

## Chemical Practice Chronicles

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**In this issue:**

Messages from the incoming chair and vice-chair 2  
Roy Issac and Drew Patty

Announcements 4

Articles and Case Law

*Helsinn v. Teva*: Supreme Court Clarifies “On Sale” Bar Under 35 U.S.C §102 7  
Wan Chieh (Jenny) Lee, Fay Kaplun & Marcin, LLP

Combine the Label with Phase III Clinical Results and a Carefully Crafted, Mirroring US Patent Application to Achieve Longer Patent Exclusivity for US Bio/Pharm Patents: Strategic Considerations and Opportunities Raised by *Sanofi v. Watson*. 9  
Tom Irving, Michele Bosch, and Stacy Lewis. Finnegan

USPTO Issues Interim Procedure to Request PTA Recalculation for an IDS Filed With a Safe Harbor Statement and a New Safe Harbor Form. 13  
Andrew B. Freistein, Wenderoth, Lind & Ponack, LLP

*Novartis v. Ezra* and *Novartis v. Breckenridge*: Cracks in the Armor of ODP Portending Well for Innovative Pharma? Adriana Burgy, Tom Irving and Stacy Lewis . Finnegan 17

International Focus

A Glimpse into China’s Progress on Introducing Supplementary Patent Certificates, Patent Linkage and New Data Protection 23

Xiaoyang Yang, Michael Lin, Marks & Clerk Intellectual Property Agency (Beijing) Limited

Chemical Practice Committee Leadership And Contact Information 27

Editors: Dolly Kao (Dolly@kaoip.com)  
Wan Chieh (Jenny) Lee (jlee@fkmiplaw.com)

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**Message from the incoming chair, Roy Issac**



Dear AIPLA Chemical Practice Committee Members:

I am honored to assume the chair position of the Chemical Practice Committee. As one of the few subject matter committees of the AIPLA, our committee has the enormous responsibility to safeguard the development of patent law related to chemical, life sciences, materials, petroleum and related industries. Life sciences, in particular, is undergoing a revolutionary change in the way drugs and diagnostics are developed. The landscape of treatment options is changing in a rapid pace with the introduction of cell-based therapies, biologics, and RNA based drugs. The Chemical Practice Committee, has the obligation to promote laws and policies that influence innovation in these areas. The previous chairs, Carol Nielsen, Jeffrey Townes and Bill Kezer, have implemented the groundwork to accomplish the goals set forth by this committee. To name a few, the Chemical Practice Committee created industry specific subcommittees, an international committee and a notable newsletter covering pertinent issues. In addition, the Chemical Practice Committee has fostered relationships with the USPTO and other governmental agencies to promote our policy goals. Together, we can work with AIPLA leadership to promote legislative changes. I invite you to consider the many avenues for you to make an impactful presence at AIPLA. Please join us by participation in subcommittees, advocacy through our newsletter and attendance in committee programs. Myself, Drew and Carol look forward to hearing from you.

Sincerely,

Roy Issac

Director, Intellectual Property Counsel

Allergan plc.

roy.issac@allergan.com

**Message from the incoming vice-chair, Drew Patty**



Dear Committee Members,

I'm excited to have the opportunity to work with Roy Issac and the rest of the leadership of this committee. I want to thank Carol Nielsen for her tireless leadership over the past four years! Working with her on programs over the past two years has been great fun. My major objectives over the next two years will be to help our committee maximize the value that is offered by, and our members maximize the value they actually receive from, the Chemical Practice Committee. If there is anything more I can do to help achieve these objectives, please let me know.

Best regards,

Drew Patty

## **Announcements**

### **Change of Committee Leadership**

At the 2018 Annual Meeting, we transitioned to a new leadership team, with Roy Isaac taking on the role of chair, and Drew Patty taking on the role of vice-chair, of the Chemical Practice Committee. Roy Isaac is the Director and IP Counsel to Allergan plc headquartered Dublin, Ireland, but with an office located in New Jersey.

Drew Patty, is the Team Leader of the Intellectual Property Group of McGlinchey Stafford, located in Baton Rouge Louisiana.



Please thank our outgoing Chair of the Chemical Practice Committee, Carol Nielsen, of Nielsen IP Law LLC (Houston, Texas) for her tireless dedication and leadership of the Chemical Practice Committee over the past five years and welcome our incoming Chair, Roy Isaac, and incoming Vice-Chair Drew Patty.

We look forward to growing the Chemical Practice Committee under the new leadership team!

## **2019 AIPLA Mid-Winter Institute**

Please join us at the upcoming 2019 AIPLA Midwinter Institute which 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 on Thursday, January 31, 2019 from 3:30-5:30 pm ET entitled **“Opinions and Pre-Litigation Due Diligence – Effectively Considering Joint and Contributory Infringement.”** The panel will be broken down into three sub-topics:

(1)***Issues and Considerations in Drafting Opinion of Counsel Involving Joint and Contributory Infringement*** presented by Dominick A. Conde, Venable Fitzpatrick, New York, NY;

(2)***Issues and Considerations in Pre-Suit Investigations and Due Diligence in Joint and Contributory Infringement Claims*** presented by Aaron Fahrenkrog, Robins Kaplan, Minneapolis, MN; and

(3)***Ethical Considerations in Pursuing Joint and Contributory Infringement Claims*** presented by Karen Boyd, Turner Boyd, LLP, Redwood City, CA

### **Abstract**

Induced infringement, joint infringement, and contributory infringement are theories often relied on by patent owners to prove that a defendant's allegedly infringing product infringes asserted method claims of a patent. These theories often arise in pharmaceutical Hatch-Waxman cases. This article reviews recent, significant case law behind all three theories and sets forth considerations for attorneys who are drafting opinion of counsel on induced, joint, and/or contributory infringement claims.

We look forward to seeing everyone at this interesting and thought provoking session!

## **2019 Spring Meeting**

For the AIPLA 2019 Spring Meeting in Philadelphia, PA May 15-17, 2019, the Chemical Practice Committee plans to hold a joint meeting with the Public Education Committee, where a panel presentation will address new developments in Inherency, Inherent Obviousness and Selection Inventions.

### **2018 Annual Meeting**

Our committee jointly hosted a CLE Educational Session with the Emerging Technologies Committee entitled **“Powering Our Future with The Future of Power: Emerging Trends in Energy Storage Technologies”** on Friday, October 26 from 3:30-5:30 PM. The panelists provided an overview of recent technological developments in the emerging area of energy storage, in particular, battery technologies. The panelists also discussed various patent prosecution strategies for developing a worldwide patent portfolio for protecting inventions in this emerging technical area. In particular, the panelists discussed considerations for drafting claims in this emerging area and strategies for addressing issues that may arise during prosecution of patent applications relating to energy storage technologies. The panelists then proceeded to present recent developments in licensing and joint venture activities and discussed various licensing and funding considerations when counseling clients regarding IP strategies in this developing technical field. The presentation was well received by the attendees and sparked a lively discussion between the panelists and attendees. A copy of the panelists’ presentation is available on the Chemical Practice Committee microsite.



