitoring would involve annual assessments comparing the patented medicine's Canadian list price to the international price criteria of the initial price review, as well as comparing the changes in the Canadian list price against the Consumer Price Index (CPI). This means that even if an initial price review concludes that a price is non-excessive, a future review could reverse that determination and find that a price is excessive, even if a patentee restricts its list price increases to CPI.

C. In addition to the initial price review and post-initial price review process, a complaint to the PMPRB about a medicine's price could trigger an assessment. The PMPRB has asked for feedback on whether complaints that trigger an investigation should be limited, for example, to federal and provincial/territorial governments, to public and private payors, or to anyone except those with a direct commercial interest.

D. Following an initial, post-initial (annual), or complaint-based review, an in-depth price review may be required to assess compliance. At this stage, PMPRB staff would consider domestic and international therapeutic class comparisons, as well as changes in CPI, to determine whether a price is excessive.

Within this price review framework, the PMPRB proposes that there be no distinction between "existing" medicines that received marketing approval before July 1, 2022 and "new" medicines that were approved after the PMR amendments came into force. Existing Medicines would be afforded a transition period to adapt to the new guidelines before being subjected to further review. The discussion guide suggests that a one-, two-, or three-year transition period is under consideration.

In addition to those items noted above, the PMPRB is seeking feedback on various topics, including how to assess the similarity between a patented medicine and a comparator for domestic price comparison during an in-depth review, how CPI will be used (e.g., one-year increases or combined), and whether to engage with external advisors for scientific evaluations. The PMPRB would also like stakeholders' views on excluding patented biosimilars and patented vaccines from the price review framework, instead only assessing the prices of these products if there is a complaint.

Stakeholders were invited to provide feedback to the PMPRB by September 11, 2024.

Interim Guidance

Patented medicines that have been approved by Health Canada since July 1, 2022 have not undergone a price review by the PMPRB. The PMPRB is currently operating under interim guidance as a temporary measure that is intended to provide some clarity to patentees while the new guidelines are under development.

According to the interim guidance (most recently amended as of September 27, 2023), the price of a new patented medicine (i.e., a medicine approved by Health Canada on or after July 1, 2022) is considered "reviewed" if its list price is below the median international price of the PMPRB11. The list price remains "under review" if it is above the median international price of the PMPRB11. The PMPRB has stated that once new guidelines are in place, no potential excess revenues will be applied for any sales of new medicines made during the interim period.

For patented medicines that received marketing authorization from Health Canada prior to July 1, 2022, the price will not trigger an investigation if the price remains at or below the non-excessive average price that was most recently communicated to patentees by the PMPRB, and no list price increase is taken other than permitted CPI during the first filing period of 2022. The interim guidance does not expressly state that CPI increases could be taken in subsequent years; however, Section 85(1) of the *Patent Act* requires that CPI be a factor taken into consideration when assessing whether a medicine's price is excessive.

It is important to note that a "reviewed" price may be reassessed after the interim period ends and new final guidelines are in place, depending on the particulars of the final guidelines.

Conclusion

As noted, the PMPRB solicited feedback on the discussion guide through September 11, 2024. Once the feedback is assessed, the PMPRB has indicated that it intends to publish draft guidelines by the end of 2024. There will be another opportunity for feedback on the draft guidelines at this stage. The PMPRB proposes to finalize and implement the guidelines in 2025 unless further rounds of consultation are necessitated by the feedback received. The interim guidance will remain in effect until final guidelines are implemented.

Post-filed data at the EPO: What's next for plausibility following G 2/21?

By Catherine Keetch[14]

Before G 2/21

For many years, the concept of "plausibility" has been a central tenet of European patent practice despite its complete absence from the European Patent Convention. In an ideal world, a patent application would include all of the information and evidence required to support a technical effect. Of course, we do not live in an ideal world. In particular, in the context of inventive step we do not know which prior art documents will be uncovered by the patent office or an opponent. The EPO's requirement to follow the "problem-solution" approach to analyze inventive step generally requires some kind of evidence of the attainment of an unexpected technical effect or improvement over the closest prior art. Whilst it is possible to argue that an invention relates to a non-obvious alternative solution to a problem, thus not requiring evidence of an improvement over the prior art, in practice this can be very challenging. Therefore, discussions of inventive step at the EPO often center around whether there is enough information or data in the application as filed to support a particular technical effect, for example, improved efficacy, a new medical use, or a synergistic effect of a combination of compounds.

The concept of "plausibility" arrived in the early 2000s, essentially asking whether there is enough information in the application as filed to make it **plausible** for a person skilled in the art to conclude that a technical effect has been achieved. Although post-filed evidence could be used to support an inventive step, there needed to be enough disclosure in the application as filed to at least make the technical effect plausible.
EPO Board of Appeal Decisions T 1329/04, T609/02, and T578/06 were influential decisions. This case law is summarised in the headnote to T 1329/04, as follows:

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> The definition of an invention as being a contribution to the art… requires that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve… … even if supplementary post-published evidence may in the proper circumstances also be taken into consideration, it may not serve as the sole basis to establish that the application indeed solves the problem it purports to solve.

Referral to the Enlarged Board

Over subsequent years, the concept of plausibility in the assessment of post-filed data in the context of inventive step became cemented in European practice, but a divergence in how the Boards of Appeal considered plausibility began to emerge. This came to a head in the proceedings before the Board of Appeal in T 116/18 where the Board of Appeal identified three possibility standards for plausibility and post-filed evidence:

1) *Ab initio plausibility*: post-filed evidence may be relied upon if the relevant technical effect(s) associated with the distinguishing technical features of the invention are plausible from the disclosure of the original application as filed.

2) *Ab initio implausibility*: post-filed evidence may be relied upon if there is no reason to conclude that the technical effect(s) associated with the distinguishing technical features of the invention are not plausible from the disclosure of the original application as filed.

3) *No plausibility standard*: any and all evidence of a technical effect associated with the distinguishing technical features of the invention may be admitted. In effect, no threshold for the reliance upon post-filed evidence exists.

In light of the identified divergence, the referring Board of Appeal sought clarification from the Enlarged Board of Appeal (the highest authority at the EPO) as to the allowability of post-filed evidence to demonstrate a technical effect in support of inventive step.

The three questions referred to the Enlarged Board of Appeal were:

> 1. Should an exception to the principle of free evaluation of evidence (see *e.g.*, G 3/97, Reasons 5, and G 1/12, Reasons 31) be accepted in that post-published evidence must be disregarded on the ground that the proof of the effect rests exclusively on the post-published evidence?
>
> 2. If the answer is yes (the post-published evidence must be disregarded if the proof of the effect rests exclusively on this evidence), can the post-published evidence be taken into consideration if, based on the information in the patent application in suit or the common general knowledge, the skilled person at the filing date of the patent application in suit would have considered the effect plausible (*ab initio* plausibility)?

