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Chemical Practice Chronicles

Newsletter of the AIPLA Chemical Practice Committee

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In this issue:

Editors: Dolly Kao, Wan Chieh (Jenny) Lee, and Jill A. Hecht

Dear AIPLA Chemical Practice Committee Members:

It is my sincere pleasure to introduce to you our new leadership team, Roy Issac, Director of Intellectual Property of Allergan and Drew Patty, Team Leader of the Intellectual Property Group of McGlinchey Stafford, headquartered in Baton Rouge Louisiana, who take on the role of chair and vice chair, respectively, effective at the 2018 Annual Meeting. Both Roy and Drew have extensive experience in patent matters in the chemical arts. Given their creativity and enthusiasm, I am certain that we will see big things from them in their new roles on this committee - a truly unique committee of attorneys, agents and law students who focus on chemistry and intellectual property law on a global basis. Simply put, Roy and Drew are the perfect choice for leading our committee into the future. Be sure to reach out to each of them. I know that they will appreciate your support as they implement their vision of the committee.

My leadership role with this committee has been a five-year journey. Looking back, this role has provided me with opportunities and friendships that I might not have had otherwise. Along the way, we have had a lot of fun: sharing information and stories - both professional and sometimes personal; planning meetings and events (particularly, our sponsored happy hours!); reaching out to legal colleagues and scientific gurus; and deciphering (or should I say "stressing over") the effect of office proposals and memos on client portfolios, not to mention challenging case law while working to make this committee a viable source of continuing legal education. All in all, it has been an exciting and enlightening experience.

As the Chair of the Chemical Practice Committee, most memorably, I found helping hands and support from our members when least expected. So, as I sign off, two small words come to mind:

Thank you!

First, I thank the AIPLA Executives and Board of Directors for the opportunity to chair this committee, and work side by side with extremely talented, dedicated people. This experience has been irreplaceable as I grew into it along the way both professionally and personally. AIPLA executives and the AIPLA Board have been extremely supportive and kind.

Next, I must express my gratitude to certain individuals who have truly energized the committee over the past five years and have served it diligently and with open mind and heart.

So, like Jimmy Fallon (albeit without the help of his professional writers), I take a pause to write some "thank you notes" immediately below:

Thank you, Jeff Townes, for convincing me years ago that the AIPLA Chemical Practice Committee really is where it is at.

Thank you, Roy Issac, for steady guidance and enduring confidence in me and the willingness of people to help.

Thank you, Drew Patty, for taking on more than was asked of you and getting it done, on time,

with i's dotted and t's crossed.

Thank you, Kimberly Braslow and Jeremy McKown, for spicing up our committee with a joint committee webinar and happy hour and for your sincere enthusiasm of patent protections of small molecule drugs!

Thank you, Matt Barton, for crossing Europe and the Atlantic Ocean to participate in our meetings and educating our membership on all of the "legal happenings" going on outside the borders of the United States.

Thank you, Dolly Kao, for reaching out to me last year, and then stepping up to the task of our newsletter and, thank you, Jill Hecht, for sharing your talent (and speed!) in putting it all together.

Thank you, Jenny Lee, for your interest and enthusiasm in AIPLA and this committee, handling our website, sharing the responsibility of the newsletter and most prominently, consistently offering the "application of" your super intelligence and your willingness to just being there when you are needed.

Thank you, Bob Titus, for your love of chemistry as well as your creativity in developing themes for many of our programs, and most importantly, thank you for generating a picture in my mind of a committee that is interesting, active, and fun for its members.

And, thank you, all of you who did not receive one of the foregoing "thank you notes" but have served the AIPLA Chemical Practice Committee in numerous, generous ways. For you, there is a quote that embodies the attitude and mindset of all who have served with me on this committee:

"There is no limit to the amount of good you can do if you don't care who gets the credit."
Ronald Reagan 40th President of the United States

Thanks again,
Carol Nielsen

Announcements

2018 Annual Meeting

Please join us at the upcoming AIPLA Annual Meeting in Washington, DC, October 25-27, where the Chemical Practice Committee and the Emerging Technologies Committee will jointly present a timely and interesting program entitled **"Powering Our Future with The Future of Power: Emerging Trends in Energy Storage Technologies."** The program will present an overview of this technical field, recent developments in licensing, R&D funding and joint ventures, and examine IP strategies. It is scheduled for **Friday, October 26, from 3:30-5:30pm**, with a happy hour social to follow. We look forward to seeing you there!

EAG Laboratories Happy Hour at the 2018 AIPLA Annual Meeting!

When:	Friday October 26, 2018 5:30pm to 6:30pm
Where:	Marriott Wardman Park LOBBY BAR
Tickets to be provided:	At the Chemical Practice and Emerging Technologies Joint Committee Educational Session October 26, 2018 3:30 to 5:30 pm

EAG Laboratories has been a proud sponsor of the AIPLA and the Chemical Practice Committee Happy Hour for the past several years. We are a global scientific services company operating at the intersection of science, technology and business. The scientists and engineers of EAG apply multi-disciplinary expertise, advanced analytical techniques and a "we know how" resolve to answer complex questions.

EAG Laboratories has been providing technical support for legal projects for the past 15 years. Our scientists have been helping plaintiff's attorneys protect and defend their clients' intellectual property, as well as assisting defendant's attorneys by providing results used in prior art and in validity defenses. EAG offers chemical analysis, chemical synthesis, physical testing, materials characterization and expert testimony for litigation support. This testing has supported ANDA/Hatch Waxman associated litigation. Our scientists have testified before the Consumer Product Safety Commission, International Trade Commission, Federal Courts and State Courts. From Pharmaceuticals to medical devices, from consumer electronics to aerospace materials, "WE KNOW HOW" to provide the right testing to support your strategy. We offer quick response, confidentiality and scientific integrity. Please contact Ila Sharm isharma@eag.com for more information or visit https://www.eag.com/intellectual-property/.

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2019 AIPLA Mid-Winter Institute

The 2019 AIPLA Midwinter Institute will be held from January 30, 2019 to February 2, 2019 at the Marriott Tampa Waterside Hotel & Marina in Tampa, FL. The Chemical Practice Committee will be hosting a joint CLE Educational Session with the Patent Law Committee. The Thursday afternoon session will be from 3:30-5:30 pm ET and is entitled **"Opinions and Pre-Litigation Due Diligence – Effectively Considering Joint and Contributory Infringement."**

Comments to Recent USPTO Section 101 Guidelines

In May 2018, the AIPLA Patent Law committee solicited comments in response to the USPTO's Request for Comments on Determining Whether a Claim Element is Well-Understood, Routine, Conventional for Purposes of Subject Matter Eligibility implementing new rules relating to the Federal Circuit's a decision *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018). Numerous members of the Chemical Practice committee participated in this process and compiled a memorandum providing detailed insights and analysis, particularly as it may impact those in the chemical practice, for consideration by the Patent Law committee.

2018 Spring Program

Our committee was busy at the 2018 AIPLA Spring Meeting participating in two separate events, both of which were great successes!

On Tuesday, May 15, 2018 from 7:00 to 9:00 AM at the Corporate Committee Breakfast Meeting, our vice chair of the Chemical Practice Committee, Roy Issac, counsel for Allergan, provided a committee update and his own perspective on the state of chemical patent practice. Roy spoke to the Corporate Practice Committee at their breakfast meeting regarding our committee updates and things that we are watching as chemical practitioners. While chemical practice is a specialty practice, the industries served are expansive as many new innovations in consumer products start with technological advances in the use of raw materials, chemical processing and/or changes to chemical composition. We welcome participation of our committee members in educating, mentoring and networking with others who serve different industries, particularly those whose work touches on chemical innovation in consumer products and processes of producing the same. A copy of Roy's presentation is available on the Chemical Practice committee microsite.

Our committee also jointly hosted a CLE Educational Session with the Patent Agents Committee entitled "**Welcome to the Machine: The Impact of the Application of Computational Techniques and Artificial Intelligence to the Chemical Arts"** on Wednesday, May 16, 2018 from 3:30 to 5:30 PM. The panelists began with an overview of the current state of computational chemistry, virtual reactors, and simulated biological systems. Then, the panel engaged in a lively discussion regarding the intersection of discoveries made by artificial intelligence and patent law, and explored issues relating to patent eligibility, predictability versus obviousness, enablement and written description. The panel

proceeded to discuss a hypothetical with thought provoking input from the audience that explored the complexities of discoveries made with the assistance of artificial intelligence and the complexities under patent law relating to what constitutes an invention and considerations regarding inventorship for discoveries made using artificial intelligence. The presentation sparked a lively debate regarding developing patent law challenges involving this new cutting-edge technology, and was well received by the attendees.

An Issued Life Science MPF U.S. Patent Claim: Ex parte Gleave

Tom Irving, and Stacy Lewis [1, 2]

Ex parte Gleave[3] is a landmark decision to the extent PTAB approved a pharmaceutical composition claim under 35 USC §112(f), otherwise known as means-plus-function (MPF) claims.

35 USC §112(f) reads "an element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof."

Section 112(f) provides a tool for patent applicants to, in a controlled way, literally cover equivalents by providing for literal infringement by structure, material, or acts that perform the same function. Historically MPF claims have been used in the mechanical and electrical/ computer fields. According to P.J. Federico's 1952 commentary on the then-brand new 1952 Patent Act, life science MPF claims were contemplated from the birth of the statutory provision:

> The last paragraph of section 112 relating to so-called functional claims is new. It provides that an element of a claim for a combination (and a combination *may be not only a combination of mechanical elements,* ***but also a combination of substances in a composition claim****, or steps in a process claim*) may be expressed as a means or step for performing a specified function, without the recital of structure, material or acts in support thereof.

Commentary on the New Patent Act (U.S.C. 1952), republished in JPOS: March 1993, http://www.ipmall.info/hosted_resources/lipa/patents/federico-commentary.asp#Application_for_Patent (emphasis added).

For patent drafters practicing in the U.S. life sciences, the means-plus-function claim format may provide more accuracy and clarity than purely structural characterization and may end up providing broader scope.[4] This alternative claim format is worth considering.

[1]Tom Irving is a partner in the Washington, DC office of Finnegan. Stacy Lewis is a law clerk with Finnegan.

[2]These materials have been prepared solely for educational and entertainment purposes to contribute to the understanding of U.S. intellectual property law. These materials reflect only the personal views of the authors and are not individualized legal advice. It is understood that each case is fact specific, and that the appropriate solution in any case will vary. Therefore, these materials may or may not be relevant to any particular situation. Thus, the authors and Finnegan, Henderson, Farabow, Garrett & Dunner, LLP (including Finnegan Europe LLP, and Fei Han Foreign Legal Affairs Law Firm) cannot be bound either philosophically or as representatives of their various present and future clients to the comments expressed in these materials. The presentation of these materials does not establish any form of attorney-client relationship with these authors. While every attempt was made to ensure that these materials are accurate, errors or omissions may be contained therein, for which any liability is disclaimed.

