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# THE SEDONA CONFERENCE

# *Commentary on Patent Litigation Best Practices: Biopharma Litigation Chapter*

A Project of The Sedona Conference
Working Group 10 on Patent Litigation Best Practices (WG10)

OCTOBER 2021 PUBLIC COMMENT VERSION
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The Sedona Conference

# The Sedona Conference Commentary on Patent Litigation Best Practices: Biopharma Litigation Chapter

## A Project of The Sedona Conference Working Group on Patent Litigation Best Practices (WG10)

OCTOBER 2021 PUBLIC COMMENT VERSION


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# Preface

Welcome to the October 2021 Public Comment Version of The Sedona Conference *Commentary on Patent Litigation Best Practices: Biopharma Litigation Chapter*, a project of The Sedona Conference Working Group on Patent Litigation Best Practices (WG10). This is one of a series of Working Group commentaries published by The Sedona Conference, a 501(c)(3) research and educational institute dedicated to the advanced study of law and policy in the areas of antitrust law, complex litigation, and intellectual property rights. The mission of The Sedona Conference is to move the law forward in a reasoned and just way.

WG10 was formed in late 2012 under the leadership of its now Chair Emeriti, the Honorable Paul R. Michel and Robert G. Sterne, and led from 2014 to 2017 by Chair Emeritus Gary Hoffman. The Sedona Conference and the entire patent litigation community owe them a great debt of gratitude. The mission of WG10 is "to develop best practices and recommendations for patent litigation case management in the post-[America Invents Act] environment." The Working Group consists of approximately 200 active members representing all stakeholders in patent litigation.

The WG10 Biopharma Litigation drafting team was launched in 2016, and the draft *Biopharma Litigation Chapter* was a focus of dialogue at the WG9/WG10 Joint Midyear Meeting in Pasadena in February 2016, the WG9/WG10 Joint Annual Meeting in Houston in February 2017, the WG9/WG10 Joint Annual Meeting in Philadelphia in March 2019, and the WG9/WG10 Joint Online Annual Meeting in November 2020.

This *Chapter* represents the collective efforts of many individual contributors. On behalf of The Sedona Conference, I thank in particular the Editors-in-Chief for this *Chapter*, Teresa Rea and Matthew Powers, and the Chapter Editors Deborah Fishman, Philip S. Johnson, and Steven Lieberman, who have led this drafting process and have reviewed the comments received through the Working Group Series review and comment process. I also thank everyone else involved for their time and attention during the drafting and editing process, including Paul Ehrlich, Nicholas P. Groombridge, R. Eric Hutz, Josephine Liu, Jennifer P. Nock, Erik J. Olson, Matthew A. Pearson, and Maureen L. Rurka.

The Working Group had the benefit of candid comments by the Honorable Stanley R. Chesler, the Honorable Sue Robinson (ret.), and the Honorable Leda Dunn Wettre, who are serving as Judicial Advisors for this *Biopharma Litigation Chapter*. The statements in this Commentary are solely those of the nonjudicial members of the Working Group; they do not represent any judicial endorsement of the recommended practices.

Please note that this version of the *Biopharma Litigation Chapter* is open for public comment through January 31, 2022, and suggestions for improvements are welcome. After the deadline for public comment has passed, the drafting team will review the comments and determine what edits are appropriate for the final version. Please send comments to comments@sedonaconference.org or fax them to 602-258-2499.

The *Chapter* will be regularly updated to account for future significant developments impacting this topic. The Sedona Conference hopes and anticipates that the output of its Working Groups will evolve into authoritative statements of law, both as it is and as it should be.

Craig W. Weinlein
Executive Director
The Sedona Conference
October 2021

# *Foreword*

Patent litigators have always recognized differences between the biopharma and high-tech industries. The scientific unpredictability of the art and regulatory requirements to make and sell biopharma products have always set the biopharma industry apart. The vehicle for patent dispute resolution for biosimilars (large-molecule, biologic products that are made in and from living organisms) is governed by the Biologic Price Competition and Innovation Act of 2011 (BPCIA), while litigation for generic drugs (small-molecule, chemically synthesized drugs) and the Abbreviated New Drug Application (ANDA) process is set forth in the Hatch-Waxman Act of 1984. These FDA regulatory frameworks impact a number of aspects of generic drug or biosimilar patent litigation, including the protective order, access to FDA filings as well as disclosure of FDA correspondence, the timing of litigation, as well as the available remedies. These distinguish biosimilar patent litigation and generic drug patent litigation from each other and, in particular, from litigation of high-tech patents that are not subject to any comparable legislative regime.

This *Commentary on Patent Litigation Best Practices: Unique Aspects of Biopharma Patent Litigation Chapter* provides Best Practice recommendations to counsel, parties, and the courts on how to navigate the relevant statutes and unique landscape involved in biopharma litigation. This *Chapter* does not cover all aspects of biopharma patent litigation, but rather focuses primarily on those aspects where biopharma patent litigation differs from other types of patent litigation. It primarily focuses on biosimilar and generic drug patent litigation and provides case management Best Practice recommendations to permit the full and fair presentation of all substantive issues by both branded and generic/biosimilar parties.

For branded versus branded (i.e., innovator versus innovator) biologics litigation, there are a number of unique substantive patent law issues and case management issues that may arise, but for purposes of this *Chapter*, we have focused primarily on providing consensus Best Practice recommendations for the unique issues that arise in case management of requests for injunctive relief.[1] This *Chapter* does not focus on branded versus branded small-molecule drug litigation, simply because it is not prevalent.[2]

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1 Some other substantive issues that have unique applications in branded biologics litigation include claim scope, Section 112 issues, doctrine of equivalents infringement, Section 271(e)(1) as a defense to infringement, among others, but this *Chapter* does not address these because WG10 was not able to bring any Best Practice recommendations to consensus.

2 There are a number of reasons for this, including differences in patent coverage, regulatory exclusivities, and pricing. The composition-of-matter patents that typically protect small molecule drugs are much less likely to cover a different, independently developed small molecule drug than in the biologics space, where both composition-of-matter and manufacturing patents may be infringed by separately developed and differentiated biologics. In addition, regulatory exclusivity on a new chemical entity is relatively short in comparison to biologic regulatory exclusivity, and once generic competition enters the market, pricing is much more competitive for small molecule generic drugs than for biosimilar therapeutics. As a consequence, there is a disincentive for an innovator small molecule company to separately develop a similar drug (similar enough to fall within the scope of patent coverage) and seek separate regulatory approval for that drug when there is less time on market in the absence of potential generic competition to recoup that investment.

Biopharma patent litigation often involves antitrust issues, particularly in the settlement of biosimilar and small-molecule generic drug litigation, but antitrust issues are outside the scope of this *Chapter*.

The editors would like to express their appreciation to the members of the drafting team, including the Honorable Stanley R. Chesler, the Honorable Sue Robinson and the Honorable Leda Dunn Wettre, who served as judicial advisors for this effort. The drafting team included members from a variety of perspectives and interests, and their insight and persistence in driving this *Chapter* to completion is appreciated.

Matthew Powers
Chair, Working Group 10 Steering Committee

Teresa Rea
Vice-Chair, Working Group 10 Steering Committee

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Philip S. Johnson
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# *Biopharma Litigation Best Practices "At a Glance"*

# I. Introduction

Biologic and pharmaceutical patent litigation differ from other types of patent litigation in important ways. Most significantly, generic drugs and biosimilar therapeutics are reviewed and approved under regulatory frameworks—the Hatch-Waxman Act governing the Abbreviated New Drug Application (ANDA) process and the Biologics Price Competition and Innovation Act (BPCIA) governing the Abbreviated Biologics License Application (aBLA) process—that include specific provisions for resolving patent disputes between the original NDA/BLA holders (i.e., the reference product manufacturers or branded companies) and the ANDA/aBLA holders (i.e., the generic or biosimilar manufacturers). The interplay between these regulatory frameworks and patent litigation creates unique substantive and case management issues that are explored in this *Commentary on Patent Litigation Best Practices: Unique Aspects of Biopharma Patent Litigation Chapter*.

While many issues of substance and case management in biopharma patent cases are handled similarly to other litigated technologies, this *Chapter* focuses on those issues that are unique to or take on special significance in biopharma patent litigation. For starters, while the pleadings standards for biopharma patent cases are the same as non-biopharma patent cases, the consequences of a motion to dismiss may have profound reverberations in terms of statutory remedies in the generic drug/ANDA context in particular. Likewise, this *Chapter* considers unique discovery issues that arise in generic drug/ANDA and biosimiliar/BPCIA cases, including how to protect and disclose a substantial amount of information before any lawsuit is filed. Likewise, patent challenges before the Patent Trial and Appeal Board and concomitant requests for stay, which have become a normal fixture in patent litigation in recent years, have unique reverberations in the context of generic or biosimilar patent cases that, by statute, are designed to be litigated within a set period of time.

Biologic and pharmaceutical patent litigations also frequently call on courts to balance the public's interest in encouraging and rewarding the discovery and development of new drugs and biologics against that of making differentiated, life-altering, or life-sustaining therapies available to patients who may benefit from them. Not only are these public interest injunction issues relatively rare in other patent litigation, but their prevalence in biotherapeutic patent litigation has important case management implications, which we explore further in this *Chapter*.

This *Chapter* provides a framework for analysis of this complicated area of practice and Principles and Best Practice recommendations for the bench and bar to fairly present and resolve the issues that arise in biopharma patent litigation.

# II. Overview of Hatch-Waxman and BPCIA Litigation

## A. OVERVIEW OF HATCH-WAXMAN (ANDA) LITIGATION

The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") created an Abbreviated New Drug Application (ANDA) procedure regulated by the Food and Drug Administration (FDA), that in certain circumstances allows generic drugs to be approved based upon the same safety and efficacy test data earlier produced and used by the drug's originator to gain the first FDA approval of that drug. Among the circumstances addressed are those relating to whether the proposed marketing of the generic drug would occur after the patents pertaining to the original "brand name" drug expire, or if not, whether the ANDA applicant can certify that the proposed generic product would not infringe any valid claim of the originator's patents pertaining to the proposed generic product.[3]

The Act is intended to strike a balance between two competing policy interests. On the one hand, the Act sought to induce and reward the pioneering development of new drugs and treatments by providing a set of incentives for branded drug manufacturers to conduct new developments and testing, in exchange for restoration of a portion of the originator's patent term lost because of FDA-required premarket testing and for up to five years of regulatory exclusivity.

On the other, the Act sought to facilitate the efficient marketing of low-cost, generic versions of the branded drugs as promptly as possible. The Act does this by exempting generic manufacturers from patent infringement for activities relating to the development and submission of information to the FDA in connection with its ANDA application, limiting the testing an ANDA applicant needs to show that a generic will be bioequivalent to its branded counterpart, and shortening the normal FDA-approval time by authorizing the ANDA applicant to claim the benefit of the branded drug's original clinical testing.[4]

The Hatch-Waxman Act also includes incentives to encourage generic companies to challenge patents pertaining to the brand name drug. The first ANDA applicant ("first filer") to successfully challenge such a patent is rewarded with 180 days of market exclusivity relative to all other would-be generic entries. This exclusivity allows the first filer (or first filers, if multiple ANDAs are filed on the same day) to sell its generic product for a period of time without generic competitors. This head

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3 Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271), as amended by the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

4 The ANDA application process is abbreviated because preclinical (animal) and clinical (human) data to establish safety and efficacy are not required. Instead, the ANDA can rely on the safety and effectiveness data submitted by the original innovator in the New Drug Application (NDA) of the drug to be copied, and gain an approval based on data establishing bioequivalence between the generic product defined in the ANDA and the reference brand name drug. Thus, instead of completing lengthy procedures for new drug approval, which previously could not be conducted until the brand-name drug patents expired without risking patent infringement, the Hatch-Waxman Act created an expedited pathway for entry of generic drugs into the United States.

start gives the first filer a potentially significant marketing and revenue advantage over its other generic competitors.

The Act further establishes a framework for addressing patent disputes when a generic manufacturer seeks to obtain FDA approval of the proposed generic product. The Act first requires the originator of each FDA-approved drug to list its patents pertaining to that drug in an FDA-maintained registry, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book."[5] This framework then requires each generic manufacturer filing an ANDA with the FDA—commonly referred to as a "patent certification"—to include one of the following certifications with its application: (1) that the drug has not been patented; (2) that the patent has already expired; (3) that the generic drug will not go on the market until after the expiration of the relevant Orange-Book-listed patents; or (4) that each relevant Orange-Book-listed patent is not infringed or is invalid.[6] If an ANDA application certifies a patent is invalid, unenforceable, or not infringed, the applicant must notify the reference product manufacturer (also known as the New Drug Application or NDA holder) via a "paragraph IV notice letter," of its position, and must further provide a detailed statement for the basis of its assertion that the relevant patent is invalid, unenforceable, or not infringed. The paragraph IV notice letter provides notice to the patent owner that an ANDA has been filed by someone seeking to market a generic product before patent expiration. Typically, such a generic market entrant will spend several months or even several years analyzing the patent situation before it provides the notice letter and triggers litigation.

Each paragraph IV certification of non-infringement or invalidity made by a generic manufacturer effectively kicks off an ANDA patent litigation. The paragraph IV certification creates district court jurisdiction for any ensuing patent dispute between the ANDA filer and the patented drug manufacturer over the subject of that certification. The Hatch-Waxman Act accomplishes this through subsection (e) of 35 U.S.C. § 271, which makes the filing of an ANDA an artificial or technical act of infringement. This satisfies the case or controversy requirements and gives the patentee standing to file suit against the generic manufacturer.

After receipt of the paragraph IV certification, the patent owner may immediately file a patent infringement suit against the generic manufacturer.[7] If the patent owner does so within 45 days of receiving such a certification, the Hatch-Waxman Act provides for an automatic regulatory stay of the FDA's approval of the ANDA for the proposed generic product pending the district court's resolution of the dispute or 30 months from the notice letter, whichever occurs first.[8] Such a stay does not deprive the FDA of its jurisdiction to continue to examine the ANDA application, and the

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5 This publication lists all commercial drug products approved in the United States along with the patents relevant to the active drug ingredient, as well as formulations, inert ingredients, and uses. Typically listed patents include compound patents, formulation patents, and method of treatment or use patents.

6 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV) (with each paragraph I-IV listing each of the four patent certification options).

7 In most instances, a patent holder will receive paragraph IV certifications from multiple generic manufacturers and will file suit against multiple defendants in the courts where there is jurisdiction.

8 21 U.S.C. § 355(j)(5)(B)(iii). In the event that this regulatory stay is less than seven and one-half years from the date of approval of the new active ingredient, the 30-month stay may be extended "by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval" of a new active ingredient. *See* 21 U.S.C. § 355(j)(5)(F)(ii).

FDA's practice is to continue review and even grant tentative approval, with final approval pending resolution of the case. Lengths of ANDA examinations vary considerably depending upon the timing of the ANDA filing, the original product, the would-be generic, the sufficiency of the bioequivalence testing, the proposed labeling for the generic product, and many other factors. If the FDA completes its review of the ANDA prior to the district court's ruling or the expiration of the 30-month period, it will issue an "approvable" letter, indicating that the FDA intends to allow the ANDA when it is able to do so.

The purpose of providing an automatic stay is to permit the parties to resolve the merits of any patent enforcement action before permitting a generic drug to enter the market.[9] Congress recognized that premature generic entry could harm the branded company and could generate significant damage claims against the generic manufacturer. Accordingly, the stay was designed to minimize the risk of irreparable harm to the branded company and the generic company incurring liability for potentially significant damage awards. The 30-month period was chosen as a reasonable approximation of the time it should take a court to resolve the patent dispute on its merits. District courts normally implement a litigation schedule that will enable a final district court decision before the end of (but often close to expiration of) the 30-month stay. The timing of the district court's decision in an ANDA case is significant to all involved parties. A court decision in favor of the ANDA filer will terminate the 30-month stay early, while one adverse to the ANDA filer will keep the generic drug off the market until the subject patent expires (unless that decision is later reversed by the Federal Circuit). On the other hand, if a court decision has not been rendered by the end of the 30-month stay, the ANDA filer may be eligible to obtain final FDA approval (if the FDA review is complete) and, if the 30-month stay is not extended by the court for good cause shown, will have the right to make an "at risk" launch of its generic product. Because such a launch is made at risk of infringement, an ANDA filer may decide not to launch the generic pending the district court's decision (or any final decision from the Federal Circuit).