> 3. If the answer to the first question is yes (the post-published evidence must be disregarded if the proof of the effect rests exclusively on this evidence), can the post-published evidence be taken into consideration if, based on the information in the patent application in suit or the common general knowledge, the skilled person at the filing date of the patent application in suit would have seen no reason to consider the effect implausible (*ab initio* implausibility)?

G 2/21

This referral resulted in the issuance of Decision G 2/21 by the Enlarged Board of Appeal in March 2023.

Decision G 2/21 was highly anticipated by European practitioners, and it was hoped that the decision would provide much-needed clarity on how to assess post-filed data. However, for many of us G 2/21 only provided more uncertainty. Most patentees were relieved to see that the Enlarged Board maintained that post-filed data could be used to support an inventive step, answering question 1 above as follows:

> Evidence submitted by a patent applicant or proprietor to prove a purported technical effect relied upon for acknowledgement of inventive step of the claimed subject-matter may not be disregarded solely on the ground that such evidence, on which the effect rests, had not been public before the filing date of the patent in suit and was filed after that date.

However, the answer to the other referred questions was much more surprising, with no mention at all of the term "plausibility," despite this being central to the referral. According to headnote II of G 2/21 (emphasis added):

> A patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would derive said effect as being **encompassed by the technical teaching and embodied by the same originally disclosed invention.**

Therefore, a new test was born, to be used when considering whether a technical effect can support an inventive step. But what does "encompassed by the technical teaching and embodied by the same originally disclosed invention" mean, and has the concept of plausibility disappeared completely? Regarding the latter, some explanation is provided by the Enlarged Board of Appeal in paragraph 92 of their decision:

> The term "plausibility" that is found in the case law of the boards of appeal and relied upon by the referring board in questions 2 and 3 of the referral and the reasons for it, does not amount to a distinctive legal concept or a specific patent law requirement under the EPC, in particular under Article 56 and 83 EPC. It rather describes a generic catchword seized in the jurisprudence of

> the boards of appeal, by some national courts and by users of the European patent system.

Thus, the Enlarged Board tends to dismiss the focus on the buzzword "plausibility," although the remainder of the decision makes clear that the underlying considerations have not gone away, with the subsequent paragraphs setting out the new test:

> 93. The relevant standard for the reliance on a purported technical effect when assessing whether or not the claimed subject-matter involves an inventive step concerns the question of what the skilled person, with the common general knowledge in mind, would understand at the filing date from the application as originally filed as the technical teaching of the claimed invention. The technical effect relied upon, even at a later stage, needs to be encompassed by that technical teaching and to embody the same invention, because such an effect does not change the nature of the claimed invention.
>
> 94. Hence, a patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would consider said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention.

The Enlarged Board of Appeal explicitly acknowledge "the abstractness of some of the aforementioned criteria," and many commentators considered that G 2/21 raised more questions than it answered, but subsequent Board of Appeal decisions interpreting this case are beginning to provide guidance on how this test should be applied.

Subsequent Decisions Interpreting G 2/21

One of the earliest Technical Board of Appeal Decisions interpreting G 2/21 was the final decision relating to T 116/18 from the Board that referred the original questions to the Enlarged Board. The Board in this case commented that patent applicants do not have complete freedom to rely upon any purported technical effect at any stage of proceedings before the EPO. The Enlarged Board of Appeal required there to be a threshold to prevent the filing of applications directed to speculative "armchair" inventions made only after the filing date. They also separated the new test into two separate requirements, "which must be met cumulatively for a patent applicant or proprietor to be able to rely on the purported technical effect,", namely the skilled person would derive said effect as being: (i) encompassed by the technical teaching; and (ii) embodied by the same originally disclosed invention.

The Board held that the assessment as regards requirements (1) and (2) has to be made based upon the broadest technical teaching of the application as filed with regard to the claimed subject matter. As such, requirement (1) may be met where the claimed subject matter is only conceptually comprised by the broadest technical teaching of the application as filed. This means that the effect "need not be literally disclosed by way of a positive verbal statement," provided that the skilled person would recognize that the effect is "necessarily relevant to the claimed

subject matter." Taking this construction of the test identified in G 2/21, the first requirement seems to provide a low barrier to patentability.

With regard to requirement (2), the Board of Appeal formulated the following question as being relevant to the assessment of whether a particular technical effect is "embodied by the originally disclosed invention": "Would the skilled person, having common general knowledge on the filing date in mind, and based on the application as-filed, have legitimate reason to doubt that the purported technical effect can be achieved with the claimed subject-matter?"

According to the Board of Appeal, requirement (2) is to be met unless the answer to the above question is yes.

Many people have suggested that this approach largely corresponds to the previously identified standard of "*ab initio* implausibility," and, thus, is potentially not in line with the intentions of the Enlarged Board, who deliberately decided not to endorse this concept.

The Board of Appeal further confirmed that, in its view, it was not a necessary requirement for the application as filed to contain experimental proof that the purported technical effect is actually achieved for the subject matter in question.

Thus, this technical Board of Appeal appeared to apply a particularly pro-patentee interpretation of G 2/21. Other subsequent technical Board of Appeal decisions also appear to provide a favourable interpretation for patentees.

Board of Appeal Decision T 1891/21 relates to a case with claims directed to an electrode specifying that "the number of manganese atoms contained in the lithium manganese iron phosphate is more than 50% and less than 100% relative to the total number of manganese atoms and iron atoms." The proposed technical effect was a higher initial coulombic efficiency, and the patentee submitted post-filed data showing that the increase in coulombic efficiency is greater when the relative number of manganese atoms is high.

The Board noted that all of the examples related to manganese containing materials with a high number of manganese atoms and the patent discloses that a relative number of manganese atoms of more than 50% and less than 100% leads to improved initial coulombic efficiency.

Based on this, the Board concluded that the post-published data "supports the indicated general teaching in the patent that a high proportion of manganese contributes to an improved initial coulombic efficiency." The Board also stated that "furthermore, no counter-evidence is available." This appears to be in line with the established approach to inventive step taken by Boards of Appeal where the benefit of the doubt regarding the achievement of a technical effect lies with the patentee if the effect is plausible and no counter evidence is provided by an opponent (see, *e.g.*, T 534/12).