[3]*Ex parte Gleave*, Appeal 2012-004973 (P.T.A.B. Jan. 22, 2014).

[4]For further discussion, see the seminal article on the subject: Tang, Wanli, "Revitalizing the Patent System to Incentivize Pharmaceutical Innovation: The Potential of Claims with Means-Plus-Function Clauses," 62 *Duke L.J.* 1069 (2013).

The Story of an Issued Life Science MPF Claim

The original claims in Gleave, not in MPF format, read:

> 1. A method for treatment of a cancer characterized by elevated expression of hsp27 as compared to non-cancerous tissue of the same type in an individual suffering from the cancer, comprising the step of administering to the individual a therapeutic composition effective to reduce the amount of active hsp27 in the cancer cells.
>
> 14. A pharmaceutical composition comprising a therapeutic agent effective to reduce the amount of active hsp27 in cancerous cells exposed to the therapeutic agent, and a pharmaceutically acceptable carrier.

On the filing date, however, a preliminary amendment was filed canceling all claims and presenting independent claims 25 and claim 33, introducing "means for" with emphasis added:

> 25. (new) A pharmaceutical composition comprising a therapeutic agent effective to reduce the amount of active hsp27 in cancerous cells exposed to the therapeutic agent, and a pharmaceutically acceptable carrier, wherein the therapeutic agent is an antisense oligonucleotide having a sequence complementary to SEQ. ID NO. 91, wherein the oligonucleotide comprises at least ten bases complementary to bases 744-764 of SEQ. ID NO. 91, and wherein the antisense oligonucleotide is 12 to 35 nucleotides in length.
>
> 33. (new) A pharmaceutical composition comprising a
>
> (a) ***means for*** reducing the amount of active hsp27 in cancerous cells by sequence specific interaction with Seq. ID No. 91 and
>
> (b) a pharmaceutically acceptable carrier.[5]

The preliminary amendment also presented claims 34 and 35, depending directly or indirectly from claim 33:

> 34. (new) The pharmaceutical composition of claim 33, wherein the means for reducing the amount of active hsp27 in cancer cells is an oligonucleotide, and the oligonucleotide consists of 12 to 35 nucleotides.
>
> 35. (new) The pharmaceutical composition of claim 34, wherein the oligonucleotide is an antisense oligonucleotide complementary to Seq. ID No. 91.

In presenting the new claims, Applicants made clear an intent to invoke §112(f):

> In the new claim set, claims 33-35 are also presented directed to a generic pharmaceutical composition in which the active ingredient is referred to in means plus function language. It is intended to invoke 35 USC § 112, sixth paragraph, such that this refers to the compositions disclosed in the application that accomplish this function, and equivalents thereof.

[5]The "sequence specific" language ultimately was removed from claim 33.

The PTO erroneously rejected claims 33-35 as not entitled to the effective date of the 2002 and 2003 provisional applications but rather only entitled to the actual filing date of the preliminary amendment:

> None of the applications disclose [sic] the limitations of newly added claims 33 and 34. … [T]he claim language is not supported by the instant specification or the priority documents.
>
> * * *
>
> With regards to the means plus function language of claim 33, the instant specification does not describe any means for reducing the amount of active hsp 27 via sequence specific interaction other than by antisense oligonucleotide or RNAi inhibition.
>
> Therefore, the claims are broader than the instant disclosure, as this is not a defined genus that has been described by the specification. The specification does not have a sufficient disclosure of the structure that corresponds to the claimed function. Means plus-function claims require disclosure in the specification even if the means are already well known in the art. It is not clear what structure is required to meet the limitation of resulting in sequence specific interaction, but clearly this would include triplexes, miRNA molecules, and aptamers, which are not disclosed in the specification.

The USPTO also made an erroneous written description rejection and an anticipation rejection based on Baracchini ("the oligonucleotide of Baracchini et al. meets the instant structural limitations"), a reference that would mistakenly hang over the claims all the way to the decision on appeal reversing that rejection years later.

Applicants responded, adding a new claim 36, depending from claim 33.

> 36. (new) The pharmaceutical composition of claim 33, wherein the means for reducing the amount of active hsp27 in the cells is a double-stranded RNA molecule.

Applicants also targeted the Examiner's erroneous failure to construe the claims as MPF:

> The Examiner has failed to make a determination of the scope of the claims using the standards of this section of the statute, but rather has asserted a scope that is seemingly broader than the claim scope. See MPEP § 2181. Applicants submit that this step must be performed before the Examiner can properly apply any rejection."

The PTO then issued a final rejection regarding MPF claims 33-36, maintaining the position that the claims were not entitled to the benefit of the priority date, lacked written description, and were anticipated:

> Specifically, the documents do not disclose a pharmaceutical composition comprising any means for reducing the amount of active hsp27 in cancerous cells by sequence specific interaction with SEQ ID NO: 91; and do not disclose wherein the means is an oligonucleotide consisting of 12-35 nucleotides, as it appears as if the only disclosure of oligonucleotides of this length are antisense oligonucleotides, as required by claim 35.

With respect to the MPF claim language, the examiner repeated its position from an earlier rejection.

> With regards to the means plus function language of claim 33, the instant specification does not describe any means for reducing the amount of active hsp 27 via sequence specific interaction other than by antisense oligonucleotide or RNAi inhibition. Therefore, the claims are broader than the instant disclosure, as this is not a defined genus that has been described by the specification. The specification does not have a sufficient disclosure of the structure that corresponds to the claimed function.

Responding after final, Applicants persevered and again urged that the examiner failed to correctly construe a claim in MPF format:

> Here, claims 33 and 34 are directed to a combination (a pharmaceutical composition) and one of the elements is recited in mean-plus-function format. Thus, the first thing the Examiner must do in determining the scope of the claims is to consult the specification to see the structures, materials or acts described in the specification . . . .
>
> By law, claims 33 and 34 have a scope which is the disclosed structures, plus equivalents. If the Examiner is arguing that triplexes, miRNA molecules and aptamers are equivalents of the disclosed antisense and siRNA, then these embodiments fall within the scope of the original disclosure and are entitled to the priority date of at least April 18, 2003. If on the other hand (as appears from the written description rejection) the Examiner is asserting that these are not equivalent, then these options are not within the scope of the claim, and applicants are still entitled to at least a priority date of April 18, 2003 for Claims 33 and 34. Clarification of the Examiner's interpretation of the claims is requested.
>
> Claims 33 and 34 are rejected under 35 USC § 112, first paragraph as lacking written description. The Examiner specifically identifies two means for accomplishing the stated function, but argues that the claims are broader than this. The only way this could be legally true is if the alternatives are art-recognized equivalents of the specifically named structures (i.e. antisense and siRNA). The Examiner has not taken a position as to whether or not the structures that make up the allegedly not described scope are art recognized equivalents . . . .

The failure to treat the MPF claim properly compromised, according to Applicants, the anticipation rejection also:

> In order to anticipate a means-plus-function limitation, Baracchini would have to disclose a sequence that (1) performed the function of reducing hsp27; and which (2) was identical to or the equivalent of a structure disclosed in the application. The Examiner has not made either of these showings.
>
> Baracchini's SEQ ID No. 3 is not identified as being able to reduce hsp27, and the Examiner has not argued that such activity is expected to be inherent in the Baracchini sequence. Without such a showing, there can be no anticipation.

The USPTO issued an advisory action, ruling that the reply did not place the application in

condition for allowance. Applicants engaged in a pre-brief appeal conference. The rejection was withdrawn in view of Applicant's brief in its pre-brief conference request.

That joy for Applicants proved to be short-lived. After prosecution was reopened, Applicants received yet another nonfinal rejection. In addition to making the same priority application analysis, the USPTO made a written description rejection, a prior art rejection, and a new indefiniteness rejection under §112(b).

In response, Applicants amended only claim 33 to delete "by sequence specific interaction with Seq. ID No. 91" as follows:

> Claim 33. (currently amended) A pharmaceutical composition comprising a
>
> (a) means for reducing the amount of active hsp27 in cancerous cells [by sequence specific interaction with Seq. ID No. 91] and
>
> (b) a pharmaceutically acceptable carrier.

Applicants argued that were §112(f) applied properly, the rejections would be overcome.

The USPTO responded with yet another non-final rejection based solely on 102 and 103, relying primarily on Baracchini.

Applicants filed a notice of appeal, and tried, unsuccessfully this time, another pre-brief conference request. Again, Applicants argued the examiner was not properly analyzing the claim's scope under §112(f):

> The structures that are disclosed in specification for accomplishing the stated function (reducing the amount of active hsp27 in cancerous cells by sequence specific interaction with Seq ID No. 91) are Seq ID Nos. 1-82 which are antisense oligonucleotides, and Seq ID Nos. 83-90, which are the sense strand of an *[sic]* double0-stranded inhibitory RNA molecule. Thus, the proper scope of the claims is these sequences, and the equivalents thereof. The Examiner, however, has interpreted the claims as encompassing anything capable of achieving the stated function. This is an improper application of the relevant law.

A panel of three examiners rejected these arguments, and the application proceeded to appeal.

In addition to arguing why claim 33 should be construed as a MPF claim, Applicant added a policy argument in its Appeal Brief:

> Indeed, the Examiner and her art unit appear to be making every effort to avoid having to actually apply proper mean plus function claim interpretation in this case. Although the biotech art units may see few means plus-function claims, Appellants are not aware of any art units or technology areas that are excluded from interpreting means-plus-function limitations in the manner articulated by *In re Donaldson.* The anticipation rejection should therefore be reversed.

Answering, the USPTO argued the correctness of the rejections, and, with respect to the MPF issue, concluded:

> Although applicant argues that *[sic]* manner that means-plus-function claims are interpreted by the examiner's art unit, the examiner has interpreted the claim

> in light of the disclosure of the specification.
>
> The instant claims are not limited to the specific oligonucleotides exemplified in the specification and the oligonucleotide of Baracchini et al. meets the structural limitations set forth in the instant disclosure. In order for the instant claim scope to be enabled, the compound of Baracchini et al. would result in the claimed function.

Applicants filed a reply, along with request for oral hearing.

The Board reversed the examiner's rejection, framing the issues as follows:

- Has the Examiner properly interpreted the means plus-function language in the claim?
- Does the cited prior art teach a structure disclosed in the Specification as having the recited claimed function?

Relying on *Donaldson* and other precedent, PTAB reasoned:

> Thus, as articulated in MPEP 2181, "the USPTO *must* apply 35 U.S.C. 112, sixth paragraph in appropriate cases, and give claims their broadest reasonable interpretation, *in light of and consistent with* the written description of the invention in the application." [Emphasis added.] *(See also,* Br. 3.)
>
> A structure disclosed in the specification qualifies as a "corresponding structure" if the specification or the prosecution history "clearly links or associates that structure to the *function* recited in the claim." *B. Braun Med., Inc. v. Abbott Labs.,* 124 F.3d 1419, 1424 (Fed. Cir. 1997). With means plus-function claiming, the narrower the disclosed structure in the specification, the narrower the claim coverage. *Ibormeith IP, LLC v. Mercedes-Benz USA, LLC,* 732 F.3d 1376, 1381 (Fed. Cir. 2013). In making our determination, we apply the preponderance of the evidence standard. *See, e.g., Ethicon, Inc. v. Quigg,* 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).
>
> We agree with Appellants that the structures disclosed in the Specification as having the function recited in the claims are limited to (a) the specific antisense oligonucleotides in Example 1, (b) the specific RNAi molecules of Example 5, and (c) equivalents thereof, that are effective in reducing the amount of hsp27 in cancerous cells.

