AIPLA

American Intellectual Property Law Association

Chemical Practice Chronicles

Newsletter of the AIPLA Chemical Practice Committee

Spring 2024 Volume 12 Issue 1

Editors:

Andrew B. Freistein (AFreistein@wenderoth.com)
Sommer Zimmerman, Ph.D. (zimmermans@ballardspahr.com)
Jenny Lee (jlee@haugpartners.com)
Ali Anoff (anoff.a@pg.com)
Joshua B. Goldberg (JGoldberg@Nathlaw.com)
Dolly Kao (Dolly@kaoip.com)
Valerie Moore, Ph.D. (VMoore@ktslaw.com)
Warren Zitlau (warren.zitlau@cahnsamuels.com)

Dear Members of the Chemical Practice Committee,

As we celebrate World IP Day, it gives us great pleasure to release the 2024 Spring edition of the AIPLA Chemical Practice Chronicles, which highlights unique issues in Chemical Patent Practice from around the world.

First, we would like to express our deepest gratitude to Andrew Freistein and Sommer Zimmerman, the co-Editors-in-Chief, for their outstanding dedication and hard work in curating this exceptional newsletter.

We would also like to extend our sincere thanks to Jeremy McKown, our board liaison, for his valuable guidance and support, bridging the gap between our committee and the AIPLA Board.

Furthermore, we would like to thank all the subcommittee chairs for their exceptional efforts in providing our members with high-quality educational and networking opportunities.

Since the 2023 AIPLA Annual Meeting, our committee has been actively engaged in several initiatives that provide education, networking and advocacy opportunities to our members. At the 2023 AIPLA Annual Meeting, we proudly sponsored a panel that included Vincent Shier of Haynes & Boone as a speaker on the topic of "How OUS Jurisdictions Handle AI and Inventorship/The State of AI in Chemical and Biology US Patents." The presentation provided an insightful overview of patent issues at the interface of AI and the life sciences. Our committee has also been a part of AIPLA's advocacy in preparing written comments a draft interagency guidance framework for considering the exercise of march-in right by to the National Institute of Standards and Technology (NIST). Additionally, we have held quarterly committee calls, provided monthly legal updates on our microsite, and facilitated in-person and virtual networking opportunities.

In two weeks, we will host our 2nd Advanced Chemical Practice Institute, in collaboration with the Biotechnology Committee. The program will be on May 14-15, 2024, prior to the Spring Meeting in Austin, TX. This unique advanced course, will address hot button issues including advanced claim drafting, claim construction, written description, enablement, and recent legislative proposals. Details for the program are provide in the following pages.

Additionally, if you plan to be at the Spring Meeting, we are co-hosting a social event with the Biotechnology Committee on Thursday, May 16 at 5:00-7:00 pm at the Moonshine Grill, 303 Red River Street, across from the Hilton. Please RSVP to the Biotechnology Committee Social Chair, Gillian Banten at gillian@craft-mktg.com by Monday, May 13. We are still looking for sponsors for the event, so if you are interested, please email Gillian.

We hope to see all of you at the upcoming Advanced Chemical Practice Institute, Spring Meeting, or our next committee call.

Warm regards,

Jenny Lee, Chemical Practice Committee Chair
Ali Anoff, Chemical Practice Committee Vice Chair

Committee Schedule

Date	**Activity**
December 7, 2023	Committee Quarterly Meeting (online) – 2PM ET • Committee Ice Breaker / Introductions • Overview of Subcommittees
April 23, 2024	Committee Quarterly Meeting (online) – 2PM ET • Committee Business • March-In Rights Under The Bayh-Dole Act -- Brian R. Stanton, Ph.D., Stanton Consulting Services, LLC • Artificial Intelligence and IP: Impacts on other disciplines – John Osha, Osha Bergman Watanabe & Burton LLP
May 14-15, 2024	2024 Advanced Chemical Practice Institute
May 16-18, 2024	AIPLA Spring Meeting
July 2024	Committee Quarterly Meeting (online) – 12PM ET Agenda: TBD
September 2024	Committee Quarterly Meeting (online) – 2PM ET Agenda: TBD
October 24-26, 2024	AIPLA Annual Meeting

2024 AIPLA ADVANCED CHEMICAL PRACTICE INSTITUTE TUESDAY & WEDNESDAY, MAY 14-15, 2024

Hilton Austin
500 E 4th St
Austin, TX, USA

This event is designed for patent attorneys and patent agents actively practicing in the chemical and related arts and will be presented from both prosecution and litigation perspectives. This advanced course equips practitioners to prepare and prosecute patent applications, withstand challenges from PTAB and district courts, including such hot button issues as advanced claim drafting, claim construction, written description, enablement, and legislative proposals. Attendees will be armed with strategies and best practices to maximize the scope of patent protection while minimizing challenges to the validity and enforceability of the patents. The program also offers information that will assist in client counseling and making strategic portfolio and business decisions.

The schedule for the Institute is 1:30 – 5:00 PM Central, Tuesday, May 14 and 8:30 AM – 5:30 PM on Wednesday, May 15. Registration includes access the all event materials via the event App, all coffee breaks, breakfast and lunch on Wednesday, as well as a Networking Event on Tuesday evening.

Register at https://www.aipla.org/detail/event/2024/05/14/default-calendar/2024-advanced-chemical-patent-practice-institute

Tentative Program Schedule
(*as of May 1, 2024*)

DAY 1
Tuesday, May 14, 2024

1:30PM – 2:00PM **REGISTRATION**

2:00PM – 2:15PM **WELCOME REMARKS – DAY 1**

Ann M. Mueting
AIPLA President
Mueting Raasch Group
Minneapolis, MN

Thomas L. Irving
Program Master of Ceremonies
The Marbury Law Group, PLLC
Reston, VA

2:15PM – 3:45PM **DRAFTING STRATEGIES FOR CONQUERING THE WORLD**

Patent attorneys practicing in US, Europe, China, and Japan will speak to requirements of enablement and sufficiency of disclosure across jurisdictions including specific practice tips as to when and how to handle objections and rejections related to indefiniteness, including how to present data *in vitro* vs *in vivo*/clinical trial data and computer-generated data and when post-filing data can be relied on. The panelists will also provide insight on how to avoid clarity objections, including the inclusions of definitions in the specification as well as the interpretation of terms such as "about," "approximately," and "substantially" in various patent offices. The panel will offer best practice solutions for presenting genus claims for prosecution across jurisdictions as well as the inclusion of parameters, measurement methods functional features in claim language. Further, this panel will speak to the need for fallback positions to ensure allowance of claims and appropriate claim scope.

Moderator: **Chloe Hollway**
Hoffman Eitle
Munich, Germany

Speakers: **David Albagli**
White & Case, Local Partner
Tokyo, Japan

Joanna Brougher
Indivior PLC
BioPharma Law Group, PLLC
Chesterfield, Virgina

Toby Mak
Tee & How
Beijing, China

Toby Simpson
Hoffman Eitle
Munich, Germany

3:45PM – 4:00PM **BREAK**

4:00PM – 5:00PM **THE FUTURE OF ENERGY: NAVIGATING THE TRANSITION IN THE WORLD OF PATENTS**

The energy transition from fossil fuels to renewable energy sources has both economic and practical implications and raises concerns of sustainability. Management of energy resources is evolving and transforming everyday as innovative solutions are needed to address climate change and the world's complex energy challenges. The chemical practitioner can adapt and be a positive influence on this new business environment through an understanding of the implications of the energy transition generally, and how the energy transition may impact intellectual property strategies. Our panel of experts will address how practitioners can meet clients' evolving needs in this new wave of innovation.

Moderator: **Carol Nielsen**
AIPLA Board of Directors 2019-2022
Nielsen IP Law LLC
Houston, Texas

Speakers: **Melody van Denzen**
ConocoPhillips
Houston, Texas

Tori Reinhart
CGG
Houston, Texas

5:00PM **DAY 1 ADJOURNMENT**

TBD **NETWORKING DINNER (LOCATION TBD)**

DAY 2
Wednesday, May 15, 2024

8:00AM – 8:30AM **BREAKFAST**

8:30AM – 8:45AM **WELCOME REMARKS – DAY 2**

Wan Chieh (Jenny) Lee
AIPLA Chemical Practice Committee Chair
Haug Partners LLP
New York, NY

Ali Anoff
AIPLA Chemical Practice Committee Vice-Chair
The Procter & Gamble Company
Cincinnati, OH

8:45AM –10:15AM **DRAFTING AND PROSECUTING PATENT APPLICATIONS TO SURVIVE A MARKMAN HEARING: CLAIM CONSTRUCTION CASE STUDIES**

Patents prepared and prosecuted with a focus on future challenges can increase the likelihood of providing desired protection. For instance, the statements made in a patent application or during prosecution can influence the outcome of a Markman hearing. The panel will delve into recent cases where claim construction played a pivotal role in litigation outcomes. Drawing from these cases, the panel will provide practical insights and tips on how to optimize patent application and claim drafting to strengthen the chances of success in future litigation.

Moderator: **Tony Prosser**
Knowles Intellectual Property Strategies
Atlanta, Georgia

Speakers: **Ali Anoff**
The Procter & Gamble Company
Cincinnati, OH

Laura Smalley
Harris Beach PLLC
Rochester, New York

Michelle O'Brien
The Marbury Law Group, PLLC
Reston, Virginia

10:15AM – 10:30AM **BREAK**

10:30AM – 12:00PM **CHEMICAL PATENT CONUNDRUMS: INDUSTRY EXPERTS SHARE SOLUTIONS FOR PATENT PROSECUTION CHALLENGES**

This interactive panel brings together experts from diverse sectors to share their experiences and strategies in addressing common hurdles faced in chemical patent practice. Gain valuable insights as our esteemed speakers delve into their unique approaches, providing practical solutions and invaluable guidance to overcome the intricacies of patent prosecution in the chemical domain.