In T 2735/19, the Board held that due to the disclosure in the application as filed of the mechanism of action of a cancer therapeutic, namely, the direct action of the compound on DNA, this compound could be expected to have a general effect on tumours and not to be limited to a

single cancer type. Therefore, the consideration of post-published evidence confirming this effect on additional tumour types was in line with the principles established in G 2/21 (Reasons 77 and 93), namely, that the purported effect is encompassed by the technical teaching of the application as filed and that it is embodied by the same originally disclosed invention.

A further decision in which a technical Board of Appeal allowed post-filed data to support an inventive step following G 2/21 was T 0728/21. In this case, the patentee submitted post-filing data showing an advantage of 1:1 microcrystalline cellulose: lactose on dissolution. The board decided that this data could be taken into account to support inventive step, arguing as follows:

> According to G 2/21 a technical effect may be relied upon for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention. The application as originally filed (WO 2011/019413) explicitly addressed the dissolution of tablets comprising a solid dispersion as an aspect of the disclosed invention (see paragraph [0031]) and specifically described the claimed tablet composition as an embodiment of the disclosed invention. The effect of the optimization of the dissolution associated with the specific tablet composition defined in claim 1 of the main request may therefore in accordance with the principles established in G 2/21 be taken into account for the assessment of inventive step.

Therefore, the objective technical problem was defined as the provision of a tablet formulation comprising a solid dispersion of amorphous ivacaftor that exhibits optimized dissolution, and an inventive step was acknowledged.

Board of Appeal Decision T 873/21 related to a combination of known compounds for use in treating metabolic disorders in horses. In this case, the patentee submitted post-filed data to support a synergistic interaction of the two compounds. Synergy was not mentioned in the application as filed. There was a reference to improved insulin sensitivity, but no data was provided in the application as filed to support an improvement, let alone to support a synergistic effect. However, the Board held that "the therapeutic synergistic effect substantiated in D16 was derivable from the original application, and that the data of D16 only provided a quantification of the obtained improvement in insulin sensitivity described in the original application." [Reasons 3.3.2]

The Board, therefore, went on to conclude that the synergistic effect relied upon by the appellant was encompassed by the technical teaching of the original application in light of the common general knowledge regarding the therapeutic effects of separate compounds, and was embodied by the originally disclosed invention since it was clearly the preferred combination in the original application. In line with G 2/21, the technical effect demonstrated by the post-published experimental data provided in D16 was thus to be taken into account when assessing the inventiveness of the claimed subject-matter.

This conclusion may be surprising to many in light of the well-established lack of predictability of synergistic effects (see for example T 1814/11). Indeed, another Board in T0681/21 interpreted G 2/21 differently, and did not allow post-filed data to support a synergistic effect where there was no mention of synergy in the application as filed.

In this case, the application as filed did not describe or provide any evidence for a synergistic effect arising from the combination of a silicone with CPP, and the patentee attempted to rely on post-filed evidence of the synergistic effect. The Board held:

> the fact that the application as filed (page 2, lines 7-8) indicates the CPP to be a preferred cationic polymer without explaining the reason for this preference cannot foreshadow that the claimed combination would provide any type of synergism. The respondents did also not file any evidence that it was common general knowledge that silicone and cationic polymers may provide a synergism in terms of improved softness.
>
> Therefore, it follows from the above reasons that the alleged synergistic effect would not have been considered by the skilled person as being encompassed by the technical teaching of the application as filed and has to be disregarded.
>
> (Reasons, 1.2.3)

Other cases in which the Board did not take post-filed evidence into account include T 887/21. In this case an effect was described in the application as filed (the prevention of secondary infections following viral infections such as influenza), but the Board held that the post-filed data supported a different effect (inhibition of Salmonellae outside the context of epithelial adherence), and this latter effect was not encompassed by the technical teaching of the application as filed.

In T 258/21, the Board of Appeal did not allow reliance upon post-filed evidence, stating that the technical effect "was neither contemplated nor even suggested in the application as filed." The claims were directed to clevidipine for use in a method of reducing ischemic stroke damage, and the patentee argued that the post-filing data supported the effects of improved activity and reduced side-effects using clevidipine compared to other antihypertensive agents. The original application contained no experimental data relating to the claimed therapeutic indication but did contain certain statements regarding the compound's biological activity: "The present invention is based on the discovery that clevidipine… is effective in reducing stroke damage and/or lowering blood pressure in a patient with a stroke… Clevidipine provides the optimal balance of efficacy, precision (titratability), and safety." It can be seen that the approach of the Board in this case is quite different from the more permissive approach of the Board in T116/18.

Sufficiency of Disclosure

The remit of G 2/21 was solely to consider when post-filing data could be relied on to support an inventive step. However, of course the concept of plausibility is also well-established in the context of sufficiency of disclosure, and the Enlarged Board did comment on sufficiency of

disclosure, concluding that there is essentially no change in how post-published evidence should be considered in the context of this provision, see paragraph 77 of the Decision:

> The reasoned findings of the boards of appeal in the decisions referred to above make clear that the scope of reliance on post published evidence is much narrower under sufficiency of disclosure (Article 83 EPC) compared to the situation under inventive step (Article 56 EPC). In order to meet the requirement that the disclosure of the invention be sufficiently clear and complete for it to be carried out by the person skilled in the art, the proof of a claimed therapeutic effect has to be provided in the application as filed, in particular if, in the absence of experimental data in the application as filed, it would not be credible to the skilled person that the therapeutic effect is achieved. A lack in this respect cannot be remedied by post-published evidence.

Take Home Messages

The impact of G 2/21 is still unravelling, but it is clear that the use of post-filing data to support an inventive step is here to stay. It may be that this decision has led to a slight softening in the requirements to have an inventive step acknowledged by the EPO when relying on post-filed data. In some cases, it may be possible to rely on technical effects supported by post-filing data even when there is no explicit mention of the effect, let alone any relevant data in the application as filed. However, as can be seen from the above discussion, the position is far from settled, and highly dependent on the facts of the case. Unlike novelty, the assessment of inventive step will always have a subjective element. Best practice still dictates that a patent application should include as much information and data as possible to support a technical effect. Even if no data is available, there is also value in prophetic statements regarding a technical effect, although too many spurious claims in a patent application can of course dilute the credibility of a described effect.

The "Bolar" Exemption in Europe

By Dr. Holger Tostmann[15]

In Europe, in essence, two mechanisms for exemption of medicinal products from patent protection exist. First, the so-called "*research exemption*" permits the use of a patented invention (e.g., a process or a compound) for *research purposes* (e.g., to determine specific properties or effects of a protected medicinal products). For example, in Germany, a research exemption is codified by German national law since 1981, exempting from the effects of a patent all "*acts done for experimental purposes relating to the subject-matter of the patented invention*". This or a similar

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research exemption can also be found in the national law of all other relevant European jurisdictions.