**Helsinn v. Teva: Supreme Court Clarifies “On Sale” Bar Under 35 U.S.C §102**Wan Chieh (Jenny) Lee<sup>1</sup>

On January 22, 2019, the Supreme Court issued a unanimous opinion in *Helsinn v. Teva* confirming that the America Invents Act (“AIA”) did not change the “on sale” bar under 35 U.S.C. §102. The pre-AIA version of the patent statute stated that:

“A person shall be entitled to a patent unless... the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.” 35 U.S.C. §102(b) (2006 ed.) (*emphasis added*).

The enactment of the AIA in 2011 changed §102 of the patent statute to:

“A person shall be entitled to a patent unless... the claimed invention 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 claim invention.” 35 U.S.C. §102(a)(1)(*emphasis added*).

The question considered by the Supreme Court in *Helsinn v. Teva* is “[w]hether the sale of an invention to a third party who is contractually obligated to keep the invention confidential places the invention ‘on sale’ within the meaning of §102(a),” enacted by the AIA. See *Helsinn Healthcare, S.A., v Teva Pharm. USA, Inc.*, 586 U.S. \_\_\_ (2019). In the decision, the Supreme Court specifically considered whether addition of the statutory language “or otherwise available to the public” to §102(a) by the AIA altered the well-settled pre-AIA interpretation of the on-sale bar. See *id.* at \*1. The Supreme Court unanimously held that it did not. See *id.*

In this case, the patentee, Helsinn Healthcare S.A. (“Helsinn”), developed the drug Aloxi, which includes the active ingredient palonosetron, for treating chemotherapy-induced nausea and vomiting. On April 6, 2001, Helsinn entered into two agreements with a third-party:

- (1) a license agreement that granted the third-party the right to distribute, promote, market and sell 0.25 mg and 0.75 mg doses of palonosetron in the United States in exchange for upfront payments and future royalties on distribution of these doses; and
- (2) a supply and purchase agreement where the third-party agreed to purchase exclusively from Helsinn the 0.25 mg and 0.75 mg palonosetron products, or whichever of the two were approved by the FDA.

Under both agreements, the third-party was required to maintain any proprietary information confidential. However, the existence of these agreements, without any reference to specific dosage formulations covered by the agreements, were announced in a press release and reported in filings with the Securities and Exchange Commission (SEC). On January 30, 2003, which is more than two years after the execution date of these agreements, Helsinn submitted its first patent filing, a provisional patent application, for the 0.25 mg and 0.75 mg dosage formulations of palonosetron.

<sup>1</sup> Wan Chieh (Jenny) Lee is Counsel at Fay Kaplun & Marcin LLP based in New York, NY

The Supreme Court affirmed the Federal Circuit's finding that the April 2001 agreements qualified as a sale more than one year before Helsinn filed its provisional application, and is, therefore, prior art under §102(a) of the AIA, even though the third party was contractually obliged to keep the invention confidential. See *id.* at \*8-9. The Supreme Court emphasized that the patent statute has long included an on-sale bar and that there is a substantial body of case law extending over 20 years interpreting the meaning of the on-sale bar. See *id.* at \*1 and 5-6. The Supreme Court specifically cites to its pre-AIA precedent in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 67 (1998), which established that an invention was considered "on sale" if it met the two-prong test that "the product must be the subject of a commercial offer for sale" and "the invention must be ready for patenting" but did not require that the sale make the details of the invention available to the public. See *id.* at \*1 and 6. The Supreme Court also emphasized that the Federal Circuit, which has "exclusive jurisdiction" over patent appeals, "has long held that 'secret sales' can invalidate a patent." See *id.* at \*7. The Supreme Court explained that the AIA was enacted in 2011 against this backdrop of well-settled case law and, therefore, is presumed to have adopted the earlier (*i.e.*, pre-AIA) judicial construction of the on-sale bar. See *id.* The Supreme Court held that the statutory language "or otherwise available to the public" was added as a catchall phrase that "captures material that did not fit neatly into the statute's enumerated categories but is nevertheless meant to be covered," and was not sufficient to upset the well-settled judicial interpretation of the term "on sale" adopted in §102(a)(1) by the AIA. See *id.* at \*8.

The Supreme Court's decision in *Helsinn v. Teva* clarified that the body of pre-AIA case law interpreting the scope of the on-sale bar are to remain applicable under the AIA and settled the recent debate as to whether confidential sales can be available as prior art under the AIA. Therefore, it is important to continue to evaluate patent filing strategies before entering into any agreements with third parties that may be construed as a sale of the invention (*e.g.*, license agreement, supply agreement, marketing agreement, etc.) to avoid creating potential "secret sale" prior art under 35 U.S.C. §102(a)(1) against later patent filings.



**Combine the Label with Phase III Clinical Results and a Carefully Crafted, Mirroring US Patent Application to Achieve Longer Patent Exclusivity for US Bio/Pharm Patents: Strategic Considerations and Opportunities Raised by *Sanofi v. Watson***

by

Tom Irving, Michele Bosch, and Stacy Lewis<sup>1,2</sup>

**Decision:** *Sanofi v. Watson*, 875 F.3d 636 (Fed. Cir. 2017)

This case raises intriguing possibilities, particularly for the strategically-minded U.S. practitioner working closely with a client during Phase III clinical trials and who files a patent application that includes the Phase III results before those results are published.

**Background:**

The invention at issue in *Sanofi v. Watson*, was dronedarone, an antiarrhythmic agent directed towards the treatment of heart rhythm problems in patients with atrial fibrillation. The commercial embodiment prescribed in the U.S. is known as Multaq<sup>®</sup>.

Sanofi filed a patent application on a dronedarone composition in 1998, after which Sanofi conducted clinical trials for approximately a decade. The Phase III clinical trial results eventually led to (1) filing a priority application in France and an international application, which resulted in the U.S. patent at issue, 8,410,167, in 2009, and (2) FDA approval of Multaq<sup>®</sup>.

Sanofi originally filed a claim broadly reciting a method of treatment comprising administering dronedarone

I. A method of decreasing the risk of mortality, cardiac hospitalizations, or the combination thereof in a patient, said method comprising administering to said patient an effective amount of dronedarone or a pharmaceutically acceptable salt thereof, with food.

However, the specification, both in the U.S. and in France, strategically recited clinical study results, including contraindicated symptoms, severe heart failure dangers, and patient

<sup>1</sup> Tom Irving is a partner in the Washington, DC office of Finnegan. Michele Bosch is a partner in the Washington, D.C. office of Finnegan. Stacy is a law clerk with Finnegan.

<sup>2</sup> 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. 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.

cardiovascular risk factors. The Multaq<sup>®</sup> label similarly included all of those details in the clinical trial data section.