Moderator: **Andrew S. Chipouras**
Honigman LLP
Kalamazoo, MI

Speakers: **Joshua B. Goldberg**
Nath, Goldberg & Meyer
Alexandra, VA

Rachel Kahler
General Mills
Minneapolis, MN

R. Andrew Patty II
Past AIPLA Chemical Practice Committee Chair
Phelps Dunbar LLP
Baton Rouge, LA

12:00PM – 12:45PM **LUNCH**

12:45 PM – 2:15 PM **NAVIGATING THE CHANGING PATENT LANDSCAPE FOR OBVIOUSNESS-TYPE DOUBLE PATENTING AND UNCONVENTIONAL SOURCES OF PRIOR ART**

The panel will discuss recent updates that have significant impact to patent strategies for obviousness type double patenting in the US and around the world, and unconventional sources of prior art, in particular, information obtained from clinicaltrials.gov postings, EMEA protocols, conference presentations, or press releases. The panelists will discuss the potential impact of recent changes and practice tips for managing developing worldwide patent portfolios.

Speakers: **Sean Brock**
GSK
Philadelphia, PA

Wan Chieh (Jenny) Lee
Haug Partners LLP
New York, NY

Melanie Szweras
Bereskin & Parr LLP
Toronto, Canada

Holger Tostmann
Wallinger, Ricker, Schlotter, Tostmann
Munich, Germany

2:15 PM – 3:45 PM **CHARTING UNCERTAIN WATERS: CLAIM DRAFTING IN LIGHT OF EVOLVING WRITTEN DESCRIPTION AND ENABLEMENT REQUIREMENTS**

Solid claim drafting has become critical considering evolving requirements under 35 U.S.C. § 112. Learn the latest best practices after *Amgen v. Sanofi* in drafting chemical, pharmaceutical, and biotech claims, including means-plus-function claims. This session will offer practical guidance in view of USPTO-allowed claims, PTAB precedent and Federal Circuit decisions.

Moderator: **Jocelyn Ram**
The Broad Institute of MIT and Harvard
Cambridge, MA

Speakers: **Sharon Crane, Ph.D.**
Haynes and Boone, LLP
Washington, DC

Sherry Knowles
Knowles Intellectual Property Strategies
Atlanta, GA

3:45PM – 4:00PM **BREAK**

4:00PM – 5:30PM **WHAT IN THE WORLD IS GOING ON WITH PATENTS? AN UPDATE**

This panel will address ongoing administrative efforts and legislative proposals in Europe and the United States that impact the patent procurement process and potentially transform patent rights of chemical inventions. EP counsel will highlight updates to the EPO Guidelines for Examination and the impact of a recent EPO decision when evidence may be relied upon for inventive step. US counsel will discuss current US legislation proposals and administrative policy initiatives that could change the state of march-in rights, clarify patent eligible subject matter for 21st century technologies, and impact one of the most misunderstood anticompetitive business behaviors across industries: product hopping. The panel will also touch on patent reform legislation purported to reduce the price of drug products.

Speakers: **Matthew Barton**
Forresters IP LLC
Munich, Germany

Carol Nielsen
AIPLA Board of Directors 2019-2022
Nielsen IP Law LLC
Houston, Texas

Jeremy McKown
AIPLA Board of Directors
Johnson and Johnson
New Brunswick, NJ

Toby Simpson
Hoffman Eitle
Munich, Germany

5:30 PM **ADJOURNMENT**

2024 AIPLA ADVANCED CHEMICAL PRACTICE INSTITUTE PLANNING COMMITTEE

WAN CHIEH (JENNY) LEE
Chemical Practice Committee Chair
Haug Partners
New York, NY

ALI ANOFF
Chemical Practice Committee Vice-Chair
The Procter & Gamble Company
Cincinnati, OH

THOMAS L. IRVING
Chemical Practice Committee, Programs Subcommittee Chair
The Marbury Law Group, PLLC
Reston, VA

STACY LEWIS
Chemical Practice Committee, Programs Subcommittee Chair
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
Washington, DC

DEBORAH L. DRAZEN
Chemical Practice Committee, Programs Subcommittee Chair
Johnson & Johnson
New Brunswick, NJ

LAURA W. SMALLEY
Biotechnology Committee Chair
Harris Beach, PLLC
New Brunswick, NJ

MELANIE SZWERAS
Biotechnology Committee Vice-Chair
Bereskin & Parr LLP
Toronto, Ontario, Canada

ANDREW S. CHIPOURAS
Honigman LLP
Kalamazoo, MI

JOSHUA B. GOLDBERG
Nath, Goldberg & Meyer
Alexandra, VA

CHLOE HOLLWAY
Hoffman Eitle
Munich, Germany

CAROL NIELSEN
AIPLA Board of Directors 2019-2022
Nielsen IP Law LLC
Houston, Texas

R. ANDREW PATTY II
Past Chemical Practice Committee Chair
Phelps Dunbar LLP
Baton Rouge, LA

In re Cellect Poses an Obvious Dilemma

By Sommer Zimmerman, Ph.D[1]

Background

In August 2023, the Federal Circuit in *In re Cellect* held that in evaluating unpatentability for obviousness-type double patenting (ODP) of a patent that has received patent term adjustment (PTA), the relevant date is the reference patent's expiration date after PTA is added.[2] Cellect promptly filed a petition for rehearing *en banc*. A flood of amicus briefs in support of a rehearing ensued, filed by key players in the pharmaceutical industry including AbbVie, Merck, Novartis, AstraZeneca, and Johnson & Johnson, among others. Although the petition was ultimately denied, this case has ongoing implications. These implications, together with additional cases that may yet be impactful, are summarized here.

ODP always trumps PTA

35 U.S.C. § 154(b) provides three bases by which patent term can be adjusted due to various delays in prosecution. Specifically, these bases include (1) if the USPTO fails to take certain actions within certain time periods ("A" delay); (2) if the USPTO fails to conclude prosecution within three years of the actual filing date ("B" delay); and (3) if issuance is delayed due to secrecy orders, derivation proceedings, or successful appellate review ("C" delay). The statute further clarifies that "[n]o patent *the term of which has been disclaimed* beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer" (emphasis added). Thus, the statute clearly imposes a limitation by which the presence of a terminal disclaimer voids any additional term that may be granted by PTA.

In *Cellect*, however, a terminal disclaimer was not present in any of the patents at issue. Yet, the Federal Circuit deemed this essentially irrelevant. According to the *Cellect* panel, "ODP for a patent that has received PTA, *regardless [sic] whether or not a terminal disclaimer is required or has been filed*, must be based on the expiration date of the patent after PTA has been added" (emphasis added).[3]

The *amici curiae* briefs were adamant that the position of the panel is a clear misinterpretation of Congressional intent, noting that the "reference to terminal disclaimers [in Section 154(b)] made

[1] Sommer Zimmerman, Ph.D., is an associate of Ballard Sparhr and works in the office located in Atlanta, Georgia, U.S.A. (https://www.ballardspahr.com/People/Attorneys/Z/Zimmerman-Sommer; https://www.ballardspahr.com/).

[2] See also *Gilead Sciences, Inc. v. Natco Pharma Limited*, 753 F.3d 1208 (Fed. Cir. 2014), which held that a later-granted patent can render an earlier-granted patent invalid for ODP. Neither of the patents at issue in *Gilead* received PTA.

[3] *In re Cellect*, 81 F.4th 1216, 1229 (Fed. Cir. 2023).

clear that Congress specifically considered ODP in establishing PTA."[4, 5] Under the panel's interpretation, however, the presence of ODP in and of itself is sufficient to null any additional term awarded by PTA. The presence – or absence – of a terminal disclaimer is inconsequential.

Patents expiring later due to PTA are always susceptible to challenge in view of earlier-expiring obvious variant patents

It is well established that the judicially created doctrine of ODP is firmly rooted in equitable considerations, focusing on preventing patentees from obtaining an unjustified extension of patent term.[6] In this way, the doctrine secures against improper extensions of term due to "gamesmanship" of the patentee.[7]

The decision in *Cellect* makes clear that although ODP outweighs PTA, and although equity is yet a component of ODP, it is <u>not</u> a component of PTA. Simply stated, an equitable analysis is not sufficient to evaluate a patentee's entitlement to their PTA award. "[T]he risk remains for multiple assignees to seek past damages."[8] Moreover, "good faith during prosecution does not entitle [Cellect] to a patent term to which it otherwise is not entitled."[9] Rather, additional concerns such as patent expiration dates must be contemplated.[10] What is not clear, however, is whether good faith remains a part of the analysis at all.[11]

Moreover, it does not matter if the reference patents are in the same patent family and, therefore, subject to examination by the same patent Examiner, nor does it matter if the Examiner raises a rejection based on ODP or not.[12] There is no presumption that the reference patent was considered. Indeed, the *Cellect* panel suggests quite the opposite, noting that the "fact that this case is before us here without terminal disclaimers having been required itself strongly suggests that the examiner did *not* consider the issue" (emphasis added).[13]

Thus, in families for which multiple patents exist, if any one of those patents receives PTA, the PTA itself is sufficient to put that patent at risk for challenge due to ODP.

---

[4] Brief of *Amici Curiae* Abbvie Inc. and Innovation Alliance in Support of Appellant on Rehearing (November 27, 2023).

[5] See also Brief of *Amicus Curiae* American Intellectual Property Law Association in Support of Appellant's Petition for Rehearing En Banc (November 22, 2023) (stating that the statute "provides only that *if* a terminal disclaimer has been filed, PTA cannot extend a patent's expiration beyond the date specified in the disclaimer").

[6] See, *e.g.*, *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985) and *In re Schneller*, 397 F.2d 530 (CCPA 1968).

[7] See, *e.g.*, *Abbott Labs v. Lupin Ltd.*, 2011 U.S. Dist. LEXIS 53846 (D. Del. 2011) and *Novartis Pharm. Corp. v. Breckenridge Pharm., Inc.*, 909 F.3d 1355 (Fed. Cir. 2018).

[8] *Cellect* at 1230.

[9] *Id.*

[10] See also *Gilead*.

[11] See, *e.g.*, *Cellect* Rehearing Petition at page 14 ("the Panel went even further and ruled that equities simply do not matter at all. Indeed, the Panel explicitly stated that an applicant's good faith is irrelevant").

[12] *Cellect* at 1228 (irrespective of whether the examiner "had the opportunity, and perhaps the obligation, to reject certain of the pending claims" for ODP, so, too, Cellect had the opportunity to file a terminal disclaimer).

[13] *Cellect* at 1231.