## B. OVERVIEW OF BPCIA LITIGATION

The Biologic Price Competition and Innovation Act (BPCIA), which was passed as part of the Affordable Care Act, for the first time allowed developers of products similar to a previously approved biologic (the "reference product") to rely upon the safety and efficacy test data submitted to the FDA by the original developer of that product (the "reference product sponsor") for the purpose of gaining marketing approval of a "biosimilar." A biologic therapeutic (also known as a "biologic") is any medicine made using a living organism. Biologics are larger and more complex than traditional pharmaceuticals, which are chemically synthesized. Also, because biologics are made from living organisms and not synthesized in a laboratory, they are inherently variable. As a consequence, biosimilar products are different from "generics" because while a biosimilar may be very similar to a biologic reference product, it is not identical to the reference product. Therefore, biosimilar manufacturers must demonstrate that their proposed products are "highly similar to the reference product notwithstanding minor differences in clinically inactive components" and "there

[9] Ben Venue Labs., Inc. v. Novartis Pharm. Corp., 146 F. Supp. 2d 572, 579 (D.N.J. 2001) ("[T]he purpose of the 30-month stay is . . . to create an adequate window of time during which to litigate the question of whether a generic will infringe the patented product, without actually having to introduce the generic product to the market." (citing 130 Cong. Rec. H9118 (daily ed. Sept. 6, 1984) (statement of Rep. Waxman); 130 Cong. Rec. S10504 (daily ed. Aug. 10, 1984) (statement of Sen. Hatch)).

are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency."[10]

Both the BPCIA and the Hatch-Waxman Act are intended to facilitate the marketing of competitive products while providing a streamlined, efficient process to resolving patent disputes. They both permit the generic or biosimilar applicant to rely, in part, upon the safety and efficacy test data submitted by the reference product sponsor. They both provide incentives to the generic or biosimilar manufacturers to file applications as early as practicable, including exclusivity periods for being the first to file (FTF) certain types of applications. But the BPCIA differs from the Hatch-Waxman Act in several ways. While FDA approval under the Hatch-Waxman Act relies on bioequivalence studies, the BPCIA relies on studies demonstrating no clinically meaningful differences from the reference product in safety, purity, and potency. The BPCIA contains longer and more timing restrictions on when a biosimilar applicant may submit and obtain approval of a biosimilar to a newly approved biologic product, but it contains no automatic stay of FDA approval triggered by a lawsuit like Hatch-Waxman does. Accordingly, for some biosimilar products, FDA approval may occur before patent litigation is even initiated or completed. Moreover, there are no Orange Book listing requirements imposed on the reference product sponsor for relevant patents, nor are there patent certification and notice requirements imposed on the biosimilar applicants. Instead, the BPCIA creates a framework in which the reference product sponsor and biosimilar applicant may negotiate over the potential patents to be litigated before the litigation commences.

Before the passage of the BPCIA, each biologic submitted to the FDA for approval needed to undergo a full complement of safety and efficacy testing and obtain separate and independent regulatory approval, regardless of how similar that product might be to a previously approved therapeutic biologic. Absent prohibiting patent protection, developers of biologics could conduct that testing and gain regulatory approval for their biologics without regard to when other similar biologics had been approved. Competing drugs, all of which target the same condition, might each be independently developed by competing biologics manufacturers without reliance on their competitors' safety and efficacy data.

The BPCIA specifies that for parties wishing to rely on another product's safety and efficacy testing, a biosimilar application may first be filed beginning four years after the original approval of the reference product, but further specifies that no such application will be approved until 12 years after the original approval of the reference product.[11] Depending upon the filing date of the biosimilar application, a period of up to eight years may thus be provided during which the parties may work to resolve any patent infringement issues.

While the BPCIA does not require that all patent issues be resolved before biosimilar approval and marketing, the BPCIA does provide for a fairly elaborate number of prelitigation information exchanges between the patent owner and biosimilar applicant. These information exchanges—which have become known as the "patent dance"—are intended to identify which of the reference product sponsor's patents may be asserted to cover the proposed biosimilar, which patents the parties wish to litigate immediately, and which patents the parties are willing to defer litigating at least until after

10 *See* 42 U.S.C. § 262(i)(2).

11 *See* 42 U.S.C. § 262(k)(7)(A)-(B).

the FDA has approved the biosimilar for marketing.[12] The patent dance begins when the biosimilar (or "subsection k") applicant[13] discloses its Abbreviated Biologics License Application that was submitted and accepted by the FDA—known as the aBLA—and other relevant information to the reference product sponsor. The reference product sponsor is then required to identify relevant patents that it may assert. The BPCIA has been interpreted by the Supreme Court as providing a biosimilar applicant the option, rather than the requirement, to participate in the patent dance,[14] and many litigants may engage in only a portion of the information exchange or may opt out of the exchange altogether. However, one consequence of foregoing the patent dance is that a patent owner may but is not obligated to bring suit sooner and, if it does so, may avoid certain restrictions placed on the number of patents that may be initially asserted in an enforcement action.[15]

The patent provisions of the BPCIA allow for patent litigation between the patent holder and the biosimilar applicant to begin before the applicant markets its biosimilar.[16]

The BPCIA further contemplates that a permanent injunction will be entered if the patent owner prevails on the merits prior to the biosimilar product's approval. In particular, 35 U.S.C. 271(e)(4)(D) provides:

> the court **shall order a permanent injunction** prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, and **the biological product has not yet been approved because of section 351(k)(7) of such Act**. (emphasis added.)

However, because there is no counterpart in the BPCIA to the 30-month regulatory stay of Hatch-Waxman, biosimilar products may be approved by the FDA before the merits of the reference

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12 The BPCIA contemplates that the parties will engage in the "patent dance" before litigation is filed, though the subsequent issuance or acquisition of relevant patents by a reference product sponsor may require updating the information exchange. 42 U.S.C. § 262(l).

13 Biosimilar applicants are often referred to as "subsection k" applicants, in reference to 42 U.S.C. § 262(k), which provides the abbreviated pathway for licensure of biosimilar or interchangeable biological products.

14 Sandoz v. Amgen, 582 U.S. __, 137 S.Ct. 1664 (2017).

15 In order to facilitate this "dance," the BPCIA prohibits the premature filing of declaratory judgment cases, and under certain conditions for certain patents, limits future collection of past damages to reasonable royalties. In particular, 35 U.S.C. 271(e)(6)(B) provides:

> In an action for infringement of a patent described in subparagraph (A) [action for listed patents brought out of time requirements in the law or dismissed without prejudice], **the sole and exclusive remedy** that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, **shall be a reasonable royalty**. (emphasis added.)

16 42 U.S.C. § 262(l)(8) (Notice of Commercial Marketing and Preliminary Injunction).

product sponsor's patent enforcement action against the biosimilar product have been resolved. The remedies available in connection with a lawsuit brought under the BPCIA are discussed further below.

In addition to any patent concerns, many scientific, business, and regulatory factors bear on the biosimilar applicant's decision as to when to file a biosimilar application. The BPCIA's timing for patent-dance disclosures is triggered by the filing of a biosimilar applicant's aBLA. In cases where the reference product has already been on the market for a considerable period of time, some or all of the reference product's marketing exclusivity may already have passed.[17] If filed early enough to allow the patent issues to be finally resolved before the biosimilar is approved, the biosimilar applicant may be relieved of the risks of any patent damages and the potential disruption of its biosimilar marketing were a patent-based injunction to be entered after the biosimilar's launch. Nonetheless, patent issues are only one of many important factors, and other circumstances and considerations may favor later filing of the biosimilar application.

## C. THE AMERICA INVENTS ACT/USPTO PATENT TRIAL AND APPEAL BOARD AND BIOPHARMA LITIGATION

Under the America Invents Act (AIA), the former United States Patent and Trademark Office (USPTO) Board of Patent Appeals and Interferences was renamed the Patent Trial and Appeal Board (PTAB) effective September 16, 2012. The AIA created new proceedings by which parties can challenge the validity of patents after issue (i.e., grant), the most important being inter partes review (IPR), post-grant review (PGR), and covered business method review.

As stated in *The Sedona Conference Commentary on Patent Litigation Best Practices: Parallel USPTO Proceedings Chapter*:

> The AIA's new post-grant procedures were designed in part to address significant criticism of the pre-AIA patent system. To address concerns that resolving patent disputes in the district courts takes too long, the AIA instituted time limits, mandating that these proceedings be resolved one year from institution, with a possible six month extension upon a showing of good cause, or an extension in the case of joinder.[18]

As discussed above, the Hatch-Waxman Act strove to balance the interests of the public along with innovator and generic pharmaceutical companies, and its litigation framework was a key element to ensuring this balance. PGR and IPR proceedings on biopharmaceutical patents were not available at the time the legislation was passed and may affect the balance set forth in the statute and also alter

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[17] As noted above, 42 U.S.C. § 262(k)(7)(A) provides that no biosimilar may be approved until a date that is 12 years after the regulatory licensure of the reference product sponsor. At the same time, 42 U.S.C. § 262(k)(7)(B) provides that a biosimilar application may not be filed until 4 years after licensure of the reference product. Thus, a biosimilar applicant has theoretically up to eight years available to engage in the patent dance before launch.

[18] The Sedona Conference, *Commentary on Patent Litigation Best Practices: Parallel USPTO Proceedings Chapter ("Stage One")* (October 2016), at 2. For Principles and Best Practice recommendations for Parallel USPTO Proceedings between the federal district courts and the USPTO/PTAB, *see id. ("Stage One")* and *("Stage Two")* (July 2017), *available at* https://thesedonaconference.org/publication/Parallel_USPTO_Proceedings.

the process for resolving patent disputes as originally contemplated in the Act. Examples of why this may be so include:

- the ability to initiate PTAB proceedings prior to the earliest date of Hatch-Waxman litigation (as the AIA does not contain the Hatch-Waxman Act's requirement effectively prohibiting patent owners from suing generic companies until after the filing of their ANDA),
- the potential for PTAB proceedings to extend beyond the 30-month period intended to complete litigation, and
- the possible use of district court litigation and PTAB proceedings by multiple ANDA filers to provide numerous opportunities to challenge a patent may delay a final adjudication of patent infringement and validity.

The BPCIA also provides a four-year period before any patent challenges can be made by the biosimilar applicant, and thus may trigger similar consideration relative to the early or concurrent use of PTAB proceedings.[19]

The *Sedona WG10 USPTO Parallel Proceedings Chapter* introduces its detailed discussion on these issues in the general litigation context by stating:

> Addressing concerns of serial petitions and that a "race to the bottom" might occur with parties gaming the two systems, Congress included in the AIA a provision estopping post-grant petitioners from later raising any arguments that could reasonably have been raised before the PTAB.[20] Yet the PTAB may choose not to consider or address all of the claims raised by petitioners in an institution decision, which can create significant issues for any subsequent district court when considering issues of estoppel after the PTAB proceeding.

In this *Biopharma Chapter*, WG10 only highlights some of the competing considerations between the framework of the America Invents Act and the Hatch-Waxman Act and the BPCIA, without taking a position on which should take priority in which circumstances, as there is not WG10-wide consensus on these issues. For a more detailed discussion of the interplay between PTAB challenges and ANDA and BPCIA litigation, see Section V.C below.

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19 *See supra* note 17.

20 35 U.S.C. §§ 315(e)(2), 325(e)(2).

# III. Pleading Standards for Biopharmaceutical Cases—Unique Considerations

Pleading requirements in patent cases have been the subject of significant attention in recent years. In particular, courts have focused on whether and how the *Iqbal*[21] and *Twombly*[22] standards should be applied, and the effect of the abolition of Form 18 in the December 2015 amendments to the Federal Rules of Civil Procedure. The broad purpose of these changes was to discourage pro forma pleadings lacking evidentiary support, and to ensure that, under the notice pleading standard, defendants would receive fair notice of the asserted basis for the claims against them. The Sedona Conference's Working Group 10 has developed best practices on this subject.[23] Broadly speaking, that guidance applies to biopharmaceutical cases, and this section treats only certain unique elements that arise for cases concerning biologics.

With certain important exceptions, the series and nature of prior exchanges of information that occur between biopharmaceutical patent holders and alleged infringers mean that pleadings play a less significant role in giving the patent holder or their alleged infringer notice regarding the nature and scope of the claims of each party regarding infringement and invalidity. On the one hand, this means that the alleged infringer is less at risk that it will lack the information it needs to mount an effective defense. On the other hand, it means that a patent holder will often (although not always) have access to the information necessary to target its allegations of infringement in a way that identifies the claims that are at issue and the compounds, formulations, or methods that it accuses. Particular care should be taken in the more unusual cases in which either the patent holder lacks information about the accused infringer's process or product or where the patent holder is asserting a claim regarding a patent that did not go through the exchange process included in either the ANDA or BPCIA processes.

Historically, the great majority of patent litigation in the biopharmaceutical area consisted of ANDA cases brought under the procedures of the Hatch-Waxman Act. In these cases, it has been rare to encounter pleadings that are insufficient to provide notice or that are otherwise inadequate. The Hatch-Waxman Act confers jurisdiction to federal courts to resolve patent infringement disputes by treating the act of submitting an Abbreviated New Drug Application for marketing approval to the FDA as an act of patent infringement.[24] And, if the ANDA applicant intends to begin marketing

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21 Ashcroft v. Iqbal, 556 U.S. 662 (2009).

22 Bell Atlantic v. Twombly, 550 U.S. 554 (2007).

23 *See* The Sedona Conference, *Commentary on Patent Litigation Best Practices: Pleading Standards Under* Iqbal-Twombly *Chapter* (October 2017), *available at* https://thesedonaconference.org/publication/Pleading_Standards.

24 Notably, one court has held that a patentee-plaintiff in receipt of a paragraph IV certification relating to one of its Orange Book-listed patents may state a claim for infringement by alleging its interest in the patent, its receipt of a paragraph IV certification, the filing of an ANDA or NDA, and its contention that the defendant's proposed product will infringe. *See* Belcher Pharms., LLC. v. Int'l Medication Sys, Ltd., 379 F. Supp. 3d 326, 330–31 (D. Del. 2019).

before the expiration of any patents listed in the Orange Book with respect to the approved drug product, it must provide a detailed explanation of its invalidity and noninfringement positions to the "NDA holder" (i.e., the branded company whose New Drug Application was approved by the FDA, authorizing the marketing of the drug). As a result of the information exchanges that have taken place between the parties before litigation is commenced, the pleadings in ANDA cases have tended to be significantly more detailed than was required under the old Form 18. Typically, the complaint in an ANDA case identifies the relevant NDA, the approved drug product and its indications, the ANDA, and at least the salient facts about the information provided by the defendant to the plaintiff in the paragraph IV notice letter prior to the filing of the complaint. In non-ANDA biopharmaceutical cases—of which there have historically been relatively few—pleading practices appear to have largely followed the style of ANDA complaints and likewise tend to include information regarding the accused product, the patented product if there is a commercial embodiment, and their respective FDA approvals. To summarize then, the "bare bones" patent infringement complaint has generally not been a problem in this field.

There are situations in which an ANDA plaintiff may have to plead its complaint with less than complete information. For example, where the parties have been unable to agree to the terms of an offer for confidential access, the plaintiff may not have received information relevant to a determination of infringement or noninfringement of some or all listed patents. Because the filing of an ANDA with a paragraph IV notice letter constitutes a technical act of infringement and given the very significant consequences of failing to bring suit within the prescribed statutory time period—loss of the 30-month stay of ANDA approval—plaintiffs will almost always bring suit within the allotted 45-day window to commence litigation.

A similar situation can emerge in biosimilar litigation with respect to which FDA approval is sought under the Biologics Price Competition and Innovation Act, or BPCIA. Under the holdings of the Supreme Court (and the Federal Circuit, on remand) in *Amgen v. Sandoz*, a biosimilar applicant may elect not to disclose to the reference product sponsor its FDA submission or aBLA, other information that describes the process or processes used to manufacture the biological product, or additional information requested by the reference product sponsor. The submission of the aBLA is an act of infringement of any assertable patents under 35 U.S.C. § 271(e)(2)(c), but as a practical matter the reference product sponsor may not know which of its patents could reasonably be asserted to be infringed, especially for example where the patents are directed to methods of manufacture.[25] Both law and practice are still evolving in this area, and it remains to be seen how plaintiffs will address such a lack of information.

If the information exchange under the BPCIA has taken place, the alleged infringer has provided its FDA application and other information under 42 U.S.C. § 262(l)(2), and the reference product sponsor has provided a list of assertable patents under 42 U.S.C. § 262(l)(3)(A), the parties, in some respects, may each have more information about each other's positions than in a typical patent lawsuit. Nonetheless, where the parties have completed this exchange process, the dismissal of a subsequent complaint can raise additional issues. Under the BPCIA remedy provisions codified at 35 U.S.C. § 271(e)(6)(A) and (B), if an action asserting such a patent is dismissed without prejudice or not fully prosecuted by the patent holder, the patent holder's remedy in a subsequent action may be

[25] A similar situation (where the patent holder lacks full knowledge of its patents that can reasonably be asserted) can also arise in Hatch-Waxman litigation where an ANDA applicant does not agree to provide its ANDA to the NDA holder.

limited to a reasonable royalty. Thus, at least arguably, a consequence of a successful motion to dismiss without leave to amend might be to cut off the plaintiff's right to lost profits damages or injunctive relief if the action is subsequently refiled with a new complaint that cures the original pleading defect. Given the short history of BPCIA litigation, this situation has yet to be addressed by the courts.