The second mechanism, termed the "*Bolar exemption*" allows generics manufacturers to perform *activities related to market authorization or approval* under local pharmaceutical law before a patent expires, thus enabling market entry immediately after expiration of an originator's patent. This exemption also applies to biosimilars. The following remarks are focused on the Bolar exemption aspect (and not on the specifics of the research exemption mentioned above).

In the end, both exemptions are governed by national law in each jurisdiction. However, at least for the member states of the European Union (EU), the Bolar exemption is based on EU Directive 2001/83/EC as last amended by EU Directive 2004/27/EU (for a proposed further amendment see the discussion below).

The basic "mechanism" of an EU directive is that a directive does not become law directly, in each jurisdiction, but that the directive needs to be transposed into local law by the legislative of each member state. Not surprisingly, this generally leads to substantial differences in implementation and results in a lack of harmonization.

The stated aim of the presently valid Directive 2004/27/EU is to not unnecessarily delay the arrival of generic medicinal products on the market. The most relevant passage of the Directive is Art. 10(6), which reads:

> *Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3, and 4 [referring to reference medicinal products, generic medicinal products and biological medicinal products] and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.*

The language of Art. 10(6) of the Directive leaves at least the following questions open:

- While generic medicinal products and biological medicinal products are explicitly mentioned, the development of *new* drugs or "variants" of existing drugs is not addressed.
- It is not clear whether the exemption only covers the Applicant for market authorization or also Third Parties involved in the process.
- It is not clear whether only EU market authorization is covered or also activities directed at jurisdictions outside of the EU.
- It is not clear what is meant by "*consequential practical requirements*" (pricing? marketing? …)

To discuss some divergent aspects, in **Germany** the Bolar exemption applies to any activities to obtain marketing approval, also in jurisdictions outside of the EU. In the **UK** (presently not a member of the EU) "*any activity*" carried out for the purposes of "*medicinal product assessment*" is deemed to fall under the "Bolar" privilege. By contrast, according to the **French** Bolar exemption, the privileged acts must be "*necessary*" for the performance of clinical trials *as required by*

the regulatory authorities. In **Italy**, the legislator did not seem to have the intention to limit the Bolar exemption to generic products, i.e. the exemption could also apply to other drugs. Also, Italian law seems to include as exempt activities related to authorization outside the EU. By contrast, it seems that **Dutch** courts apply the research exemption restrictively and that the Dutch Bolar provision is limited to generics.

As mentioned above, the Directive related to the Bolar exemption has been last modified in 2004. However, significant new developments were initiated on April 26, 2023, when the EU Commission published the so-called "***EU Pharma Packaging***" proposal, which aims to clarify the concept of the Bolar exemption under EU law and to thereby address the lack of harmonization. In fact, the Commission's proposal for a new Directive confirms in its recitals that the current Bolar exemption is "*fragmented across the Union and it is considered necessary in order to facilitate the market entry of generic, biosimilar, hybrid and bio-hybrid medicinal products, to clarify its scope in order to ensure a harmonized application in all Member States* […]".

Specifically. Art. 85 of the Draft Directive stipulates that the following activities are not to be regarded as infringement of patent rights or SPCs [underlining added]:

> *(a) studies, trials and other activities conducted due to generate data for an application for:*
> *(1) a marketing authorization of generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent regulations;*
> *(2) health technology assessment as defined in regulation (EU) 2021/2282;*
> *(3) pricing and reimbursements;*
>
> *(b) the activities conducted exclusively for the purposes set out in point (a), may cover the submission of the application for a marketing authorization and the offer, manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers.*
>
> *The exception shall not cover the placing on the market of the medicinal products resulting from such activities.*

The type of medicinal products covered by the Bolar exemption now also includes "hybrid" (or biohybrid) medicinal products [defined by the European Medicines agency (EMA) as follows: "*a medicine that is similar to an authorized medicine containing the same active substance, but where there are certain differences between the two medicines such as in their strength, indication or pharmaceutical form*"].

Standard health technology assessment such as pricing and reimbursement activities are now expressively included under Art. 85 as exempted, which is more specific than the ambiguous concept of "*consequential practical requirements*" in the 2004 Directive.

Importantly, the Bolar exemption is expanded to explicitly include third party suppliers and service providers (CMOs etc.).

While all of this may be seen as a potential concern for innovator/originator pharmaceutical companies, the last sentence reproduced above (re)emphasizes that the Bolar exemption does *not* extend to the actual entering onto the market. Overall, the new Draft Directive clarifies that the Bolar exemption is confined to conduct studies and trials and other activities needed for the regulatory approval process and strives to balance the interests of generic/biosimilar companies to enter the market directly once patent protection expires with the innovator's/originator's interest to obtain a return on their significant investment.

This "*pharma package*" including the new Directive is at an early stage and the proposal first must be discussed by the European Parliament and the Council. No timeline has yet been adopted, but experience shows that it will be several years before a final draft can be adopted.

In another recent development relevant for the European market, the Bolar exemption is also codified in the new **Unified Patent Court** Agreement (UPCA), namely in Art. 27(b) UPCA, which simply "re"-cites Art. 10(6). No court decision related to this exemption is on record yet, which is no surprise since the UPC has only started taking cases in June of 2023. Since the entry of the UPCA into force, several EU Member States have (further) amended their national laws to implement the UPCA provisions.

Inherently Obvious: What is happening?

By Stacy Lewis and Adriana Burgy[16]

"Inherently obvious." Is that an oxymoron? Perhaps, but it's a reality for patent practitioners.

For years, it was settled case law that inherency belonged in an anticipation analysis but not an obviousness one. "That which may be inherent is not necessarily known; obviousness cannot be predicated on what is unknown." *In re Spormann*, 363 F.2d 444 (CCPA 1966).

Anticipation focuses on what is disclosed in the prior art. Thus, a prior art disclosure may *inherently* disclose a claim element even where a person of ordinary skill in the art would not have recognized that inherent element at the time of invention. *See, e.g., Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373 (Fed. Cir. 2003).

Then the courts started accepting that inherency may supply a missing claim limitation in an obviousness analysis, though with the caveats that use of inherency in obviousness "must be carefully circumscribed" and the limitation must be the "natural result" of the combination of prior art elements. *See, e.g., PAR Pharms. v. TWI Pharms.*, 773 F.3d 1186 (Fed. Cir. 2014). This modern trend can be traced to the 2011 Federal Circuit decision *In re Kao*, 639 F.3d 1057 (Fed. Cir. 2011).