The issued version of claim I of Sanofi's '167 patent recited all those details as claim limitations:

A method of decreasing a risk of cardiovascular hospitalization in a patient, said method comprising administering to said patient an effective amount of dronedarone or a pharmaceutically acceptable salt thereof, twice a day with a morning and an evening meal, wherein said patient does not have severe heart failure, (i) wherein severe heart failure is indicated by: a) NYHA Class IV heart failure or b) hospitalization for heart failure within the last month; and (ii) wherein said patient has a history of, or current, paroxysmal or persistent non-permanent atrial fibrillation or flutter; and (iii) wherein the patient has at least one cardiovascular risk factor selected from the group consisting of:

- I. an age greater than or equal to 75;
- II. hypertension;
- III. diabetes;
- IV. a history of cerebral stroke or of systemic embolism;
- V. a left atrial diameter greater than or equal to 50mm; and
- VI. a left ventricular ejection fraction less than 40%.

At first blush, one skilled in U.S. patent law might readily conclude that such a lengthy patent claim passes muster under 35 U.S.C. §§ 102 and 103 but might wonder how the claim would succeed under the written description and enablement sections of §112(a). And how would anyone infringe, either directly or indirectly, such a lengthy patent claim? The answers follow.

The Multaq<sup>®</sup> label recited the clinical trial data, cross referencing the same in the label's Indications and Usage section:

Multaq<sup>®</sup> is indicated to reduce the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation (AF) [see Clinical Studies (14)]. (emphasis added)

Sanofi provided in Section 14 of the label results from the pivotal ATHENA trial and other clinical studies. In particular, Sanofi included results from the 2005-2008 large scale, pivotal outcome ATHENA clinical study, and also the EURIDIS, ADONIS, and ANDROMEDA clinical studies.

In later litigation, this ingenious label/patent application combination strategy trapped the generic manufacturers into proposing the same labeling for generic versions of Multaq<sup>®</sup>, ultimately sealing their fate for infringement purposes. On its way to victory, Sanofi had to clear a hurdle of convincing the court that its label provided a basis for showing a specific intent to induce infringement.

Outcome: The district court held that Sanofi's patents were valid<sup>3</sup> and that the generic label provided a basis for a finding of intentional encouragement of infringement and thus inducement to infringe. *Id.* at 644. "Watson and Sandoz 'kn[o]w that their proposed labels would actually cause physicians to prescribe dronedarone to patients with the cardiovascular risk factors claimed' and that 'such a use would infringe the '167 patent'." *Id.* at 644-45.

The Federal Circuit affirmed, finding that the label referred to the clinical studies. As noted above, the clinical studies set forth all the risk factors recited in the claims, and the Sanofi patent claim recited those risk factors. According to the Federal Circuit: "The content of the label in this case permits the inference of specific intent to encourage the infringing use." *Id.* at 646. "[T]he inference in the present case is based on interpreting the label's express statement of indications of use and the internally referred-to elaboration of those indications." *Id.*

The Federal Circuit, furthermore, highlighted: "[t]he reference to the Clinical Studies section (14) of the label expressly directs the reader to that section for elaboration of the class of patients for whom the drug is indicated to achieve the stated objective, i.e. reduced hospitalization. Section 14 leads with and features a subsection on the ATHENA study...[a]nd it is only the ATHENA subsection...that identifies a class of patients as having been shown to achieve reduced hospitalization from use of dronedarone...The label thus directs medical providers to information identifying the desired benefit for only patients with the patent-claimed risk factors.'" *Id.* at 645. (emphasis added)

Sanofi won, successfully quelling the generic challenge. Sanofi thus achieved the valuable result of 10 more years of patent exclusivity; the first patents relating to dronedarone expired in the middle of 2018, but the Federal Circuit upheld the '167 patent expiring in 2029!

The Federal Circuit found irrelevant the defendants' evidence of substantial non-infringing uses. In contrast to contributory infringement under 271(c), there is no such restriction on induced infringement under 271(b).

#### Prosecution Take-Aways

The *Sanofi v. Watson* patent claim might alarm U.S. patent drafters for its narrowness, with a concomitant fear of ease of designing around. This decision undercuts those causes of alarm in the context of (1) clinical trial results, (2) a properly drafted patent application setting forth the pivotal outcome of clinical trial(s), and (3) inclusion in the label of the results of the pivotal outcome clinical trials, as well as (4) reference to the pivotal outcome clinical trials in the Indications and Usage portion of the label. To the extent, as in *Sanofi v. Watson*, the generic/biosimilar manufacturer has to copy the label to obtain FDA approval, method-of-treatment claims that appear to be very narrow can defeat the generic/biosimilar manufacturers where the claim limitations are based on a U.S. patent specification that closely corresponds with the label language and the Phase III clinical trial results. And, of course, for this strategy to work in the U.S. the initial patent application loaded with all that clinical trial information must be filed BEFORE the clinical trial results become disabling prior art under 35 U.S.C. § 102(a) in the absence of any 102(b) exception(s).<sup>4</sup>

<sup>3</sup> Sanofi experienced no problems under any of 35 U.S.C. §§ 102, 103, and 112.

<sup>4</sup> And of course, the innovative pharma company will want to pursue drug substance and drug product claims.

Consider drafting claims based on a specification reporting results of Phase III clinical trials that will be included in the label and that will be referenced in the Indications and Usage portion of the label.

What Phase III results can you include in all of the patent specification, the clinical studies portion of the label, and the Indications and Usage portion of the label? Consider making the label a set of instructions to the physician to treat patients who satisfy all of the claimed method of treatment steps.

Will an alleged infringer be able to carve out the clinical studies and the Indications and Usage?

Early and frequent coordination between the patent arm and the regulatory arm of the NDA holder/reference product sponsor will help facilitate this strategy.

Carefully draft use codes to comply with FDA standards and to be of the same scope as the claimed method of treatment, as well as the results of the Phase III clinical studies.

Marshal support from the entire labeling—not just the indications and usage section—to support a use code that is not overly broad.

Keep in mind induced infringement of method of treatment claims when you draft the use code.

## USPTO Issues Interim Procedure to Request PTA Recalculation for an IDS Filed With a Safe Harbor Statement and a New Safe Harbor Form

Andrew B. Freistein<sup>1</sup>

### I. Summary

For years, the USPTO's patent term adjustment ("PTA") computer program has been unable to properly calculate PTA when an information disclosure statement ("IDS") had been filed with a 30-day safe harbor statement under 37 C.F.R. § 1.704(d), requiring patentees to request a PTA recalculation. As part of their effort to modernize their information technology systems, on November 2, 2018, the USPTO issued an interim procedure for patentees to request recalculation of the PTA based **solely** on their failure to recognize the safe harbor statement filed with an IDS.<sup>2</sup> The USPTO also introduced a new form for applicants to use in making a safe harbor statement when filing a new IDS.<sup>3</sup> The interim procedure went into effect on November 2, 2018.