Another potential basis for a motion to dismiss is failure to meet the venue requirements of the patent statute. Now that the Supreme Court has generally restricted venue in its *TC Heartland* decision,[26] the courts are beginning to address whether *TC Heartland* will similarly restrict venue in Hatch-Waxman and biosimilar cases under the BPCIA, both of which rest on statute-based technical infringements that may be viewed as being of national scope. At least one court has ruled that *TC Heartland* "clearly" applies to ANDA cases.[27]

As noted above, the consequences of dismissal might be very severe in BPCIA litigation. The same is true in the ANDA context where even if a suit is refiled in a forum where venue is proper, the result may be forfeiture of an automatic 30-month stay. Patent cases must proceed in federal court. Thus, given the potential prejudicial effect of a dismissal in both ANDA and BPCIA litigation, patent holders often file "protective" suits to cover all bases for personal jurisdiction and venue. However, where possible, it may make sense for parties to try to attempt to reach agreement on venue for filing suit to avoid dismissal or transfer issues. In any event, in light of *TC Heartland*, it seems likely that venue disputes will now become significantly more common in biopharmaceutical cases.

**<u>Best Practice 1</u> – In determining any motion to dismiss on the pleadings in an ANDA case, at least the following factors should be considered:**

- **whether the plaintiff has undertaken a reasonable investigation to assess infringement,**
- **the plaintiff's efforts to gain access to information for pleading purposes,**
- **the scope of the information exchanged before the lawsuit was filed,**
- **whether other venues are already available for the suit,**
- **any evidence of gamesmanship or unclean hands by either party, and**
- **potential relief for the defendant other than dismissal that may cure a lack of notice.**

In view of the considerations discussed above, best practices in this area should balance a defendant's need for fair notice of the claims against it with the scope of information available to the parties in the individual dispute and the potentially prejudicial consequences of dismissal to the

[26] TC Heartland LLC v. Kraft Foods Group Brands LLC, 581 U.S. ___ (2017).

[27] Bristol-Myers Squibb Co. v. Aurobindo Pharma USA Inc., Nos. 17-374-LPS, 17-379-LPS, 2018 WL 5109836 at *5–6 (D. Del. Oct. 18, 2018).

patent holder in an ANDA or BPCIA case. In deciding a motion to dismiss, a court should understand what really underlies the motion and the claim of lack of notice. For example, where a patent holder has attempted to ascertain venue for filing suit and defendant has provided no information, courts may opt to transfer suits or ensure that the patent holder is in a position to proceed in another venue rather than dismiss for improper venue. Likewise, if the patent holder has attempted to obtain additional information about the generic or biosimilar applicant's regulatory submission and the applicant has not provided such information, a court may opt to permit leave to amend rather than a motion to dismiss for failure to state a claim.

# *IV. Discovery Issues Unique to Biopharma Litigation*[28]

**Best Practice 2 – Access to information in the ANDA and aBLA should be provided to the patent holder under terms that balance the patent holder's need for certain information in order to assess claims of patent infringement with protections for the ANDA/aBLA applicant's confidential information.**

Litigation related to ANDAs and aBLAs frequently implicates a party's confidential and trade secret information, such as the manufacturing process for the accused product, formulation details, and sales data. As discussed in detail below, early production of the ANDA and aBLA is advantageous for all parties, as an initial matter by facilitating the plaintiff's identification of the specific claims at issue and its production of infringement contentions. However, confidentiality issues must be addressed prior to production. Although the Hatch-Waxman Act and BPCIA provide some default protections, parties often find these protections insufficient and prefer to negotiate a protective order with more tailored provisions.

## A. HATCH-WAXMAN CASES

Cases brought under the Hatch-Waxman Act differ from the typical patent infringement action in several respects. One of the salient differences is that the litigation is based on an artificial act of infringement: the filing of an ANDA that includes a paragraph IV certification as described above.[29] As noted, by comparison with a typical patent infringement action outside the biopharmaceutical area, the defendant in a Hatch-Waxman case not only has a greater opportunity to develop its positions well in advance of the litigation, but also is subject to a statutory requirement that it do so.

After receiving the notice letter, the patent holder has just 45 days to file a patent infringement suit in order to trigger an automatic 30-month stay of FDA approval of the ANDA. Because the ANDA product is not yet marketed at the time the notice letter is served, the patent owner does not have access to the product to analyze it for infringement before filing the complaint.

Under the Hatch-Waxman Act, the applicant is incentivized to offer access to the ANDA with its notice letter. Doing so allows the applicant to file a declaratory judgment action if the reference product sponsor does not sue within 45 days of receiving the notice letter. While most ANDA applicants provide an offer for confidential access to the ANDA along with the notice letter, the negotiation of a suitable confidentiality agreement takes time and sometimes is not accomplished within the 45-day period allotted for the patent holder to file its complaint. Accordingly, the patent

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[28] This Section incorporates by reference The Sedona Conference Working Group 10 C*ommentary on Patent Litigation Best Practices: Chapter on Discovery*, which provides principles and best practice recommendations for patent litigation in general. The Sedona Conference, *Commentary on Patent Litigation Best Practices: Chapter on Discovery* (Dec. 2015 Edition), *available at*: https://thesedonaconference.org/publication/Commentary_on_Patent_Litigation_Best_Practices_Discovery_Chapter.

[29] *See* Sect. II.A (Overview of Hatch-Waxman (ANDA) Litigation), *supra*.

holder in a Hatch-Waxman infringement suit has relatively little time to develop its infringement contentions compared to a typical patentee-plaintiff.

Because of this, there is a question whether the defendant in a Hatch-Waxman action should be required to disclose its contentions regarding infringement, validity, and enforceability before the plaintiff patent holder is required to set forth its contentions. Several jurisdictions have special rules applicable to Hatch-Waxman cases that address the order of contentions, timing, and standards for amending contentions, and have come to different positions on these issues.

The District of New Jersey, in its Local Patent Rule 3.6, has adopted a system in which the defendant ANDA filer produces its invalidity and noninfringement contentions before the patentee produces its full infringement contentions. The rule requires the patentee to serve a list of asserted claims within seven days after the initial scheduling conference. The defendant serves its invalidity and noninfringement contentions 30 days after the initial scheduling conference, and plaintiff then has 45 days to serve its infringement contentions. The rule also requires an ANDA filer to produce its entire ANDA on the date when it answers or otherwise responds to the complaint. The Northern District of Ohio has adopted a similar rule for Hatch-Waxman cases.[30]

In contrast to the District of New Jersey and the Northern District of Ohio, Hatch-Waxman cases in the District of Delaware follow the approach typical in most patent cases, requiring the plaintiff to disclose asserted claims and infringement contentions, followed by the defendant's disclosure of invalidity contentions. For example, under the District of Delaware's Default Standard for Discovery in Patent Cases, the plaintiff identifies the accused products and asserted patents within 30 days after the Rule 16 conference, defendant produces the core technical documents related to the accused products (e.g., the ANDA) within 30 days thereafter, plaintiff produces an initial infringement claim chart within 30 days after receipt of the technical documents, and defendant produces initial invalidity contentions within 30 days of the claim chart.[31] Most other courts, which do not have special rules for Hatch-Waxman cases, similarly require the plaintiff to serve infringement contentions before the defendant serves invalidity contentions.

Under either system, early production of the ANDA will facilitate the exchange of meaningful contentions early in the case. The plaintiff must have access to the relevant portions of the ANDA to evaluate the accused product and determine which claims can reasonably be asserted against the ANDA product. Allowing the plaintiff to identify asserted claims and develop its infringement contentions early in the case can narrow the number of claims at issue and simplify the defendant's invalidity contentions.

Notably, while the District of New Jersey requires the defendant to serve invalidity contentions before receiving full infringement contentions, the court nonetheless requires plaintiff to first identify the asserted claims. The purpose of this rule is to avoid unnecessary effort by the defendant

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30 N.D. Ohio L. Pat. R. 3.9 (Disclosure Requirements for Patent Cases Arising Under 21 U.S.C. § 355 (commonly referred to as "the Hatch-Waxman Act"), PatentRules_39.pdf (uscourts.gov).

31 Although the local patent rules for the District of Delaware are not specific to Hatch-Waxman cases, several judges have specific scheduling orders for use in Hatch-Waxman cases. These scheduling orders generally follow the Delaware Default Standard with respect to the order of exchange of invalidity and infringement contentions.

in generating invalidity contentions for claims that are not at issue in the case.[32] This is an important consideration, which is best achieved when the schedule for exchange of contentions allows sufficient time between the identification of asserted claims and the deadline for production of invalidity contentions. Unless the defendant knows which claims are at issue well before its contentions are due, it will in practice be forced to prepare invalidity contentions for all possible claims.

Early production of the ANDA benefits both parties by avoiding delays and inefficiencies in the development of the parties' contentions. As a best practice, parties and the courts should facilitate production of the ANDA as early in the case as practicable. This may be accomplished by agreeing to confidentiality terms pre-suit following a defendant's offer of confidential access, by proceeding under a default protective order provided by the court, or by entering a suitable protective order early in the case. Issues that may arise in the negotiation of the protective order are discussed in Section IV.B below.

## B. THE INITIAL PRODUCTION OF THE ANDA/aBLA AND THE EXCHANGE OF CONTENTIONS

**<u>Best Practice 3</u> – Early disclosure by the generic/biosimilar applicant of its ANDA/aBLA application helps streamline the case for the parties and the court.**

As discussed in detail below, both the Hatch-Waxman Act and BPCIA encourage the generic or biosimilar applicants respectively to produce their ANDA/aBLA application under appropriate confidentiality terms before litigation, but such production is not mandatory under either law. The subsequent exchange of information between the parties that is thus initiated facilitates a better understanding by both parties of the basis of the suit and the likely defenses at the outset of the case, compared with other types of patent infringement cases.

### 1. BPCIA Cases

Biosimilar cases, brought under BPCIA, are also subject to unique rules that in some respects differ markedly from the Hatch-Waxman regime. One significant difference is that cases under the BPCIA can involve patents on methods of manufacturing the product, whereas such patents are not permitted to be listed in the Orange Book and thus are typically not at issue in Hatch-Waxman litigation. Accordingly, BPCIA cases potentially involve many more patents than a Hatch-Waxman litigation.[33]

Another significant difference is that under the BPCIA, there is no patent registry equivalent to the Orange Book. The biosimilar applicant must independently research the patents owned or controlled by the reference product sponsor to determine which patents might be asserted against its product. The defendant in a BPCIA case thus has significantly less advance notice of the patents that will be asserted against it in comparison to a Hatch-Waxman defendant. However, the BPCIA

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32 D.N.J. L. Pat. R. Explanatory Note for 2011 Amendments.

33 As one example, the patent estate covering Humira® (adalimumab) reportedly includes nearly one hundred U.S. patents. Complaint at 3, *In Re:* Humira (Adalimumab) Antitrust Litigation, No. 1:19-cv-01873 (N.D. Ill. Mar. 18, 2019).

incentivizes a prelitigation information exchange, commonly referred to as the "patent dance." If the biosimilar applicant opts to start the patent dance, then the reference product sponsor is required to identify relevant patents that it may assert. The patent dance thus narrows and identifies the relevant patents that the biosimilar applicant needs to consider, and it narrows the universe of patents for litigation.

The biosimilar applicant starts the patent dance by disclosing its biosimilar application to the FDA (i.e., the aBLA) to the reference product sponsor. In addition to the aBLA itself, the statute contemplates potential for production of "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application."[34] These disclosures are followed by an identification of assertable patents by the reference product sponsor.[35] Within 60 days, the biosimilar applicant must then provide a detailed statement describing its contentions with respect to invalidity, unenforceability, and noninfringement.[36] The biosimilar applicant may also identify any additional patents that it believes reasonably could be asserted against the aBLA product. Sixty days later, the reference product sponsor provides its infringement contentions and its positions regarding validity and enforceability for the identified patents.[37] The parties then engage in negotiation or exchanges to determine which patents (if any) will be the subject of a "first wave" litigation.[38] The BPCIA allows the biosimilar applicant to limit how many patents may be asserted in the first wave litigation.[39]

The Supreme Court has held that the sole consequence under federal law for the biosimilar applicant's decision not to disclose the contents of its aBLA to the reference product sponsor and start the patent dance is the one that is statutorily specified—the patent owner can then immediately bring a declaratory judgment action for infringement.[40] The Court declined to address the question as to whether further liability or injunctive relief might be available under state law, remanding that issue for further consideration. On remand, the Federal Circuit dismissed the state law claims based on preemption.[41]

BPCIA cases will thus fall into two categories: those in which the prelitigation exchange of contentions took place via the patent dance process and those in which it did not. It is difficult to see a compelling reason to treat the second category of cases differently from any other action for patent infringement: the plaintiff will commence the case by bringing suit on one or more patents of its choice, and the normal pretrial procedures may then be followed.

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34 42 U.S.C. § 262(*l*)(2)(A) (2019).

35 *Id.* § 262(*l*)(3)(A)(i).

36 *Id.* § 262(*l*)(3)(B)(ii)(I).

37 *Id.* § 262(*l*)(3)(C).

38 *Id.* § 262(*l*)(4)–(5).

39 *Id.* § 262(*l*)(5)(A), (B)(ii).

40 Sandoz Inc. v. Amgen Inc., 582 U.S. __, 137 S. Ct. 1664, 1675 (2017).

41 Amgen Inc. v. Sandoz Inc., 877 F.3d 1315, 1330 (Fed. Cir. 2017).

Analogous to the Hatch-Waxman cases discussed above, in BPCIA cases where the parties did not participate in the patent dance, production of the aBLA early in the case will facilitate the plaintiff's identification of the specific claims at issue and its production of infringement contentions.

Where the patent dance has taken place, the biosimilar applicant will have already provided the aBLA and preliminary noninfringement, invalidity, and perhaps unenforceability contentions pursuant to subsection 262(l)(3)(B)(ii)(I), but on an expedited schedule. The patent holder will have provided responsive contentions pursuant to subsection 262(l)(3)(B)(iii), and thus the issues will have been joined.

### 2. Facilitating the Production of the ANDA/aBLA

**<u>Best Practice 4</u> – In cases where the ANDA or aBLA was not produced before litigation began, the parties and the court should move expeditiously to enter an appropriate protective order and produce the relevant portions of the ANDA or aBLA early in the case, either with the defendant's response to the complaint or shortly thereafter.**

Generally, production by the generic applicant of the complete ANDA will be appropriate. Depending on the issues involved in the case, however, it may be appropriate for the defendant to withhold highly sensitive information (e.g., manufacturing and/or quality control processes) that is not relevant to the issues in the case (e.g., where infringement of compound claims is not contested and the asserted claims involve only formulation components or methods of use).[42]

If the generic/biosimilar applicant has declined to disclose its ANDA/aBLA pre-suit, the parties and the court should move expeditiously to enter an appropriate protective order and produce the relevant portions of the ANDA/aBLA as early in the case as practicable. Prompt resolution of these threshold issues will be necessary before meaningful exchange of infringement and invalidity contentions, as required by many patent local rules, can take place. Production of the relevant documents will help the parties move the case forward expeditiously. This will help achieve the typical goal of resolving Hatch-Waxman cases at the district court before the expiration of the 30-month stay. Although BPCIA cases do not involve a 30-month stay and will have case-specific timing considerations, they will ideally proceed at a pace that allows resolution before the aBLA receives FDA approval, so as to avoid the need for temporary injunction proceedings.

[42] For example, in *In re* Copaxone 40mg Consolidated Cases, the parties stipulated that defendants would not produce the portions of the ANDA concerning the manufacturing process for, composition of, or chemistry, manufacture or control of glatiramer acetate, and defendants would not contend, argue, or offer any proof that the ANDA product is different from the glatiramer acetate product recited in the claims of the patent. *See* Stipulation And [Proposed] Order Resolving Discovery Dispute at 1–2, *In re* Copaxone 40mg Consolidated Cases, No. 1:14-cv-01171, Document 191 (D. Del. Feb. 10, 2016).