The Board further concluded:

> We agree with Appellants that, "[t]he Examiner has not presented any evidence to indicate that Sequence ID No.3 of Baracchini is equivalent in function to Sequence ID No. 76 .... [T]he common sequence makes up only 1/3 of Sequence ID No. 76. The Examiner has not provided sufficient evidence that the partial sequence complementarity would necessarily have the same function, as claimed."
>
> We agree with Appellants and find that the Examiner has not shown that one of ordinary skill in the art would have, without more, accepted that complementa-

> rity of 7 /20 non-consecutive bases would necessarily provide the claimed function of reducing the amount of active hsp27 in cancerous cells. The anticipation rejection is reversed.
>
> The obviousness rejection rests on the Examiner's flawed interpretation of Baracchini in the anticipation rejection. Bertrand does not overcome the deficiencies of Baracchini. Therefore, we also reverse the obviousness rejection

With the successful appeal, the claim issued and was entitled to 903 days of patent term adjustment. U.S. Pat. No. 8722872 issued May 13, 2014 and will expire March 24, 2026 (Oct 2, 2023 + 903 days PTA).

Take-Away Messages for Practitioners

What lessons are there for practitioners from a real-life example of an issued life science MPF claim? [6]

For those drafting claims related to a regulated industry, narrow claims are not necessarily bad; they can provide satisfactory claim scope. And if broader claims are desired, carefully draft the specification to encompass all embodiments intended to be covered by the language.

Taking care to carefully link the "means for" in the claim to the specification will help avoid prior art and avoid written description and enablement issues. This may mean added difficulty for third parties challenging patentability at the PTAB or validity in district court.

Since MPF claims are construed to include statutory equivalents to what is linked in the specification, the analysis of equivalents of an MPF claim is one of literal infringement by structure, material, or acts that perform the same function., rather than the far less certain doctrine of equivalents. The potential uncertainty of the scope of literal statutory equivalents also creates challenges to third-party design-arounds.

There are challenges to consider though. Narrowness and linking to the specification may not provide satisfactory protection in specific circumstances. Defining statutory equivalents is not a very clear area of the law, and the USPTO treatment of an MPF claim may be inconsistent or even, in life sciences, reluctant to the point of necessitating appeals.

[6] See also the USPTO training materials claims 5 and 6 at https://www.uspto.gov/patent/laws-and-regulations/examination-policy/examination-guidance-and-training-materials

The Future of Pharmaceutical IPRs: Does the Hatch-Waxman Integrity Act of 2018 Have Any Integrity?

Jonathan Bachand, Knobbe Martens [1]

The crux of Senator Orrin Hatch's proposed Hatch-Waxman Integrity Act[2] is relatively simple. Senator Hatch believes that if a generic drug applicant wants all of the benefits of the Hatch-Waxman Act or if a biosimilar applicant wants all of the benefits of the Biologics Price Competition and Innovation Act (BPCIA) they should not be allowed to file post grant proceedings such as inter partes reviews (IPRs) or post grant reviews (PGRs) with the Patent Trial and Appeal Board (PTAB) as allowed by the America Invents Act (AIA).

Senator Hatch filed the proposed amendment on June 14, 2018, purportedly "to restore the careful balance the Hatch-Waxman Act struck to incentivize generic drug development." In the opinion of Senator Hatch, the AIA created post grant proceedings to deal with patent trolls and aid the high technology industry, but such proceedings are unfair to drug innovators when the Hatch-Waxman Act and BPCIA already provide procedures for challenging the validity of pharmaceutical patents. Senator Hatch made the following statement to the Senate Judiciary Committee regarding his proposed legislation: [3]

IPR is a critical tool for fighting patent trolls and is of particular importance to the tech community. But it also threatens to upend the careful Hatch-Waxman balance by enabling two separate paths to attack a brand patent.

First is Hatch-Waxman litigation, which contains numerous carefully calibrated requirements affecting timing, market exclusivity, and FDA approval. Second is IPR, which is a much blunter instrument than Hatch-Waxman and which contains none of the important industry-specific balancing features that come into play in Hatch-Waxman litigation.

Senator Hatch has on at least two occasions directly addressed his belief that IPRs upset the "careful balance" of the Hatch-Waxman Act. At both the 2017 AIPLA Annual Meeting and the 2018 Federal Circuit Judicial Conference, Senator Hatch spoke about this issue and his belief that legislation was needed to correct this perceived problem. Hatch's speeches, his comments to the Senate Judiciary Committee, and the text of the proposed legislation itself, evidence a misunderstanding of the purpose of post-grant proceedings under the AIA and ignore that the PTAB has not been a "death squad" for pharmaceutical patents. The proposed legislation would do nothing to incentivize generic drug development and would simply bring back a way for brand pharmaceutical companies to delay market entry—relying on patents

[1]Jonathan Bachand is a partner in the Washington, D.C. office of Knobbe Martens specializing in patent litigation involving medical device makers and pharmaceutical companies. This article expresses the opinion of the author only and his views should not be attributed to Knobbe Martens or any of its clients.
[2]*See* Press Release entitled "Hatch Amendment to Incentivize Generic Drug Development," available at https://www.hatch.senate.gov/public/index.cfm/2018/6/hatch-amendment-to-incentivize-generic-drug-development. ("Hatch Press Release").
[3]*See id.*

that never should have issued.

Post Grant Proceedings are about Identifying Bad Patents, not Bad *Tech* Patents

In 2004 testimony to the House Intellectual Property Subcommittee, Michael Kirk, then Executive Director of AIPLA, provided testimony regarding the need for a post grant proceeding to determine the validity of a patent:[4]

Any time patents are issued which, on their face, appear to be of questionable validity, it reflects negatively on the patent system and undermines the confidence of business and consumers. While the validity of such patents may be tested through litigation or ex parte or inter partes reexamination, these proceedings all suffer substantial disadvantages.

Litigation is very expensive . . . . According to the most recent [AIPLA] Economic Survey, the average cost of patent litigation, including the costs of discovery, ranges between $500,000 and $3,995,000 per party, depending on the amount at risk.

In addition, it is only possible to test a patent's validity through litigation if the patentee brings an infringement action against a competitor or provides the competitor with standing to bring a declaratory judgment action based on threats by the patentee. Thus, a competitor cannot challenge a patent in litigation before the competitor incurs the costs and risks of developing and marketing a product. Even where litigation is available to test the validity of a patent, the recent National Academy of Sciences report . . . [noted] that such litigation typically does not occur until 7 to 10 years after the patent is issued and final decision is not reached for another 2 to 3 years. Until the litigation has been concluded, there is uncertainty in the marketplace and uncertainty in the technology as to the scope of the patent right.

These reasons apply to pharmaceutical patents just as they do tech patents. Hatch-Waxman litigation, as with regular litigation, is "very expensive." A generic drug manufacturer seeking to sell a lower cost version of a patented drug is only able to "test a patent's validity through litigation if the patentee brings an infringement action against a competitor," and a generic drug manufacturer can "not challenge a patent in litigation before [] incur[ring] the costs and risks of developing and marketing a product."

Post grant proceedings help identify and clear away "bad" patents in a cost-effective matter. The AIA does not limit the proceedings to certain technology areas and there is no reason that generic drug developers or biosimilar developers should not also be able to use these proceedings to challenge patents that appear invalid. As a policy matter, the ability to rely on "bad patents" to extend brand name drug monopolies does not further Hatch-Waxman's "careful balance." Therefore, based on the policy underpinnings of Hatch-Waxman, the use of post-grant proceedings by generic applicants would not appear to have any impact on the development of new pharmaceuticals, but could encourage generic applicants to challenge bad patents in a more cost effective and efficient way.

[4]See Joe Matal, "A Guide to the Legislative History of the American Invents Act: Part II or II," The Federal Circuit Bar Journal, Vol. 21, No. 4 at 600-601 ("Matal").

Moreover, IPRs and PGRs do not provide generic applicants with a "second bite at the apple," as Senator Hatch contends[5] The AIA contains estoppel provisions that serve to prevent multiple challenges to the validity of a patent on the same grounds. Instead, these proceedings provide both parties with a cost-effective way of resolving patent challenges—potentially even before drug development is pursued—helping to ensure that good patents are not challenged in litigation and preventing the creation of drug monopolies based on patents that never should have issued.

The PTAB Has Not Become a Death Squad for Brand Patents

Statistics released by the PTAB also illustrate that Senator Hatch's proposed legislation is seeking to solve a problem that does not exist. On March 13, 2018, the PTO released the results of a study on IPRs and PGRs involving Orange Book listed patents.[6] In the first five years of the proceedings there were 389 petitions challenging Orange Book listed patents. Although the institution rate of petitions (66%) was similar to the overall institution rate across all technologies (68%), the PTO only held all challenged claims unpatentable in 46% of cases that went to a final written decision—significantly lower than the 66% rate for all other technologies. These statistics indicate that the PTAB is aware of the value of pharmaceutical patents and less likely to hold such patents unpatentable.

The PTAB Is a More Effective Forum to Decide Validity Issues

IPRs and PGRs provide a cost-effective way for innovator companies and follow-on companies to determine whether a patent should have been issued. The administrative patent law judges who decide the merits of these cases are experienced patent practitioners who understand how to review prior art and the difference between what is truly innovative and what is truly obvious. The process also takes less time than a Hatch-Waxman litigation. If a petition is instituted the PTAB is required to provide a decision within 12-months, and may only extend that deadline an additional 6 months if they can show good cause. In contrast, most district courts in a Hatch-Waxman case will not decide issues of validity until the parties are up against the 30 month stay date. This means validity issues can be decided by the PTAB approximately a year before the same issue would be decided by a district court. The PTAB proceedings would also occur at a greatly reduced price. To the extent invalidity challenges can all be resolved at the PTAB, and infringement is not contested, it is possible that the time and expense of district court litigation can be avoided for both parties.

The availability of post grant proceedings to follow-on drug applicants also decreases the case burdens of district court judges who are not patent specialists and have crowded dockets that include criminal cases and complex civil litigations. The Integrity Act would burden busy courts with determining whether certain patents are valid or invalid after expensive trials on the merits, when such determinations could have been made by the PTAB and have been binding on all parties.

[5]See Hatch Press Release.
[6]Available at: https://www.uspto.gov/sites/default/files/documents/chat_with_the_chief_march_2018.pdf

Is There an Imbalance to Hatch-Waxman That Needs Correcting?