### II. Patent Term Adjustment (PTA)

Under 35 U.S.C. § 154(b), a patentee is entitled to PTA in the event the issuance of a patent is delayed due to administrative delays during prosecution. In general, a patentee is entitled to PTA for the following reasons: (A) when the USPTO fails to take certain actions during the examination and issue process within specific time frames;<sup>4</sup> (B) when the USPTO fails to issue a patent within three years of the filing date;<sup>5</sup> and (C) when there are delays from interference or derivation proceedings, secrecy orders, or successful appellate review.<sup>6</sup>

However, there are many conditions and limitations on accruing PTA. In particular, 35 U.S.C. § 154(b)(2)(C) states that the period of adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to

<sup>1</sup> Andrew Freistein is a Partner with Wenderoth, Lind & Ponack, LLP in Washington, DC.

<sup>2</sup> "Interim Procedure", Federal Register, Vol. 38, No. 213, pp. 55102-55104 (November 2, 2018), available at: <https://www.govinfo.gov/content/pkg/FR-2018-11-02/pdf/2018-24004.pdf>

<sup>3</sup> Form PTO/SB/133, available at: <https://www.uspto.gov/sites/default/files/documents/sb0133.pdf>

<sup>4</sup> 35 U.S.C. 154(b)(1)(A)

<sup>5</sup> 35 U.S.C. 154(b)(1)(B)

<sup>6</sup> 35 U.S.C. 154(b)(1)(C)

conclude prosecution of the application”,<sup>7</sup> and [t]he Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.”<sup>8</sup>

The Director’s regulations are set forth in 37 C.F.R. § 1.704. Under § 1.704(c), there is a PTA reduction if an IDS is filed (1) after a notice of allowance or after an initial reply by the applicant, or (2) as a preliminary paper or as a paper after a decision by the Board or a Federal court that requires the USPTO to issue a supplemental Office Action.<sup>9</sup> There is also a reduction when a request for continued examination (“RCE”) is filed after a notice of allowance.<sup>10</sup>

### III. The 30-Day Safe Harbor Statement

However, there are some limited exceptions to these IDS reductions. § 1.704(d) provides that a paper containing only an IDS in compliance with §§ 1.97 and 1.98<sup>11</sup> will not be considered a failure to engage in reasonable efforts to conclude prosecution, if the IDS is accompanied by one of the statements set forth in § 1.704 (d)(1)(i) or (d)(1)(ii) (i.e., the “safe harbor statement”). Similarly, § 1.704(d) also provides that an RCE containing only a compliant IDS will not be considered a failure to engage in reasonable efforts to conclude prosecution, if the IDS includes the safe harbor statement.

A compliant safe harbor statement must state that “each item of information contained in the IDS:

(1) Was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the IDS; or

(2) Is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the IDS.”<sup>12</sup>

<sup>7</sup> U.S.C. § 154(b)(2)(C)(i)

<sup>8</sup> U.S.C. § 154(b)(2)(C)(iii)

<sup>9</sup> 37 C.F.R. §§ 1.704(c)(6), 1.704(c)(8), 1.704(c)(9) and 1.704(c)(10)

<sup>10</sup> 37 C.F.R. § 1.704(c)(12)

<sup>11</sup> 37 C.F.R. §§ 1.97 and 1.98 provide regulations on the timing (§ 1.97) and content (§ 1.98) requirements of filing an information disclosure statement.

<sup>12</sup> 37 C.F.R. § 1.704(d)(1)(i) and § 1.704(d)(1)(ii) (note that “the Office” is the USPTO)

#### IV. The Interim Procedure

The USPTO currently uses a computer program based upon the information recorded in their PALM system to calculate PTA. Unfortunately, the program cannot determine whether an IDS includes a compliant safe harbor statement. It simply treats the IDS as if the safe harbor statement is not included, and often treats the IDS as a failure to engage in reasonable efforts to conclude prosecution under § 1.704(c). To correct the PTA, Patentees must file a request for reconsideration in compliance with § 1.705, explaining why the PTA calculation is wrong, and pay the \$200 processing fee.<sup>13</sup>

The USPTO is developing new software, which recognizes the safe harbor statement. In the meantime, the new interim procedure permits a patentee to request recalculation of the PTA where the **only** reason for recalculation is the USPTO's failure to recognize a timely filed safe harbor statement accompanying an IDS. Under the interim procedure, the \$200 processing fee is waived, and patentee must submit form PTO/SB/134, "Request for Reconsideration of Patent Term Adjustment in View of Safe Harbor Statement Under 37 CFR 1.704(d)".<sup>14</sup> This procedure is effective as of November 2, 2018 and will remain in effect until the USPTO updates the PTA calculation computer program.

Notably, if the request for recalculation is not based solely on the USPTO's failure to recognize a timely filed compliant safe harbor statement, then the patentee must file a request for reconsideration under § 1.705 and pay the processing fee. Although the processing fee is waived under the interim procedure, any necessary extension of time fees are not waived.<sup>15</sup> Additionally, the interim procedure cannot be used as a basis to recover a previously paid processing fee filed with a request for reconsideration under § 1.705.<sup>16</sup>

<sup>13</sup> 37 C.F.R. § 1.705 and § 1.18(e)

<sup>14</sup> Form PTO/SB/134 is available at: <https://www.uspto.gov/sites/default/files/documents/sb0134.pdf>

<sup>15</sup> A request for reconsideration of PTA filed under § 1.705(b) is due within two months of the issue date of the patent and requires a \$200 processing fee under § 1.18(e). The two-month due date is extendable for up to five months with payment of an extension of time fee under § 1.136(a). Under the new interim procedure, the \$200 processing fee is waived, but the extension of time fees are not waived.

<sup>16</sup> Interim Procedure, Fed. Reg., vol. 38, no. 213, p. 55104, col. 2.

The Office of Petitions will manually review each request filed under the interim procedure and provide a recalculation. A patentee dissatisfied with the Office's recalculation is permitted to file one response within two months of the mail date of the Office's recalculation. The two-month deadline is not extendable.<sup>17</sup> If no response to the Office's recalculation is filed, then the USPTO will *sua sponte* issue a certificate of correction that reflects the Office's recalculation.<sup>18</sup>

If a dissatisfied patentee responds to the Office's recalculation and the USPTO maintains the recalculation, then a Director's decision will be issued confirming the recalculation. The Director's decision is appealable to district court..<sup>19</sup>

## V. New Form PTO/SB/I33

In order to assist the USPTO in recognizing when a compliant safe harbor statement accompanies an IDS, the USPTO has also created new form PTO/SB/I33 ("Patent Term Adjustment Statement Under 37 CFR 1.704(d)").<sup>20</sup> The USPTO will update the PTA computer program to recognize submission of the new form. Filing the new form is not mandatory, but it is "very strongly recommended", because the failure to use the form can result in the USPTO not recognizing a safe harbor statement accompanying an IDS.<sup>21</sup> Applicant may not alter form PTO/SB/I33 for submission.<sup>22</sup>

<sup>17</sup> *Id.* Under 35 U.S.C. § 154(b)(3)(B)(ii), a patentee is given one opportunity to request reconsideration of the PTA. Patentee's request for reconsideration to the Office of Petition's recalculation is the "one" opportunity.