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In *Kao*, the court held that the claimed formulation was obvious, and the specified food effect was an inherent property that did not render the claimed formulation nonobvious. *See also Santarus, Inc. v. Par Pharms., Inc.*, 694 F.3d 1344 (Fed. Cir. 2012) (holding that the claims were obvious based on an inherent property of the claimed formulation). Using language very similar to an inherent anticipation analysis language, the court in *LBT IP I LLC v. Apple Inc.*, 2023 U.S. App. LEXIS 14376 (Fed. Cir. June 9, 2023), stated:

> "[T]o rely on inherency to establish the existence of a claim limitation in the prior art in an obviousness analysis," Apple must show the activation/reactivation limitation is "necessarily present" or "the natural results of the combination of elements explicitly disclosed by the prior art." . . . Mr. Andrews' testimony failed to meet this standard for inherent disclosure.

Id. at *8-9.

Obviousness focuses on the knowledge of a person of ordinary skill in the art at the time of the invention. In *Honeywell Int'l Inc. v. Mexichem Amanco Holding S.A.*, 867 F.3d 1348 (Fed. Cir. 2017), the court explained that "all properties of a composition are inherent," and thus when considering the obviousness of a composition what matters is whether its properties are known and expected. *Id*. at 1355. This tension between inherency (which allows for later recognition) versus obviousness (in which hindsight is forbidden) has led to blurry reasoning in applying inherency in an obviousness analysis, but it is an argument raised regularly by patent challengers so one that patent owners must prepare for. So far, it is usually a tough standard to meet. Below are two recent examples, one from a district court and one from the Patent Trial and Appeal Board ("the Board").

District Court

In *Bausch Health Ir. Ltd. v. Padagis Isr. Pharms. Ltd.*, 2022 U.S. Dist. LEXIS 216602 (D. NJ Dec. 1, 2022), the limitation at issue read: "wherein the composition . . . is capable of providing synergistic efficacy and synergistic reduction of at least an adverse event selected from the group consisting of itching, burning, and stinging in said treating."

According to the district court, this was not obvious because the patent challenger (Padagis) did not demonstrate "that the claimed synergy limitations are properties of the composition or treatment method that would have been reasonably expected by a POSA as of the Priority Date. The significance of this determination is that Padagis has failed to demonstrate that the synergy limitations of the combination patent claims at issue are inherent and obvious." *Id*. at *100-101.

PTAB

In *BTC Corp. v. TG Biotech Co., Ltd.*, IPR2022-00998, Paper 44 (P.T.A.B. Nov. 13, 2023), Petitioner asserted that the concentrations disclosed in the prior art and experimental reports rendered the claimed concentrations inherently obvious.

The PTAB found that the Petitioner did not show the claims are unpatentable because Petitioner's evidence failed to show that the prior art necessarily resulted in the claimed concentration. The experimental data was rejected because it deviated from the prior art protocols and used an impure DB (damulin B) standard which made the results unreliable.

Conclusion

The Federal Circuit repeatedly stated that inherent obviousness is a narrow doctrine. An inherent limitation must *necessarily* be present in the combination of references. It is not enough to merely show that it is likely to be present. *See Pers. Web Techs., LLC v. Apple, Inc.*, 917 F.3d 1376 (Fed. Cir. 2019); *LBT IP I LLC v. Apple Inc.*, 2023 U.S. App. LEXIS 14376 (Fed. Cir. June 9, 2023).

Moreover, inherent properties of a new combination are only unpatentable if those properties were not unexpected at the time of the invention. Compare *Allergan, Inc. v. Sandoz, Inc.*, 726 F.3d 1286 (Fed. Cir. 2013) (unexpected benefits not inherently obvious) with *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, 903 F.3d 1310 (Fed. Cir. 2018) (expected properties may be inherently obvious). But measurements or functional limitations that are not unexpected and/or do not add to the novelty of the claimed invention may be obvious. *See In re Couvaras*, 70 F.4th 1374 (Fed. Cir. 2023), where the Federal Circuit upheld an obviousness rejection because "[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent."

Patent owners should beware of limitations that can be cast as an "inherent property" and thus lack patentable weight. If a challenger shows a property is inherent, "there is no question of a reasonable expectation of success in achieving [the property]." *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 946 F.3d 1322, 1332 (Fed. Cir. 2020). "To hold otherwise would allow any formulation — no matter how obvious — to become patentable merely by testing and claiming an inherent property." *Santarus, Inc. v. Par Pharm. Inc.*, 694 F.3d 1344, 1354 (Fed. Cir. 2012).

Patent owners are reminded to challenge any unsupported conclusions or reliance on only common sense. *See SSI Techs., LLC v. Dongguan Zhengyang Elec. Mech. Ltd.*, 2024 U.S. Dist. LEXIS 93391, *19-20 (W.D. Wis. May 23, 2024) ("Fourth, a party must meet a high standard to use an inherent disclosure to establish obviousness, *PAR Pharm., Inc. v. TWI Pharms., Inc.,* 773 F.3d 1186, 1195-96 (Fed. Cir. 2014), and Ganssle's superficial explanation of the purported inherent disclosure of a chimney in Clayton doesn't meet it. . . . Conclusory assertions about obviousness like Ganssle's are not enough to survive summary judgment.").

T1076/21 – Shifting of the Burden of Proof at the EPO

By Simon Curtis[17] and Matthew Wells[18]

Introduction

The European Patent Office (EPO) provides a single patent examination and granting procedure across the 39 Contracting States of the European Patent Convention (EPC). Following grant, third parties may centrally challenge the validity of a European patent *via* opposition proceedings before an Opposition Division consisting typically of three technically qualified Examiners. A decision of an Opposition Division may be appealed to one of the EPO's Technical Boards of Appeal, which will provide a final decision on the case. Although a final decision from the EPO takes effect in all Contracting States in which the patent is in force, further challenges to the validity of the patent may be made in the relevant national court(s), including the Unitary Patent Court (UPC) if applicable.

There are several grounds that may be raised during opposition and appeal proceedings concerning the validity of the patent. In all cases, the burden of proof lies with the opponent to show that the patent does not comply with the relevant article of the EPC. This burden of proof is usually discharged with documentary evidence. Clearly, where a lack of novelty is alleged, a document describing the invention and bearing a reliable date of publication (such as a published patent application) would usually be enough to meet that burden.

However, in other grounds, including "insufficiency" (whether the European patent discloses the invention in a manner sufficiently clear and complete for it to be carried out by the skilled person using the information contained in the specification and the common general knowledge; Articles 100(b) and 83 EPC), more demanding evidence may be needed. When making an argument of insufficiency, the opponent must raise serious doubts that are substantiated by verifiable facts (T19/90) to discharge its burden.