I have had the pleasure of spending a significant part of my career in patent law representing generic drug makers in cases arising out of the Hatch-Waxman Act. Most people would agree that Hatch-Waxman has been an enormous success and has helped curb increases in pharmaceutical costs in the United States while still spurring innovation of new pharmaceuticals. That said, Hatch-Waxman, even accounting for amendments that occurred in 2003 via the Medicare Modernization Act, is not perfect. There are still ways that brand pharmaceutical companies can "game" the system to create barriers to entry. Some of this gamesmanship has been partially resolved by the courts, but other continues to this day .[7] Although these games upset the balance the Hatch-Waxman Act created, and do so in a manner that is detrimental to the public, Congress has not felt a need since the 2003 amendments to make any changes to the law.

Given the bipartisan concern about rising healthcare costs, however, one recent ploy of some brand pharmaceutical companies has caught the attention of Congress. In order to file an abbreviated new drug application ("ANDA") under Hatch-Waxman, a generic company must first perform tests on its product and the brand product to show that the products are "bioequivalent." Naturally, a generic manufacturer may only test the brand product, if it has the product in its possession. This means that the generic manufacturer must be able to obtain samples of the brand drug. Exploiting this necessity, some brand drug makers used their Risk Evaluation and Mitigation Strategy (REMS) programs to make it virtually impossible for a generic to obtain the needed brand samples. Although the brand companies contend the REMS programs are needed for patient safety, the net result of the more draconian rules is to prevent generic manufacturers from obtaining samples, which prevents the filing of ANDAs and staves off generic competition.

In a town where Republicans and Democrats refuse to agree on almost any issues of importance, this use of REMS programs has received attention from both sides of the aisles. In order to fix this imbalance to Hatch-Waxman, the Senate is currently considering the Creating and Restoring Equal Access to Equivalent Samples Act ("CREATES Act").[8] The CREATES Act would, *inter alia*, give generics the ability to file lawsuits against brand pharmaceutical companies who refuse to provide samples of their drug products. Senator Patrick Leahy (D-VT) introduced the legislation and it had 30 co-sponsors: 15 Republicans, including the late Senator John McCain, 14 Democrats, and 1 Independent.

In today's Washington, the CREATES Act found agreement between Democrats such as Dianne Feinstein (D-CA), Claire McCaskill (D-MO), Sherrod Brown (D-OH), and Cory Booker (D-NJ) and Republicans like Mike Lee (R-UT), Tom Cotton (R-AR), Ted Cruz (R-TX), Rand Paul (R-KY), and Lindsey Graham (R-SC), all who signed on as co-sponsors to the bill.[9] On June 14, 2018, the Senate Judiciary Committee voted 16 to 5 to report the bill to the Senate floor, after the Pharmaceutical Research and Manufacturers of America spent a

[7]The Supreme Court's decision in *Caraco Pharm. Labs, Ltd. v. Novo Nordisk*, 566 U.S. 399 (2012) illustrates one such abuse by brand pharmaceutical companies regarding overbroad "use codes" that prevented generics from relying on a section viii statement to design around method of use patents.
[8]Text of Bill Available at: https://www.congress.gov/bill/115th-congress/senate-bill/974/text
[9]https://www.congress.gov/bill/115th-congress/senate-bill/974/cosponsors.

reported $10 million on lobbying efforts in the first quarter of 2018 to fight against the CREATES Act.[10]

Despite his purported concern with the "integrity" of the Hatch-Waxman Act, Senator Hatch voted against bringing the bill to the floor. In remarks to the committee, Senator Hatch admitted that the goal of the CREATES Act was "laudable," stating that "generics need to be able to obtain access to samples so they can conduct the tests and research necessary to achieve bioequivalency."[11] Senator Hatch, however, indicated that he could not support the bill because it "could incentivize non-meritorious litigation."[12]

The same, of course, could be said of the Senator's Hatch-Waxman Integrity Act. By preventing generics and biosimilar applicants from challenging bad patents via IPRs and PGRs the Federal courts will be burdened with litigation by brand companies seeking to delay market entry by generics by litigating patents that otherwise could have been invalidated by the PTAB in less expensive proceedings.

Conclusion

To the extent the "careful balance" of the Hatch-Waxman Act is in jeopardy, it is due to gamesmanship by brand pharmaceutical companies to extend monopolies over their brand name drugs. Congress should work to proactively address ways brand pharmaceutical companies are abusing the system, and the CREATES Act is a step forward in the right direction. In contrast, the Hatch-Waxman Integrity Act would increase the cost of drugs by excluding pharmaceutical patents from validity challenges in IPRs and PGRs. The existence of bad patents, however, is not part of the "careful balance," and Congress should protect the ability of generics and biosimilar applicants to challenge such patents in PTAB proceedings.

[10]http://thehill.com/policy/healthcare/384176-phrma-spends-record-amount-on-lobbying-amid-drug-pricing-fights
[8]Text of Bill Available at: https://www.congress.gov/bill/115th-congress/senate-bill/974/text
[11]See Hatch Press Release.
[12]See *id.*.

Recent Decisions Relating to What Constitutes "A Printed Publication" Under 35 U.S.C §102

Wan Chieh (Jenny) Lee[1]

35 U.S.C. §102(a) provides that a reference may qualify as prior art against a patent application if it "was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." The category of "a printed publication" can include formally printed materials, *e.g.*, scientific periodicals or textbook. However, Courts have also interpreted "a printed publication" to encompass more than these formally printed materials on paper, such as, *e.g.*, an orally presented paper at a conference [2], a slide presentation displayed at a conference[3], or a posting to an internet newsgroup[4]. Whether a reference qualifies as a "printed publication" has also become an issue of increasing significance in view of the popularity of Inter Partes Review ("IPR") challenges, which can be raised "only on the basis of prior art consisting of patents or printed publications." 35 U.S.C. §311(b).

In 2018, the U.S. Court of Appeals for the Federal Circuit ("CAFC") revisited the standards for what qualifies as a "printed publication" and considered some less conventional forms of potential prior art. Below is a brief summary of three recent decisions by the CAFC demonstrating that a video and slide presentation distributed at industry meetings, information presented in a public FDA regulatory hearing and subsequently made available on the FDA website, and a product catalog distributed at a trade show may all be potential sources for "printed publication" prior art under 35 U.S.C. §102.

Medtronic, Inc. v. Barry

In *Medtronic Inc. v. Barry*, 891 F.3d 1368 (Fed. Cir. 2018), the CAFC revisited the standard for determining whether a non-traditionally printed reference qualifies as "a printed publication" under 35 U.S.C. §102. *See id.* at 1379-1383. In particular, the CAFC reviewed an appeal of an IPR proceeding from the U.S. Patent and Trademark's Patent Trial and Appeals Board ("PTAB") for patents relating to spinal surgical tools owned by Dr. Mark Barry.

The petitioner, Medtronic, submitted a video demonstration and a related slide presentation, which were presented to spinal surgeons at industry meetings. *See id.* at 1375-6. A CD containing the video demonstration was distributed at three separate programs:

1) a meeting of a study group of 20 experts within the field of spinal deformity;
2) a meeting open to surgeons other than those in the study group and was attended by approximately 20 surgeons; and

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[2]*See Massachusetts Institute of Technology v. AB Fortia*, 774 F.3d 1104 (Fed. Cir. 1985)(holding that an orally presented paper to a group interested in the subject matter, and copies of the paper disseminated to six persons without restriction qualified as a printed publication under §102).
[3]*See In re Klopfenstein*, 380 F.3d 1345 (Fed. Cir. 2004) (holding that a slide presentation that was displayed prominently for three days at a conference with no expectation that the information would not be copied or reproduced by those viewing it qualified as a printed publication under §102).
[4]*See Suffolk Tech v. AOL, Inc.*, 752 F.3d 1358 (Fed. Cir. 2014)(holding that a posting to a Usenet newgroup directed to those having ordinary skill in the art to be a printed publication under §102).

3) a meeting open to surgeons other than those in the study group and was attended by approximately 55 surgeons.

See id. at 1379. Relevant portions of the slide presentation were also distributed at the third meeting. *See id.* The PTAB did not consider the video demonstration and related slide presentation to constitute a printed publication within the scope of 35 U.S.C. §102. The PTAB reasoned that video demonstration and slide presentation were not sufficiently accessible to the public because the first meeting distributed the materials only to experts who were members of a selected study group having certain membership criteria, and not publicly accessible to ordinarily skilled artisans. *See id.* at 1380.

On appeal, the CAFC vacated the PTAB's finding and remanded the case for further reconsideration of the video demonstration and slide presentation as "a printed publication" under 35 U.S.C. §102. *See id.* at 1383.

The CAFC indicted that whether a reference qualifies as a "printed publication" under 35 U.S.C. §102 "involves a case-by-case inquiry into the facts and circumstances surrounding the reference's disclosure to members of the public." *See id.* at 1382 (*quoting In re Klopfenstein*, 380 F. 3d 1345, 1350 (Fed. Cir. 2004). The court emphasized that the "touchstone" to this inquiry is public accessibility. *See id.* at 1380. One way for showing public accessibility is by demonstrating that a reference was sufficiently indexed or cataloged in a library. *See id.* at 1380 -1381. However, the video demonstration and slide presentation in this case were not stored for public access after the conference. *See id.* at 1380. Therefore, the inquiry here is "whether the distribution of certain materials to groups of people at one or more meetings renders such materials printed publications under §102(b)." *Id.* at 1381. The CAFC explained that the materials need not be indexed or searchable if it was "sufficiently disseminated" at the time of their distribution at the conferences. *See id.* The CAFC further instructed the PTAB to consider a number of factors in evaluating whether the video and slide were "sufficiently disseminated" at each of the three meetings, in particular:

- the size and nature of the meetings;
- whether the meetings are open to people interested in the subject matter;
- whether there is an expectation of confidentiality;
- whether there are any policies or practices associated that would give rise to an expectation of confidentiality; and
- whether there is an expectation f sharing the information gained.

See id. at 1382-1383.

Jazz Pharmaceuticals, Inc., v. Amneal Pharmaceuticals, LLC

Approximately one month after the *Medtronic Inc. v. Barry* decision, the CAFC in *Jazz Pharm. Inc. v. Amneal Pharm., LLC*, No. 2017-1671 (Fed. Cir., July 13, 2018) considered whether another type of non-traditionally printed reference (*i.e.*, regulatory meeting materials) qualifies as "a printed publication" under 35 U.S.C. §102.

This case is an appeal of IPR proceedings for patents relating to Jazz's pharmaceutical product Xyrem®. *See id.*, slip op. at 2. The PTAB held certain claims of Jazz's patents relating to Xyrem® to be obvious in view of materials generated during a regulatory review meeting before the U.S. Food and Drug Administration ("FDA"). *See id.* at 4. In particular, the PTAB

considered background materials (including FDA preliminary clinical safety review of Xyrem® and a Xyrem® briefing booklet), meeting minutes, video, transcript and slides on the FDA website of an advisory committee meeting (collectively "ACA materials") to constitute "a printed publication" under 35 U.S.C. §102. *See id.* at 3-4 and 7. This particular FDA advisory committee meeting was announced in a Federal Register Notice as being "open to the public" and allowed interested parties to present at the meeting. *See id.* at 14. The Federal Register Notice also provided a hyperlink to the FDA website where background material would be posted before the meeting, and the meeting minutes, transcript, and slides would be posted after the meeting, as well as instructions for accessing these materials. *See id.* at 3 and 14.