<sup>18</sup> *Id.*

<sup>19</sup> *Id.* Under 35 U.S.C. § 154(b)(4), a patentee can appeal the Director's decision to the U.S. District Court for the Eastern District of Virginia within 180 days after the date of the Director's decision.

<sup>20</sup> Form PTO/SB/I33, available at: <https://www.uspto.gov/sites/default/files/documents/sb0133.pdf>

<sup>21</sup> Interim Procedure, Fed. Reg., vol. 38, no. 213, p. 55104, cols. 2-3.

<sup>22</sup> *Id.* at col. 3.



## **Novartis v. Ezra and Novartis v. Breckenridge: Cracks in the Armor of ODP Portending Well for Innovative Pharma?**

By Adriana Burgy, Tom Irving and Stacy Lewis<sup>1,2</sup>

### **Introduction**

The Federal Circuit issued decisions in *Novartis AG v. Ezra Ventures LLC*, -- F.3d \_\_\_, 2018 WL 6423564 (CHEN, Moore, Stoll) and *Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical*, -- F.3d \_\_\_, 2018 WL 6423451 (CHEN, Prost, Wallach) on Dec. 7, 2018. Both cases address obvious-type double patenting (“ODP”) issues that arise out of timings relative to the Uruguay Round Agreements Act of 1994 (hereafter “GATT”).<sup>3</sup> And, as we shall see, both decisions are in favor of the patent owner, Novartis.

### **Background**

In *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014), the Federal Circuit held that a later-issued but earlier-expiring patent could qualify as a double patenting reference against an earlier-issued but later-expiring patent if the claims of the two patents are not patentably distinct. The court focused on expiration dates and the policy objective that at the expiration of a patent, the public has a right to use the invention claimed. The Court in *Gilead* explained that the expiration date “guarantees a stable benchmark that preserves the public’s right to use the invention ... when that patent expires.”<sup>4</sup>

### **Ezra**

In *Novartis v. Ezra*, the Federal Circuit addressed whether a second-filed, second-issued patent can be asserted as an ODP reference against a first-filed, first-issued patent where the statutorily defined patent terms are different due to pre-URAA and post-URAA status and a patent term extension.

Timelines from the decision:

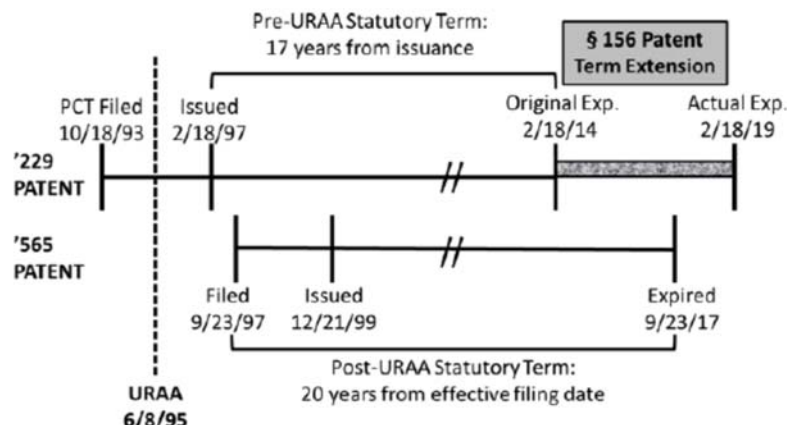
<sup>1</sup> Adriana Burgy is a partner in the Washington, DC office of Finnegan. Tom Irving is a partner in the Washington, DC office of Finnegan. Stacy Lewis is called to the New York bar and works as a law clerk with Finnegan.

<sup>2</sup> 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. 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.

<sup>3</sup> The Uruguay Round Agreements Act (URAA) of 1994 was enacted as part of a larger multilateral treaty called the General Agreement on Tariffs and Trade (GATT). The URAA changed the U.S. patent term to 20 years from the earliest effective non-provisional filing date. Before the URAA, the U.S. patent term was 17 years from issuance. When the URAA was enacted, there was provision for a transition period when patent owners could choose the longer of 17 years from issuance or 20 years from filing. See Uruguay Round Agreement Act, Pub. L. No. 103-465, 108 Stat. 4809, 4983 (1994), amending 35 U.S.C. § 154.

<sup>4</sup> *Gilead*, 753 F.3d at 1216. That policy, of course, has limits not before the Court in *Gilead*. First, any patents issuing from divisional applications filed in response to a restriction requirement are protected from a finding of ODP under a safe harbor if consonance of the restriction requirement is maintained. 35 U.S.C. § 121. Also, it has long been known in the U.S. patent system that a second-expiring patent that is patentably distinct from a first-expiring patent does not improperly extend the term of the first expiring patent, irrespective of whether pre-GATT or GATT applies. See e.g., *UCB, Inc. v. Accord Healthcare, Inc.*, 890 F.3d 1313 (Fed. Cir. 2018), where the claims to a later-expiring species were held patentably distinct from an earlier-expiring genus.

Timelines from the decision:



Novartis' patent, U.S. 5,604,229, was filed before the June 8, 1995, effective date of the URAA (pre-GATT in this article, whereas any patent filed on or after the effective date of URAA, including U.S. Patent 6,004,565, is referred to as GATT in this article). As such, the '229 pre-GATT patent had a patent term of 17-years from issue, and the original expiration date was Feb. 18, 2014. Novartis was awarded a patent term extension (PTE) of 5 years under 35 U.S.C. §156 to extend the expiration date of the '229 patent, at least for certain claims, to Feb. 18, 2019. The '229 pre-GATT patent claimed compounds, including fingolimod, a component of the Gilenya<sup>®</sup> drug commercially marketed in the U.S.

Novartis sued Ezra for infringement of the '229 patent after Ezra filed an ANDA to market a generic version of Gilenya<sup>®</sup>. Novartis also held a GATT patent related to Gilenya<sup>®</sup>, U.S. 6,004,565, claiming a method of administering fingolimod. The '565 GATT patent issued from an application filed after the effective date of the URAA, so its patent term was 20-years from filing. The '565 GATT patent expired on Sept. 23, 2017, after the original expiration of the '229 pre-GATT patent but before the PTE of the '229 pre-GATT patent is to expire on February 18, 2019.

Ezra argued that the '229 pre-GATT patent should at least be terminally disclaimed past the expiration date of the '565 patent. That would have resulted in a loss of PTE for the '229 pre-GATT patent.

Novartis relied on footnote 6 from the *Gilead* case to support their arguments that there was no need to disclaim the '229 pre-GATT patent back to the September 23, 2017, expiration date of the '565 GATT patent.