The risk imposed by an award of PTA is invalidation of the patent in its entirety

Upon affirming the decision of the USPTO Patent Trial and Appeal Board that the claims at issue are unpatentable for ODP, the *Cellect* panel further affirmed that the Cellect patents themselves were invalid because of ODP and not only in respect of the additional PTA term. Specifically, the panel stated, "invalidation of only the adjustment would be tantamount to granting a retroactive terminal disclaimer" and "would in effect give Cellect the opportunity to benefit from terminal disclaimers that it never filed."[14]

This ruling makes evident that an award of PTA to one patent amongst a family of others brings with it not only a risk that the additional term (*i.e.*, the PTA award) can be lost but a risk that the patent itself may be invalidated – a result that could have devastating consequences to a damages award. If a disclaimer is filed in the challenged patent before the reference patent expires, a patentee may yet be entitled to truncated damages (*i.e.*, damages for the original patent term minus the PTA award).[15] If, however, the reference patent has expired such that the patentee no longer has the option to file a terminal disclaimer, the challenged patent may be subject to invalidation, in which case the entire damages award would be forfeit. As Intellectual Property Owners Association (IPO) puts it, "the Congressionally-authorized grant of patent term adjustment is a poison pill that invalidates the patent in its entirety."[16, 17]

Additional recent ODP cases worth noting

Allergan v. MSN

Allergan holds a New Drug Application for Viberzi® (eluxadoline), which is approved for the treatment of irritable bowel syndrome with diarrhea. Both Sun and MSN submitted Abbreviated New Drug Applications to market and sell generic versions of Viberzi® and also filed Paragraph IV certifications for certain patents owned by Allergan, including the '356 patent.[18] Allergan filed suit against Sun and MSN alleging infringement. In response, Sun argued, *inter alia*, that the asserted claim of the '356 patent is invalid for ODP.

The '356 patent is one of three patents from the same family. Although the '356 patent issued before the other two patents, it expired after them due to PTA. In analyzing the facts of the case, the district court purports to "apply the rule dictated in *In re Cellect*," stating that "ODP depends

[14] *Id.*

[15] Under 35 U.S.C. § 286, a patentee cannot recover damages for infringement committed more than six years before the infringement complaint was filed.

[16] Brief for *Amicus Curiae* Intellectual Property Owners Association in Support of Appellant (November 27, 2023).

[17] But see *Boehringer Ingelheim International GmbH v. Barr Laboratories, Inc.*, 592 F.3d 1340 (Fed. Cir. 2010), noting that a retroactive terminal disclaimer can yet be filed after patent grant to overcome an ODP rejection *so long as* the reference patent is still pending ("a patentee may file a disclaimer after issuance of the challenged patent or during litigation, even after a finding that the challenged patent is invalid for obviousness-type double patenting"). See also *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005).

[18] US 7,741,356

solely on patent expiration dates and should not be influenced by equitable concerns."[19] "The 'first-filed, first-issued' distinction is immaterial."[20]

Acadia Pharm. v. Aurobindo Pharma

Acadia Pharmaceuticals, Inc. owns several patents directed to pimavanserin, which is the active ingredient in Nuplazid®. Nuplazid® is approved for the treatment of hallucinations and delusions associated with Parkinson's disease. MSN filed an Abbreviated New Drug Application for a generic version of Nuplazid® that was since approved by the FDA. Acadia filed suit against MSN. Both parties filed cross-motions for summary judgment regarding the validity of the '740 patent[21] for ODP over the '271 patent.[22] The '740 patent issued on October 13, 2009 and received grants of both PTA and PTE. The '271 patent was filed after the '740 patent issued, and claims priority to a series of continuation applications reaching back to a divisional of the '740 patent.

The key issue was whether the '740 patent is entitled to the benefit of the safe harbor provision of 35 U.S.C. § 121[23] even though the '271 patent was not filed before the '740 patent issued. The district court found that the requirement that the application be "filed before the issuance of the patent" does not apply whereas here, the challenged patent issued from the original application. Thus, the '740 patent is protected by the safe harbor provision.

The court also addressed the question of whether the '271 patent was a proper ODP reference against the '740 patent. Although noting that the *Allergan* court interpreted *Cellect* as cutting off ODP even when the patent is the first-filed and first-issued patent in its family, the *Acadia* court disagreed, noting that "[i]f a later-filed patent is used as a reference, the logic and purpose of ODP is flipped on its head."[24] Pointing to statements by the Federal Circuit in *Cellect* that ODP only applies to "later-filed obvious variations of earlier-filed, commonly owned claims," the *Acadia* court noted that *Cellect* did not challenge the availability of the reference patents for an ODP challenge, but instead focused on the impact of ODP on a PTA award. Thus, the availability of the reference patents was not considered in *Cellect*. As such, the court concluded that the '740 patent claims, which were filed before the '271 patent claims, were entitled to their full term.

Key Takeaways

The effects of the *Cellect* decision need not have significant impacts on day-to-day patent filing strategies. To the extent available, divisional filing practice should be leveraged, but continuation filings should still be utilized as well. Terminal disclaimers need not be proactively filed, and PTA should still be accepted. Indeed, if a patentee has no plans to enforce their patent, no further

[19] *Allergan USA, Inc. v. MSN Labs Priv. Ltd.*, 2023 U.S. Dist. LEXIS 172641, at *60.
[20] *Id.*
[21] US 7,601,740
[22] US 9,566,271
[23] The § 121 safe harbor provision states: "A patent issuing on an application with respect to which a requirement for restriction … has been made, or on an application filed as a result of such requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application."
[24] *ACADIA Pharm. v. Aurobindo Pharma.*, C. A. 20-985-GBW (D. Del. Dec. 13, 2023)

action or consideration in this regard need be taken. If, however, a patentee *does* plan to enforce their patent, this is where the crucial distinction lies.

For high value patents (*i.e.*, patents that are likely to be enforced), US family members should be monitored, and, as a family member nears expiration, the remaining family members should be proactively evaluated for ODP issues. If one is found, the patentee is advised to file a terminal disclaimer to moot the issue before that family member expires to ensure that the entire patent term is not in jeopardy.

Protecting And Enforcing Chemical and Pharmaceutical Inventions in India-Recent Updates

By Sharad Vadehra[25]

Background

The importance of protecting chemical and pharmaceutical inventions in India cannot be overstated. The Indian chemical industry contributes around 7% to the nation's Gross Domestic Product (GDP). Further, India is the 6th largest producer of chemicals in the world and 3rd in Asia. This has aided the Indian chemical industry to capitalize on forthcoming opportunities. Given these factors, the importance of protecting chemical and pharmaceutical inventions in India becomes undeniable.

Indian Patents Act, 1970

Section 2(1)(j)

In order to be patentable, an invention must satisfy the criteria as laid down under Section 2(1)(j) of the Indian Patents Act, 1970. The invention should be novel, consisting of inventive step and industrially applicable per the following:

- Section 2(1)(j): "invention" means a new product or process involving an inventive step and capable of industrial application;
- Section 2(1)(ja): "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art; and
- Section 2(1)(ac): "capable of industrial application", in relation to an invention, means that the invention is capable of being made or used in an industry.

According to the absolute definition of an invention under Section 2(1)(j), the subject matter must be a product or a process.

[25] Sharad Vadehra is the Managing Partner at KAN & KRISHME in New Delhi, India, https://kankrishme.com

India has an absolute novelty requirement. Novelty is one of the prerequisites for deciding on patent eligibility of the invention.

The "inventive step" plays a vital role in deciding whether a patent should be granted to a proposed invention. An "inventive step" must be a feature which is not excluded subject matter itself. However, the patentee may cite economic significance or technical advance in relation to any of the excluded subjects to obtain a patent on such excluded subject matter.

In addition to the golden trio of the requirements of novelty, inventiveness and industrial applicability, Indian patent applications must also defeat the infamous Section 3 of the Indian Patents Act.

A look at the various provisions of Section 3 of the Act shows that of all the clauses concerning non-patentable subject matters clauses (c), (d), (e), (i) and (j), are the most relevant provisions with respect to pharmaceutical and chemical inventions.

Section 3(c)

Under Section 3(c) of the Indian Patents Act, 1970, "the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature" is not considered an invention.

Section 3(d)

Section 3(d) precludes the patentability of the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance are considered the same substance, unless they differ significantly in properties with regard to efficacy.

In order to establish that a new form differs significantly in properties with regard to efficacy, it is on the applicant to provide sufficient data comparing the efficacy of the new form with that of the known substance.

Section 3(e)

According to Section 3(e), an invention is not considered a patentable subject matter if it is a substance obtained by a **mere admixture resulting only in the aggregation** of the properties of the components thereof or a process for producing such substance.

The synergistic effect should not be interchangeably used as far as efficacy is concerned, and the applicant must be careful when submitting synergistic data.

Section 3(i)

Under Section 3(i), any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic, or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products is *not* patentable.

Past Indian Controllers have interpreted Section 3(i) narrowly and have been hesitant to allowability of diagnostic methods, *i.e.*, *in vivo* and *in vitro* methods, because the Indian Patents Act, 1970 does not differentiate amongst the method of diagnosis carried outside the human or animal body (*in vitro*) from what has been carried inside the body (*in vivo*). However, due to evolving Patent practice some of the Controllers are now considering *in vitro* diagnostic methods as patentable subject matter because they are not conducted within a living body but rather on tissues or fluids removed from the body and in a laboratory.

Section 3(j)

According to Section 3(j), plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals are *not patentable*.

Recent Case Law Involving Chemical and Pharmaceutical Inventions

The Chinese University of Hong Kong Knowledge Transfer Office v. The Assistant Controller of Patent and Design (High Court of Madras, October 12, 2023)

Brief Facts

This appeal challenged the impugned Order passed under Section 15 of the Indian Patents Act, by way of which the Appellant's application no. 4812/CHENP/2012 for grant of patent was rejected by the Assistant Controller of Patents on the ground that the invention fall under the purview of Section 3(i) of the Indian Patents Act and is not patent eligible.

Decision of the Court

The Court held that the term "diagnostic" is juxtaposed in Section 3(i) with words such as "medicinal" or "surgical", which are undoubtedly forms of treatment. Accordingly, the expression "diagnostic" should not be construed in isolation but should be understood *noscitur a sociis*, *i.e.*, in association with the accompanying words of Section 3(i) read as a whole. The Court thus held that the word "diagnostic" should be limited to diagnostic processes that disclose pathology for the treatment of human beings.