On appeal, the CAFC affirmed that the ACA materials were sufficiently publicly accessible to constitute "printed publication" prior art under 35 U.S.C. §102. The CAFC again emphasized public accessibility as a key factor for determining whether a reference qualifies as a printed publication under 35 U.S.C. §102. *See id.* at 13. The CAFC reiterated that "[a] reference is considered publicly accessible 'upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence can locate it.'" *See id.* at 13 (*quoting In re Wyer*, 655 F.2d 221, 226 (CCPA 1981)). Here, the CAFC determined that the Federal Register Notice widely disseminated the ACA materials through a hyperlink to a public website, the information was made available for a substantial amount of time, *i.e.*, more than two-month before Jazz's critical date, and that the ACA materials were distributed via public domain that could not have provided an expectation of confidentiality. *See id.* at 16-18.

Interestingly, the court noted that "[w]hether the disseminated material is addressed to or of interest to persons of ordinary skill is also relevant to the public accessibility inquiry." *See id.* at 17. However, the parties in this case did not challenged the PTAB's finding that "a person of ordinary skill would have been familiar with the Federal Register and motivated to look for noticed related to drug distribution, safety and abuse prevention." *See id.* (*internal quotations omitted*). Based on this unchallenged finding, the CAFC concluded that "wide dissemination of a reference through a publication like the Federal Register that those of ordinary skill would be motivated to examine is a factor strongly favoring public accessibility." *Id.* at 18.

The CAFC also rejected Jazz's assertion that the ACA materials were not publicly accessible because there is no showing that these materials were indexed or searchable. *See id.* at 19. The CAFC held that indexing and searchability is not a requirement for a reference to be considered a printed publication under 35 U.S.C. §102. *See id.* In addition, the CAFC again relied on the unchallenged finding by the PTAB that one of ordinary skill in the art would have had reason to review the Federal Register, in combination with the general indexing of the Federal Register, to conclude that the notice of was "meaningfully indexed" for one of ordinary skill in the art to find it. *See id.* at 19-21. It should be noted that the CAFC limits this holding to the particular unchallenged finding by the PTAB in this case, and expressly states that this holding is not "a *per se* rule that every notice in the Federal Register satisfies the requirements for prior art," and reiterates a case-by-case analysis. *See id.* at 21.

GoPro Inc. v. Contour IP Holding LLC

The CAFC in *GoPro, Inc. v. Contour IP Holding LLC*, No. 2017-1894 (Fed. Cir. July 27, 2018) once again considered whether a non-traditionally printed reference, namely, a catalog displayed and distributed at a trade show, qualify as "printed publication" under 35 U.S.C. §102

in an appeal of IPR proceedings. *See id.*, slip op. at 2-5.

The patents at issue in this case relate to "action sport video cameras or camcorders that are configured for remote image acquisition control and viewing" owned by Contour IP Holding LLC. *See id.* at 2. The petitioner, GoPro, submitted a GoPro sales catalog which was displayed and distributed for a period of five days at a trade show for an organization focused on sport vehicles as well as related apparel, parts and accessories. *See id.* at 3-4. The trade show was attended by "approximately 150 vendors and more than 1,000 attendees, including actual and potential dealers, retailers, and customer of portable [point of view (POV)] video cameras." *See id.* at 4. GoPro also continued to make its catalog available to actual and potential customers, dealers, and retailers through its website, direct mail and other means of distribution. *See id.* During the IPR proceedings, Contour also submitted evidence demonstrating that the tradeshow was open exclusively to dealers, and not the general public. *See id.* at 4 and 7. The PTAB concluded that this GoPro sales catalog did not qualify as a printed publication under §102 because the trade show was not open to the general public, and that there had been no evidence that someone ordinarily skilled in the art actually attended this dealer-only trade show. *See id.* at 10. The PTAB explained that "a person ordinarily skilled in the art would not be interested in the dealer show because it was not an academic conference or camera industry conference, but rather a dealer show for action sports vehicles…." *See id.* at 7.

The CAFC vacated the PTAB's finding and held that the GoPro sales catalog was indeed a printed publication under §102 after a review of various factors. *See id.* at 11. In particular, the CAFC found the PTAB's interpretation for public accessibility to require distribution at conferences that are specifically targeted towards the camera industry be overly narrow. *See id.* at 8. Instead, the CAFC concluded that the dealer trade show focused on both action sport vehicles and accessories relating to action sport vehicles (which includes POV action cameras) and therefore, does not preclude, and would likely include persons ordinarily skilled and interested in POV action cameras. *See GoPro, Inc. v. Contour IP Holding LLC,* No. 2017-1894, slip op. at 8-10. The CAFC also rejected Contour's argument that the trade show was not open to the general public and concluded that "although the general public at large may not have been aware of the trade show, dealers of POV cameras would encompass the relevant audience such that a person ordinarily skilled and interested in POV action cameras, exercising reasonable diligence, should have been aware of the show." *See id.* at 10-11. The CAFC further considered the dissemination of the GoPro catalog with no restrictions as another contributing factor supporting that the catalog was intended to be disseminated to the general public. *See id.* at 11.

In summary, these three recent CAFC decisions demonstrate that various types of meetings (*e.g.*, scientific conferences, regulatory meetings, trade shows) that often occur during the course of academic research, commercialization of a pharmaceutical product, or marketing and sales activities, may potentially give rise to "printed publication" prior art references under §102. Therefore, it is important to regularly engage meeting participants and evaluate patent filing strategies before information is shown or disseminated to external recipients in view of factors, such as, the nature of scientific, regulatory or other types of meetings, the target audiences for such meetings as compared to persons considered to be one of ordinary skill in the art, and whether there is any expectation of confidentiality at such meetings.

Actavis v Lilly: When Does 'Black' Mean 'White'?

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In this article we consider the UK Supreme Court decision in *Actavis v Lilly*[1] and how it has significantly changed the law of patent infringement by equivalents in the UK.

Case summary

The case concerned Eli Lilly's patent, EP 1 313 508, which claimed a combination of pemetrexed disodium with vitamin B12 for the prevention of tumour growth.

During prosecution, Lilly's claim was limited to the disodium salt form of pemetrexed. The examiner rejected Lilly's initial claims to 'antifolates' as a general class, and also to 'pemetrexed'.

Litigation was initiated by Actavis, who sought declarations of non-infringement in the UK, as well as in France, Italy and Spain. Given the cross-jurisdictional nature of the remedy sought by Actavis, the validity of the patent was not challenged [3]. Actavis argued that the scope of Lilly's patent should be limited to disodium salt forms of pemetrexed only. As Actavis's products contained different pemetrexed counter ions[4] they said that these would not infringe.

Both the lower courts agreed with Actavis and held that there was no direct infringement as the alternative pemetrexed forms did not fall within the claim. The Court of Appeal did, however, decide there was indirect infringement. Both parties appealed to the Supreme Court.

Lord Neuberger delivered the unanimous judgment of the Supreme Court, which allowed Lilly's appeal and held that Actavis's products would infringe Lilly's patent (both directly and indirectly) in the UK, France, Italy and Spain.

Background to infringement by equivalents

The English court's approach to construction was considered by the Supreme Court alongside Article 69 EPC, which provides that the extent of protection conferred by a European patent shall be determined by the claims, which should be interpreted using the description and drawings.

Article 69 raises the question: how far can you go beyond the wording of the claims when determining what falls within their scope of protection? The protocol to Article 69 elaborates on this, explaining that the extent of protection should not be limited to a strict, literal interpretation of the claims, nor should the claims serve only as a rough guideline. Instead, inter-

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[2]Actavis UK Limited and others v Eli Lilly and Company ([2017] UKSC 48)
[3]The English courts will only hear an infringement action in respect of a foreign jurisdiction where validity of the patent is not in question.
[4]Pemetrexed dipotassium pemetrexed ditromethamine and pemetrexed diacide (the free aid form).

pretation should be a position between these two extremes in order to combine fair protection for the patentee with a reasonable degree of legal certainty for third parties. The Courts have had to grapple with how this compromise should be applied to achieve the objectives of Article 69 and different approaches have been adopted by different member states. The protocol also requires member states to take 'due account' of equivalents, a provision which was added by EPC 2000 and which came into force in 2007. This requirement was not, therefore, in force during much of the development of English case law on infringement by equivalents.

Whilst not addressed by the Supreme Court, Article 84 EPC is also relevant, as it requires claims to clearly define the subject matter for which protection is sought. The rationale behind this provision being that the claims should enable the protection conferred by a patent to be determined for the purpose of assessing infringement[5].

The English case law prior to the protocol has evolved around three seminal cases: *Catnic,*[6] *Improver*[7] and *Kirin-Amgen.*[8] In *Catnic*, the House of Lords introduced the principle of 'purposive construction' in determining whether or not a claim to a support member 'extending vertically' would cover support members angled slightly off 90 degrees. In *Improver*, the Court considered how best to determine infringement by variants and set out the three so-called '*Improver*' questions which have since been widely applied[9].

In the House of Lords' decision in *Kirin-Amgen*[10] in 2004, Lord Hoffman confirmed that 'purposive construction' of patent claims was the correct approach and should be the overriding, guiding principle in determining infringement. In that case, the House of Lords held that the EPC (pre-introduction of the protocol) effectively prevented extending protection outside the wording of claims and therefore firmly shut the door on a doctrine of equivalents in UK patent law. The question instead was "what the person skilled in the art would have understood the patentee to be using the language of the claim to mean".

In the present case, the UK Supreme Court has moved away from the question of interpretation and breathed new life into the so-called *Improver* questions.

A shift in the approach to claim interpretation and the scope of protection

The Supreme Court stated that the problem of infringement is best approached by addressing the following two issues:

1. Does the variant infringe any of the claims as a matter of normal interpretation; and, if not,
2. Does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial?

If the answer to either of those questions is "yes" then there is infringement, otherwise there is not. By separating these two issues, the Supreme Court deemed it would avoid 'conflating'

[5]G002/88
[6]*Catnic Components Ltd v Hill & Smith Ltd [1982] RPC 183*
[7]*Improver Corp v Remington Consumer Products Ltd [1990] FSR 181*
[8]*Kirin Amgen Inc and others v Hoechst Marion Roussel Limited and others [2004] UKHL-46*
[9]The original *Improver* questions are set out in the table below.
[10]*Kirin Amgen Inc and others v Hoechst Marion Roussel Limited and others* [2004] UKHL-46

the question of interpretation, self-evidently raised by issue one, with scope of protection, raised by issue two.