### 3. The Amendment of Infringement and Invalidity Contentions

**<u>Best Practice 5</u> – The pre-suit contentions exchanged in Hatch-Waxman or BPCIA litigation should be converted to formal contentions early in the case, with an opportunity to amend contentions provided where appropriate.**

Given the expedited nature of the pre-suit exchanges and the large number of patents potentially involved at the outset of the patent dance, the pre-suit exchanges should not be binding on the parties. Nonetheless, there may be value in converting these statements into formal contentions as required by most patent local rules. Early exchange of binding infringement and invalidity contentions, as required by most local patent rules, can help the parties and the court to crystallize the issues in the case, identify key terms for claim construction, and keep the case on track for resolution before expiration of the 30-month stay in Hatch-Waxman litigation, or before a biosimilar applicant receives FDA approval.

However, it is also appropriate that there should be a mechanism to permit subsequent amendment of contentions where appropriate. Some local rules permit amending contentions only by order of the court upon a finding of good cause.[43] Nonlimiting examples of such circumstances include situations in which the aBLA/ANDA-filer learns information in discovery that it could not reasonably have known through pre-suit diligence, when the court's claim construction materially changes a party's interpretation of the claim, or when a change in invalidity or infringement contentions is useful or necessary to respond to a position taken by the other party as to infringement or validity. Considerations and best practices regarding the amendment of contentions are discussed further in *The Sedona Conference Commentary on Patent Litigation Best Practices: Discovery Chapter*, Best Practice 19.[44]

## C. PROTECTIVE ORDER AND ACCESS ISSUES FOR HATCH-WAXMAN AND BPCIA CASES

**<u>Best Practice 6</u> – The parties should agree to prelitigation phase protective orders that are substantively the same as the litigation phase protective orders.**

Hatch-Waxman and BPCIA cases differ from typical patent litigation in that the statutory scheme encourages pre-suit exchanges of confidential information (i.e., the ANDA or aBLA and related manufacturing information). If such pre-suit exchanges occur, the parties will negotiate a prelitigation protective order to govern the exchange. It is advisable for the parties to consider the terms that will be desirable for the litigation phase protective order because the prospect of different rules in the prelitigation and litigation phases creates logistical difficulties. As a best practice, parties should agree to restrictions in the prelitigation confidential access agreement that will also serve in the litigation phase protective order.

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43 *See, e.g.*, N.D. Cal. Patent L.R. 3-6; D.N.J. L. Pat. R. 3.7.

44 The Sedona Conference, *Commentary on Patent Litigation Best Practices: Discovery Chapter* (Dec. 2015), *available at*: https://thesedonaconference.org/publication/Commentary_on_Patent_Litigation_Best_Practices_Discovery_Chapter.

Under the Hatch-Waxman Act, the applicant is incentivized to offer the patent holder access to the ANDA with its notice letter to the patent holder detailing why it contends the patent is not infringed or is invalid or unenforceable. Doing so allows the applicant to file a declaratory judgment action if the reference product sponsor does not sue within 45 days of receiving the notice letter. By statute, the offer of confidential access must describe restrictions as to persons entitled to access and on the use and disposition of any information accessed.[45] Any person provided an offer of confidential access may only review the application for the limited purpose of evaluating possible infringement of the patent and may not disclose information to any person other than a person provided an offer of confidential access.[46] Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.[47]

Under the BPCIA, the applicant is similarly incentivized to provide the reference product sponsor with confidential access to the aBLA and related manufacturing information within 20 days from the FDA's acceptance of the aBLA for review.[48] Otherwise, the patent dance does not take place, and the sponsor instead may bring a declaratory judgment action at any time on any patent.[49] The BPCIA includes within it default terms for confidential access by the reference product sponsor of the biosimilar applicant's confidential information.[50] These terms govern the use of confidential information "until such time as a court enters a protective order regarding the information."[51]

This section discusses the statutory protections for prelitigation access that are provided in the BPCIA and identifies additional litigation phase considerations that parties may wish to proactively address. The best practice recommendations below apply to ANDA cases as well as those under the BPCIA.

### 1. Recipients of Information

**<u>Best Practice 7</u> – The parties should agree to prelitigation confidential access provisions that provide access for outside and appropriate in-house counsel and for technical experts.**

#### a. Outside and in-house counsel

The BPCIA states the applicant shall provide the aBLA to outside counsel and in-house counsel subject to the confidentiality terms set forth in the statute.[52] The BPCIA also contemplates access by a representative of the owner of a patent that is exclusively licensed to the reference product

45 21 U.S.C. § 355(j)(5)(C)(i)(III) (2018).

46 *Id.*

47 *Id.*

48 42 U.S.C. § 262(*l*)(1)–(2).

49 *Id.* § 262(*l*)(9)(C).

50 *Id.* § 262(*l*)(1).

51 *Id.* § 262(*l*)(1)(F).

52 *Id.* § 262(*l*)(1)(B)(i).

sponsor and who has retained a right to assert the patent or participate in litigation concerning the patent.[53]

Outside counsel includes "[o]ne or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor . . . ."[54] There is no limit provided in the statute for the number of attorneys from an outside firm or the number of outside firms that a reference product sponsor may designate.[55] The statute limits the number of in-house counsel to one individual.[56] However, the parties should consider circumstances when access by more than one in-house attorney may be warranted, such as different technical areas of responsibility or expertise.

**<u>Best Practice 8</u> – The protective order should permit parties to challenge the designation of confidential materials at any time in the litigation.**

In negotiating prelitigation phase protective orders for both Hatch-Waxman and BPCIA cases, the parties should also consider the effect of including an "Outside Counsel Only" tier of confidential information in the protective order. Whether correctly or not, in practice most documents are produced under the highest level of confidentiality available under the protective order. When documents are produced on an "outside counsel only" basis, logistical issues can arise for in-house counsel overseeing the litigation.

While in-house counsel does not need access to all documents produced during fact discovery, the ability to review documents that are cited in or attached to court filings and expert reports may be important. Damages claims, and related documents cited in damages reports, are especially important. In-house counsel needs to be apprised of damages claims so as to advise internal stakeholders and to determine materiality for FTC and investor reporting requirements. The parties should be sensitive to these issues and take into account the importance of allowing in-house counsel to consider the strength of the case and the magnitude of the potential damages at issue.

One option may be to include provisions in the protective order to adjust the designation of materials included with or cited in expert reports and court filings to allow access by in-house counsel. Another option is to streamline the process of disputing confidentiality designations. Courts can assist in this process by designating a magistrate judge to expeditiously decide disputes regarding access to confidential information.

As a best practice, this *Chapter* recommends that parties be permitted to object at any time to the confidentiality designation assigned to documents produced by the other party. This avoids unnecessary disputes over designation of documents early in the litigation, but allows challenges to be raised when the importance of certain documents has become apparent.

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53 *Id.* § 262(*l*)(1)(B)(iii).

54 *Id.* § 262(*l*)(1)(B)(ii)(I).

55 *Id.*

56 *See id.* § 262(*l*)(1)(B)(ii)(II).

#### b. Party Experts

The expertise of outside consultants often is helpful in assessing whether a claim of patent infringement may be reasonably brought, and in assessing whether additional information may be needed in order to make that assessment. The BPCIA provides that a patentee must obtain the prior consent of the biosimilar applicant in order to provide information in the aBLA to outside scientific consultants.[57] Such consent by the biosimilar applicant "shall not be unreasonably withheld."[58]

In both BPCIA and Hatch-Waxman cases, the parties should agree to access for outside technical consultants of the reference product sponsor, provided that the technical experts: (a) agree to maintain the information as confidential and (b) agree to use the information solely for the purpose of assisting in determining whether a claim of patent infringement may be reasonably brought. The parties should agree to a procedure to permit the ANDA or aBLA applicant to object to experts prior to disclosure being made.

### 2. Prosecution Bar

The BPCIA provides that counsel recipients of the biosimilar applicant's confidential information "do not engage, formally or informally, in patent prosecution relevant or related to the reference product."[59] Although recipients of the confidential information may only use the information for the "sole and exclusive purpose of determining . . . whether a claim of patent infringement could reasonably be asserted,"[60] the patent prosecution bar with respect to the reference product addresses a concern of inadvertent disclosure of the information. ANDA applicants will seek a similar prosecution bar in Hatch-Waxman cases.

#### a. Post-Grant Proceedings

**<u>Best Practice 9</u> – Counsel who receives another party's confidential information generally should not be disqualified from participation in post-grant proceedings, but should be barred from participating, directly or indirectly, in any amendment of patent claims in such proceedings.**

The parties may wish to expressly address whether the prosecution bar applies to participation in administrative post-grant challenges to patents, such as *Inter Partes* Review, Post-Grant Review, or Oppositions. In many cases, the parties can agree that participation in such administrative proceedings is permissible so long as counsel who has received the other party's confidential information is not permitted to participate in amendment of claims in the administrative proceeding. If a patent owner wishes to make claim amendments in the proceeding, separate counsel who has not received confidential information may be designated to draft such amendments. This may involve retaining a separate law firm to handle claim amendments. Alternatively, the parties may

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57 *Id.* § 262(*l*)(1)(C).

58 *Id.*

59 *Id.*

60 *Id.*

agree that individuals from the same firm as litigation counsel may participate in claim amendments so long as they have been "walled off" from accessing confidential information produced in the litigation.

Restrictions such as the prosecution bar may be challenging for in-house counsel at smaller companies, where the intellectual property department sometimes consists of a single individual. In these circumstances, the parties should be sensitive to in-house counsel's need to understand the merits of the litigation while also overseeing concurrent post-grant proceedings. One solution may be for the in-house counsel to sign an addendum to the protective order agreeing not to provide any strategy toward amendment of claims in administrative proceedings.

#### b. Regulatory Bar

The BPCIA does not include a bar on participation in regulatory communications with the FDA, but aBLA applicants—and ANDA applicants in Hatch-Waxman cases—will generally want to include one. Such a bar prohibits those who have had access to another party's confidential information from involvement in submitting regulatory documents or communications to the FDA, such as citizen's petitions. Like the prosecution bar, the regulatory bar addresses a concern that an individual would inadvertently use the other party's confidential information in developing strategy or arguments for presentation to the FDA.

#### c. Review vs. Access

The BPCIA provisions regarding confidential access to the aBLA prior to litigation apply to persons who "receive" the confidential information.[61] In negotiating prelitigation protective orders for both BPCIA and Hatch-Waxman cases, the parties may wish to address whether the prosecution bar and any regulatory bar apply to all persons who have access to the other party's confidential information (e.g., members of the same firm who are not formally walled off from accessing the information), or only to those persons who have actually reviewed confidential information.

## D. SCOPE OF DISCOVERY: PROPORTIONALITY

The latest amendments to the Federal Rules of Civil Procedure went into effect on December 1, 2015. After much discussion about the burdens of discovery, Rule 26(b)(1) was amended to focus the scope of permissible discovery. The amendments eliminated the prior lenient standard that had persisted for decades, allowing for discovery requests that were "reasonably calculated to lead to the discovery of admissible evidence."[62] The amended Rule 26(b)(1) now sets forth a standard rooted in relevance and "proportionality." The amended rule reads:

> Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the

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61 *See* 42 U.S.C. § 262(*l*)(1).

62 FED. R. CIV. P. 26 advisory committee's note to 2015 amendment.

> proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

According to the Advisory Committee Notes accompanying the 2015 amendment, the amendment "restores the proportionality factors to their original place," which was to "deal with the problem of overdiscovery." The amendment was not intended to "change the existing responsibilities of the parties and the court to consider proportionality," nor did it place the entire burden of addressing proportionality on the party seeking discovery.

Courts' reactions to amended Rule 26 have been mixed. Some courts have rejected the notion that proportionality is new, explaining that various aspects of the proportionality assessment were taken into account under the prior version of the rule. Other courts have said that the amended rule places additional burdens on a party requesting discovery when faced with objections by the responding party. But again, the burdens do not fall solely on the requesting party. As set forth by the Advisory Committee, "[t]he parties and the court have a collective responsibility to consider the proportionality of all discovery and consider it in resolving discovery disputes." Thus, while the requesting party must account for these considerations, the amended rule does not permit "the opposing party to refuse discovery simply by making a boilerplate objection that it is not proportional."

In applying the amended rule thus far, many courts have looked at the dollar value of the case, and the expense of the requested discovery relative to the amount in controversy in assessing proportionality. Such an assessment should not stop there in patent cases arising under the Hatch-Waxman Act or the BPCIA, because the high-dollar value of these cases and the fact that they involve healthcare and pharmaceutical products could, at some level, be used to attempt to justify any and all discovery requests. In Hatch-Waxman and BPCIA cases however, time is often the most valuable thing at stake, and overbroad discovery that unnecessarily consumes time and the limited resources of the court may be counterproductive to reaching a fair, just, and timely result. Accordingly, courts evaluating discovery requests in these cases should also consider the other factors—including the scope of the patent claims in dispute, the discovery that is most relevant to resolving the infringement and invalidity issues attendant to those claims, and the facts underlying any equitable and public interest issues the court may be called on to decide.

**<u>Best Practice 10</u> – Each of the factors set forth in Federal Rule of Civil Procedure 26(b)(1) should be considered in a proportionality evaluation on the scope of permissible discovery in Hatch-Waxman and BCPIA cases, and not solely the amounts in controversy.**

Indeed, the analysis should balance the monetary stakes among each of the factors to determine whether discovery is proportional to the needs of the case. For example, while a party seeking discovery must articulate the ways the underlying information bears on the issues in the case, a party opposing discovery—who often has greater knowledge about which information can be readily retrieved—should explain why the discovery is unduly burdensome. This could include consideration of the accessibility of the information, time constraints of the case, and ways to reduce the burden or expense of discovery, such as using tools for reliably searching electronically stored information. Nonspecific boilerplate objections that the discovery would be unduly burdensome should not be sufficient, regardless of the size of the party opposing the discovery. And "consideration of the parties' resources does not foreclose discovery requests addressed to an

impecunious party, nor justify unlimited discovery requests addressed to a wealthy party."[63] If the parties cannot settle on a mutually acceptable scope of discovery to reasonably provide information relevant to the disputed issues, the court should consider each of the factors in making a case-specific determination of the appropriate scope of discovery.

One of the factors in the analysis is the relevance of the requested information to the issues that are truly in the case. For example, in a patent case where the parties stipulate that the accused products infringe, extensive discovery about the accused product may not be proportional, especially if the requesting party cannot articulate a sensible explanation for how the information is relevant. In biopharma cases where only invalidity is at stake, discovery about the accused product that goes beyond the ANDA or biosimilar application itself will often not be relevant, and parties will often agree on stipulations that limit such discovery in exchange for a stipulation of infringement.

## E. MULTIPLE DEFENDANT ISSUES

The Supreme Court's *TC Heartland* decision in 2017 limited venue for patent infringement suits to the defendant's state of incorporation, where the defendant has committed acts of infringement, or has a regular and established place of business, making it more difficult to bring a single suit against multiple defendants in a single forum.[64] *TC Heartland* will increase the number of instances in which ANDA and aBLA defendants are spread across different venues in separate cases. Courts still have tools to coordinate generic or biosimilar litigations involving multiple defendants and different forums, including Multidistrict Litigation (MDL)[65] and various forms of informal cooperation between judges. Thoughtful use of these tools is necessary to approach a pre-*TC Heartland* level of efficiency in resolving these cases.

### 1. Coordination and Consolidation of Cases in Different Venues

**<u>Best Practice 11</u> – Where joinder of all ANDA or aBLA defendants in one suit is not possible, courts should coordinate and resolve jointly as many pretrial issues as practicable while tailoring the coordination to account for the scope of each case and any defendant-specific issues.**

Coordination between cases, whether in the same or different forums, can foster judicial economy and minimize the likelihood of inconsistent rulings. Where Hatch-Waxman or BPCIA litigations are filed across multiple venues, the cases will be tried individually. But there are still advantages to be gained from pretrial coordination, particularly with respect to claim construction, discovery, and dispositive motions.

There are sound reasons to coordinate and resolve claim construction issues in a single proceeding. A claim construction order applicable to multiple cases provides consistency in claim scope across those cases. Claim construction undergirds many merits issues, including infringement and validity, and having one common set of constructions promotes predictability. Joint claim construction

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63 *Id.*

64 TC Heartland LLC v. Kraft Foods Grp. Brands LLC, 581 U.S. __, 137 S. Ct. 1514, 1518 (2017).

65 28 U.S.C. § 1407.

proceedings also conserve judicial resources. Claim construction issues are generally amenable to coordinated resolution because the intrinsic evidence is common to all cases. Accused products are generally irrelevant to claim construction, and thus defendant-specific noninfringement arguments would not preclude coordination.

There are challenges to consolidating claim construction proceedings even in cases filed close in time. Courts often impose strict limits on the number of terms to be construed and the length of briefs to be filed. Courts should ensure there is sufficient flexibility in procedural rules to accommodate evidence and argument from the entire defendant group. Another issue is that where claim construction is consolidated in one court, the judges that will receive cases for trial postconsolidation, as in the case of MDL consolidation, are less familiar with the patents than they would be in a standalone case. One approach where there are fewer cases to coordinate is for the judges to sit together in a joint *Markman* hearing. Logistical issues such as the cost of travel may preclude this option for some courts, though videoconference participation in joint hearings can provide a similar benefit.