Furthermore, the Court held that in the realm of diagnostic processes, the embodiments of a claimed invention are relevant solely for determining whether the invention inherently points towards a diagnosis for treatment. If such a process fails to reveal pathology for any reason, it cannot be deemed diagnostic under Section 3(i) of the Act.

The Court also held that a screening test that identifies the disease, disorder or condition, albeit subject to confirmation by definitive tests, would still qualify as "diagnostic" for purposes of Section 3(i) because the provision does not use the qualifier "definitive."

The Court articulated that the assessment should focus on whether the test is inherently capable of identifying the disease, disorder, or condition for treatment. This assessment should envision persons skilled in the relevant art, including medical professionals, interpreting the results. If such individuals cannot diagnose the disease, disorder or condition based on the process because it is not designed for such diagnoses, then the process, regardless of its label as screening or otherwise, would not qualify as diagnostic under Section 3(i) of the Act.

In this case, the Court held that amended claims 1 and 9 of the invention pertain to drawing a biological sample from a pregnant female subject and thereafter testing the nucleic acid molecules in such biological sample with a view to identify the foetal fraction, *i.e.*, the proportion of cell free foetal DNA in the biological sample. The Court noted that medical literature indicates that the foetal fraction should be not less than 4% to enable further testing to identify chromosomal aberrations, such as chromosomal aneuploidies. Until that stage is reached, pathology is not uncovered and, consequently, treatment is not possible.

The Court held that the claimed invention is *per se* incapable of identifying the existence or otherwise of a disease, disorder or condition and further testing would be required for such purpose. The Court therefore held that while the scope of Section 3(i) should not be unduly curtailed by limiting it to *in vivo* or definitive diagnosis, the scope should also not be unduly expanded by implying the words "relating to" diagnosis. The Court held that determination of foetal fraction is related to diagnosis but is not "diagnostic."

The Court also suggested that an amendment in the law, such as to restrict Section 3(i) to only *in vivo* methods, may be considered by the legislators to incentivize inventors in these areas.

Vifor (International) Limited & Anr Vs MSN Laboratories Pvt Ltd & Anr (High Court of Delhi, February 9, 2024)

Brief Facts

Vifor asserted that its product-by-process claim in IN'536 covered a product, regardless of the process used for its manufacture, and the claim was infringed. Vifor asserted that the process limitations described an exemplary process to prepare Ferric Carboxymaltose (FCM), a drug used to treat iron deficiency, and do not limit the claim to mandate the use of the recited process. Thus, according to Vifor, the claim covers the product *per se* regardless of the process used by the alleged infringer in its preparation.

Decision of the Court

The Court found that product-by-process patents are neither unconventional nor unknown, and that the existing Indian patent regime contemplates such claims. "One principle which finds resonance across jurisdictions and stands embodied even in the guidelines framed by the IPO [Indian Patent Office], EPO [European Patent Office] and the USPTO [United States Patent and Trademark Office] is that a product-by-process claim would be accepted and accorded statutory protection, only if the product itself be novel. They further interpreted that irrespective of the language in which such a claim may be couched, it is necessary that such a patent application speak of a novel product. It is this foundational precept on which product-by-process claims are tested." The Court further held that product-by-process claims pertain to a product which is novel and inventive and unknown in the prior art and thus, it would remain a product which would fall within the ambit of Section of 48(a) of the Patents Act. "The difficulty in discerning the scope of such claims would not constitute a valid basis to deprive a true invention of the protection which the Act confers. It would be incorrect to rule that product-by-process claims must be inevitably curtailed by process terms."

The Court went on to hold that any reference to process in a product-by-process claim acts as an aid to explain the novel attributes of a new product unknown in the prior art. Separate tests of novelty do not apply between grant of patent and the examination of an allegation of infringement. As long as a product-by-process claim pertains to a product which is novel and has no parallel in the prior art, the mere fact that the patentee chooses to describe the invention more exhaustively by reference to process terms, and in light of the difficulties of expression alluded to above, the tests should remain unchanged.

The Court further held that a product-by-process claim would necessarily have to be examined on the anvil of a new and unobvious product irrespective of the applicant having chosen to describe the invention by referring to a process of manufacture. The mere adoption of the product-by-process format would not result in a novel product being downgraded to Section 48(b) of the Patents Act. It would inevitably have to be tested on principles enshrined in Section 48(a); the question of patentability is to be examined and evaluated independent of the allocation of an International Non-proprietary Name (INN) to a chemical formulation. Conferral of an INN cannot be accepted as constituting irrefutable evidence of an invention and could at best be viewed as corroborative of an assertion of a patentable product having been obtained.

The Court rendered the judgment while considering an appeal filed by Vifor against a single-judge's order refusing to issue an injunction that prohibited pharmaceutical companies from making FCM. The Court set aside the single-judge's order. The Court held that "It is this foundational and conceptual mistake which renders the impugned judgment unsustainable. The learned Judge has fundamentally erred in understanding product-by-process claims as 'limited to a product obtained through a specific process feature.' The view taken is rendered further untenable since it appears to have been the uncontested position before the learned Judge that FCM was not known in the prior art."

Conclusion

India has one of the largest chemical industry and pharmaceutical industry worldwide. Also, India has one of the largest markets and consumer base in the world. Therefore, for any company entering Indian market, it becomes mandatory to protect chemical and pharmaceutical inventions by obtaining and enforcing Patents. To obtain a Patent for chemical and pharmaceutical inventions, it is very important to properly draft the application. The Patent application should comply with all the requirements specified above. In particular, the application should provide sufficient disclosure of the invention. Sufficient examples of various embodiments of the invention should be disclosed. Additionally, there should be enough data supporting the efficacy and/or synergistic effect. Also, there are some unique requirements and limitations under Indian Patents law, which has been identified above and which must be considered while drafting and prosecuting applications and litigating patents in the field of chemical and pharmaceutical inventions.

Case Analysis and Strategies for Patent Linkage Litigation in Taiwan

By George J. H. Huang[26]

Summary

The Patent Linkage System in Taiwan may encourage generic drug makers to challenge the patent rights of brand drug makers and enter the market before patent expiration. The system provides a 12-month market exclusivity period for the first generic filer of a P4 declaration[27]. This makes a big difference. In the past, generic drug makers could only passively wait until the brands' patents expired before entering the market. Consequently, the Patent Linkage System also leads to a large number of pharmaceutical patent suits. This article summarizes court judgments of civil infringement litigations derived from the patent linkage system since its implementation in Taiwan in 2019, and provides strategies for brands and generic drug makers under this system. Included is summaries of four recent decisions rendered by the Taiwan Supreme Administrative Court holding that patent information of drugs with new usage dose shall not be considered as a new drug based on Article 7 of the Taiwan Pharmaceutical Affairs Act, and therefore cannot be listed in the Taiwan Food and Drug Administration.

[26] George J.H. Huang is the Director and Attorney at Law at Wisdom International Patent & Law Office in Taipei, Taiwan, https://www.wisdomlaw.com.tw/m/home.php

[27] For a detailed introduction of Taiwan's Patent Linkage System, please refer to Wisdom News Vol. 33 "New Patent Linkage System in Taiwan: an effective solution to drug patent infringement disputes" (https://www.wisdomlaw.com.tw/m/405-1596-99032,c12252.php?Lang=en).

Latest Trends of P4 Litigation

Summary of P4 litigation judgments

Case No.	Plaintiffs and Defendants	Result	Patent Invalidation
IPCC 2020 Min Zhuan Su Zi No. 46 Judgment	*Merck Sharp & Dohme (MSD) v China Chemical & Pharmaceutical*	Brand drug maker WON	Dismissed
IPCC 2020 Min Zhuan Su Zi No. 51 Judgment	*AstraZeneca AB v Novartis Taiwan*	Brand drug maker LOST	Not judged
IPCC 2020 Min Zhuan Su Zi No. 79 Judgment IPCC 2021 Min Zhuan Shang Zi No. 31 Judgment	*F. Hoffmann-La Roche AG v Celltrion Healthcare*	Brand drug maker LOST in the first and second instances	Invalidated
IPCC 2021 Min Zhuan Su Zi No. 4 Judgment	*MSD v TSH Biopharm*	Brand drug maker LOST	Not judged
IPCC 2021 Min Zhuan Su Zi No. 11 Judgment	*AstraZeneca UK Limited, AstraZeneca AB v Standard Chem & Pharm*	Brand drug maker WON	Dismissed
IPCC 2021 Min Zhuan Su Zi No. 9 Judgment IPCC 2022 Min Zhuan Shang Zi No. 9 Judgment	*AstraZeneca AB v TSH Biopharm*	Brand drug maker WON The 2nd instance vacated the original judgment	Not filed
IPCC 2021 Min Zhuan Su Zi No. 8 Judgment IPCC 2022 Min Zhuan Shang Zi No. 6 Judgment	*Bayer HealthCare LLC v Synmosa Biopharma*	Brand drug maker LOST in the first and second instances	Invalidated
IPCC 2022 Min Zhuan Su Zi No. 32 Judgment	*NOVARTIS AG v Lotus Pharmaceutical*	Brand drug maker WON	Dismissed
IPCC 2022 Min Zhuan Su Zi No. 51 Judgment	*Bayer HealthCare LLC v Lotus Pharmaceutical*	Brand drug maker LOST	Not judged
	Bayer HealthCare LLC v Novartis Taiwan	The lawsuit is still in progress	

The cases of *Bayer HealthCare v Synmosa Biopharma*[28], *Bayer HealthCare v Lotus Pharmaceutical* and *Bayer HealthCare v Novartis Taiwan* all relate to the patented medicine, Nexavar®, film-coated tablets from Bayer HealthCare. Nexavar® is still protected by two patents. Although both generic drug makers, Synmosa Biopharma and Lotus Pharmaceutical, won their cases, the strategies adopted by these two companies were different. Synmosa Biopharma successfully challenged Bayer's two patents (the polymorph patent and composition patent of sorafenib) entirely based on the arguments of patent invalidation. Taiwan Intellectual Property and Commercial Court (IPCC, IP Court) rendered all 26 claims of these two patents obvious both in the first and second instances. On the other hand, Lotus Pharmaceutical amended its formulation of excipients in their

[28] For more information about *Bayer HealthCare v Synmosa Biopharma*, please refer to Wisdom News Vol. 60 "Part I - First Victory for Generic Drug Company: Bayer's Anti-cancer Drug Nexavar® Patent Successfully Challenged under New Patent Linkage System" (https://www.wisdomlaw.com.tw/m/405-1596-106276,c12252.php?Lang=en) and Wisdom News Vol. 71 "Part II - First Victory for Generic Drug Company: Bayer's Anti-cancer Drug Nexavar® Patent Successfully Challenged under New Patent Linkage System" (https://www.wisdomlaw.com.tw/m/405-1596-107465,c12252.php?Lang=en, https://www.wisdomlaw.com.tw/m/405-1596-116302,c12252.php?Lang=en).

generic drug, and successfully challenged Bayer under a P4 declaration based on non-infringement arguments.