Lord Neuberger's judgment went on to explain that treating scope of protection as an issue of interpretation was wrong in principle and could lead to the wrong outcome in many scenarios. He respectfully criticised Lord Hoffman's reasoning in *Kirin-Amgen* and the UK's approach in *Catnic* and *Improver* for doing just that. As a result, issue two involves not merely identifying what the words of the claim mean to the skilled addressee but also requires consideration of how far the scope of protection should extend beyond that meaning.

Applying this approach to the present case, it was clear on issue one that Actavis's products did not infringe. In no way could pemetrexed dipotassium, pemetrexed ditromethamine or the pemetrexed free acid fall within the term 'pemetrexed disodium' as a matter of normal interpretation. The question was therefore whether these products infringed because they were an immaterial variant. In answering this, the Court revisited the three questions set out in *Improver*[11].

The Supreme Court stressed the importance of the correct application on question one and three, and reformulated question two entirely.

A comparison of the original (left) and re-formulated (right) Improver questions

Question 1	Does the variant have a material effect upon the way the invention works? If YES, the variant is outside the claim. If NO, consider next question.	Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, ie the inventive concept revealed by the patent?
Question 2	Would this (ie that the variant had no material effect) have been obvious at the date of publication to the reader skilled in the art? If NO, the variant is outside the claim	Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?
Question 3	Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If YES, the variant is outside the claim	Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

Reformulating the Improver questions

Whilst the original *Improver* questions were a guide to purposive construction, the new questions are a guide as to how to go beyond purposive construction.

The first question looks at the result achieved by the variant and the way that result is achieved. We no longer consider the way the invention works at the level of generality of the claims, but rather whether the variant achieves "substantially" the same result in "substantially" the same way as the inventive concept. The new focus on "the problem underlying the invention" or "the inventive concept" means that much will turn on the level of generality at which

[11] which, after introduction of the protocol on Article 69, also became known as the 'protocol' questions

the inventive concept is set. Patentees will seek to define the inventive concept as widely as possible to argue that the alleged infringement produces the same result in the same way, whilst potential infringers will argue the opposite.

The second question as it stood was deemed to place too high a burden on the patentee, as it required the skilled person to determine for themselves whether it would be obvious that the variant had no material effect on the way the invention worked, which itself required figuring out whether the variant would work at all. To reduce the burden on the patentee, the Supreme Court determined that this question should be asked on the basis that the skilled person knows the variant achieves a particular result. In other words, they are left only to answer whether it is obvious that the variant works in 'substantially the same way' as the invention. This imbues the skilled person with more knowledge than he would have had at the priority date and makes it more likely that a variant will fall within the scope of this question. The difficulty in applying this question will be to separate things which relate to the result with things that relate to ways of achieving the result. Once this separation is made, it is not clear when this question could ever be answered 'no'. Once the skilled person knows what the variant is, is told that it achieves the same result as the inventive concept, how often will it not be obvious that it does so in the same way?

If the answer to the first two questions is 'yes', the third question involves asking whether the patentee nonetheless intended that strict compliance with the literal meaning of the claim was an essential requirement of the invention. Despite use of the term 'literal', it seems this is a reference to 'normal' or 'purposive' construction of the claim, as the analysis here is whether the scope of protection should be limited to normal interpretation, or whether it should extend beyond that meaning. Reference to the 'invention' is again considered to be to the inventive concept.

On the facts in *Actavis*, the inventive concept was deemed to be that the toxic effects of antifolates could be reduced by the co-administration with vitamin B12. The evidence was that pemetrexed with an alternative counter ion (such as potassium) would work in exactly the same way as pemetrexed with a sodium counter ion. Actavis's variants therefore achieved the same result in the same way. It is interesting to consider if, given the wide interpretation of the inventive concept to 'antifolates', any antifolate that prevents tumour growth (including those entirely unrelated to pemetrexed) would have satisfied this first question.

On the second question, the lower courts considered that because some (albeit routine) experimentation was required to determine if alternative salts would be suitable, this was enough to conclude that it would not be obvious to the skilled chemist that the variants would work at the priority date. On the reformulated question, however, once the chemist is told the variants do in fact work, the Supreme Court was able to find that it would be considered obvious that it achieved that result in the same way. This question was therefore also satisfied. Again, if a company discovered an alternative antifolate that also demonstrated reduced toxicity when administered with B12, once the skilled person is told the same result is achieved it is likely that it will be obvious this is achieved in substantially the same way. This could lead to a situation where a variant that was unforeseeable and inventive at the priority date could nevertheless fall within the scope of protection.

On the final question, the Supreme Court held that strict compliance with the wording of the claim was not required, contrary to what the lower courts had held. The Supreme Court considered that the Court of Appeal placed too much emphasis on construing the claim and not enough on the protocol to Article 69. Despite the claim being to the disodium embodiment, the inventive concept was deemed to be the co-administration of an antifolate with B12 to reduce toxicity; the patent specification did not teach any advantage of using sodium over other antifolates and it was generally known that cations other than sodium could be suitable. The use of sodium was therefore not an essential requirement of the inventive concept. The Supreme Court decided therefore, that there was no plausible reason why a rational patentee should want to place such a narrow limitation on the invention as to limit it to pemetrexed disodium only. This question therefore also permits a departure from the language of the claims and to consider instead the inventive concept, with the potential uncertainty which that entails.

On the facts, the variants in Actavis's products were therefore held to be immaterial and to directly infringe Lilly's patent.

Impact of the decision

Any test which produces a result such that pemetrexed dipotassium can infringe a claim to 'pemetrexed disodium' is bound to lead to confusion and uncertainty. There may be fields of study where terms are inherently ambiguous and allowances must be made because of difficulty in finding language which can sufficiently cover developments made post-priority. But, chemistry is arguably not such a field. The skilled chemist is able to identify with relative precision a species, such as pemetrexed disodium, or a genus, such as pemetrexed or antifolates. The Supreme Court has therefore cast aside unambiguous language, which would be clearly understood by the skilled person, in order to broaden the boundary to scope of protection. Once this grip on the language of the claim is lost, how do you define with certainty where the patentee's protection stops?

The Supreme Court has of course provided the reformulated *Improver* questions as a guide to determine what makes a variant immaterial, but these are merely guidelines that may require adaptation depending on the facts of the case. This will lead to much debate about what exact questions should be asked in any particular case.

It is not clear how the decision is compliant with the protocol or indeed the requirement for clarity under Article 84. In cases such as *Actavis*, the claims no longer perform their function of determining the scope of protection and it is therefore unclear how third parties will determine with any certainty what is covered and what is not.

When will a patentee be held to the wording of their claims?

Lord Neuberger explained that in some scenarios, restriction to the wording of the claim may be supported by the prosecution file. The UK courts had previously discouraged the use of the prosecution file to aid claim construction and scope of protection. To quote Lord Hoffman in *Kirin-Amgen* 'life is too short for the limited assistance the file can provide' as it is always

open to the patentee to argue that any such concession made in prosecution was not in fact necessary.

The Supreme Court now proposes a 'sceptical but not absolutist' approach, where reference to the file would be appropriate in limited situations, including where (a) the point at issue is truly unclear if one confines oneself to the specification and claims of the patent, and the contents of the file unambiguously resolve the point, or (b) it would be contrary to the public interest for the contents of the file to be ignored.

Whilst these exceptions are narrow, practitioners will no doubt review the contents of the file history in even greater detail to ascertain whether such a situation is applicable. In this case, whilst Actavis sought to limit Lilly's claim to the narrower wording accepted by the EPO, the Supreme Court held that the reasons behind the amendments in prosecution (lack of support and added matter) did not justify a departure from the preliminary conclusion of infringement. The suggestion is that only an express statement made in prosecution that the patent would not be asserted against the type of variant at issue (to navigate around prior art, for example) would be enough to justify holding the patentee to the wording of the claim. This narrow approach is in contrast to similar situations in the US, where the wider principle of 'file wrapper estoppel' is established.

Will there be knock-on effects for validity?

The question of whether this decision will change how the courts approach validity has already been raised. At present, for lack of novelty or inventive step attacks, the prior art is compared with the invention set out in the claims of the patent as normally interpreted. Will we now see attacks comparing variants of the prior art with the wider scope of protection of the claim? This would be in line with the so-called '*Gillette defence*' - that that which infringes after grant, if made available to the public before the application is filed, will anticipate the patent and render it invalid. This was not discussed by the Supreme Court. Lord Neuberger did, however, clearly draw the line between disclosure of the patent and scope of protection. Indeed, early signs from the English High Court suggest that the doctrine of equivalents should not apply to the assessment of novelty[12].

Rather than validity attacks based on variants, we may instead see an 'angora cat' paradox pad its way into UK law. Will a patentee be permitted to construe its claims narrowly during prosecution to avoid the prior art only to broaden its claim post-grant to encompass variants during a later claim for infringement? This could lead to situations where an infringer may be doing no more than working the prior art, but nevertheless infringe the patent.

Conclusions

Lilly's contribution to the art was significant and the Supreme Court appeared to think that the examiner's position, which lead to a claim limitation to the disodium embodiment, was not necessarily correct. Nevertheless, should the Courts be applying Article 69 broadly to overcome what they think are harsh decisions of examiners? Many think not (if indeed this was the

[12] *Generics (U.K.) Limited and others v Yeda Research and Development Company Limited and others* [2017] EWHC 2629 (Pat)

motivation of the Court) given the recourse open to patentees to lodge an appeal during examination or file a divisional seeking the broader claim.

Despite the controversy of the decision, the genesis seems to have been a long while in the making. Neuberger J (as he then was) proposed the exact approach now adopted by the Supreme Court in *Kirin-Amgen*, where he stressed the importance of considering the technical contribution to the art and not merely the wording of the claim. His decision then was overturned on appeal but now as President of the Supreme Court, perhaps we should have seen this approach coming.

The decision will have knock-on effects for infringement cases in the English courts and, potentially, in countries where UK Supreme Court decisions are persuasive. The extent to which the lower courts will apply the reformulated *Improver* questions to different technology remains to be seen and will be tested by patentees for months, if not years, to come. We are likely to see the biggest battle ground in defining the inventive concept of the patent, as this will ultimately determine how broad the patentee's scope of protection will be. Predicting where the infringement line will be drawn is not straightforward and therefore, in the meantime, freedom-to-operate considerations and work-arounds to existing rights will inevitably be re-scrutinised.

What Pharma Patentees Need to Known About Canada's CSP Regime

Osman Ismaili, Caroline Henrie and Dolly Kao, Perry & Currier/Currier & Kao*

Introduction

As part of Canada's obligations under the Comprehensive Economic and Trade Agreement Between Canada and the European Union (CETA), the Certificate of Supplementary Protection (CSP) regime was implemented on September 21, 2017. It is administered by Health Canada and maintained pursuant to the *Certificate of Supplementary Protection Regulations* (the *Regulations*) and the *Patent Act* (the *Act*).

Application

Certain patents related to human and veterinary drugs may qualify for a CSP granting up to two additional years of protection (s.116(3) of the *Act*). An application for a CSP is to be filed with the Minister of Health (the Minister) within a prescribed period (s.106(3) of the *Act* and s.6(2) of the *Regulations*)). The current fee payable to file an application for a CSP is $9191 CDN.