Footnote 6 said that there are exceptions to the pre-GATT rule that later-issued patents expired later, such as in the case of a patent that qualifies for term extension. *Gilead v. Natco*, 753 F.3d at 1215, n6. And since the patent term extension was obtained by adherence to the relevant law and procedures, the extension beyond September 23, 2017 was, according to Novartis, a justified extension. Ezra argued that in *Novartis* should not be allowed to extend the '229 pre-GATT patent's claims beyond the expiration of the '565 GATT patent's method claims because that effectively extended the '565 GATT patent in contravention of 35 U.S.C. §156, which limits PTE to one patent.

Agreeing with Novartis, Judge Stark in the District Court of Delaware relied on the Federal Circuit's analysis of the legislative history for 35 U.S.C. § 156 to decide that Congress left the choice of which single patent term to extend in the hands of the patent owner. *Merck & Co. v. Hi-Tech Pharma. Co.*, 482 F.3d 13717, 1323 (Fed. Cir. 2007). Judge Stark accepted as a given that this flexibility legally allowed for the "de facto" extension of the second issued '565 GATT patent due to patent term extension of the first to issue, i.e., the '229 pre-GATT patent. Judge Stark entered a judgment finding the '229 pre-GATT patent valid, unexpired, enforceable, and infringed.

As we predicted in our article of July 26, 2018, after the oral argument,<sup>5</sup> the Federal Circuit held in favor of Novartis. And also, in doing so, the *Ezra* Federal Circuit upheld Judge Stark's decision to honor a patent owner's choice of which patent term to extend:

[N]othing in the statute restricts the patent owner's choice for patent term extension among those patents whose terms have been partially consumed by the regulatory review process. Importantly, Congress did not, through §156, compensate a loss of term for all patents affected by regulatory review. In striking a balance between the competing interests of new drug developers and low-cost generic competitors, Congress limited a PTE grant for such a patent owner to only one of its patents

*Id.* at \*4.

Any "effective" extension of the '565 GATT patent is a "permissible consequence of the legal status conferred upon the '229 pre-GATT patent by § 156." *Id.* The Federal Circuit quoted its decision in *Merck v. Hi-Tech*:

Congress chose not to limit the availability of a patent term extension to a specific patent and instead chose "a flexible approach which gave the patentee the choice." 482 F.3d at 1323. As long as the requirements for a patent term extension recited

<sup>5</sup> Bruneel, Lewis, and Irving, "ODP: Cracks in the Armor? An Alert regarding the pending Breckenridge and Ezra Federal Circuit Appeals," (July 26, 2018), <https://www.finnegan.com/en/insights/blogs/prosecution-first/odp-cracks-in-the-armor-an-alert-regarding-the-pending-breckenridge-and-ezra-federal-circuit-appeals.html>

in § 156(a) are met, the Director of the Patent and Trademark Office “shall” grant a PTE on the patent of patentee's choice. See 35 U.S.C. § 156(e)(1).

*Id.*

Furthermore, “as a logical extension” of *Merck*, ODP “does not invalidate a validly obtained PTE[.]” “[I]f a patent, under its pre-PTE expiration date, is valid under all other provisions of law, then it is entitled to the full term of its PTE.” *Id.* at \*5.

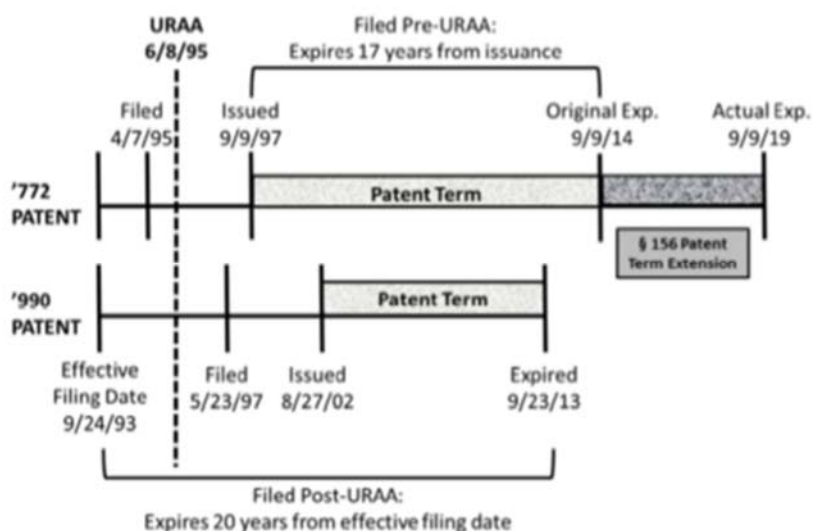
Significantly, the Federal Circuit in *Ezra* also noted that “agreeing with *Ezra* would mean that a judge-made doctrine [ODP] would cut off a statutorily-authorized time extension.” *Id.* at \*6. It “decline[d] to do so.” *Id.*

### **Breckenridge**

In *Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical*, Judge Andrews in the District of Delaware, held that a later-filed, earlier-expiring, GATT patent could serve as an ODP reference to invalidate a first-filed, later-expiring pre-GATT patent and thus deny that pre-GATT patent from enjoying a full seventeen-year term from issuance.

Novartis' patent, 5,665,772 was filed pre-GATT, and expired 17 years from issuance, on September 9, 2014, as shown below in the timeline. Due to a five-year PTE, the '772 pre-GATT patent's term expires, for at least certain claims, on September 9, 2019. The asserted invalidating reference, Novartis's GATT patent, U.S.6,440,990, was filed after, and issued after the '772 pre-GATT patent, but expired before the '772 pre-GATT patent. Both patents claimed the same priority date. Because of GATT, the lifespan of the '772 pre-GATT patent encompasses and extends beyond that of the '990 GATT patent, even without considering the PTE.

Judge Andrews, relying on *Gilead v. Natco*, *supra*, found that the '990 patent was a proper double patenting reference for invalidating the '772 patent (see schematic below from Federal Circuit decision).



At the Federal Circuit oral argument, the Judges asked “Isn’t this *Gilead*?” Novartis pointed to footnote 6 of *Gilead* where the Court said the public’s right to practice the expired patent may be further limited by some other means established by Congress, such as a patent term extension. Novartis also emphasized the idea that this would not be an unjust extension, pointing out that PTE is authorized by statute.

As predicted in our July 2018 article, *supra*, the Federal Circuit reversed the district court decision:

[O]ur opinion [in *Gilead*] was limited to the context of when both patents in question are post-URAA patents. ... Here we have one pre-URAA patent (the '772 patent) and one post-URAA patent (the '990 patent), governed by different patent term statutory regimes. Our decision in *Gilead* thus does not control the present situation. Instead, the correct framework here is to apply the traditional obviousness-type double patenting practices extant in the pre-URAA era to the pre-URAA '772 patent and look to the '772 patent's issuance date as the reference point for obviousness-type double patenting. Under this framework, and because a change in patent term law should not truncate the term statutorily assigned to the pre-URAA '772 patent, we hold that the '990 patent is not a proper double patenting reference for the '772 patent. Accordingly, we reverse.