The two IP court cases, *2021 Min Zhuan Su Zi No. 4 Judgment* (*MSD v TSH Biopharm*) and *2021 Min Zhuan Su Zi No. 9 Judgment* (*AstraZeneca AB v TSH Biopharm*), relate to Cretrol®, a new drug of a new therapeutic compound produced by TSH Biopharm. The active ingredients of Cretrol® are the same as those of MSD's Ezetrol® and AstraZeneca's Crestor®. MSD and AstraZeneca each owns patent rights to related indications. When filing their abbreviated new drug application (ANDA), TSH Biopharm carved out the related indications based on the stipulation of Paragraph 48-20 of Taiwan Pharmaceutical Affairs Act and filed declarations of non-infringement. However, MSD and AstraZeneca still filed lawsuits against TSH Biopharm. The IP court rendered the *2021 Min Zhuan Su Zi No. 4 Judgment* in *MSD v TSH Biopharm* in which TSH Biopharm prevailed. As for *AstraZeneca v TSH Biopharm*, TSH Biopharm lost this case in the first instance (*2021 Min Zhuan Su Zi No. 9 Judgment*), but the original judgment was vacated in the second instance due to the expiration of the patent term.

In *2020 Min Zhuan Su Zi No. 46 Judgment* (*MSD v China Chemical & Pharmaceutical*), *2021 Min Zhuan Su Zi No. 11 Judgment* (*AstraZeneca UK Limited, AstraZeneca AB v Standard Chem & Pharm*) and *2022 Min Zhuan Su Zi No. 32 Judgment* (*NOVARTIS AG v Lotus Pharmaceutical*), the patent invalidity arguments by the generic drug makers were dismissed, and the brand drug makers won the three IP court cases.

In *F. Hoffmann-La Roche AG v Celltrion Healthcare*[29], Roche did not file a complaint against Celltrion within the specified time period (45 days). As a result, Celltrion initiated a request for a declaratory judgment holding that Roche has no rights based on the disputed patent, and that the patent was subject to various grounds for revocation. The IP court ruled in favor of Celltrion for a declaratory judgement and to the various grounds for revocation. Roche appealed and lost again. Notably, the two court decisions were made before the implementation of Article 60-1 of Taiwan Patent Act.

Latest Trends of Patent Listing

Recently, with respect to patent listings in the Taiwan Drug Patent Linkage Registration System, the Taiwan Supreme Administrative Court Affirmed that patent information of old drugs having a new dose cannot be listed in the Taiwan Food and Drug Administration (TFDA).

The Taiwan Supreme Administrative Court issued rulings on November 23, 2023, November 30, 2023 and December 7, 2023, that a drug with a new dose is not considered a new drug as defined in Article 7 of the Taiwan Pharmaceutical Affairs Act. Therefore, the patent information thereof cannot be submitted or registered on the Taiwan Drug Patent Linkage Registration System of the TFDA[30].

[29] For more information about *F. Hoffmann-La Roche AG v Celltrion Healthcare*, please refer to "Court Affirms Legal Validity of Erroneous Prior Art Disclosure: Celltrion Healthcare Taiwan v. F. Hoffmann-La Roche AG" (https://www.wisdomlaw.com.tw/m/405-1596-113711,c12252.php?Lang=en).

[30] Taiwan Supreme Administrative Court Shang Zi No. 531 (2022), Taiwan Supreme Administrative Court Shang Zi No. 532 (2022), Taiwan Supreme Administrative Court Shang Zi No. 110 (2023), and Taiwan Supreme Administrative Court Shang Zi No. 165 (2023).

Beginning under Chapter IV-1 "Patent Linkage of Drugs" of Taiwan Pharmaceutical Affairs Act implemented in 2019, the Ministry of Health and Welfare (the superior entity of the Taiwan Food and Drug Administration) provided the Drug Patent Linkage Registration System for pharmaceutical companies to submit patent information of drugs. The system automatically publishes the information. However, after manually examined by the Ministry of Health and Welfare, it was found that certain drugs submitted by some pharmaceutical companies were merely drugs with changed doses, not new drugs. This patent information was not allowed to be submitted. The Ministry of Health and Welfare decided to withdraw such registrations. Among those who had their registrations withdrawn, four pharmaceutical firms, Merck & Co., Inc. Taiwan Branch (MSD), Allergan Pharmaceuticals Taiwan Co., Ltd., Novartis Taiwan Co., Ltd. and CIMA LABS INC., were dissatisfied and filed a petition. Their petition was dismissed by the Executive Yuan. They then appealed to the Taipei High Administrative Court.

In MSD's and Allergan's cases, the Taipei High Administrative Court ruled against both MSD and Allergan. They appealed to the Taiwan Supreme Administrative Court, but the appeal was dismissed on November 23, 2023. The court held that if only the dose of a drug is changed without changing its ingredients, then it is not a "new drug" as defined in the Taiwan Pharmaceutical Affairs Act. The court further held that the determination of whether the laws were amended to expand the definition of "new drug" and the scope of what is listed in the patent linkage system should be determined by the Legislative Yuan, not the Executive Court, based on the principle of separation of powers under the Constitution.

For the remaining cases, although the Taipei High Administrative Court first ruled in favor of the pharmaceutical firms Novartis and CIMA LABS,[31] the Taiwan Supreme Administrative Court later ruled in favor of the Ministry of Health and Welfare on November 30, 2023 and December 7, 2023, based on the same reasoning as the MSD and Allergan decisions. The court found, based on the definition in the Paragraph 2, Article 48-3 of the Taiwan Pharmaceutical Affairs Act, that the legislators limited drug patent information that can be submitted for registration inventions of "substances", "composition or formulation" and "medical use". The legislators did not intend to limit a drug that could be applied to the patent linkage system to "drugs which are of the preparations having new active ingredients, new therapeutic compounds or new method of administration" as defined in Article 7 of the same law. The Taipei High Administrative Court deemed that the "new drug" in the Chapter IV-1 of the Taiwan Pharmaceutical Affairs Act referred to a drug that was recently granted a brand drug license (within a specific time period). However, such judgment was reversed by the Taiwan Supreme Administrative Court.

According to these four decisions of the Taiwan Supreme Administrative Court, it is now the law that a drug with a changed dose is not considered a "new drug" based on in Article 7 of the Taiwan Pharmaceutical Affairs Act, and patent information on the new dose cannot be submitted or registered in the Taiwan Drug Patent Linkage Registration System.

[31] Taipei High Administrative Court Su Zi No. 844 (2021), Taipei High Administrative Court Su Zi No. 1060 (2021).

Strategies for Pharmaceutical Patent Linkage Litigation

Both polymorph and compound patents are critical parts of a pharmaceutical patent portfolio. The compound patent is the core of the pharmaceutical patent portfolio and expires earliest. The polymorph patent is the second line of defense for protecting the compound, highly related to the ultimate commercialized pharmaceutical preparation, and it can effectively prolong the lifecycle of a drug.

Most polymorph patents are directed to new crystalline forms of known compounds. The inventiveness of these patents mainly depends on whether the claimed polymorphs generate unexpected technical effects. Therefore, the applicants should disclose sufficient technical effects and comparative data of the new polymorphs in the specification, and emphasize the differences between the new polymorphs and the amorphous form or other known polymorphs of the known compounds. Based on these strategies, the applicant can assert that the polymorphs exhibit multiple technical effects or at least exhibit unexpected technical effects regarding a certain property not only during prosecution of the application, but also during patent litigation. Also, it may be more likely for post-filed experimental data to be admissible. Specifically, based on the technical effects described in the specification, the applicant can submit post-filed experimental data to prove that the technical effects are unexpected.

With respect to patent linkage litigation, the IP court tends to render the decision of the first instance within one year after the plaintiff files the suit. The trial proceedings for patent linkage litigation are intensive and speedy. Before filing a P4 declaration, the generic drug makers must map out strategies in advance to defend lawsuits filed by the patent owner/brand drug maker. Furthermore, in patent infringement litigation in Taiwan, the judge usually asks the plaintiff and defendant to determine disputed issues on the date of first oral argument. If the generic drug makers assert that the patent right should be invalidated, they must submit all invalidation evidence on the date of the second oral argument and determine combinations of evidence. The generic drug makers cannot submit additional new invalidation evidence or new combinations of evidence thereafter. As a result, generic drug makers should conduct meticulous prior art search and analysis with the goal of successfully invalidating the patent before filing their P4 declaration, thereby establishing the invalidation evidence and combinations of evidence as early as possible.

Clinical Trials as Prior Art for Pharma Patents in Europe

By Dr. Holger Tostmann[32]

Introduction

Due to ever more stringent transparency rules and readily available public electronic data bases for clinical trials, the design or result of clinical studies are increasingly publicly available early and earlier in the process. Therefore, the publication of a trial design often becomes relevant for patent applications filed in parallel with the trial. This article discusses specific scenarios how clinical trials can become prior art for the two main claim categories for pharma patents in Europe (composition claims and second medical use claims) and how to avoid or minimize the impact of a clinical trial (design) as prior art.

In good news for sponsors of clinical trials, the handing out of medicaments to patients during a clinical trial should not constitute a so-called *"public prior use"* if the ***EMA Guidelines for Good Clinical Practice*** are followed, i.e., drugs given to patients during a clinical trial do not necessarily become prior art simply because a member of the public *could* have had access.