Sometimes, such as where the presence of an unusual parameter in the claim leaves a weak presumption of sufficiency, argument alone can win out for an opponent. Nonetheless, it is usually necessary for the opponent to prove their position by way of additional evidence. Where the subject matter is chemical, this might be experimental re-workings of the examples or parts of the claim showing that the invention cannot (or cannot always) be reproduced. Only then can the burden of proof shift back to the patentee.

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In T1076/21, a Board of Appeal has provided further colour on the shifting of the burden of proof, specifically in the situation where the Opposition Division has already found a patent to not meet the requirements of sufficiency of disclosure. The decision also underlines the challenges for parties who do not file facts and evidence at the earliest opportunity.

Background and Facts

In T1076/21, the patent at issue relates to a grain-oriented electrical steel sheet. Claim 1 requires a specific ratio of tensile stresses created on the steel sheet by both an oxide coating formed on top of the steel surface and a glass coating formed on top of the oxide coating. This ratio of tensile stresses was essential to achieve the desirable coating adhesion and magnetic characteristics of the product.

At first instance, the Opposition Division revoked the patent for the invention being insufficiently disclosed. It was not possible, said the Division, to reproduce the claimed invention reliably from the parameters disclosed in the examples. The opponent relied only on the text of the patent to support its position. Its argument was that the examples disclosed samples that had been subjected to the same process parameters for manufacturing the oxide layers but that resulted in very different end properties, with some satisfying the requirements of granted Claim 1 and others failing to do so. There was something missing, went the argument, in the instruction to the skilled person about how to achieve the invention.

On appeal by the patentee, the Board issued a preliminary opinion indicating that it disagreed with the Opposition Division and that the invention was sufficiently disclosed. The Board was of the view that the patent taught that the thickness of each of the glass coating and oxide coating was correlated to the tensile stress created by each coating layer. Moreover, the effect was achieved when the thickness of the oxide layer was within a certain range. The patent also taught that the thickness of the glass layer should have a certain relationship to that of the oxide layer. Given that disclosure, the skilled person would have been able to provide a grain-oriented electrical steel sheet having the claimed ratio of the tensile forces without facing an undue burden.

In seeking to win over the Board, the opponent-respondent assumed that the burden of proof on appeal had rested first with the patentee following the revocation of the patent at first instance. The Board's written opinion had, in the view of the opponent-respondent, shifted that burden back to them, with the consequence that the Board ought to provide them with the opportunity to file evidence of the insufficiency in the form of a joint expert declaration.

However, the Board did not admit this declaration and pointed out that the opponent-respondent's insufficiency argument remained unsupported by evidence. Consequently, the Board found the sufficiency attack unsuccessful and overturned the Opposition Division's decision to revoke the patent. The case was remitted to the Opposition Division to consider the other grounds of opposition, including novelty and inventive step, which had been raised.

The Grounds for the Decision

Central to the Board of Appeal's decision was the question of which party bears the burden of proof on appeal concerning sufficiency of disclosure. From an extensive analysis of EPO jurisprudence, the Board concluded that the burden of proof regarding the facts, arguments and evidence on the substance (which initially lies with the opponent) does not shift to the patentee just because a patent has been revoked by the Opposition Division due to an alleged insufficient disclosure.

Rather, the Board confirmed that the same principle applies as before the Opposition Division: the burden of proof rests initially on an opponent, who must raise serious doubts concerning the sufficiency of the patent that are substantiated by verifiable facts. Formal reasons, such as a decision of the Opposition Division, do not shift this burden.

The decision also distinguishes between a burden to substantiate a case in opposition or appeal proceedings, and a burden of proof on the substance of a case. On the former, a party (in this case the patentee) appealing against a decision must substantiate their case by setting out the reasons for setting aside the decision under appeal (Article 12(3) RBPA). It is enough to indicate the arguments why an Opposition Division's reasoning is flawed. On the latter, an opponent is still required to prove its position. Were this not the case, the only possibility for a patentee to challenge a decision under appeal would be to disprove the evidence on which a decision against it was based. That would not be an appeal as such but an entiraty new debate.

In the case at hand, the Board of Appeal's finding regarding the burden of proof on appeal shaped their treatment of the opponent's submission of a joint expert declaration that was filed after its summons to oral proceedings. Having not filed evidence of insufficiency before the Opposition Division, the opponent was hoping that it could augment its case with some during the appeal phase.

The EPO's Boards of Appeal divide appeal proceedings into three periods with increasingly strict requirements for the admittance of new facts and evidence (Articles 12 and 13 RPBA). The final period is often triggered by the issuance of the summons to oral proceedings, after which *any* amendments to a party's appeal case (including facts or evidence not already admitted into proceedings) will not be taken into account unless there are exceptional circumstances that are justified by cogent reasons (Article 13(2) RBPA).

In the case at issue, the Board found that an opinion in disagreement with an Opposition Division could not be considered an exceptional circumstance. Consequentially, the requirements for the opponent's joint expert declaration to be admitted into the proceedings were not fulfilled. The opponent did not get its second chance to make good its case and its arguments on insufficiency ultimately failed. The opponent had never met its burden of proof, in the view of the Board, so there was little to be reversed in any case.

Practice Points for US Practitioners

Although T1076/21 arguably does not break new ground, it is a useful reminder that parties should make their complete case at the commencement of appeal proceedings, irrespective of the findings of the Opposition Division at first instance. Failure to make a complete case in a Grounds of Appeal could lead to key facts and evidence being considered late-filed by the Board of Appeal and consequently not admitted into the proceedings. More generally, there is even a risk that facts and evidence submitted in later stages of opposition proceedings will not be not admitted by the Opposition Division, with Boards of Appeal being generally reluctant to overturn those discretionary admissibility decisions.

The EPO applies a principle of the free evaluation of evidence, meaning that it is not bound by rules dictating the forms or respective weight that must be applied to different pieces of evidence, provided that the evidence is admissibly submitted. Instead, the only decisive factor is whether the appropriate body at the EPO, be that the Opposition Divisions or Boards of Appeal, is personally convinced of the truth of a factual allegation in view of the evidence. As such, useful forms of evidence include documentary evidence, such as prior art documents, reports of experiments, witness statements, and inventor declarations; cross-examination of witnesses; and inspection of articles.

In practice, however, the EPO's strength lies in the assessment of documentary evidence, with the typically one-day oral hearings providing limited scope for taking evidence orally, such as by the cross-examination of witnesses. Even within the category of documentary evidence, Opposition Divisions and Boards of Appeal are most comfortable dealing with prior art documents, common general knowledge documents, and experimental reports. Less weight tends to be put on inventor declarations and expert reports, perhaps due to the absence of formal sanctions available to the EPO for false statements.