*Id.* at \*2.<sup>6</sup>

According to the Federal Circuit, its *Gilead* reasoning was “rooted in the consequences that flow from the implementation of the URAA's new patent term rule under which a patent expires 20 years from the effective filing date[.]” *Id.* at 6. In this [*Breckenridge*] case, the order of expiration of the patents is by operation of statute; there was no “patent prosecution gamesmanship.” *Id.*

The Federal Circuit also distinguished its decision in *AbbVie, Inc. v. Mathilda & Terence Kennedy Institute of Rheumatology Trust*, 764 F.3d 1366 (Fed. Cir. 2014), which, like *Gilead*, involved two post-URAA patents and where the earlier-filed patent had an earlier issuance date and earlier expiration date. In *Breckenridge*, as shown in the schematic above, there was, in contrast, one pre-GATT patent and one GATT patent. And the earlier filed pre-GATT patent had an earlier issuance date but, in contrast, a later expiration date.

Using the pre-URAA ODP framework, the '772 patent issued before the '990 patent. Therefore, the '990 could not exist as a double patenting reference against the '772 patent.

The Federal Circuit concluded:

<sup>6</sup>Note that, as shown in the schematic above, the '990 GATT patent issued **AFTER** the '772 patent.

The fact that the law for the term of a patent changed, resulting in the later-issued '990 patent having an earlier expiration date than it would have pre-URAA, should not affect the '772 patent's statutorily-granted 17-year patent term. Rather than Novartis receiving a windfall with a 17-year term for its '772 patent, its '990 patent's term was truncated by the intervening change in law. To find that obviousness-type double patenting applies here because a post-URAA patent expires earlier would abrogate Novartis's right to enjoy one full patent term on its invention.

*Id.* at \*8.<sup>7</sup>

### Conclusion

The Federal Circuit decisions, *Ezra* and *Breckenridge*, both authored by Judge Chen and issued on the same day, came out strongly in support of honoring the patent term awarded by statute to the patent owner. The decisions clarified that *Gilead's* and *AbbVie's* focus on expiration dates in the ODP analysis are restricted to situations involving patents filed post-GATT. We shall see if a future Federal Circuit, perhaps *en banc*, ultimately abrogates the ODP rulings in *Gilead* and *AbbVie*.

<sup>7</sup>Note, Novartis' patent also survived an IPR challenge by Breckenridge, IPR2016-00084, Paper 73 (P.T.A.B. Jan. 11, 2018).

## A Glimpse into China's Progress on Introducing Supplementary Patent Certificates, Patent Linkage and New Data Protection

Xiaoyang Yang<sup>1</sup> and Michael Lin<sup>2</sup>

In April 2017, Chinese Premier Li Keqiang indicated in an executive meeting of the State Council China's resolution to strengthen intellectual property protection and to make available supplementary patent certificates (hereinafter the "SPC") and data protection to innovative drug.<sup>3</sup> In May 2017, the National Medical Products Administration (hereinafter the "Administration", formerly China Food and Drug Administration) issued *Announcement on the Policies for Encouraging Innovation in Drugs and Medical Devices and Protecting the Rights and Interests of Innovators (draft for public comment)* (hereinafter the "Announcement"), proposing a general framework of patent linkage and a new data protection regime.<sup>4</sup>

More than one year has passed since the speech of Premier Li Keqiang and the Administration's *Announcement*. Below is a glimpse into the status of each of SPCs, patent linkage and data protection on their way to being realized.

### Supplementary Patent Certificates (SPCs)

On January 4, 2019, the Standing Committee of the National People's Congress (hereinafter the "SCNPC") released the draft amendments to the Chinese *Patent Law* for public comment.<sup>5</sup> Article 43 of the draft amendments allows for SPC, and provides that innovative drugs introduced to the Chinese market concurrently with overseas market could be eligible for a maximum of five-years extension to the patent term, wherein the remaining patent term after the extension should be no greater than fourteen years.<sup>6</sup>

It is likely that the draft amendments would be reviewed by the SCNPC at least once more, and so it remains to be seen whether the SPC provisions will be sustained and/or revised.

<sup>1</sup>Xiaoyang Yang is a Canadian barrister and solicitor, Chinese patent attorney, and associate at Marks & Clerk (Beijing).

<sup>2</sup>Michael Lin is a partner and manager of the Life Sciences group in Marks & Clerk's Hong Kong and Beijing offices. He is an Ohio attorney and U.S. patent attorney.

<sup>3</sup>"Li Keqiang Chaired Executive Meeting of State Council: Determining to Develop 'Internet+ Medical and Health' Measures", official website of Central Government: [http://www.gov.cn/guowuyuan/2018-04/12/content\\_5282000.htm](http://www.gov.cn/guowuyuan/2018-04/12/content_5282000.htm).

<sup>4</sup>"Notice of the Administration's Call for Public Comment on *Announcement on the Policies for Encouraging Innovation in Drugs and Medical Devices and Protecting the Rights and Interests of Innovators (draft for public comment)* (No. 55 of 2017)", official website of Administration: <http://www.nmpa.gov.cn/WS04/CL2101/228871.html>.

<sup>5</sup>"Draft Amendments to Patent Law Calling for Public Comment", official website of National People's Congress: [http://www.npc.gov.cn/npc/flcazqyj/2019-01/04/content\\_2070155.htm](http://www.npc.gov.cn/npc/flcazqyj/2019-01/04/content_2070155.htm).

<sup>6</sup>A comparison chart highlighting the major amendments is accessible through the website of Patent Protection Association of China: <http://www.ppac.org.cn/notice/detail-40.html>.



## Patent Linkage

On December 29, 2018, the National Health Commission issued a notification relating to supply and use of generic drugs, confirming that the government may introduce patent linkage.<sup>7</sup> However, the notification appears to be somewhat cautious when mentioning patent linkage, merely stating that the government will “gradually explore a patent linkage system”.<sup>8</sup> However, the draft amendments to the *Patent Law* released on January 4, 2019 do not mention patent linkage.