On the other hand, and in not so good news, case law of the EPO Boards of Appeal is quite clear that at least Phase II clinical (design) data is generally highly relevant for the assessment of inventive step of a so-called second medical use claim, i.e. a claim directed at the new medical use of a known compound. Importantly, the trial design alone, i.e., simply proposing a specific study arm design, can be seen as creating an expectation of success. Scenarios under which this almost "automatic" "expectation of success" may not apply are discussed below.

"Mechanisms" for clinical trials becoming prior art in Europe

In general, there are two fundamental "mechanisms" by which a clinical trial may become available as prior art in Europe.

First, any *documentation* produced in the framework of a clinical trial, be it a study design or the results of the trial, becomes prior art on the date on which the design/data is/are published, for example, the day data or a design are published in an electronic database of a government agency. Such databases can include, for example, the Clinical Trial Information System (CTIS) of European Medicines Agency (EMA) in case of clinical studies conducted in the European Union (EU).

In a separate "mechanism", once the clinical trials are conducted and medical personnel hands out samples to patients, the actual substance as handed out may become publicly available as a so-called *"public prior use"*.

[32] Dr. Holger Tostmann is a German and European Patent Attorney and a Partner at the Wallinger Ricker Schlotter Tostmann Law Firm in Munich, Germany

The criteria for establishing such public prior use were established many years ago by the EPO Boards of Appeal, not specifically in the framework of clinical trials, but for any kind of information, including devices or substances that may be accessible to the public during cooperations, fairs, in a sale, or the like (where no "published" record exists). The key criterion developed by the EPO Boards of Appeal is that there is no requirement to show that a member of the public actually *had* access to the presentation, device, or substance, (only) but that a (one) member of the public who is under no obligation to maintain secrecy at least has had the *theoretical possibility* to access the relevant information.

In the framework of clinical trials, if a sample is handed out to a patient and the patient is under no explicit agreement to keep the sample confidential or "under control", this handing out to a patient may constitute a public prior use (examples will be provided below).

These different "mechanisms" of clinical trials becoming prior art are of different relevance for the two key claim categories for pharma patents in proceedings before the European Patent Office (EPO). These two key claim categories are:

- Claims directed at a pharmaceutical composition; and
- Second medical use claims, i.e., claims directed at a known compound or composition for a specific previously unknown (typically second) medical use, for example a new indication, a new patient group, or a new dosage regimen.

A key difference between the written record and the above discussed "public prior use" is that, if a *public* prior use can be ruled out, for example because the sponsor did not at any time lose control and all samples were returned to the sponsor, this is then considered as non-public prior use. As such, the prior use is no longer available for both novelty and inventive step purposes. In contrast, if a written document becomes part of the public record, it is not only relevant for novelty but also for inventive step.

Public prior use if control over study is lost

Regarding the above outlined "mechanism" of public prior use in clinical trials and novelty of compound claims, the leading case law up until recently was T 7/07 [Ethinylestradiol (contraceptive) / BAYER PHARMA AG]. Claim 1 of the patent in question relates to a combination preparation and reads:

> *A pharmaceutical composition in an oral dosage form comprising, as a **first** active agent, drospirenone in an amount […] and as a **second** active agent, ethinylestradiol in an amount […] together with one or more pharmaceutically acceptable carriers or excipients, wherein said drospirenone is in **micronized** form.*
> [highlighting and omissions added]

During clinical trials, this combination preparation was handed out to patients. In fact, the clinical trial participants were informed of the ingredients in the combination preparation they received and were not required to sign a confidentiality agreement. Also, from parallel court proceedings in the US, it was known that not all unused drugs were returned. Therefore, the possibility did

exist that a member of the public could have had access to this preparation and could have analyzed its composition. It was determined that nothing was claimed that could have not been determined by routine experiments by a technical expert having access to this preparation, including the fact that the combination was formulated in a micronized form.

Therefore, the only question before the EPO Board of Appeal was whether the handing out of this combination preparation to patients constituted a *public* prior use as discussed above.

Accordingly, the Board of Appeal concluded that the study sponsor lost control over this clinical study and that it was, in principle, at least possible for a skilled person to have had access to the preparation and therefore analyze and determine the composition and the internal structure of the preparation. Consequently, the Board of Appeal denied novelty of claim 1.

The Board of Appeal also found there was no indication that the participants were implicitly *("tacitly")* bound to any confidentiality agreement, if for no other reason than because patients were given the tablets to take them home with them and the participants were in no way barred from disposing of the drugs as they desired. One solution to this problem of potentially losing control over a study by handing out samples to patients would be to have all patients sign a confidentiality agreement, in advance of participation in the study. This, however, does not appear to be practical for larger Phase II studies, in which often thousands of patients are involved. Requiring patients to sign NDAs would also be counter to the requirements of transparency and would impose restrictions on how patients can discuss their medical treatment with their doctors or their families.

Based on this conundrum, it is good news for the sponsors of clinical trials that a robust mechanism is now available to rebut the assumption that control over the study was lost, namely by way of complying with the EMA Guidelines for Good Clinical Practice.

In fact, in a more recent Board of Appeal case explicitly addressing the above-discussed T 7/07, namely in Board of Appeal case T 670/20 [Daiichi Sankyo Ltd. vs. Hexal AG / Generics Ltd.], novelty was acknowledged since these Guidelines were followed. Claim 1 of the patent at issue in this case reads [highlighting and omissions added]:

> *A pharmaceutical composition, wherein the composition is a coated tablet, […] coated with at least one agent selected from […], wherein the tablet comprises […]*
> *(A) […] [edoxaban], a pharmacologically salt thereof, or a hydrate of any of these;*
> *(B) a sugar alcohol; and*
> *(C) a water-swelling additive.*

Clinal trial documents D19 and D20 showed that the trial started prior to the effective date of the patent and that the tablets handed out to patients were in accordance with claim 1. Therefore, the remaining question was whether the patients to which the samples were given were members of the public and whether a third party could at least have theoretically analyzed the samples. In contrast to what the Board of Appeal held in T 7/07, in the case T 670/20, the Board of Appeal held that the sponsor of the trial did not lose control over the drugs, essentially based on the

fact that the entirety of the clinical trials were carried out in accordance with the EMA Guidelines for Good Clinical Practice.

These Guidelines explicitly require adherence to a prescribed protocol and assurance of *drug accountability*. In the view of the Board of Appeal, this implies that the patients who participated in the trials agreed to return the unused medication. Accordingly, in the view of the Board of Appeal, the participating patients entered a "special relationship" with the investigators of the trial and were not members of the public that could freely dispose the samples.

Mere announcement of clinical trial typically not novelty destroying

As mentioned above, an important claim category for pharma patents in Europe is the so-called *"second medical use claim"*. Such claims are not method of treatment claims, as such claims are not allowable in proceedings before the EPO due to the prohibition of patenting medical treatment *per se* in order to keep doctors' activity free of patent concerns. Rather, the second medical use a claim format, which is accepted in the EPO, relates to a (known) compound or composition which is further defined, i.e. *"purpose-limited"* by a specific medical use, for example, a specific indication, a specific patient group, or a specific dosage regime.

An example of such a second medical use claim is the basis for T 239/16 [Zoledronic acid / Novartis]:

> ***Zoledronic acid*** *or a pharmaceutically acceptable salt thereof or any hydrate thereof* ***for use in a method of treating osteoporosis*** *in which the zoledronic acid or the pharmaceutically acceptable salt therefore or the hydrate thereof is administered intravenously and intermittently and* ***in which the period between administrations is about one year.***
> [highlighting added]

The publicly available document at issue in this case had the title *"Information for the patient concerning the study 42446 02 041"* and disclosed the indication (treating osteoporosis) and the active ingredient (zoledronic acid).

The patent proprietor did not contest that the patients had received this medication for this specific treatment and that they were also encouraged to discuss the treatment with their respective families and their family doctors. Therefore, there was no doubt that this information, particularly the drug used, was publicly available.

However, the second relevant question, which is specific for second medical use claims (which are "purpose"–limited to the claimed indication and to the claimed dosage regime), is whether the mere announcement of studies to be conducted also implies an actual treatment.

Based on the announcement of a study with a certain medicament for a certain indication alone, in the view of the Board of Appeal, there remained a "residual doubt" that the effect, i.e. the (successful) treatment of post-menopause osteoporosis in patients receiving an intravenous dosage of specifically 4 mg of zoledronic acid specifically once a year, is or will be achieved.

Therefore, the Board of Appeal concluded that the trial design document D55 did not directly and unambiguously disclose the effective treatment of osteoporosis and thus did not anticipate the second medical use claim.

It is indeed established case law that the mere statement that a certain therapy is currently explored or that a medicament is evaluated in a clinical study does not amount to the disclosure of the *achievement* of a clinical benefit in human patients (T 158/96, T 715/03, T 1859/08 and T 2506/12). In fact, special circumstances are required to conclude that an actual therapeutic effect was already known, for example, previous studies, comments by doctors, and the like.

However, and importantly, this positive finding with respect to **novelty** did not help the patent overall since the same prior art document D55 was then used as the closest prior art (i.e., as the most promising springboard to arrive at the claimed subject-matter) in the assessment of **inventive step**.

In D55, five different study arms (with different dosage regimens) were presented in exactly the same manner (listed as alternatives under five bullet points). Based on this structure, in accordance with the EPO-specific "problem-solution"-approach used for the assessment of inventive step, the Board of Appeal indicated *each* of the five (different) study arms could be selected as a valid starting point. In fact, as a specific "feature" of this approach, hindsight is indeed allowed to start with the assessment of the question whether a specific dosage regime is obvious from that study arm that is the *closest* to the claimed subject-matter, i.e., the study arm exploring the one-year treatment.

Once this promising starting point was settled, the Board of Appeal indicated it was difficult not to conclude that successful treatment was a likely (or "obvious") outcome. A potential reason why a skilled person would have *not* had a reasonable expectation of success starting from this specific arm would have been if there were any prior data or an indication that the active ingredient behaved *differently* than other medicaments of the same class that had already been successfully tested in this dosage regimen. However, no such indications could be substantiated in this case. To make matters worse, as one of the specific circumstances of this case, there were also speculative documents available indicating that the effects of zoledronic acid would last at least twelve months.

Hence, the Board of Appeal concluded that the skilled person would have been able to follow the dosage regime of this specific study arm and therefore would have arrived at the claimed subject-matter in an obvious manner. In sum, the set-up of the clinical study as disclosed in D55 did create an expectation of success, and inventive step was denied.