Eligibility

The following requirements set out in s.106(1) of the *Act* must be met in order for a patented invention to receive supplementary protection: a) the patent is not void and meets any other prescribed requirements; b) the filing date of application for the patent application was on or after October 1, 1989; c) the patent pertains to a medicinal ingredient or combination of medicinal ingredients contained in a drug for which authorization for sale was issued on or after September 21, 2017; d) the authorization for sale is the first issued with respect to the medicinal ingredient or combination; e) no other CSP has been issued with respect to the medicinal ingredient or combination; and f) if an application for marketing approval, equivalent to an authorization for sale, has been submitted in a prescribed country with respect to the medicinal ingredient or combination of medicinal ingredients before the application for authorization for sale was filed with the Minister, the application for the authorization for sale was filed before the end of the prescribed period beginning on the day on which the first such application for marketing approval was submitted.

Protection afforded

The CSP offers the same rights, privileges and liberties that are provided by the patent to which the CSP attaches, with respect to the making, constructing, using and selling of a drug

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containing the medicinal ingredient, or combination of medicinal ingredients, set out in the CSP, either by itself or in addition to any other medicinal ingredient. However, making, constructing, using or selling the medicinal ingredient or combination of medicinal ingredients for the purpose of export from Canada will not be deemed infringement (s.115(1)-(2) of the *Act*).

Best Practices

- Diligently pursue drug approvals in Canada to avoid a reduction in the CSP term: The Minister may reduce the term of a CSP in response to unjustified delays in obtaining the authorization of the sale. (s.116 (3)-(4) of the *Act*). The CSP regime favors timely introduction of new drugs into Canada. The prescribed period for filing an application for the authorization for sale is 24 months if the application for the CSP is filed before September 21, 2018, or 12 months in any other case. (s.106(1)(f) of the *Act* and s.6(1)(b) of the *Regulations*).
- Stay up to date on patent maintenance fees.
- Review pending patent applications and amend claims (if possible) to take advantage of the CSP regime.
- Review patents relating to the same medicinal ingredient or combinations of medicinal ingredients and select the most appropriate patent for seeking supplementary protection under the CSP regime. Only one CSP is available per medicinal ingredient or combination. Medicinal ingredients which differ only with respect to prescribed variations will be considered the "same" medicinal ingredient. (s.105(1) –(6) of the *Act* and s.2 of the *Regulations*)
- When exercising due diligence in reviews and opinions, remember to consult the CSP Register in addition to the patent database of the Canadian Intellectual Property Office as CSPs do not appear on the latter.

K&P's INTELLECTUAL PROPERTY HIGH COURT DECISION REPORT IN MARCH, 2018

Kawaguti & Partners

1. How should Disincentive Factor be Considered for Examining Inventive Step?

Nippon Steel & Sumitomo Metal Corporation v. JFE Steel Corporation, Case No. 2017 (Gyo-Ke) 10041&10042 (Decision rendered on March 12, 2018)

The Patentee, JFE obtained a patent relating to a hot-pressed member in 2013. Against Claims 1 to 5 of the JFE's patent, Nippon Steel & Sumitomo Metal (NSSM) filed an invalidation trial with the JPO in 2013. During the trial proceedings, JFE demanded a correction of claims. The JPO admitted the correction, and rendered a decision of invalidation on the grounds of lacking inventive step on Claims 1 to 3, while dismissed the NSSM's demand on Claims 4 and 5 in 2016. NSSM filed an appeal against the JPO's decision on Claims 4 and 5, and JFE filed an appeal against the JPO's decision on Claims 1 to 3 to the IPHC in 2017.

Claim 1 of the corrected JFE's patent at issue claims as follows:

> A hot-pressed member comprising a steel sheet having a composition containing, by % by mass, C: 0.15 to 0.5%, Si: 0.05 to 2.0%, Mn: 0.5 to 3%, P: 0.1% or less, S: 0.05% or less, Al: 0.1% or less, N: 0.01% or less, and the balance including Fe and unavoidable impurities, a Ni-diffusion region which is present in a surface layer of the steel sheet, and an intermetallic compound layer and a ZnO layer which are provided in order on the Ni-diffusion region, the intermetallic compound layer corresponding to a g phase present in a phase equilibrium diagram of a Zn-Ni alloy,
> wherein … .

One of the main issues in this case related to how a disincentive factor should be considered for examining inventive step. The IPHC answered to the issue as follows:

In the JPO's decision, the JPO found that there were 3 differences between the invention claimed in Claim 1 of the patent at issue and the invention disclosed in prior art reference 1 (p.a.r. 1). The first difference was that the former did not contain Ti, while the latter contained 0.02% of Ti. The JPO further found (i) that p.a.r. 3 demonstrated steel sheets not containing Ti (steel types A and C) as well as a steel sheet containing Ti and B (steel type B) in the working examples; and (ii) that p.a.r. 3 stated that Ti may be added … for effectively bringing out the effect of B, and that it is also possible to add Ti to improve the strength. On the basis of the above findings, the JPO decided on the first difference that those skilled in the art could have easily made not to contain Ti in the invention disclosed in p.a.r. 1 which did not contain B depending on a desired strength.

However, the IPHC overturned the above JPO's decision for reasons stated below:

> P.a.r.1 mentioned (i) that harden steels to which high strength and high hardness were imparted by quenching after heat-forming, for example, steel sheets listed in Table 1, were particularly preferable as the hot-pressed steel member; (ii) that steel type A contained 0.02 mass% of Ti, steel types B to D contained

Kawaguti & Partners is an intellectual property law firm headquartered in Japan.

> 0.01 mass% of Ti, and steel type E not containing Ti contained 12 mass% of Cr, which was not contained in steel types A to D, among the 5 steels listed in Table 1; and that (iii) a steel sheet having a Zn-Ni alloy coating on the steel type A showed good properties.
> Further, although p.a.r. 3 stated as found by the JPO, these descriptions did not deny containing Ti in steel sheets not containing B, nor show that it was preferable not to contain Ti depending on desired strength in the case of steel sheets not containing B. **Rather, p.a.r. 3 disclosed that Ti may be added to improve the strength.**
> Accordingly, it was acknowledged that **there was no motivation not to contain Ti which had an effect of improving strength of steel sheets for those skilled in the art having regard to p.a.r.s 1 and 3, rather that there was a disincentive factor not to do so**.

Conclusively, the IPHC upheld the JFE's appeal on Claims 1 to 3, and cancelled the JPO's decision on Claims 1 to 3, while dismissed the NSSM's appeal on Claims 4 and 5.

Both of JFE and NSSM filed an appeal to the Supreme Court against this decision, and thus the decision is NOT final and binding.

K&P's Comments

This decision provides a positive example of a "disincentive factor", which is one of the important positive factors for acknowledging inventive step under the Japanese practice. As seen from the above decision, excluding from the claimed invention a feature which may positively contribute to any effect in a prior art reference can be a disincentive factor.
(by Katsumasa OSAKI, Patent Attorney)

In March 2018, the IPHC handed down 24 decisions including the above case on patent, and overturned the previous decisions in 10 cases.
In March 2018, the IPHC handed down 4 decisions on trademark, and overturned the previous decision in 2 cases.
In March 2018, the IPHC handed down 2 decision on industrial design, both of which maintained the previous decisions.

> P.a.r.1 mentioned (i) that harden steels to which high strength and high hardness were imparted by quenching after heat-forming, for example, steel sheets listed in Table 1, were particularly preferable as the hot-pressed steel member; (ii) that steel type A contained 0.02 mass% of Ti, steel types B to D contained 0.01 mass% of Ti, and steel type E not containing Ti contained 12 mass% of Cr, which was not contained in steel types A to D, among the 5 steels listed in Table 1; and that (iii) a steel sheet having a Zn-Ni alloy coating on the steel type A showed good properties.
> Further, although p.a.r. 3 stated as found by the JPO, these descriptions did not deny containing Ti in steel sheets not containing B, nor show that it was preferable not to contain Ti depending on desired strength in the case of steel sheets not containing B. **Rather, p.a.r. 3 disclosed that Ti may be added to improve the strength.**

THREE KEY THINGS TO KNOW ABOUT THE CHANGING LANDSCAPE OF COMMERCIALIZATION OF PHARMACEUTICALS IN CHILE

Francesca Rodríguez Spinelli, Alessandri Attorneys at Law[1]

The commercialization of pharmaceutical drugs in Chile is facing one of its most important moments in history as it seeks to strike a balance between the private and public interests. Extremely high out-of-pocket costs of branded pharmaceuticals have negatively impacted the public's access to health and renewed the debate on whether the government should help regulate sales prices for pharmaceuticals in the country. Indeed, a number of amendments are currently pending before the Chilean legislative bodies. The debate is naturally confronting the positions of the pharmaceutical industry, patients and the Chilean government in its double role as guarantor of the right to life and health and promoter of the economic development of the country.

1. "Drugs II": should the government intervene in the commercialization of pharmaceuticals?

Since 2015, the Chilean Parliament has been discussing the so-called Bill "Drugs II", which seeks to update the regulations concerning bioequivalence, in place since 1967, while preventing the vertical integration between pharmacies and pharmaceutical laboratories. The bill is being reviewed and several changes are being promoted by the current Chilean president and legislators. If approved, the bill will bring several important challenges to manufacturers, distributors, pharmacies, drugstores, health professionals and patients including:

- Doctor's prescription should be exclusively under the "International Nonproprietary Name" (INN).
- Pharmacies' obligation to inform the customers on the generic versions available for the drugs prescribed by their doctors under the INN.
- Drug labeling changes, so that the product packaging includes the INN in a size that is at least one third of the main faces of the packaging, while the trademark may not exceed one fifth of the space used by the INN.
- Greater faculties for the Institute of Public Health, in terms of granting marketing approvals for pharmaceutical medicaments under their INN and requesting the patent right holders to include in their patent applications the INN corresponding to the claimed pharmaceutical compounds.

Some apprehensions have been raised concerning pharmacies and their pharmacists if the bill is finally approved, as they would have increased ability to influence and direct the consumer's purchasing decision. Another concern, given that Chile lacks an effective standardization system on pharmaceutical bioequivalence, is that the bill could essentially codify a law that restricts the exercise of the medical profession. In addition, there is a perception that the bill

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could potentially promote collusion practices between pharmaceutical companies and pharmacies. The fear is not unfounded as from 2008 to 2012 some of the main pharmacy chains in Chile were found to have participate in price fixing schemes related to at least 222 pharmaceuticals, most targeted for the treatment of chronic diseases.
In May 2018, the Chilean president announced that one of the main goals of his administration is to achieve a substantial reduction of the drugs prices —of at least 30%—and demand greater transparency of the pharmaceutical industry. In this sense, the Chilean president proposed additions to the bill that seek to accomplish the following:

- encourage the use of the INN in medical prescriptions, establishing the exchangeability between the bioequivalent generic products and the trademarked ones;
- create an online drug price comparator (www.tufarmacia.gob.cl) to allow locating the closest pharmacies offering the best price for a particular pharmaceutical products; and
- permit the sale of certain pharmaceutical products in supermarkets' and pharmacies' shelves, among other aspects.