Thus far documents published by the government have only described the patent linkage system at a high level, perhaps providing for a stay of marketing approval of no greater than 24 months.<sup>9</sup> The government has indicated<sup>10</sup>:

*Where an applicant challenges a relevant patent of a drug, the applicant shall declare non-infringement of the relevant patent and notify the patentee thereof within 20 days from the date of his application for marketing approval. Where the patentee believes his patent is infringed, the applicant shall bring an infringement action at the judiciary within 20 days from receiving the applicant's notification and notify the Drug Administrative Department. The Drug Administrative Department may issue a stay of approval of no greater than 24 months. During the stay, the Drug Administrative Department shall continue to review the applicant's application for marketing approval. Where the applicant and the patentee settle or the judiciary renders a decision of infringement or non-infringement during the stay, the Drug Administrative Department shall determine whether to grant marketing approval accordingly. Where the judiciary does not render a decision during the stay, the Drug Administrative Department may grant marketing approval. Where an applicant does not identify any relevant patent and a patentee brings an infringement action, the Drug Administrative Department may issue a stay depending on the finding of the judiciary. Where an intellectual property dispute arises from the marketing of a drug, the decision of the judiciary shall prevail.*

There is a lack of clarity as to how this proposed regime would be implemented in actual practice. For instance, it is unclear as to whether the term “challenge” refers to an invalidation proceeding before the Patent Re-examination Board.<sup>11</sup> Also, the current *Patent Law* does not appear to provide for a cause of action for the patentee's infringement action.<sup>12</sup> This is because, pursuant to Art. 69(5) of the *Patent Law*, “for the purpose of providing information needed for the regulatory examination and approval... mak[ing], us[ing] or import[ing] a patented medicine” does not constitute infringement. The draft amendments to the *Patent Law* do not specifically address this issue.

<sup>7</sup>Notification No. 53 of 2018, official website of National Health Commission: <http://www.nhc.gov.cn/tigs/s7848/201812/8311038726604686a9e91832c81584b4.shtml>.

<sup>8</sup>*ibid.*

<sup>9</sup>*Supra*, note 2.

<sup>10</sup>*ibid.*

<sup>11</sup>“Significant Policy is Coming in Pharmaceutical Sector: You Know about Chinese Patent Linkage System?”, King&Wood: <https://www.chinalawinsight.com/2018/05/articles/intellectual-property/>

<sup>12</sup>*ibid.*



The Administration has also published a *Catalogue of Marketed Drugs* including 131 drugs as of December 29, 2017, which is called the “Chinese Orange Book”.<sup>13</sup> It has been said that this catalogue will be continuously updated, and an online database has been established therefor.<sup>14</sup>

### Data Protection

There is currently a six-year protection term for “previously undisclosed experimental data and other data on a drug containing a new chemical ingredient”, pursuant to Art. 34 of the *Implementing Measures of the Drug Administration Law*.<sup>15</sup>

In May 2017, the Administration proposed a new regime for data protection, differentiating among different types of drugs and extending the protection term to a maximum of 10 years<sup>16</sup>:

Drug	Protection Term	Note
innovative new drug	6 years	Full protection term is also given to drugs on which market introduction and data protection are applied for within one year of their being approved for marketing in Europe, United States or Japan.
innovative therapeutic biologics	10 years	
innovative rare-disease/paediatrie drug	10 years	
improved rare-disease/paediatrie drug	3 years	
a drug for which a patent challenge is successful or a first generic in China	÷ ↓	
based on a drug marketed abroad	1.5 years	

About one year later, the Administration published the *Implementing Regulations for Experimental Data Protection of Drugs* (provisional version, draft for public comment), and proposed a protection regime that somewhat differs from the 2017 version:<sup>17</sup>

<sup>12</sup>*ibid.*

<sup>13</sup>“Notification of Administration on Publishing *Catalogue of Marketed Drugs* (No. 172 of 2017), official website of Administration: <http://samr.cfda.gov.cn/WS01/CL0087/220786.html>.

<sup>14</sup>Online Database of *Catalogue of Marketed Drugs*: <http://202.96.26.102/index/lists>.

<sup>15</sup>*Implementing Measures of the Drug Administration Law*, full text available at official website of Administration: <http://www.nmpa.gov.cn/WS04/CL2173/300567.html>.

<sup>16</sup>*Supra*, note 2.

<sup>17</sup>“Call for Public Comment on *Implementing Regulations for Experimental Data Protection of Drugs* (provisional version, draft for public comment)”, official website of Administration: <http://www.nmpa.gov.cn/WS04/CL2051/227856.html>.

Drug	Protection Term	Note
innovative new drug	6 years	Full protection term is only given to drugs for which clinical trials are conducted in China (solely or as a part of an international multicenter clinical trial) or market introduction is applied for concurrently with other countries/regions.
innovative therapeutic biologics	12 years	Protection based on new indication approval.
rare-disease/ <u>paediatric</u> drug	6 years	N/A
a drug for which a patent challenge is successful	protection term unspecified	

A comparison of the two proposed protection regimes suggests that the latest thoughts of the Administration appear to be to encourage the drug industry to conduct clinical trials and introduce new drugs in China.<sup>18</sup>

Also, the 2017 regime provides for a 1.5-year protection term for a generic drug for which a patent challenge is successful, whereas the 2018 regime does not specify the protection term in such a scenario. It is likely that this protection term will not be specified until the detailed provisions of the patent linkage system are set forth.

Further, the 2017 regime differentiates between innovative and improved rare-disease/paediatric drugs, whereas the grant of protection to these drugs in the 2018 regime is based on whether their indications are new.

It should be noted that amendments to the *Drug Administration Law* are currently pending, and it remains to be seen whether such amendments would have any impact on the current/proposed data protection regime.

<sup>18</sup> “Draft of Data Exclusivity Rules Released by CFDA”, China IPR: <https://chinaipr.com/2018/04/26/draft-of-data-exclusivity-rules-released-by-cfda/>.

## **AIPLA Chemical Practice Committee Leadership And Contact Information**

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Roy P. Issac, Ph.D., J.D.  
Allergan PLC  
roy.issac@allergan.com

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R. Andrew Patty II  
McGlinchey Stafford, PLLC  
dpatty@mcglinchey.com

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Carol Neilsen  
Neilsen IP Law LLC  
carol@neilsenipaw.com

### **Pharmaceutical Subcommittee**

Kimberly Braslow  
AstraZeneca  
kim.braslow@astrazeneca.com

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

Andrina Zink  
Alkermes  
Andrina.zink@alkermes.com

### **Materials Science and Natural Resource Technologies Subcommittee**

Marcus S. Simon  
Dorsey & Whitney LLP  
simon.marcus@dorsey.com

### **Law Student Subcommittee**

Jill A. Hecht  
University of Houston Law Center  
jahecht@central.uh.edu

Jorge Zamora  
University of Houston Law Center  
jazamora4@central.uh.edu

### **Newsletter Subcommittee**

Dolly Kao  
Kao IP  
Dolly@kaoip.com

Wan Chieh (Jenny) Lee  
Fay Kaplun & Marcin, LLP  
jlee@fkmiplaw.com

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Thomas L. Irving  
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP  
tom.irving@finnegan.com

Thomas J. Engellenner  
Pepper Hamilton LLP  
engellennert@pepperlaw.com

Beatriz San Martín  
fieldfisher  
beatriz.sanmartin@fieldfisher.com

### **Microsite Subcommittee**

Wan Chieh (Jenny) Lee  
Fay Kaplun & Marcin, LLP  
jlee@fkmiplaw.com

### **International Education**

Matthew Barton  
Forresters  
mbarton@forresters.co.uk

Toby Mak, Ph.D.  
Tee & Howe Intellectual Property Attorneys  
toby.mak@teehowe.com