This specific case illustrates the overall understanding that the disclosure of a clinical trial protocol (≥ Phase II) likely creates a reasonable expectation of success. As highlighted above, a particular problem in Europe is that the problem/solution-approach allows hindsight when choosing the most promising starting point within a document or within a study.

While it is generally difficult to argue inventive step of a specific medical use if said specific medical use is disclosed as an objective in a publicly available trial design or clinical trial document, there may be individual circumstances of a case that may be helpful to argue inventive step. For example, one possible argument is that even when starting from such a promising starting point, the skilled person would have had no expectation of success, for example, because a type of cancer is switched (T 385/07). Ample case law exists providing further details on the specific circumstances reinforcing or casting doubt on this assumed "expectation of success". Examples of circumstances that support "*expectation of success"* include, among others:

- Phase III provides even stronger indication of success than Phase II (Phase I generally little expectation of success);
- The claimed therapeutic belongs to a **class of compounds** known to be effective in the treatment of the disease (T 239/16, Reasons 6.5);
- The **prior art** contains no indication that the claimed therapeutic would behave differently to other compounds from the same class which are known to be effective in the treatment of the disease (T 239/16, Reasons 6.5); and
- A suitable **animal model** for the disease exists and the claimed therapeutic was tested in that animal model (T 239/16, Reasons 6.6).

On the other hand, circumstances that put an *"expectation of success"* in question include, among others:

- Complex (physical) parameters claimed, such as increase of time to disease progression (T 189/08);
- The claimed therapeutic has a chemical structure and/or belongs to a class of compounds that is dissimilar to those known to treat the disease (T 715/03, Reasons 2.4.3; T 239/16, Reasons 6.6);
- No suitable animal model for the disease was available (T 715/03, Reasons 2.2); and
- The disease is a complex disorder; there is an explicit indication in the art that conclusions as to tolerability and/or efficacy must await clinical studies (T 715/03, Reasons 2.2).

In summary, the (publication) specifics of any clinical trial should be carefully aligned with the patenting strategy.

When filing a patent early (e.g., with the objective to get on file prior to publication of a study design), particularly for Europe, enablement requirements should also be considered, i.e., suitable *preclinical* data should be included, and the compounds of interest should be sufficiently individualized already at that stage.

From past to present: shifting interpretations of the Mexican Patent Office on divisional applications.

By Sergio Olivares, Daniel Sánchez and Rommy Morales[33].

Introduction

"If the patent application encompasses multiple inventions not linked by the same inventive concept, the applicant can even file a single divisional application pursuing several of these inventions."

The coming into effect of the Federal Law for the Protection of Industrial Property (FLPIP) on November 5, 2020, was a turning point that brought substantial changes to Mexico's Industrial Property law, particularly concerning the practice with respect to divisional applications, marking the beginning of a new approach in this field. Divisional applications play a crucial role in intellectual property protection by allowing applicants to pursue distinct inventions separate from those claimed in the initial application and any prior divisional applications. In this regard, it is important to consider that Mexican law only recognizes divisional applications, unlike US law where continuation or continuation in part applications exist as well.

Before the FLPIP was enacted, the submission date of a divisional application was one of the most important points to bear in mind. Divisional applications could be filed as long as the parent case was still pending, regardless of whether said parent case was a divisional application or whether the initial application was pending or had already been granted. The implementation of the current law under FLPIP imposes new constraints and additional requirements for applicants to contemplate when filing one or more divisional applications, which directly impact the two types of divisional applications recognized by Mexican Institute of Industrial Property (IMPI): those voluntarily submitted and those submitted in response to a lack of unity of invention objection.

Voluntary divisional applications

Voluntary divisional applications are commonly used when the applicant wishes to pursue a different scope, seek protection for a different invention, or simply as a strategy to maintain the pendency of the patent family. Unlike the abrogated law, which was silent on voluntary divisional applications, the current law states that a pending initial patent application can be voluntarily divided. However, this provision does not extend to divisional applications. Voluntary divisional applications can be submitted at any time and up until before the grant fee payment or the issuance of the notice of denial, with no limit imposed on the number of divisional applications that may be submitted. Taking this provision into consideration, it is possible to submit multiple voluntary divisional applications, each directed to a different invention or group of inventions, all directly derived from the initial application while it remains pending.

[33] Sergio Olivares, Daniel Sánchez and Rommy Morales are Partners with OLIVARES in Mexico City, Mexico, www.olivares.mx

Divisional applications submitted by request of IMPI

Mexican legislation stipulates that a patent application should refer to one invention or a group of inventions sharing a single inventive concept. This requirement of unity of invention involves having a clear relationship between the essential technical features present in the invention or group of inventions, which contribute to the state of the art. During the substantive examination process, if it is found that the patent application fails to comply with the unity of invention requirement, IMPI issues an office action requesting the applicant to limit the claims to the main invention and submit one or more divisional applications for the remaining inventions.

The first invention pursued in the claims is considered the main invention, which according to the current law should be examined on the merits. However, in practice, IMPI usually allows applicants to claim the invention of interest, even if it does not always correspond to the main invention.

When faced with a unity rejection, applicants have several routes to consider. One option is to maintain the claims focused on the invention of interest while eliminating the remaining claims. Applicants have the opportunity to pursue these eliminated claims through one or more divisional applications, which must be submitted along with the response to the office action objecting to the unity of invention.

If the patent application encompasses multiple inventions not linked by the same inventive concept, the applicant can even file a single divisional application pursuing several of these inventions. This would trigger a new unity of invention objection, thereby providing a new opportunity to submit cascade divisional applications in the future.

Alternatively, applicants can choose to submit arguments to persuade the examiner that the claimed invention(s) are indeed related by the same inventive concept. Another viable approach is to make amendments to the claims, ensuring compliance with the unity of invention requirement without the need to submit divisional applications.

Restrictions for subject matter that can be pursued in divisional applications

At the time of submission, every divisional application must include the specification, claims, drawings, and sequence listings (where applicable), along with the official filing fee payment. Divisional applications are not allowed to introduce new subject matter or broaden the scope of the original application.

Divisional applications must pursue a different invention from the one claimed in the initial application and any other previous divisional application. While the law does not define what is understood by a "different invention", the law does set a clear boundary: a patent will not be granted for subject matter that is already protected by another patent or for non-substantial variation, regardless of whether the applicant remains the same.

As a consequence, IMPI could reject a divisional application seeking protection for a non-substantial variation of the subject matter claimed in the initial application or applications within the same family, although the claimed matter is not identical, when there is overlapping subject matter.

Another significant limitation found in the current law is that once an invention or group of inventions is no longer claimed when a division takes place, such inventions cannot be claimed again in the initial application or the one that triggered the division. It is important to highlight that these limitations apply not only to patent applications, but also to utility model and industrial design applications.

Cascade divisional applications

Before the entry into force of the FLPIP, cascade divisional applications were accepted by IMPI as long as the immediate predecessor application was still pending, regardless of the status of the initial application or the generation of the immediate predecessor (e.g., first-generation, second-generation, etc.).

Nevertheless, a substantial restriction was incorporated into the current law. It stipulates that divisional applications cannot consist of a division of other divisional applications unless they are deemed appropriate by IMPI or filed in response to a unity objection. Failure to meet this condition results in the application not being recognized as a divisional, thereby depriving it of the legal filing date or priority rights of the application from which it seeks to derive. Instead, it will be treated as an independent application filed on the date it was submitted to IMPI, which would finally lead to the refusal of the application due to lack of novelty in view of the publication of the initial patent application.

Regardless of this major limiting factor, the transitional articles of the new law provide an exception. The transitional articles state that patent, utility model, or industrial design applications that were pending at the time of the law's enactment would continue to be prosecuted in accordance with the provisions in force at the time they were filed.

Considering the above, the limitations imposed on cascade divisional applications should apply solely to initial (root) applications filed on or after November 5, 2020. In contrast, any applications that remained pending and were filed before this date should be prosecuted according to the preceding law.

However, the interpretation of the aforementioned legal provisions has been uncertain, as IMPI has adopted a series of varying criteria over time. This has led to a shifting landscape for divisional patent applications. The following section will explore the evolution of IMPI's interpretation and the impact it has had on the prosecution of cascade divisional applications.

Analyzing the journey of cascade divisional applications: where do we stand now?

Despite the provisions contemplated in the new law and the provisions established in the Mexican constitution that indicate that laws cannot be applied retroactively to the detriment of the

applicant, since November 5, 2020, and for approximately one year thereafter, IMPI rejected voluntary cascade divisional applications, even those that derived from applications prosecuted under the previous law.

These cascade divisional applications were not recognized as divisional patent applications, but rather were considered as independent applications under the premise that the prosecution of their initial parent case had already been concluded. In other words, divisional applications that derived from an initial application filed under the previous law were being analyzed by IMPI according to the new law just because they were filed after November 5, 2020, instead of using the law applied to the initial application.

Given the significant impact of this uncertain criteria on Mexico's patent system, OLIVARES, in conjunction with various affiliated associations, promoted a shift in criteria for the proper interpretation of the legal framework by IMPI. As a result of these efforts, in 2022, IMPI began accepting cascade divisional applications deriving from those filed under the previous law.

Unfortunately, this revised approach did not last long. Recently, IMPI reverted to its original position, dismissing voluntarily submitted cascade divisional applications once again. This time, IMPI based its arguments on a court decision, asserting that a divisional application cannot be accepted once the prosecution of the parent application has concluded. As a consequence, litigation on these matters will be necessary.