These additions are seen as a more balanced approach to the exchangeability than the bill as initially presented. For example, the original bill did not contemplate the bioequivalence condition to substitute a trademarked drug by a generic product. Requiring bioequivalence helps ensure that the branded and generics are of comparable quality, such that the patient's safety will not be compromised, while enhancing the free competition and the market transparency.

The Ministry of Health has also proposed its additions to the bill, but not without controversy. The Ministry has advocated for allowing the National Health Service System (CENABAST) to intermediate in the purchase of drugs and medical supplies between manufacturers/ distributors and private customers, such as small/community drugstores, in the case of "inaccessibility to pharmaceutical products caused by economic, financial, geographical or opportunity barriers preventing from accessing a determined drug".

This could mean a relevant change in the CENABAST's role. Currently it is a public institution only in charge of ensuring the availability of drugs, food, supplies and equipment to the Chilean public health network, thereby intermediating between private suppliers and public customers exclusively. If the Ministry's initiative is adopted, the government would directly intervene in the commercialization of pharmaceutical products under the premise of still imprecise circumstances of "inaccessibility to pharmaceutical products." Such intervention could impact the open Chilean market as the "economic, financial, geographical or opportunity barriers" preventing access to a medical treatment and/or drug could be caused by a myriad of reasons. Moreover, the intervention seems to be reductant where in justified cases and due to public health reasons, Chilean Industrial Property Law provides for legal mechanisms to grant compulsory licenses on pharmaceutical patents.

2. The Sofosbuvir Case: first compulsory license discussion in Chile

On March 2018, the outgoing Minister of Health issued a resolution determining that there are reasons of public interest to justify granting one or more compulsory licenses for the exploitation of patents protecting the active ingredient Sofosbuvir, as well as its combinations with other direct-acting retrovirals, useful for the treatment of chronic hepatitis C.

The Resolution stated that the Ministry of Health will take the necessary measures to achieve this purpose, which in practice translates into the possibility of filing a compulsory license claim before the National Institute of Industrial Property (INAPI) against at least two patents already registered for the active ingredient Sofosbuvir: Patents N° 49,840 and N° 51,404, owned by Gilead Pharmasset LLC. And Gilead Sciences Inc. (jointly "Gilead").

This Resolution is the first of its kind in Chile and responds to an initiative put forward by patients, parliamentarians and Corporación Innovarte, exposing the health problems that hepatitis C patients have been facing in Chile. According to the joint group calling for the measure, the high cost of medicines available in the local market for their treatment, versus "alternative" drugs of foreign manufacture— which they alleged-could be up to 90% cheaper than those currently available to patients in private and government run health centers —now that hepatitis C has been included in the pathologies covered by the so-called national plan of Explicit Health Guarantees (Auge-GES).

The current administration, which assumed power days after the Resolution was enacted, has inherited the public debate on its impact and reopened the conversation as to whether a more detailed analysis is needed to strike a balance between the rights of the public and the rights of the private companies developing pharmaceuticals. Among the points for discussion are:

- Actual/updated proportion of patients affected in Chile by the disease, as well as their prognosis in case of adopting the treatment with Sofosbuvir and its combinations with other direct-acting retrovirals.
- Prevalence of the disease in Chile at an endemic level, such as to establish reasons of extreme urgency that demand measures of the same order (for example, granting compulsory licenses for the manufacture, importation, sale and/or distribution of an active ingredient) and/or pharmaceutical combinations protected by one or more patents in the national territory).
- The high out-of-pocket cost implied in access to health in Chile, due to an apparent imbalance between the availability of broader Government's subsidies and the lack of an effective regulation capable of guarantee a significant co-payment between private insurers and the patient especially in the case of complex pathologies of high social sensitivity like this one.

Gilead filed an administrative action seeking reconsideration on the Resolution, as well as an invalidity action against the administrative act of the Ministry of Health that dictated the Resolution. The reconsideration action was dismissed and, as of the date of this article, the invalidity action is still pending.

Adding to the complexity of the situation is the impact that a decision in this case would have on Chile's existing obligations as party to multilateral and bilateral important commercial agreements, because of the possible effects and repercussions of a legal breach of those agreements by Chile. For example, the public seems to endorse a view that there is a deliberate delay to decide the future of the resolution because of the on-going renegotiation of Chile's Free Trade Agreement with the European Union.

The core of the debate, however, is not focused on the compulsory licenses per se, as they are transversally recognized as a legal mechanism to ensure the necessary flexibility of the patent system in certain and justified cases. The controversy is instead focused on the interpretation of the reasons that would support the grant of a patent compulsory license. For the Resolution at hand, the Ministry of Health cited "economic inaccessibility" due to the high prices of patented medicines in Chile as the bases for the public health reasons that could be used to grant a compulsory license over valid patents in Chile.

3. Amending Chilean IP Law to create an exception to infringement: preparation or manufacture of drugs "under medical prescription in certain individual cases"

In July 2018, the National Institute of Industrial Property (INAPI) proposed a bill to partially amend the Chilean Industrial Property Law by incorporating rules that would make self-executing several of the international treaties to which Chile must adhere as part of the renegotiation of the Free Trade Agreement signed with the European Union in 2003.[2] Of relevance to pharmaceutical companies are the provisions in the bill that seek to (i) incorporate the provisional applications category for patent rights; and (ii) set up new patent right limitations, such as private acts with no commercial purposes, experimental and educational acts and the preparation/manufacture of drugs under medical prescription in certain individual cases.

The bill was made available to the Industrial Property stakeholders for a brief comment period. The final version of the bill is currently being considered by the Ministry of the General Secretariat of the Presidency (SEGPRES).

The provision introducing new patent right limitations, particularly in connection with the preparation or manufacture of drugs "under medical prescription in certain individual cases" is one of the most challenging reforms pursued by this bill. For many, the language is a very broad interpretation of the patent right limitation. Not surprisingly, patent owners have raised their concerns, requesting a clarification on the extent of that phrase in the bill and urging INAPI to reconsider its wording. So far, unofficially INAPI has declared that the spirit of that legal amendment is to permit the drug portioning in consideration of certain diseases and special patient conditions. Nevertheless, it is clear that this specific aspect of the bill requires more detailed revision to secure the observance and enforcement of patent rights in Chile. Without further revision, this provision implies the possibility of creating a legal loophole for potential infringers.

Conclusion

There is no doubt that the players in the Chilean pharmaceutical market can all agree that it is necessary to balance the opportunities for access to effective medicines at increasingly convenient prices. This debate has the potential to serve as a prompt to create new and better solutions that stimulate the fair competition in the Chilean market, without discouraging or harming the pharmaceutical innovative community that benefits from longstanding protection of its

[2] The 2003 Free Trade Agreement included: The Madrid International Trademark System; the Hague International Design System, the Locarno Design Classification Agreement; the Patent Law Treaty; and the Strasbourg Agreement on Patent Classification.

COMPULSORY LICENSES – A NEW FOCUS IN RUSSIA

Kirill Osipov, ARS-PATENT[1]

The possibility to have a compulsory license to an invention granted has being existed in Russia since 1992, when the first version of the Patent Act of the Russian Federation was issued, although Soviet legal acts also contained provisions relating to a compulsory license. However, despite legal basis, no compulsory licenses have been granted so far.

Under effective Russian law, a compulsory license to an invention may be granted only in two cases:
(i) If an invention fails to be used or is insufficiently used by the patentee during four years from the patent grant date, which leads to insufficient offer of respective goods, works or services on the market, any person willing and ready to use such invention, given the patentee's refusal to conclude with such a person a license contract on terms corresponding to common practice, shall have the right to initiate legal proceedings against the patentee for the grant of a compulsory simple (non-exclusive) license for the use of the invention. If the patentee does not prove that nonuse or insufficient use of the invention is based on a valid excuse, the court shall rule the grant of the compulsory license.
(ii) If a patentee cannot use his invention without infringing thereby the rights of a holder of another patent (the first patent) to an invention who has refused to conclude a license contract on terms corresponding to common practice, the patentee (i.e. the holder of the second (dependent) patent) may initiate legal proceedings against the holder of the first patent for the grant of a compulsory simple (non-exclusive) license for the use of the invention owned by the holder of the first patent. If the patentee of the dependent invention proves that it is an important technical achievement and has a significant economic advantage over the invention of the first patent, the court shall rule the grant of the compulsory license. In this case, the holder of the first patent may also obtain a simple (non-exclusive) license for the use of the dependent invention.

The first attempt for having a compulsory license to a pharmaceutical invention granted was made by TEVA in a patent dispute with DEBIOPHARM S.A. in 2011 (court case # A40-83104/2011); however, the lawsuit was withdrawn by TEVA a little bit later. The next attempt occurred in 2017 in a patent infringement case initiated by CELGENE CORPORATION against the Russian generic company NATIVA (court case # A41-22139/2017). In that case, NATIVA filed a counterclaim requesting for a compulsory license to CELGENE's patented invention. However, the judge decided that consideration of CELGENE's claim and NATIVA's counterclaim within the same case was not reasonable, and, as a result, the counterclaim was returned to the Russian company. Not having given up, NATIVA and a co-owner thereof Mr. Oleg Mikhailov submitted the demand on the compulsory license as a new lawsuit (court case # A40-71471/2017).

[1] Mr. Osipov started his career in the field of IP in 2006. He joined the team of ARS-Patent in 2014. Mr. Osipov's focus in his practice is patent prosecution and litigation, patent searches and technology licensing in the field of pharmaceuticals, biotechnology and chemistry. He represents interests of chemical, pharmaceutical and biotech Russian and foreign companies before the Russian and Eurasian Patent Offices and the Russian courts.

In case # A40-71471/2017, NATIVA and Mr. Mikhailov requested the court to recognize Mr. Mikhailov's patented invention (a specific crystalline form of lenalidomide; later Mr. Mikhailov sold his patent to NATIVA) dependent with regard to CELGENE's invention (covers, *inter alia*, lenalidomide as such) having significant technical and economic advantages over the latter and to grant the compulsory license because before the legal proceedings CELGENE had ignored an invitation to license its invention for NATIVA. In the case, CELGENE agreed that Mr. Mikhailov's/NATIVA's invention is a dependent one and cannot be used without the use of CELGENE's invention itself. The Russian company also managed to prove that their invention had significant technical advantages over CELGENE's invention, such as enhancing the product yield, decreasing a defective product level, achieving the desired particle-size distribution of the product without additional steps to be performed, which technical advantages resulted in reducing the product unit cost, i.e. the economic advantage. As CELGENE did not present their license terms that, in their opinion, would be the most suitable, the court ruled to grant the compulsory license to the CELGENE's invention on the terms proposed by NATIVA.

Thus, case # A40-71471/2017 has become the first practical case on the grant of the compulsory license in Russia. Nevertheless, this decision of the first instance court is appealable, which still keeps a compulsory license issue open...

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