Courts coordinating multidefendant proceedings should also attempt to hear and resolve dispositive motions that present common issues. Validity issues, like claim construction, can be coordinated across cases to conserve resources and prevent inconsistent results. However, validity issues frequently turn on material disputes of fact and may not be susceptible to resolution on dispositive motions. Even if one or more validity issues can be resolved on summary judgment—for example, patent eligibility or anticipation—other issues could remain for individual trials, including obviousness and enablement, making the savings from coordination minimal.

Coordination of discovery between multiple cases can promote efficiency and preserve party resources, particularly the plaintiff's. Courts often require parties to coordinate depositions so that fact witnesses, such as the named inventors, testify only once. This presents a challenge for multidefendant proceedings because the presumptive seven-hour limit may not permit each defendant sufficient time to perform its own questioning. Courts should be made aware early in the case of concerns that default discovery limits may be unduly restrictive. Courts should entertain reasonable requests to tailor discovery limits to maintain balance between the needs of each case and the burden on the plaintiff. It is often the case that default discovery limits sized for single cases must expand to meet the needs of consolidated or coordinated multidefendant proceedings.

Protective orders require special attention where courts coordinate discovery between multiple competitor defendants. As discussed above, defendants may seek to withhold production of sensitive portions of the ANDA or aBLA, such as formulation and manufacturing information. Similarly, some portion of the discovery produced by the plaintiff may be related to specific defendants. Defendants may be able to articulate a basis to withhold production of certain sensitive materials from in-house counsel of codefendants, and courts should give serious consideration to those reservations. With an adequate protective order in place, the best practice would be for parties to produce the same materials to all other parties, but this may require permission from the court for defendants to withhold sensitive information altogether.

### 2. Special Considerations Where Defendants Have Different Interests in Moving Forward with the Litigation

As discussed above, many Hatch-Waxman litigations involve scenarios where ANDAs are not submitted close enough in time for cases to be coordinated or consolidated. It is common for multiple applications to be filed with the FDA on the earliest date on which a paragraph IV certification may be filed (typically referred to as the "NCE-1 date"[66]) in a "first wave" of cases, and for subsequent ANDAs to be filed too late for those cases to "catch up" to the first wave. Defendants should not be assumed to have compatible interests in moving forward with litigation. Courts attempting to coordinate between cases separated in time must balance the parties' competing interests while serving the institutional interests in judicial economy and in promptly resolving challenges to patents by generics.

An issue that comes up frequently with respect to "second-wave" cases is whether plaintiffs should produce invalidity/infringement contentions and expert reports from "first-wave litigants." While production of underlying prior art documents cited in contentions and expert reports is typically not an issue, the production of the contentions or reports themselves are frequently escalated to the courts as a discovery dispute. In deciding such disputes, the courts can consider the overlap of claims, counterclaims, or defenses between first- and second-wave defendants. Any concerns with respect to confidential information of first-wave defendants can be addressed by redacting out such information.

Achieving consistent claim constructions across multiple cases poses a distinct challenge. Claim construction orders are typically not comprehensive or permanent. *Markman* orders do not cover every potential issue or dispute that may arise over the scope of the asserted claims. Courts routinely limit the number of disputed terms that are addressed in any given proceeding. Courts are frequently asked to address additional disputes after a *Markman* order has issued, and some courts engage in "rolling" claim construction, where a *Markman* order is revisited as disputes surface over time, sometimes as late as trial. The unfixed nature of claim construction risks inconsistency in multidefendant scenarios. For example, defendants in a later wave of ANDA cases may seek to change a construction reached in a first-wave *Markman* proceeding that the later defendants were not parties to. Even within a single wave of defendants, a party in an individual case may seek a modified construction or the construction of a new term to resolve a dispute that arose after the coordinated or consolidated cases were returned to their original courts for trial. In evaluating whether it is necessary or prudent to deviate from a *Markman* order that affects multiple cases, courts should be mindful of the value of maintaining consistency between cases and limit such changes to instances of new evidence, new disputes, or defendant-specific issues to the extent possible. Before entertaining requests to modify the original order, courts should consider entertaining briefing on whether there are material developments in the record that require such modification.

Courts should consider whether noninfringement defenses can be taken up early to resolve as coordinated issues, or must be conducted on a defendant-by-defendant basis within each case separately. In Hatch-Waxman cases, courts should be able to address noninfringement arguments in a coordinated way. Because these issues may turn on claim construction, courts may be able to

[66] The acronym NCE-1 derives from New Chemical Entity exclusivity that allows ANDA filers to file one year prior to the expiry of the exclusivity.

include second-wave cases in a coordinated resolution of infringement. Courts should also attempt to address validity issues within a single proceeding, provided sufficient room is given to all defendants in that wave to present invalidity contentions. While there are efficiency gains in litigating invalidity in a single case, courts must be cognizant that as a constitutional matter, subsequent defendants cannot be bound by a finding of no invalidity in cases in which they are not parties. As a practical matter, most courts will look closely at another court's decision on the same issues. But later defendants may raise invalidity defenses that were not adequately presented by the first-wave filers, and fairness dictates that these defenses should receive full consideration when presented.

## F. DISCLOSURE OF FDA CORRESPONDENCE

As discussed, several jurisdictions have promulgated rules that require production of the ANDA early in the litigation, and the BPCIA requires production of the aBLA and other potentially relevant information to participate in the patent dance.[67] Some jurisdictions also require the ANDA applicant to produce FDA correspondence within a specified period of time after submission to or receipt from the FDA on an ongoing basis during litigation.[68]

Production of FDA correspondence is intended, in part, to assist the parties and the court in understanding the status of the ANDA applicant's approval and any changes in the product that might be relevant to issues in the patent infringement litigation. An issue that frequently arises when an ANDA applicant obtains tentative or final FDA approval is whether and to what extent an ANDA applicant should be required to inform the reference product sponsor of its planned launch. Knowledge of an ANDA applicant's planned launch can help the parties and the court prepare for or avoid emergency temporary restraining order and preliminary injunction proceedings. Such information, however, is often highly sensitive, competitive information that can put an ANDA applicant at a competitive disadvantage if the applicant is required to disclose it. Therefore, depending on the circumstances of the case, the parties should discuss whether this disclosure should be made. In the event of a dispute, the court should carefully weigh the need for disclosure against the need for the ANDA applicant to reveal sensitive competitive information to competitors, and if disclosure is required, on what conditions such information should be disclosed to protect the ANDA applicant's competitive position.

In addition, there are no similar rules in place for NDA/BLA holders (the original branded drug or biologics manufacturers asserting their patent rights) to produce the entirety of their original NDA/BLA applications to the Food and Drug Administration at a specified time in the litigation to the ANDA/aBLA holders (the generic drug and biosimilar manufacturers). In most cases, however, the NDA/BLA, or portions of it, will be relevant to issues in the case. For example, the NDA/BLA may be relevant to: whether the asserted claims are enabled or described; obviousness issues such as the state of the art, reasonable expectation of success or lack thereof, praise, skepticism, unexpected results, or whether the reference product embodies the claimed invention; and certain infringement issues, especially in cases involving the doctrine of equivalents. Therefore, parties and the courts should facilitate production of the NDA/BLA as early in the case as practicable in order to facilitate

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67 *See, e.g.*, D.N.J. L. PAT. R. 3.6; 42 U.S.C. § 262(*l*)(2).

68 *See, e.g.*, D.N.J. L. PAT. R. 3.6(j).

speedy resolution of the case, but the court should consider whether certain portions of the NDA/BLA need not be produced considering the actual disputed issues in the case. In addition, similar to the rules requiring ANDA applicants to produce FDA correspondence on an ongoing basis, NDA/BLA holders should do the same.

# V. Interplay between PTAB Challenges and Hatch-Waxman and BPCIA Litigation

**Best Practice 12 – In cases brought under the Hatch-Waxman Act or BPCIA, courts and the USPTO should take into consideration their respective judicial and PGR/IPR proceedings to achieve a just and efficient resolution of these disputes.**

## A. OVERVIEW OF AIA POST-GRANT CHALLENGES

The America Invents Act of 2011 authorized the USPTO's Patent Trial and Appeal Board (PTAB) to review the validity of issued patents in a streamlined adversarial proceeding. Before turning to the interplay of these PTAB proceedings with parallel ANDA and BPCIA litigation, this section provides a brief summary of some PTAB procedures. While the AIA authorized three types of post-grant challenges—inter partes reviews (IPR), post-grant reviews (PGR), as well as a transitional review for covered business method patent—IPRs and PGRs are the most relevant to biopharmaceutical patents.[69] By statute, the board is required to make a decision on institution within six months of the filing of a petition for IPR or PGR. In that decision, the board must decide if the petition has shown that there is a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims sought to be challenged. The board's final written decision must address the patentability of every patent claim challenged in the petition,[70] reviewing each and every ground raised by the petitioner.[71]

An IPR proceeding will normally take 18 months to complete as measured from the time of its first filing. This period includes about six months for the USPTO to decide whether to institute an IPR trial and 12 additional months (but no more than 18 months) for that trial to be completed and for a final USPTO decision to be rendered. Where the IPR proceeding is joined with other reviews, which is not uncommon when more than one party is seeking approval of a generic drug or biosimilar, then the actual length of time to a final written decision may substantially exceed one year from institution.[72]

A patent challenger is time-barred from filing an IPR petition more than one year after being served with a complaint alleging infringement of the patent.[73] So when there is parallel litigation, a decision

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69 The Supreme Court upheld the constitutionality of the IPR process, holding that there is no violation of Article III or the Seventh Amendment. Oil States Energy Servs., LLC v. Greene's Energy Group, LLC, 548 U.S. __, 138 S. Ct. 1365, 1379 (2018).

70 SAS Inst. Inc. v. Iancu, 584 U.S. __ , 138 S. Ct. 1348, 1354 (2018), 35 U.S.C. § 318(a).

71 AC Techs. S.A. v. Amazon.com, Inc., 912 F.3d 1358 (Fed. Cir. 2019).

72 The PTAB views joinder cases as having no deadline. Some examples where PTAB issued its final written decision after 12 months: IPR2016-00318, IPR2016-00237, IPR2016-00240, IPR2016-1340, IPR2016-0084.

73 35 U.S.C. § 315(b).

whether to file a petition for IPR often will need to be made before issues are fully developed in litigation, and sometimes even before all of the asserted claims are known.[74]

Unlike a district court proceeding, there is no Article III standing requirement for a party to bring an IPR or PGR challenge.[75] On appeal, the Federal Circuit does require that IPR appellants establish standing by showing actual injury or injury-in-fact. A patentee who seeks appeal will be able to satisfy that requirement, but an unsuccessful IPR petitioner might not if the petition is filed before a product is sold or ready to be sold. The Article III injury-in-fact requirement applies for appeals from the PTAB, with the burden falling on the IPR petitioner to show actual injury before appealing to the Federal Circuit.[76]

Because IPR proceedings are limited to challenges based on novelty and obviousness, and then only on prior art consisting of prior art patents and printed publications, even if an IPR is instituted, it may not address all of the validity issues that have been or may be raised in an ANDA or BPCIA litigation. Accordingly, validity issues relating to patent claims not made the subject of an instituted IPR trial may still need to be litigated before the district court. The PTAB now follows the same standard for claim construction during an IPR as that used by the courts—the standard set by the Federal Circuit in *Phillips v. AWH Corp.*[77]

The Sedona Conference's Working Group 10 has published as part of its *Commentary on Patent Litigation Best Practices* a chapter on Parallel USPTO Proceedings,[78] providing principles and best practice recommendations for such parallel patent proceedings in general.

## B. TIMING OF IPR/PGR CHALLENGES IN HATCH-WAXMAN LITIGATION

IPR challenges are currently seen by some as a strategic alternative for generic drug manufacturers to press certain invalidity contentions before the USPTO's Patent Trial and Appeal Board rather than the court. But the Hatch-Waxman framework hinges on a complex paradigm in which district court litigation has and will continue to play a central role. Therefore, IPR proceedings are much more likely to be an adjunct to ANDA litigation in district court rather than an alternative.[79]

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74 35 U.S.C. § 315(b). In ANDA cases, and in BPCIA cases where the parties have engaged in full disclosures under the statutory "patent dance," the product claims to be asserted are likely already known, as they are identified in the Orange Book listing that was the subject of the ANDA applicant's paragraph IV certification or were likely identified in the information exchanges provided under the BPCIA.

75 35 U.S.C. § 316(a)(11). *See also* 37 C.F.R. § 42.100(c).

76 Phigenix, Inc. v. Immunogen, Inc., 845 F.3d 1168, 1172 (Fed. Cir. 2017); RPX Corp. v. Chanbond LLC, No. 17-2346 (Fed. Cir. Jan. 17, 2018) (order dismissing appeal for lack of standing).

77 415 F.3d 1303 (Fed. Cir. 2005). 3 Fed. Reg. 51,340 (Oct. 11, 2018).

78 *See* The Sedona Conference, *Commentary on Patent Litigation Best Practices: Chapter on Parallel USPTO Proceedings ("Stage One")* (Oct. 2016), and *("Stage Two")* (July 2017 public comment version), *available at* https://thesedonaconference.org/publication/Parallel_USPTO_Proceedings.

79 In contrast, in BPCIA cases a patent challenger may seek to file an IPR/PGR several years before any district court litigation is initiated in an effort to obtain patent clearance before launch and as a possible

There are many factors parties consider before availing themselves of an IPR proceeding, and these factors influence the timing.

First, an ANDA applicant may possibly bring an IPR or PGR challenging the validity of an innovator's patent even before it ever files for regulatory approval. While both the Hatch-Waxman and BPCIA statutes make the filing of an abbreviated license application an artificial act of infringement that permits patent litigation to commence, as noted above, IPRs and PGRs do not require Article III standing. As such, a potential ANDA applicant may seek institution of an IPR at any time (subject only to the one-year limitation triggered by any infringement suit brought against it by the patent holder).[80] But even though there is no standing requirement to file an IPR/PGR petition with the PTAB, the Federal Circuit has required Article III standing in order to appeal an adverse decision from the board.[81] So, while an ANDA filer may challenge a patent before its product has received FDA regulatory approval, if it mounts a challenge too soon, it may not have sufficient standing to appeal an adverse PTAB decision.[82] If a patent challenger does not file a petition for IPR first but instead waits to be sued, the first consideration is that the IPR statute permits only novelty and obviousness validity challenges based on prior art patents and printed publications, and not other types of validity challenges or noninfringement defenses. The patent challenger therefore must weigh the strengths and weaknesses of its other validity and noninfringement positions before deciding on the timing for filing the IPR and the appropriate course of action.

More typically, ANDA applicants wait until after the district court litigation has commenced before filing any IPR/PGR petition. There are several reasons for an ANDA applicant to wait. First, a potential ANDA applicant may not wish to file an IPR early (before any district court action) because doing so may simply clear the way for its competitor ANDA applicants, who often remain unknown until the "NCE-1 date", i.e., the earliest date on which a paragraph IV notice letter may be provided to the NDA holder (the branded company whose New Drug Application was approved by the FDA, authorizing the marketing of the drug). After all, the ANDA applicant who is first to file (the "FTF" applicant) has the opportunity to get the 180-day exclusivity period. Second, because an NDA holder is required to list its patents for assertion in the Orange Book, an ANDA applicant knows the universe of assertable patents, which is typically a number that can reasonably be litigated in a single district court action. Third, the Hatch-Waxman framework providing a 30-month regulatory stay provides a predictable timeline to resolve patent challenges before launch of a generic

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alternative to litigating the patent in a district court action. *See* Section V.E (Special Considerations in BPCIA cases), *infra*.

80 Hatch-Waxman precludes parties from litigating the patent issues before an ANDA application is filed; in contrast, there is no such statutory prohibition concerning the filing of IPR petitions in the period before an ANDA filing.

81 Phigenix, Inc. v. Immunogen, Inc., 845 F.3d 1168, 1172 (Fed. Cir. 2017); RPX Corp. v. Chanbond LLC, No. 17-2346 (Fed. Cir. Jan. 17, 2018) (order dismissing appeal for lack of standing).