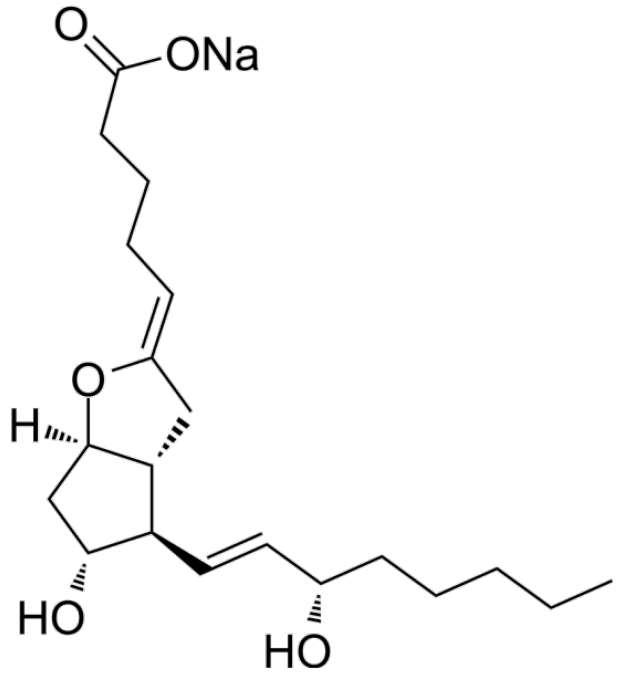
This prevailing scenario could have a profound impact on the patent landscape since it raises the potential for initiating legal actions by third parties seeking to nullify cascade divisional applications that had been previously accepted by IMPI. Parties may challenge the validity of these divisional applications based on the IMPI's interpretation of the law. Moreover, it could set a precedent, questioning the legitimacy of other cascade divisional applications, even those granted under different interpretations of the law. Facing the uncertainty of IMPI's criteria, predicting the future of divisional applications becomes quite challenging. Therefore, it is essential to stay aware of this evolving patent landscape. This will enable patent holders to adapt and formulate appropriate strategies for the timely filing of divisional applications.

Actelion v. Mylan - Construing Claim Terms Involving pH Levels

By Ryan C. Smith, Ph.D.[34]

Epoprostenol is a small molecule injectable drug for the treatment of severe pulmonary arterial hypertension.

The structure of epoprostenol (sodium salt) is depicted below:



Epoprostenol is a carboxylate, and as the asserted patents teach, its solubility and hydrolytic stability increase as the pH increases. It's not surprising that patentee Actelion Pharmaceuticals' U.S. Patent Nos. 8,318,802 ("the '802 patent") and 8,598,227 ("the '227 patent"), with claims directed to epoprostenol formulations at a high pH, would be of high interest and be subject to a claim construction dispute as to recited pH levels.

The Court of Appeals for the Federal Circuit in a recent precedential opinion vacated an infringement judgement against Mylan in *Actelion Pharmaceuticals Ltd. v. Mylan Pharmaceuticals Inc.*, 85 F.4th 1167 (Fed. Cir. 2023).[35] This appeal was from Abbreviated New Drug Application (ANDA) litigation between the parties who stipulated as to infringement if the claim term "a pH of 13 or higher" were construed to include a pH of 12.5, the pH of Mylan's product. Thus, for this matter claim construction for the term "a pH of 13 or higher" was the *ratio decidendi.*

As the Court identified, Claim 11 is representative of the asserted claims:

[34] Ryan C. Smith, Ph.D., is a Partner with Duane Morris, LLP in San Diego, CA
[35] Available at: https://cafc.uscourts.gov/opinions-orders/22-1889.OPINION.11-6-2023_2217732.pdf

11. A lyophilisate formed from a bulk solution comprising:
    (a) epoprostenol or a salt thereof;
    (b) arginine;
    (c) sodium hydroxide; and
    (d) water,
    wherein the bulk solution has *a pH of 13 or higher*, and
    wherein said lyophilisate is capable of being reconstituted for intravenous administration with an intravenous fluid.

The district court construed the term "a pH of 13 or higher" to encompass values from 12.5 to 13.4, based on the intrinsic evidence alone. The basis of the district court's reasoning was that "under its conventional significant figure meaning, the term a 'pH of 13' would ordinarily encompass those values that round up or down to 13, 12.5 to 13.4." *See Actelion Pharms. Ltd. v. Mylan Pharms. Inc.*, No. 1:20-CV-110, 2022 WL 446788, at *9 (N.D.W. Va. Feb. 14, 2022) (*Decision*). The district court held that the specification was sufficiently instructive to determine the meaning of the term because "there is nothing to indicate that Actelion intended to import any higher degree of precision to 'a pH of 13' as it is articulated in the claims at issue." *Id.* While both parties presented conflicting arguments as to the proper evaluation of a pH unit, supported by general chemistry textbooks instruction about significant figures in pH units, the district court did not address arguments based on the extrinsic evidence.

Appellant Mylan argued that that if a margin of error for a pH of 13 is needed, a pH of 13 would involve rounding to the hundredths place, "encompassing 12.995–13.004." Patentee Actelion, in seeking a broader scope of the meaning of the term, argued that "a numerical value includes rounding based on the inventor's selection of significant figures in the claims where the intrinsic record does not indicate otherwise." *Actelion*, 85 F.4th at 1170.

Mylan argued to the Federal Circuit that the claim language is a range with a stated lower limit, thereby foreclosing any further lowering by rounding. The Court disagreed, stating that "there is no blanket rule that ranges, or specifically open-ended ranges, must foreclose rounding. This is especially true in this case where, though not expressly specified, there is in fact an upper limit in the claim because, as a matter of science, pH values are often said to range from 0 to 14." [36] *Id.* at 1171. The Court also noted that claim term also lacked a term indication approximation such as the word "about." Conversely, the Court also explicitly declined to adopt a rule that every numerical term should require a qualifier of precision (e.g., "precisely") or imprecision (e.g., "about") to avoid or include rounding. *Id.*

The Court evaluated the specification and found it to be equivocal as to the use of the term "pH of 13." The specification included both the terms "13.0" and "13" when referring to a pH of 13 in the specification. The Court also noted that while the specification is directed to stable formulations of epoprostenol at high pH levels, the exemplified embodiments did not evaluate any formulation having a pH from 12 to 13, thereby foreclosing the evaluation of a formulation with a pH within the contested range (12.5 to 13.0). After determining that the specification was

[36] Chemists may forgive the Court for failing to qualify the aforementioned statement only applies to aqueous conditions because George Olah's 1994 Nobel Prize was clearly in a field which demonstrated a more expansive pH scale.

unhelpful in providing clarification to the term "a pH of 13 or higher," the Court concluded that "the specification supplies the same clarity as to the desired level of precision as muddied water." *Id.* at 1172.

The Court also evaluated the prosecution history for guidance on construing the term "a pH of 13 or higher." During prosecution, the Applicants amended the claims to "13 or higher" to traverse art-based rejections disclosing epoprostenol formulations with a pH of 12. However, the Court noted that the specification did not compare formulations with a pH of 13 to formulations with a pH of 12, let alone a pH of 12.5. Thus, the prosecution history was found to be unhelpful for claim construction. *Id.* at 1173.

Finding the intrinsic evidence unhelpful for claim construction, the Court then followed the Supreme Court's instruction that in such instances the extrinsic evidence may be consulted to help with determining "the meaning of a term in the relevant art during the relevant time period." *Id.* at 1174, citing *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331 (2015). However, it is the province of the district court to evaluate the extrinsic evidence to make factual findings about that extrinsic evidence to guide claim construction. The Court then vacated the district court's claim construction determination and judgement of infringement. The Court also remanded as a factual matter for determining "how many significant figures 'a pH of 13' has or what it would mean for a number—either for a pH value or for the concentration of hydrogen ions—to have zero significant figures." *Id.*

While precedential, this case may merely be one of *cessante ratione legis cessat ipsa lex*.[37] The wrong term may have been construed in this case as the asserted claims, no matter the meaning of the term "a pH of 13" may have been infringed under an alternative, yet one not argued, theory. The claims refer to a "lyophilisate [or lyophilized composition] formed from a bulk solution [] wherein said lyophilized pharmaceutical composition is (i) formed from a bulk solution having a pH of 13 or higher." Even if the pH of the accused product were 12.5 and outside of the range "a pH of 13", the process of lyophilization may eventually transition the accused product into a composition having a pH of 13 (or higher). Typically[38], the concentrations of non-volatile solutes increase as the solvent is removed by sublimation or evaporation. Lyophilization is the process of removing the solvent by sublimation under reduced pressure and temperature. The concentration of the base (sodium hydroxide) will therefore increase as the solvent is removed, increasing the pH. Whether a "lyphilisate" includes a composition created during the transition of the lyophilization process may be a more apt term for claim construction in this case.

In conclusion, *Actelion v. Mylan* guides that, following Supreme Court[39] and prior Federal Circuit decisions,[40] extrinsic evidence should be considered by the district court when the intrinsic evidence is unhelpful in claim construction.

[37] "When the reason for the law no longer exists, the law no longer exists."
[38] The exception being volatile solutes (e.g., ammonium bicarbonate).
[39] *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318 (2015).
[40] *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576 (Fed. Cir. 1996).

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
Sommer Zimmerman, Ph.D.
Editors-in-Chief

AIPLA Chemical Practice Committee Leadership And Contact Information

Chair
Wan Chieh (Jenny) Lee
Haug Partners
jlee@haugpartners.com

Vice-Chair
Ali Anoff
The Procter & Gamble Company
anoff.a@pg.com

Immediate Past President
R. Andrew Patty II
Phelps Dunbar LLP
drew.patty@phelps.com

Legal Developments Subcommittee
R. Andrew Patty II
Phelps Dunbar LLP
drew.patty@phelps.com

Ethan J. Ung
McCarter & English LLP
eung@mccarter.com

Newsletter Subcommittee
Andrew B. Freistein
Wenderoth, Lind & Ponack, LLP
afreistein@wenderoth.com

Sommer Zimmerman, Ph.D.
Ballard Spahr, LLP
zimmermans@ballardspahr.com

Professional Programs Subcommittee
Debbie Drazen, Ph.D.
Johnson & Johnson
ddrazen@its.jnj.com

Thomas L. Irving
Marbury Law Group
TIrving@marburylaw.com

Stacy Lewis
Finnegan, Henderson, Farabow, Garrett & Dunner LLP
Stacy.lewis@finnegan.com

International Education
Matthew Barton
Forresters
mbarton@forresters-ip.com

China Correspondent of Chemical Practice Committee's International Subcommittee
Toby Mak, Ph.D.
Tee & Howe Intellectual Property Attorneys
toby.mak@teehowe.com

Board Liaison
Jeremy McKown
Johnson & Johnson
jmckown@its.jnj.com

Amicus Committee Liaison
Rivka Jungreis
Teva Pharmaceutical Industries
Rivka.Jungreis@tevapharm.com

Women in IP Committee Liaison
Amy Schmid
Wenderoth, Lind & Ponack, LLP
aschmid@wenderoth.com