In view of the EPO's strict admissibility regime and preferred forms of evidence, instructing US counsel is encouraged to engage at the commencement of opposition proceedings with their European counterparts concerning the evidence that may be required to support sufficiency positions. The timing of submissions should be considered carefully to minimize the likelihood of non-admittance.

In our experience, many insufficiency attacks are poorly evidenced and usually fail. There are a few set-piece arguments that can be very effective without additional evidence, especially in the chemical fields, such as those relating to vague or unusual parameters. However, opponents are often hoping that evidence can be adduced later in the proceedings, leaving the position at the mercy of their resource-constrained lab teams to experiment within the teaching of the patent. Opposition Divisions *should* admit experimental data after the opposition deadline if it is *prima facie* relevant to the case, so it should be admitted if it is good. There is, of course, always an argument to be had about that point, so if experimental data can be prepared before the opposition deadline the position will be stronger. The nature of the necessary experiments and the presentation of the results are highly dependent on the individual case. US practitioners are recommended to seek advice ahead of commissioning experimental work.

One alternative to performing experiments is to search for patent publications that disclose similar examples to those in the patent in question. Where some of the examples in alternative documents produce results that fall outside the patent claims, while seemingly following the instructions in the patent, they can provide powerful "verifiable facts" to support an argument. This is especially true where the general teaching about methods in a patent is slim. A patentee's own portfolio can be a helpful place to look for this art and there is no need for it to be published before the filing date.

For patentees, the situation is quite different due to the initial burden of proof resting on the opponent. In many cases, a patentee's first response to an insufficiency attack raised in opposition proceedings can be to hide behind that burden of proof. It can be effective to criticize an attack as being no more than conjecture or a disguised attack on the clarity of the claims. The clarity of the granted claims cannot be attacked in post-grant proceedings before the EPO and, since the EPO's jurisprudence may be developing in the direction of more issues being considered as relating to clarity rather than sufficiency, this can often be useful defence for patentees.

When facing a strongly evidenced insufficiency argument as a patentee, the burden of proof may still be helpful. The EPO tends to interpret this as an invitation to side with the patentee if there is directly competing data. Repeating the experiments performed by an opponent to see if a different result can be obtained is worthwhile if resources allow. This can result in a burden of proof that has shifted to a patentee swinging back to an opponent.

Failing that, patentees can succeed by criticizing the experimental work of an opponent, arguing that a skilled person would have known from the teaching of the patent and their common general knowledge that the approach taken by the opponent would have been unsuccessful. This is effectively arguing that the burden of proof has not been discharged and thus cannot be reversed. It is also an instance where expert declarations can be helpful.

While we have concentrated here on arguments of insufficiency, it is worth noting that the same principles apply to inventive step arguments where they rest on whether a *technical problem* has been solved or a *surprising effect* has been observed. Again, the burden of proof rests first on the opponent, at least where an effect is derivable from the patent in question.

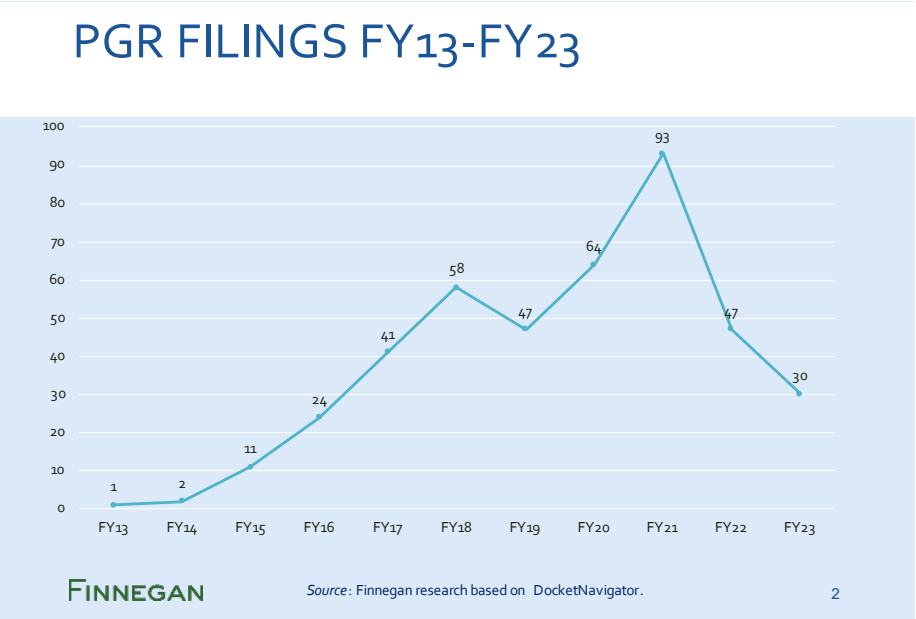
In short, opponents should note that arguments that need evidence should be well developed and supported as early in a case as possible and should expect to argue them *a priori* on appeal. Patentees can at least defend from a position of strength at both instances.

No Love for PGRs

By Stacy Lewis, Amanda Murphy, Umber Aggarwal[19]

Introduction

The America Invents Act ("AIA"), signed into law on September 16, 2011, created two types of post-grant proceedings: inter partes reviews (IPRs) and post-grant reviews (PGRs). IPRs, which may be filed against pre-AIA and AIA patents, allow for challenges on "a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications." 35 U.S.C. § 311(b). PGRs, which may only be filed against AIA patents, allow for a broader set of challenges: "any ground that could be raised under paragraph (2) or (3) of section 282(b) (relating to invalidity of the patent or any claim)." 35 U.S.C. § 321(b).[20] But uptake of PGRs remains very modest and pales by comparison to IPRs. For example, for FY19-FY23, the USPTO reports 282 PGR petitions and 6660 IPR petitions.[21] Moreover, the annual number of PGR petitions is dropping from a peak in FY21:



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[20] 35 U.S.C. §282(b)Defenses.—The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

(1) Noninfringement, absence of liability for infringement or unenforceability.

(2) Invalidity of the patent or any claim in suit on any ground specified in part II as a condition for patentability.

(3) Invalidity of the patent or any claim in suit for failure to comply with—

(A) any requirement of section 112, except that the failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable; or

(B) any requirement of section 251 [reissue patents].