82 Whether or not an ANDA has actually been filed by the IPR petitioner has weighed heavily in the analysis of whether there is injury in fact to support the petitioner's standing on appeal. With no ANDA, the alleged injury may be speculative and nonspecific. Argentum Pharms. LLC v. Novartis Pharms. Corp., No. 18-2273 (Fed. Cir. Apr. 23, 2020). The same issue arises in BPCIA cases—with no approved product, it is difficult for the petitioner to show injury in fact. Pfizer Inc. v. Chugai Pharm. Co., No. 19-1513 (Fed. Cir. Apr. 27, 2020).

drug. Finally, for an FTF applicant, filing an early IPR/PGR challenge may risk forfeiture of its 180-day exclusivity period by obtaining a final invalidity determination before it has final FDA approval.[83]

As discussed in Section V.E. (Special Considerations Relating to BPCIA) below, these timing considerations can be quite different in the context of BPCIA litigation.

When IPRs or PGRs proceed in parallel with ANDA litigation in district court, in the absence of a stay, a district court decision entered before the expiration of the 30-month stay can occur before a final written decision of the PTAB. That timing may influence a decision to stay the litigation, as described below. Also, the first proceeding to become final will have an immediate preclusive effect on the other, parallel proceeding.[84] Finality here means that the merits have been decided, including any appeal, leaving nothing but execution of the judgment. When the appeal from an IPR is decided first, for example, that has immediate issue-preclusive effect on a parallel appeal from the district court.

**<u>Best Practice 13</u> –The parties should inform the USPTO/PTAB and other tribunals of both ongoing litigation involving the same or related patents, and the potential impact of IPR or PGR proceedings on the litigation.**

The USPTO Director, who has delegated the authority to institute IPR and PGR proceedings to the PTAB, may take considerations arising from parallel ANDA litigation into account in its decision whether to institute an IPR or PGR trial. The statute provides that the Director may use his/her discretion to deny institution when parallel district court litigation on the same issues is advanced.[85] When trial in the district court is set for an earlier date than the time needed to reach a final decision in the IPR, the PTAB now considers the following factors from *Apple v. Fintiv*:

1. whether the court granted a stay, or evidence exists that one may be granted if a proceeding is instituted;
2. proximity of the court's trial date to the board's projected statutory deadline for a final written decision;
3. investment in the parallel proceeding by the court and the parties;
4. overlap between issues raised in the petition and in the parallel proceeding;
5. whether the petitioner and the defendant in the parallel proceeding are the same party;

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83 Note, however, that because an invalidity decision by the PTAB in an IPR is an administrative decision, not a judicial decision, it does not result in the lifting of a 30-month stay until it is affirmed on appeal by the Federal Circuit and the district court takes action pursuant to the appellate decision. 21 U.S.C. § 355(j)(5)(B)(iii)(I). Accordingly, many ANDA filers rely on winning the district court proceeding rather than before the PTAB (and on appeal to the Federal Circuit), because a district court decision that is favorable to the ANDA applicant will lead to an earlier end to the 30-month stay.

84 XY, LLC v. Trans Ova Genetics, 890 F.3d 1282, 1294 (Fed. Cir. 2018); Fresenius USA, Inc. v. Baxter, Int'l, Inc., 721 F.3d 1330 (Fed. Cir. 2013).

85 35 U.S.C. § 314(a).

6. other circumstances that impact the board's exercise of discretion, including the merits.[86]

ANDA litigation presents particular issues relevant to these factors. First, as described more fully in the next section, the 30-month regulatory stay may influence the district court not to stay the litigation. That, in turn, is relevant to the board's consideration of whether instituting an IPR is an efficient use of resources as part of the first *Fintiv* factor—if the litigation will continue without a stay, it is less efficient to institute. Second, and on a related note, the trial date in ANDA litigation is set with the 30-month period in mind, so the district court trial date will often be close in time with an IPR final written decision under *Fintiv* factor two. An important factor in all cases, including ANDA cases, is the overlap of the issues presented in the IPR and the district court litigation. Given the stakes, and if the petitioner is a party to the near-term ANDA litigation, the issues will often have significant overlap. Finally, the important issue of whether the parties are the same is described more fully below.

In sum, the PTAB is able to deny institution when it would be more efficient to proceed in a parallel district court case, using the *Fintiv* factors. Of course, if an IPR or PGR trial is instituted, the district court may also consider whether to grant a stay, which is the subject of the next section.

## C. INTERPLAY OF 30-MONTH REGULATORY STAY AND REQUESTS FOR STAY PENDING IPR OR PGR

In a patent infringement action between branded and generic pharmaceutical companies, the Hatch-Waxman Act[87] provides for an automatic 30-month stay of FDA approval of the ANDA for the proposed generic pharmaceutical product. The legislative history of the act makes clear that the purpose of the 30-month stay is to permit resolution of the underlying patent dispute before the generic product may enter the market.[88]

Also noted above, a party may seek IPR or PGR review of a patent asserted in Hatch-Waxman litigation, and such review may occur in parallel with Hatch-Waxman litigation. Should a party to the Hatch-Waxman litigation seek a stay of district court proceedings pending IPR review, the statutory goals of the Hatch-Waxman Act may come into conflict with the goals of the America Invents Act. Specifically, tension can arise between the Hatch-Waxman statutory goal of resolving patent issues as promptly as possible and, in any event, within the 30-month stay of FDA approval, and the statutory goal of the AIA to provide a more efficient and less costly alternative to district court patent litigation.

As such, in addition to a request for stay of litigation pending IPR review, a party (typically the patent holder) may request an extension of the 30-month regulatory stay if the district court litigation is not proceeding apace. For example, if a district court entertains a stay of ANDA

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86 Apple Inc. v. Fintiv, Inc., IPR2020-00019 (PTAB Mar. 20, 2020); NHK Spring Co. v. Intri-Plex Techs., Inc., IPR2018-00752 (PTAB Sept. 12. 2018).

87 21 U.S.C. § 355(j).

88 Because BPCIA patent litigation does not involve a stay of regulatory approval, the same tension does not exist in seeking a stay pending IPR, although a delay in the resolution of the BPCIA litigation may affect a sponsor's ability to secure a permanent injunction as a matter of right. *See* 35 U.S.C. § 262.

litigation pending IPR/PGR review, a patent holder may want to ensure that it has adequate time to litigate any issues that may remain after such review to prevent an at-risk launch and, thus, may concomitantly seek an extension of the 30-month regulatory stay.

This stay analysis is further complicated by the fact that the IPR or PGR petitioner may not be a party to the ANDA litigation, but instead may be a later generic filer.

**<u>Best Practice 14</u> – The court in considering a motion to stay an ANDA litigation in view of a pending IPR may consider the efficient, orderly management of the district court litigation and the effect of the 30-month regulatory stay.**

Courts have typically articulated the standard stay considerations as follows:

- whether a stay will simplify issues at trial,
- whether a stay would improperly delay litigation (e.g., if discovery is already complete and a trial date is set), and
- whether a stay will unduly prejudice the nonmoving party.[89]

### 1. Stay Pending IPR Review in Hatch-Waxman Cases

In the Hatch-Waxman context, there is generally a strong incentive to deny a stay request pending IPR/PGR, because courts are disinclined to allow the litigation to extend beyond the 30-month regulatory stay and hence increase the likelihood of an at-risk launch, which may lead to preliminary injunction proceedings. It has been argued that such preliminary injunction proceedings would put a significant burden on the parties and on the court, as they would create the need for accelerated fact and expert discovery to address the likelihood of success on the merits, as well as the other preliminary injunction factors, by the parties and the court in a very compressed timeframe.

Applying the standard stay considerations described above to deciding whether to stay a Hatch-Waxman litigation pending the outcome of IPR/PGR proceedings, the court may consider whether a stay would: (1) impose undue prejudice to the nonmovant; (2) simplify the issues for trial; and (3) impose improper litigation delay.

#### a. Undue prejudice or clear tactical disadvantage to the nonmovant

If a significant number of issues may still need to be resolved by the court after any IPR/PGR review, a plaintiff could be prejudiced or tactically disadvantaged by a litigation stay in the absence of tolled regulatory stay. For example, there may be asserted patent claims or defenses in the litigation that will not be addressed in the IPR proceeding(s). Under these circumstances, in the absence of a regulatory stay, the district court may be required to undertake temporary restraining order or preliminary injunction proceedings that will closely resemble the very proceedings the 30-month stay

[89] For full discussion of these considerations on motions to stay in the IPR/PGR context, *see* The Sedona Conference, *Commentary on Patent Litigation Best Practices: Parallel USPTO Proceedings ("Stage One")* (October 2016), Section IV.B (Considerations on Motions to Stay), at 20, *available at* https://thesedonaconference.org/publication/Parallel_USPTO_Proceedings.

was designed to avoid, i.e., the collection and presentation of complicated scientific and market evidence and arguments in a very compressed timeframe.[90]

#### b. Simplification and acceleration of resolution of merits patent issues

As in typical patent cases, the extent to which IPR/PGR will resolve or simplify issues in the district court litigation is an important part of the stay analysis. However, in the context of ANDA litigation, courts recognize the importance of timely resolving the underlying patent dispute to facilitate generic entry where appropriate. Moreover, in an ANDA case, the cost or inefficiency of parallel proceedings may be outweighed by the prospect of accelerated injunction proceedings if issues remain to be litigated after a stay pending IPR. Thus, both the simplification and speedy resolution of the patent challenge should be considered in the context of stays pending IPR/PGR review.

#### c. Improper litigation delays

In deciding whether a stay would be appropriate, the district court may consider both the stage of the litigation and whether either party has improperly delayed the case.

First, if a significant amount of work has already been done to advance the district court litigation, e.g., if discovery has been substantially completed and a trial date is approaching, this factor may weigh against staying the litigation.

Second, when determining whether or not to extend the 30-month regulatory stay in Hatch-Waxman litigation, some courts have cited to a party's failure to meet discovery deadlines when finding that the party failed to reasonably cooperate under Section 355(j)(5)(B)(iii).[91] For example, where a party has failed to facilitate relevant discovery, particularly where discovery is located outside of the United States (hence necessitating the party's cooperation), it may be possible to argue that the opposing party has not been reasonably cooperative. Notably, some courts have emphasized that parties requesting a regulatory stay extension must have clean hands.[92] In addition, parties should provide an estimate of the time and expenses associated with any discovery delays.[93] Parties should be careful, however, to reserve this factor for significant and truly prejudicial delays, and not bring a litany of discovery complaints.

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90 To show that an extension of the regulatory stay is being sought to maintain the status quo rather than to gain a tactical advantage, the party requesting the stay should request the submission of a status report to the court upon issuance of the final written decision in the IPR(s), so the court can lift any regulatory stay the circumstances may then warrant.

91 *See, e.g.*, Bayer Schera Pharma AG v. Sandoz, Inc., No. 1:08-cv-03710-PGG, Document 160, at 14–15 (S.D.N.Y. Sept. 2, 2010).

92 *Id.* (noting that the patent holder had never even asked for a Rule 26(f) conference with the ANDA filer, and that while the court had granted early jurisdictional discovery, the parties never made efforts to take merits discovery concurrently).

93 Shire LLC v. Watson Pharm., Inc., No. 1:11-cv-2340-JPO, Document 104, at 4 (S.D.N.Y. Sept. 25, 2012) (denying the request to extend the regulatory stay, but noted that if it had been inclined to grant the extension, it would have opted for a "specified amount of time proportionate to the length of the delay caused by a party").

### 2. Extension of the 30-Month Regulatory Stay

Practitioners and courts weighing a stay of ANDA litigation pending IPR/PGR review should consider the effect of a delay on the 30-month regulatory stay and the respective interests of the parties. A stay of ANDA litigation pending IPR/PGR review is further complicated by the fact that a party may seek to extend the 30-month regulatory stay. Unlike in typical patent litigation, a defendant in ANDA litigation may not want to do anything to delay resolution of the district court proceeding or extend the 30-month regulatory stay.

Before the passage of the America Invents Act and the implementation of IPR proceedings, there were only two decisions in which courts tolled the 30-month stay pending resolution of administrative proceedings, based on both their inherent powers and a broad interpretation of 21 U.S.C. § 355(j)(5)(B)(iii). In *Novartis Corp. v. Dr. Reddy's Laboratories,* the court granted an extension of the 30-month stay in conjunction with granting the generic manufacturer's request for stay of the ANDA litigation pending the FDA's safety and efficacy review of its proposed generic product.[94] In *Abbott Laboratories v. Matrix Laboratories,* the court granted a tolling of the 30-month regulatory stay in conjunction with granting the generic manufacturer's request for a five-year stay of litigation to await expiration of other Orange-Book-listed patents of the branded product manufacturer, explaining the extension was necessary to prevent prejudice to the branded product manufacturer.[95] The court exercised its inherent power to control its docket in both cases.[96]

To date, in the absence of the agreement of the parties, courts have yet to extend the 30-month regulatory stay in light of a pending IPR or PGR.

At least two courts have considered whether to extend or toll the 30-month stay to maintain the Hatch-Waxman status quo in the context of considering a stay of litigation in light of a pending IPR: *Eli Lilly & Co. v. Accord Healthcare Inc.*,[97] and *Alcon Laboratories Inc. v. Akorn, Inc.*[98]

In *Eli Lilly*, the court granted a litigation stay after IPR institution and declined to extend or toll the 30-month regulatory stay, finding no specific litigation delays by the generic manufacturer, as would be required to support an extension of the 30-month regulatory stay under 21 U.S.C. 355(j)(5)(B)(iii)

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94 Novartis Corp. v. Dr. Reddy's Labs., Ltd., No. 1:04-cv-0757-SAS, 2004 WL 2368007 (S.D.N.Y. Oct. 21, 2004). The court applied a three-factor test to determine whether a stay pending an IPR was appropriate, i.e., whether (1) a stay would unduly prejudice or present a clear tactical disadvantage to the nonmoving party; (2) a stay will simplify the issues in question and trial of the case; and (3) discovery is complete and whether a trial date has been set. *Id.* Under factor (1), the *Novartis* court found that Novartis would not be unduly prejudiced by the litigation stay if it was granted a commensurate extension of the 30-month regulatory stay. *Id.* at *3.

95 Abbott Labs. vs. Matrix Labs., No. 09-cv-1586, Document 49 (N.D. Ill. Nov. 5, 2009).

96 *Novartis* at *3; *Abbott Labs.* at *4–5.

97 No. 1:14-cv-00389-SEB-TAB, 2015 WL 8675158 (S.D. Ind. Dec. 11, 2015).

98 No. 15-cv-285 (RMB/JS), 2016 WL 99201 (D.N.J. Jan. 8, 2016).

(requiring the nonmovant party's "fail[ure] to reasonably cooperate in expediting the litigation").[99] In reaching its decision, the court acknowledged the tension between a litigation stay and the 30-month limit on the regulatory stay but concluded that a litigation stay was warranted because "Plaintiffs will have ample opportunity to seek an injunction once the IPRs are finally concluded, which eliminates any alleged prejudice to Plaintiffs."[100]

In *Alcon*, the district court sua sponte issued a stay pending IPR but refused to extend or toll the regulatory stay, stating that it had no authority to do so on the same grounds as in *Eli Lilly*.[101]

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In deciding whether to stay a Hatch-Waxman court litigation pending IPR/PGR review, courts should consider whether to concomitantly extend the 30-month regulatory stay to avoid undue prejudice to the litigants. It is important to remember that Congress provided the 30-month stay to permit complete resolution of patent challenges in that timeframe. It is, however, also possible for the district court action to be stayed pending IPR/PGR, and for the 30-month regulatory stay to not be extended, and the bench and bar should keep in mind potential prejudicial effect on the litigants.

## D. ADDITIONAL CONSIDERATIONS FOR STAYS IN MULTIPLE DEFENDANT ANDA CASES

As described above, the efficiency and fairness of parallel PTAB and district court litigation depends in part on the overlap of issues and whether the same parties are involved in both proceedings. Particular issues arise when multiple ANDA filers are involved in parallel challenges to the same patents.

Some ANDA patent litigations do involve a single generic challenger and a brand company patentee, but many if not most ANDA litigations involve multiple generic challengers. One common scenario occurs when multiple generic companies file ANDAs in close proximity in time. In this scenario, the paragraph IV notice letters are sent and the district court litigations are filed close in time, often in the same court. These cases are typically coordinated for claim construction and discovery and are often tried together. For example, multiple ANDA filers often submit their ANDAs on the so-called NCE-1 date, the first date an ANDA may be accepted for filing by the FDA. It is also common that

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[99] *Id.* Notably, in reaching its conclusion, the *Eli Lilly* court seemed concerned that Eli Lilly had argued in a different Hatch-Waxman case that a litigation stay pending resolution of an IPR was not prejudicial but rather beneficial to a patent owner. *See* 2015 WL 8675158, at *2; Eli Lilly & Co. v. Accord Healthcare, Inc., No. 1:14-cv-00389 SEB-TAB, Document 357, at 2–4 (S.D. Ind. Oct. 26, 2015) (Defendants' Reply Brief in Support of Defendants' Motion for Stay of Litigation). Thus, parties requesting or opposing a stay should ensure that they maintain a consistent litigation position regarding litigation stays (and commensurate regulatory stays) or be prepared to clearly explain why the circumstances of a given case are distinguishable from those of a case in which a different position was taken.

[100] *Id.* It is interesting to note that the court initially gave credence to plaintiff's concerns about the running of the clock on the 30-month stay *before* IPR institution, but, in its later opinion, stated that the concerns were "not a recognized prejudice."

[101] *Id.* (noting: "A court has discretion to extend the 30-month regulatory stay, but only if a party has 'failed to reasonably cooperate in expediting the action.' . . . Put simply, the Court is not prepared to hold—nor have Plaintiffs argued—that either party has failed to reasonably cooperate in expediting the action").

after initial litigation begins against this "first wave" of ANDA filers, additional ANDAs are submitted and later cases are filed. When the filing of later ANDAs is delayed so that it is not feasible for a later filed case to "catch-up," there can be one or more generics grouped in a "second wave" of litigation, or even a "third wave."

This section explores the issues that arise in the interplay between IPR proceedings, district court litigation, and stay requests (of both district court litigation and the 30-month regulatory stay) involving multiple ANDA filers. In particular, we consider scenarios where fewer than all of the ANDA filers in coordinated district court litigation are participating in IPR proceedings. In addition, a strategy has emerged wherein late-filing generics may choose to file IPR petitions in cases where the result of first-wave litigation was in the patentee's favor.

In general, the parties in these "waves" should strive to coordinate the cases so as not to require the court to conduct separate *Markman* hearings or trials unless absolutely necessary. While joint proceedings do require special care to avoid one generic company sharing its confidential information with another, these issues typically can and should be worked out. While true consolidation almost never occurs in these cases, they may nonetheless be closely coordinated in a manner that synchronizes schedules and often allows certain joint depositions, as well as common *Markman* hearings and trials.

Recall that the first-to-file ANDA filer (the "FTF" party) has the incentive of a 180-day exclusivity period if it succeeds in the litigation. That exclusivity may impact how the FTF generic proceeds, and is therefore a factor that the court may choose to consider in efficiently managing multiple ANDA cases. For example, FTF exclusivity may be forfeited if an FTF generic does not launch its ANDA product within a certain period of time following various "forfeiture events."[102] In practice,

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[102] The original 180-day exclusivity provision was modified in 2003 by the Medicare Prescription Drug Improvement and Modernization Act (MMA). The MMA's exclusivity changes only apply to first-filed ANDA applications submitted after December 8, 2003.

There were two ways to trigger the 180-day exclusivity period pre-MMA. First, the first filer could trigger its 180 days by commercially marketing its approved product. Second, another ANDA applicant could try to trigger the first filer's exclusivity by obtaining a judgment of invalidity or noninfringement on all the patents included in the first filer's paragraph IV certification. This immediately triggered the 180-day period even if the first filer was not ready to take advantage of its exclusivity.

The MMA changes retained the existing commercial marketing trigger (*see* 21 U.S.C. § 355(j)(5)(B)) and identified a series of forfeiture events that, if applicable, would cause the first filer to lose its exclusivity. These forfeiture events are: (I) failure to market by *the later of* (aa) 75 days after approval or 30 months after the ANDA application was submitted to the FDA, whichever is earlier; and (bb) within 75 days of the date as of which, as to each patent for which the FTF applicant filed and maintained a paragraph IV challenge: (AA) any applicant obtains a final, nonappealable decision that the patent is invalid or not infringed; (BB) there is a settlement or consent decree with a later applicant that the patents in the paragraph IV certification are invalid and/or not infringed; or (CC) all of the patents in the paragraph IV certification are delisted from the Orange Book; (II) withdrawal of the first-filed ANDA by the applicant; (III) amendment or withdrawal of all paragraph IV certifications; (IV) the first filer's failure to get tentative FDA approval within 30 months from the date the FDA accepted the application; (V) a final nonappealable decision that the first-filed ANDA applicant entered into an anticompetitive agreement with the NDA holder, patent owner or another ANDA applicant for the specific drug; or (VI) all the patents in the paragraph IV certification have expired.

the most relevant forfeiture events are: (1) failure to market within 75 days after the date any ANDA filer with tentative approval obtains a favorable court decision (including appeal) with respect to the patent(s) that entitled the first filer to exclusivity,[103] and (2) failure to obtain tentative approval within 30 months after the date on which the ANDA was filed, unless the failure is caused by a change in or a review of the requirements for FDA approval after the date on which the ANDA was filed.[104] These forfeiture provisions were intended to prevent a first-filed ANDA from blocking generic competition, including in circumstances where the FTF ANDA is delayed in obtaining FDA approval. That is, there is a public interest in the earliest possible generic competition that is consistent with the protection of the brand company's patent rights. An FTF generic may be motivated to slow down litigation in order to avoid forfeiture if it perceives a risk of not obtaining final FDA approval in time to launch within 75 days following a favorable appellate court decision, or if it perceives a risk that another ANDA applicant will win a judgment of noninfringement that does not apply to the FTF's ANDA product. A brand company may also be incentivized to preserve a first-filer's exclusivity, to avoid the risk of early generic approvals. Non-FTF generics may devise their litigation strategies in order to trigger a forfeiture by the FTF generic.

Where an FTF ANDA holder has filed an IPR, alone or with less than all generic filers, an FTF generic may seek a litigation stay and stay of regulatory review to reduce risk of forfeiting exclusivity. Considerations of judicial efficiency and fairness to all litigants will usually weigh against a stay. That is, a patentee may agree to a stay of district court litigation with the FTF generic (and potentially others). However, if non-FTF generics who are not involved in the IPR do not agree to a stay, a stay of those cases may not be appropriate. In such case, considerations of judicial efficiency would weigh in favor of proceeding with all pending ANDA litigations simultaneously.

Where one or more non-FTF ANDA holders have filed IPR/PGR petitions and parties to the IPR seek a stay of district court litigation, a stay may be appropriate in those ANDA litigations, but not the cases of other ANDA filers. A patentee and FTF generic should have the ability to proceed with district court litigation with a goal to obtain a district court decision by the end of the 30-month stay. However, a stay of non-FTF ANDA cases would not be efficient unless those non-FTF generics agreed not to relitigate issues being litigated in the cases that proceed. That is, considerations of judicial efficiency, and fairness to the patentee, suggest that a non-FTF generic seeking a stay of litigation should agree to be bound by validity decisions in the IPR and other ANDA litigations (for example, decisions on other bases of invalidity, to which IPR estoppel would not apply). Otherwise, a stay of district court litigation would not be appropriate.[105]

ANDA litigation against a non-FTF generic who files an ANDA too late to be part of a first-wave litigation may well be stayed, whether or not an IPR petition is filed. If a first-wave litigation is close to trial, or even after district court decision, the parties and the court will often agree to stay the later-filed case until an outcome is determined in the first wave. For example, IPRs have been filed when the first round of ANDA filers have fully litigated and lost the patent challenge in district

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103 *See* 21 U.S.C. § 355(j)(5)(D)(i)(I).

104 *See* 21 U.S.C. § 355(j)(5)(D)(i)(IV).

105 If a non-FTF generic files an IPR petition after substantial litigation has progressed against an FTF generic (with or without other ANDA filers in the "first wave"), a stay of the district court litigation against that later ANDA filer will often be the most efficient process.

court or on appeal. In such cases, it is rarely a good use of the parties' or the court's resources to proceed with parallel district court litigation.

**Best Practice 15 – In consolidated or coordinated district court ANDA litigation, where one or more ANDA filers have filed an IPR petition on a patent-in-suit, a court may consider inquiring of the remaining ANDA filers whether they intend to join the IPR proceeding.**

This Best Practice serves as a reminder that in these multiparty litigations, the individual interests of different ANDA filers are not always aligned, and that the most efficient, orderly, and just management of the litigation may depend upon the court's ability to understand and balance the differing interests of the parties appearing before it. By learning of the intentions of the other ANDA filers with respect to ongoing or future IPRs, all parties and the court will be in a position to best plan for the prompt and orderly resolution of the affected litigations.

As described above (Section V.B.), the USPTO Director has discretion to deny institution of an IPR proceeding when a parallel litigation is advanced, using the *Fintiv* factors. When multiple ANDA challengers are litigating in district court, the PTAB may consider the overlap of issues between the petition and the litigation. The board may also consider the IPR petitioner's position in the litigation. A relevant consideration may be whether the petitioner is an FTF party and whether the petition from a non-FTF party may disrupt the efficient resolution of the parallel litigation. It should be recognized that non-FTF generics who file a second or subsequent IPR may be doing so for the intent to disrupt the orderly resolution of first-wave issues.

In addition, the PTAB may consider whether an estoppel (or lack of estoppel) of arguments that were tried and failed in the IPR will lead to inefficiencies in the litigation.

**Best Practice 16 – In a multiparty ANDA litigation, a court may consider whether as a condition of any stay, all alleged infringers are willing to agree to be finally bound by the final decision of the PTAB in the IPR proceeding.**

Particularly in light of the 30-month window for resolving ANDA patent disputes, if a generic filer chooses not to join or be bound by an IPR proceeding, the district court may be asked to readjudicate the same or similar defenses already presented to the PTAB, in addition to any unique defenses that could only be raised in district court. In this instance, the unwillingness of an ANDA litigant to be bound could significantly undermine any efficiencies gained in staying ANDA litigation pending IPR/PGR review. When multiple IPR petitions are filed, the Director may consider in his/her discretion whether it is efficient to institute at all. The discretion to deny institution in this situation under 35 U.S.C. § 314(a) is guided by the following factors:

1. whether the same petitioner previously filed a petition directed to the same claims of the same patent;
2. whether at the time of filing the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it;
3. whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the board's decision on whether to institute review in the first petition;

4. the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition;
5. whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent;
6. the finite resources of the board; and
7. the requirements under 35 U.S.C. § 316(a)(11) to issue a final determination not later than one year after the date on which the Director notices institution of review.[106]

In ANDA cases with multiple generics, even when they are in multiple waves of litigation, the parties will be aware of many, if not all, of the prior art references involved in the litigation and raised in other IPR petitions. Thus, serial challenges risk significant inefficiencies. The PTAB may consider whether the later-filed IPR presents new arguments that were not raised by unrelated parties to an ongoing district court litigation, or whether the arguments in the subsequent IPR are redundant to the ongoing litigation and more efficiently resolved in that forum.

The grant of the 180-day period of coexclusivity to the first-filed generic provides a significant incentive to successfully challenge patents listed in the Orange Book. Yet this incentive can be destroyed if another challenge (i.e., a second-filing generic) initiates a parallel IPR challenge while litigation is pending, particularly if a number of separate petitions are filed by different challengers. Where fewer than all ANDA filers file such petitions, the remaining ANDA filers should weigh whether and when to join the original proceeding. On the one hand, where new parties join the original proceeding, the PTAB generally has had the first filer continue to take the lead. On the other hand, where the remaining ANDA filers have delayed their petitions so that joinder is not feasible, the board has begun scrutinizing whether there was good reason for that delay or whether it has given the later filer an unfair advantage.

## E. SPECIAL CONSIDERATIONS RELATING TO BPCIA CASES

Some special considerations relate to BPCIA patent challenges. As discussed in Section II.B, there is no counterpart in the BPCIA to the 30-month regulatory stay of Hatch-Waxman. Because biosimilar applicants may file their applications as soon as eight years before marketing approval, in some instances it may be possible to time and complete their challenges so that an at-risk launch will not be an issue. In other situations, such challenges will not have been completed, and the biosimilar applicants will therefore be faced with launch-at-risk decisions while the BPCIA litigation is still in progress. To mitigate this risk, some biosimilar applicants may opt to challenge patents in IPR or PGR proceedings in advance of district court BPCIA litigation.

Depending on the timing of the filing of any BPCIA infringement litigation and any corresponding IPR/PGR petition challenging the same asserted patent, it is possible that an IPR/PGR and its appeal could be finally resolved before the corresponding BPCIA district court litigation commences.

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[106] General Plastic Indus. Co. v. Canon Kabushiki Kaisha, IPR2016-01357 (PTAB Sept. 6, 2017). The same factors apply when serial petitions are filed by different parties. Valve Corp. v. Elec. Scripting Prods., Inc., IPR2019-00062 (PTAB Apr. 2, 2019).

While there is no standing requirement to file an IPR/PGR petition with the PTAB, the Federal Circuit has required Article III standing in order to appeal an adverse decision from the board.[107] So, while an aBLA filer may challenge a patent before its biologic product has received FDA regulatory approval, if an aBLA filer mounts a patent challenge too soon before FDA approval, it may not have standing sufficient to appeal an adverse PTAB decision.

On the other hand, the USPTO has recently indicated that it will begin considering whether a later-filed IPR or PGR raises cumulative or redundant issues relative to earlier IPRs and/or PGRs (even by other petitioners) and may deny institution on that basis. This means that a biosimilar manufacturer may find that an IPR or PGR may not be available to them if the same patents or same issues have already been addressed by the PTAB based on other biosimilar challenges, but rather must be pursued in district court.

Finally, because the BPCIA does not have a counterpart to the Hatch-Waxman provision that same-day filers are all treated as first filers,[108] the chances of aBLA applications being filed on the same day or around the same time are slim.

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[107] Phigenix, Inc. v. Immunogen, Inc., 845 F.3d 1168, 1172 (Fed. Cir. 2017); RPX Corp. v. Chanbond LLC, No. 17-2346 (Fed. Cir. Jan. 17, 2018) (order dismissing appeal for lack of standing).

[108] The 2003 Medicare Prescription Drug Improvement and Modernization Act (MMA) allowed for shared first-filer exclusivity. For NCE-1 filing opportunities, applicants pursuing first-filer status will all file their application on the same day and will be sued around the same time.

# *VI. Case Management of Injunctive Relief Issues in Biopharma Cases*

Requests for injunctive relief—either preliminary or permanent—often play a critical role in cases involving biopharma products. Patent protection related to an active pharmaceutical ingredient is often the central competitive barrier to entry for pharmaceuticals and biologics, and many patent holders seek to maintain that barrier, at least in significant part, by pursuing injunctive relief. Further, U.S. patent law provides a safe-harbor defense to infringement for activities that are solely for uses reasonably related to the development and submission of information needed for regulatory approval of a new biopharma product and, in the case of both the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act, specify circumstances in which injunctive relief may (or should) be granted. Patent holders in the area of biologics and pharmaceuticals may also seek to use patents to enjoin use of patented inventions that go beyond the active pharmaceutical ingredient and address specific formulations, methods of treatment, methods of manufacture, methods of purification, and other improvements related to the use of a product. The requirements for and scope of injunctive relief available for various inventions are beyond the scope of this evaluation. Nonetheless, certain common case management issues arise and are discussed below.

When considering the case management challenges presented by a request for injunctive relief, it is useful to keep in mind four overlapping factors. First, a key decision in biopharma litigation is whether an accused party will initiate an "at risk" launch. This occurs when an accused party chooses to launch a product into the market before there is a final determination as to whether its conduct would infringe a valid patent. A launch-at-risk decision has significant commercial and legal implications. A launch-at-risk takes the accused infringer outside of the statutory safe harbor discussed above and has the potential to significantly change the marketplace for the incumbent product. Further, an at-risk launch generally triggers the availability of monetary relief, including potential treble damages for willful infringement, and a right to a jury trial for the patent holder. For these and other reasons, the timing and expectations for an at-risk launch has significant case management implications. Second, each relevant regulatory regime provides different statutory limits on who can file suit, when they can file suit, what patents will be the subject of the suit, whether regulatory approval is stayed, and what remedies are available once the suit is initiated. This, in turn, affects the probability and timing of any request for injunctive relief. Third, the potential for an at-risk launch affects whether a judge or a jury will resolve factual disputes regarding infringement and validity and, in turn, will affect how factual disputes specific to a claim for injunctive relief will be resolved. Fourth, biopharmaceutical products are inherently associated with the delivery of healthcare. Whether and how such delivery will be affected by the grant or denial of injunctive relief can play a role in determining whether injunctive relief will be granted, as well as the scope of any injunction that is granted.

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Below is a discussion of specific injunctive relief issues as they arise in the different types of biopharma litigation (primarily due to different governing statutory regimes), and some best practice recommendations specific to one or more of them. In certain circumstances, the best practices carry over to other categories of cases as identified in the text.