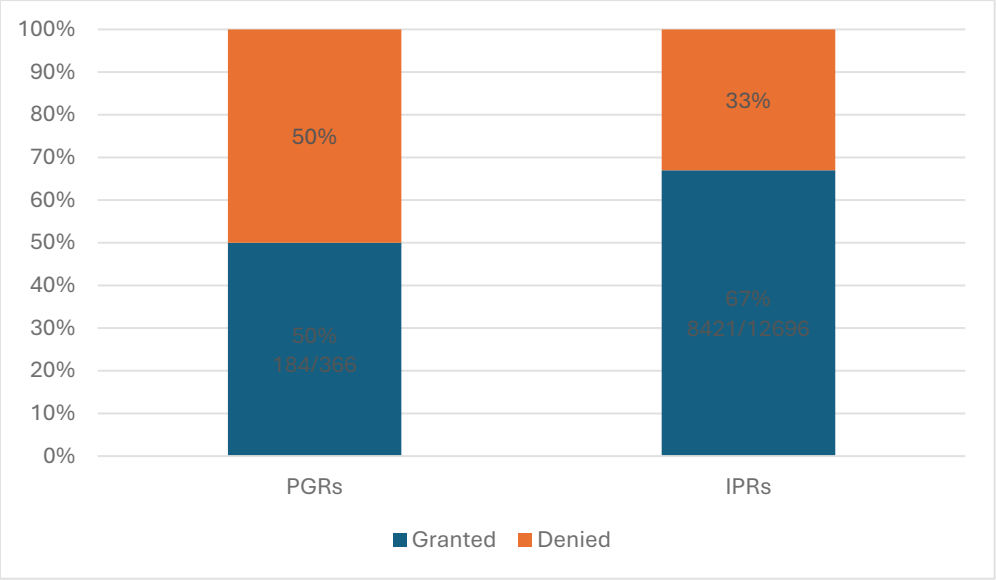
(4) Any other fact or act made a defense by this title.

[21] https://www.uspto.gov/patents/ptab/statistics

Institution

Overall, the PGR institution rate is lower than the IPR institution rate, which one might speculate follows from the slightly higher threshold for institution. For IPRs, the threshold is "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." For PGRs, the threshold is "more likely than not that at least 1 of the claims challenged in the petition is unpatentable."

PGR and IPR Institution Rates[22]

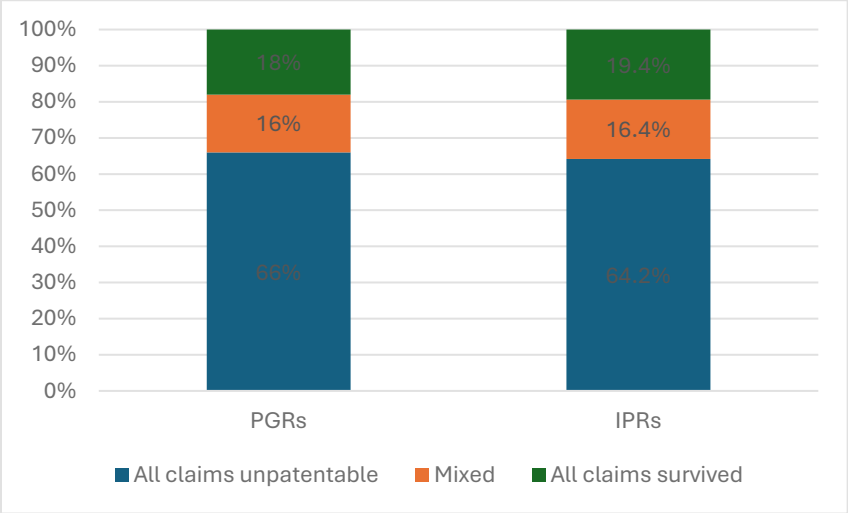


Final Written Decision

Overall, the outcomes in Final Written Decisions are remarkably similar in PGRs and IPRs.

[22] *Source* for PGRs: Finnegan research based on DocketNavigator. "Granted" includes partially granted for petitions decided pre-SAS. *Source* for IPRs: https://www.uspto.gov/patents/ptab/statistics/aia-trial-statistics-archive

PGR and IPR Final Written Decisions[23]



Why Aren't PGRs as Popular as IPRs?

It does not seem to be that challengers are having noticeably less success in PGRs than in IPRs. So there must be other reasons why the uptake in PGRs remains low.

The time limit for filing a PGR is likely one factor. A PGR petition "may only be filed not later than the date that is 9 months after the date of the grant of the patent or of the issuance of a reissue patent[.]" 35 U.S.C. § 321(note)(1)(A).[24] It may require significant resources to track your competitor's activities and be ready with a PGR petition within 9 months of a patent issuing. Many potential patent challengers may simply be unable to devote the resources necessary to meet the deadline for filing a PGR petition. Some companies have opted for pre-grant 3rd party submissions as a less expensive alternative.

The interplay between litigation and post-grant challenges could also be a factor. With IPRs, it is not uncommon for a defendant sued for infringement to file an IPR petition as a possible way to knock out the asserted patent. With PGRs, however, even if a patent owner plans to sue for infringement he will likely wait until 9 months after issuance, removing the PGR petition from the alleged infringer's options.

But perhaps estoppel is the main factor at work. With the broader grounds of challenge available in a PGR comes a broader scope of estoppels. And with the outlines and parameters of such estoppels still in some question, challengers may be deciding the risk is too great.

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[23] *Source* for PGRs: Finnegan research based on DocketNavigator. *Source* for IPRs: https://www.uspto.gov/patents/ptab/statistics/aia-trial-statistics-archive

[24] In contrast, an IPR petition on an AIA patent may be filed at any time after the 9-month PGR period ends (or after the completion of any PGR proceeding if one is filed), or at any time after a pre-AIA patent is granted. 35 U.S.C. §§ 311(c) & 321(c).

When deciding between a PGR and an IPR, petitioners should balance the timing and estoppel considerations against the strength of the additional arguments available in a PGR, especially when arguments based on prior art are not as strong as the additional arguments available in a PGR. While the institution standard is harder to meet, the Final Written Decision (FWD) statistics indicate that chances of success after institution in a PGR versus an IPR are similar. It will be interesting to see how the trends look after the next decade of post-grant trial proceedings at the PTAB.

Call For Submissions

Dear Members of the Chemical Practice Committee,

We hope you enjoyed this issue of the Chemical Practice Chronicles.

We are thrilled to announce the upcoming release of our next newsletter and invite you to be a part of it! As we strive to bring valuable insights and engaging content to our chemical practice readers, we are seeking submissions for articles that explore a wide range of topics. Whether you are a seasoned writer or new to sharing your thoughts, we welcome your unique perspectives and expertise. Don't miss this opportunity to showcase your voice and contribute to our IP community.

Please submit your articles for consideration to afreistein@wenderoth.com and zimmermans@ballardspahr.com. We look forward to reading your submissions!

Andrew B. Freistein
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