## A. HATCH-WAXMAN LITIGATION

### 1. "At Risk" Launch and Preliminary Injunctive Relief

**Best Practice 17 – In an ANDA proceeding, at the same time the parties and the court address at-risk launch, they should also address how to handle damages issues and the patentee's right to a jury trial on the timing and case management of the proceeding.**

Ordinarily, at-risk launch and preliminary injunctions are not an issue in ANDA cases because the Hatch-Waxman Act provides for a 30-month stay of regulatory review pending resolution of the underlying patent dispute. However, in cases where the 30-month stay does not apply or has expired, a generic company may decide to launch "at risk" by commercially marketing its product after obtaining FDA approval and before all outstanding patent issues with the branded company have been resolved.[109] Since any such launch would be before all patent issues were resolved, the generic company would be at risk of being found liable for patent infringement if the patents are ultimately found to be valid and infringed. The generic company may also potentially have to withdraw its product from the market, as well as a lost-profits and willful infringement claim from the branded company.

Historically, the risk of pulling product off the market or the potential for significant lost-profits damages was often enough to convince a generic company to wait until all patent issues had been resolved before launch. However, generic companies have more recently shown a greater willingness to launch at risk, particularly where district court decisions (e.g., summary judgment) made it more likely that the generic company would prevail at trial or where the generic company received a favorable final judgment from a district court.

An at-risk generic entrant must carefully weigh the risk/reward probabilities in deciding whether to launch a product before a final decision on the merits of all asserted patents has been rendered. Even if the 30-month stay has expired, a district court may look dimly on a launch that jumps the gun on the district court's impending decision. In the event of an adverse district court judgment, the generic will at the least face damages claims that may include lost profits and price erosion components, which together may total more than the gross sales of the generic product. In addition, where the patent is found to be not invalid and infringed, an injunction is likely, as the public interest favors the enforcement of valid patents. While the benefit of having a lower-cost alternative to the branded product may be taken into account, patent right itself is intended to allow for premium pricing as a reward to the inventor and as an incentive for further innovation, which may tip the public interest in favor of granting an injunction. There may, of course, be situations in

[109] This situation can occur when: (1) the branded company fails to file suit within 45 days of receiving the paragraph IV notice letter; (2) the litigation extends beyond the 30-month stay; or (3) where there is a judicial determination that the patents identified in the paragraph IV certification are invalid, unenforceable, or not infringed. In those instances, the FDA can immediately approve the ANDA, thereby allowing the generic company to market its product.

which, even in these circumstances, the public interest militates against the issue of an injunction, such as if the brand company is unable to meet demand for a life-saving product.

An "at risk" launch will change the status quo and will often convert the ongoing legal action from one seeking only equitable relief to one that also seeks monetary damages. The presence of a damages issue may entitle the patent owner to a jury trial and creates case management issues for the district court. If the district court has not yet ruled on the merits and advance notice is not provided to the patent owner and the court, a motion for a temporary restraining order may be expected together with a request for an order extending the 30-month period. If the district court has ruled on the merits and the patent owner has appealed, a motion for an injunction pending the resolution of the appeal may still be forthcoming. The generic applicant is under no legal obligation to provide such advance notice.

### 2. Permanent Injunctive Relief

The remedies in a Hatch-Waxman action are set forth in 35 U.S.C. § 271(e)(4)(A)–(C). Subsection (A) provides for relief in addition to the more traditional equitable injunction. Specifically, the court "shall" order the effective date of any approval of the drug product involved in the infringement to be a date that "is not earlier than the date of the expiration of the patent which has been infringed." Thus, courts have authority to direct the FDA to withhold or withdraw ANDA approval after a finding of infringement. Most courts apply the mandatory "shall" language as requiring issuance of an order directing the FDA to withhold or withdraw ANDA approval once infringement is established, which amounts to a de facto injunction where the traditional equitable principles underlying an injunction do not apply.

35 U.S.C. § 271(e)(4)(B) generally provides for equitable injunctive relief. This section uses permissive language that brings in the traditional factors used to evaluate whether the equitable remedy is applicable: (1) irreparable injury (with no presumption of irreparable harm); (2) inadequacy of money damages; (3) a favorable balance of the hardships; and (4) a lack of harm to the public interest by a grant of the permanent injunction.[110] Thus, a successful branded company seeking an injunction under this section still needs to satisfy all four of these requirements, and courts have denied injunctive relief where the patentee failed to make the required showing.

Despite these two different remedies, the language directing the FDA to withhold or withdraw the ANDA effectively obtains the same result, stopping the generic launch, but without having to establish the equitable requirements for a permanent injunction. As a result, successful branded companies often opt for the former alternative.

## B. BPCIA LITIGATION

The BPCIA statute, unlike the Hatch-Waxman statute, does not provide any mechanism to stay regulatory approval. Therefore, it may be common that litigation is still ongoing when a biosimilar application is approved. This raises the potential for a biosimilar manufacturer launching "at risk" to later being found to have infringed a valid patent. Under these circumstances, the company marketing the biosimilar will be at risk of paying monetary damages for the infringement, plus potential willfulness enhancements. Due to the biosimilar nature of the infringing product, it is

[110] eBay Inc. v. MercExchange, LLC, 547 U.S. 388 (2006).

possible that substantial lost profits and price erosion components may also be involved. In addition, unique damages issues may arise in situations where the fact-finder must determine if the damage caused to the patent owner by early entry into the market permanently harms the value of this aspect of its business going forward.

In the context of BPCIA litigation, as with branded biologic patent litigation discussed below, if a patent owner wants to prevent a potential infringer from launching at risk, it will need to seek a preliminary injunction to do so. The interpretation and application of the statute continue to be litigated, and the issue of injunctions has arisen very few times under the BPCIA to date.

### 1. "At Risk" Launch and Preliminary Injunctive Relief

42 USC § 262(l)(8)(B) provides a statutory mechanism for seeking preliminary injunctive relief once a biosimilar applicant provides a 180-day notice of commercial marketing (NCM) pursuant to 42 U.S.C. § 262(l)(6). This 180-day notice is intended to allow sufficient time for adjudicating a preliminary injunction motion.[111] However, the actual amount of time between the reference product sponsor filing a preliminary injunction motion under this statute and the applicant's launch may be much longer than 180 days, introducing uncertainty into the court's timeline. First, the statute does not require the reference product sponsor to file a motion for preliminary injunction; the statute merely triggers the reference product sponsor's statutory right to expand the number of patents-in-suit and to file such a motion. Second, an applicant can provide its notice more than 180 days before it plans to launch, even before it has received FDA approval.[112] This means that the applicant may not actually launch 180 days after the notice (or even be authorized to do so).

In the few BPCIA cases that have addressed post-NCM preliminary injunction motions, courts have applied the traditional four-factor preliminary injunction analysis identified in *eBay v. MercExchange*,[113] requiring proof of likelihood of success, irreparable harm, balance of hardships or equities, and no

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111 *See* Amgen Inc. v. Apotex Inc., 827 F.3d 1052, 1063 (Fed. Cir. 2016) (explaining that the 180-day period "gives the parties and the district court the time for adjudicating such matters without the reliability-reducing rush that would attend requests for relief against immediate market entry that could cause irreparable injury").

112 Sandoz Inc. v. Amgen Inc., 582 U.S. __, 137 S. Ct. 1664, 1677 (2017). An issue presented in *Amgen* was whether the BPCIA's required 180-day notice of the biosimilar's intent to market its biosimilar could be given before that product's approval, or only after. The purpose of this 180-day notice provision is to allow the patent owner to bring any necessary preliminary injunction motions on patents that the parties determined were not to be the subject of earlier litigation. The Federal Circuit concluded that the terms of the statute require the biosimilar to be approved before that notice is given. Because the biosimilar applicant must wait for expiration of the 180-day period before marketing its approved biosimilar, in instances where the biosimilar product approval occurs later than 11½ years after the approval of the reference product, this may result in some delay (but no more than 180 days) in the introduction of the biosimilar. Amgen v. Sandoz, 794 F.3d 1347 (Fed. Cir. 2015). The Supreme Court reversed, holding that the product need not be approved prior to the time notice of intent to market is given. As such, an applicant may provide 180-day notice before or after receiving FDA approval.

113 *eBay*, 547 U.S. 388.

disservice to the public interest.[114] Delay in seeking a preliminary injunction after receiving an NCM, as well as a history of licensing the relevant patents, may weigh against the irreparable harm factor.[115]

**<u>Best Practice 18</u> – In a BPCIA case, the parties and the court should discuss at the initial case management conference the possibility of a preliminary injunction motion during the pendency of a case, including the timing and proposed schedule for any preliminary injunction proceedings.**

**<u>Best Practice 19</u> – The parties and the court should consider what discovery is relevant to the preliminary injunction proceedings, and whether and how to present evidence in the proceeding (by declaration, live witness testimony, etc.).**

Parties can lessen the burden on courts from unnecessarily rushed injunction adjudication by identifying a process under which they will disclose their plans for a commercial launch. Once a reference product sponsor receives the notice of commercial marketing from the applicant, it needs to evaluate its rights and risks loss of its rights if it does not promptly pursue a preliminary injunction. Speed not only reflects appropriate urgency but also provides the court with more time to decide the motion. Similarly, the biosimilar applicant should not obligate the court to evaluate a preliminary injunction if it knows that it will not launch the product at the end of the 180-day period. Once an NCM has been provided and litigation begins, the parties should promptly explore with the court the appropriate timeline on which to hear a motion for a preliminary injunction that balances the patent holder's intellectual property rights, the parties' right to discovery, the orderly presentation of evidence to the court, any other considerations concerning evaluation of witness credibility, and the practical needs of the court.

**<u>Best Practice 20</u> – Where a launch is not expected 180 days after the Notice of Commercial Marketing is given, the parties and the court should discuss notice of any at-risk launch to permit the parties and the court time to resolve any injunction issues.**

If the biosimilar applicant does not intend to launch after the end of 180 days or if FDA approval is delayed for known reasons, adjustments should be made to the schedule so as to avoid creating unnecessary burdens on the court. Under such circumstances, the parties should discuss with the court what procedures will be used to identify the need for the patent holder to seek a preliminary injunction in a manner that gives the court adequate time to address the request. Because of the inevitable variation in the nature of the intellectual property at issue, the scope of the prior

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[114] *See, e.g.,* Genentech, Inc. v. Amgen Inc., No. 18-924-CFC, 2019 WL 3290167 (D. Del. July 18, 2019); *see also* Amgen, Inc. v. Apotex Inc., No. 15-61631-CIV-COHN/SELTZER, 2015 WL 11198250 (S.D. Fla. Dec. 9, 2015).

[115] For example, in *Genentech, Inc.*, 2019 WL 3290167, at *2–3, the court denied the preliminary injunction motion, finding movant's "undue delay in seeking [the] injunction 'negates the idea of irreparability,'" and that "a finding of no irreparable harm is also supported by the fact that Genentech has engaged in a pattern and practice of licensing the Dosage Patents" (quoting Pfizer, Inc. v. Teva Pharm., USA, Inc., 429 F.3d 1364, 1382 (Fed. Cir. 2005). The Federal Circuit affirmed the denial per curiam. 796 F. App'x 726 (Mar. 6, 2020).

disclosures, the commercial variation in the relevant markets, and the other pressures experienced by the court, it is difficult to provide specific guidelines for the relevant disclosures. Nonetheless, a patent holder should keep in mind the importance of providing the court with a full and timely opportunity to address any injunction motion, and the biosimilar applicant should not, by delay, seek to undermine the court's ability to address whether a preliminary injunction is appropriate in advance of a commercial launch.

### 2. Permanent Injunctive Relief

Thus far, despite over six years of litigation as of the time of publication, courts addressing BPCIA cases have not yet addressed the question of whether, how, and under what circumstances a permanent injunction would be appropriate before FDA approval has been obtained.

Under 35 U.S.C. § 271(e)(4)(D), in an action brought under 42 U.S.C. § 262(l)(6), a court "shall" order a permanent injunction of a biosimilar product that has been adjudicated to infringe a reference product sponsor's patent provided that the biosimilar application "has not yet been approved because of [42 U.S.C. § 262](k)(7)" (i.e., because the reference product sponsor's 12-year regulatory exclusivity had not yet expired).

Section 271(e)(4)(D) does not address the availability of a permanent injunction in cases where the biosimilar product approval precedes a final judgment on the patent issues, which means that the courts will likely resort to a conventional *eBay* analysis in deciding whether to issue one.[116] Whether, and what form, an injunction takes may depend on the nature of the patent rights that are being asserted, and information concerning the degree of similarity, and patient response, to the biosimilar, among other factors.

The potential for FDA approval before trial of the patent claims in a BPCIA case can further complicate the issue. Once approval occurs and if a defendant has taken action that falls outside the scope of the statutory safe harbor, the patent holder may have a right to a jury trial.[117] While a jury would then determine issues of liability and damages, a jury would not determine whether a permanent injunction should issue.

By definition, the applicant and the patent holder are (or are poised to be) head-to-head competitors. Thus, a patent holder is likely to seek a permanent injunction as a principal remedy in a BPCIA case.

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116 *eBay*, 547 U.S. at 391–92.

117 *See, e.g.*, Amgen Inc. v. Hospira, Inc., 944 F.3d 1327, 1331–32 (Fed. Cir. 2019) (affirming damages award of $70 million based on jury verdict).

**Best Practice 21 – The parties should discuss at the initial case management conference whether the plaintiff is seeking a jury trial and should consider how to stage injunction proceedings.**

**Best Practice 22 – The parties and the court should consider whether and how to present evidence in a permanent injunction proceeding as well as the prehearing disclosures required.**

**Best Practice 23 – As early as the initial case management conference but no later than the pretrial conference, in a bench proceeding, the parties and court should consider whether permanent injunction proceedings can and should be tried together with liability issues before the bench.**

As early as the initial case management conference but no later than the pretrial conference, parties should address with the court how disputed factual issues related to a patent holder's claim to a permanent injunction will be addressed. Among the key topics to be evaluated are: (1) when factual and expert discovery relevant to an application for a permanent injunction will be addressed; (2) when and how evidence will be presented to the court (including when or how live witnesses would be heard); and (3) how the presentation of the evidence will be addressed if a jury will be empaneled. The parties may also wish to address with the court how a patent holder's claims to alternative relief (such as ongoing royalties) in the absence of permanent injunction will be addressed. No approach has emerged as common. In at least one case, the parties and court agreed to postpone discovery related to a permanent injunction until after the merits trial.[118] However, a delay in addressing these issues with the court may risk a meaningful delay for a patent holder (or a biosimilar applicant) in resolving whether a product might launch despite a finding of liability. These concerns are likely to be of greater importance where the patent in question involves a method of manufacture or purification that may not be critical to the marketing of the biosimilar, or a method of treatment that might be addressed by a change in labeling.

**Best Practice 24 – Parties and the court should discuss and consider the scope of any injunction to ensure that it is appropriately tailored to the acts of infringement implicated by patent coverage.**

In connection with a permanent injunction proceeding, the parties and the court should consider with care the scope of the injunction sought. Injunctions should reflect the scope of the patent and not more. In other contexts, courts have also considered sunset periods or other mechanisms that balance the potential equities and concerns for the public that can arise in connection with injunctions that address intellectual property that is not critical to the continued sale of the product.[119]

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[118] Immunex Corp. v. Sandoz Inc., 2:16-cv-01118-CCC-MF, Document 620 (D.N.J. Sept. 11, 2018) (public redacted final pretrial order at 116).

[119] *See, e.g.,* Apple Inc. v. Samsung Elecs. Co., 809 F.3d 633, 645–46 (Fed. Cir. 2015) (noting the proposed sunset provision impacted the balance of hardships and public interest factors).

## C. BRANDED BIOLOGIC PATENT LITIGATION

Biologic patent litigation (between innovators of separately licensed biologic products) is different from biosimilar litigation in a few important respects.[120] First, it is entirely possible that the accused product will already be on the market when litigation is commenced. This is because unlike the biosimilar situation, there is no procedural mechanism for a prelaunch exchange of information, and the patent holder will have to rely on what it can learn from public sources. While a patent holder can bring an action for a declaratory judgment of infringement, typically that requires the accused product at least to have reached the stage of submission for FDA approval.[121]

A second major difference from biosimilar litigation is that the accused product is very likely to be differentiated, i.e., it is not necessarily "substantially similar" to or an identical copy of a reference product. While sometimes these differences may be subtle or contrived,[122] in other cases, a completely different biological product may nonetheless infringe the claims of a competitor's patent. This difference has very significant implications for injunction practice (both preliminary and permanent), because in such a situation, an injunction would remove a unique product from the market and thereby potentially deprive medical professionals of a therapy that may, in their view, be the best choice for some patients. Thus, the public interest issues are potentially much more complex in an innovator-versus-innovator dispute than in a biosimilar action.

Another important difference is that where an alleged infringer holds a separate BLA (it is not entering the market with an aBLA), it may end up entering the market before the patentee or innovator with the dominant patent position. For example, in *Amgen Inc. v. Sanofi*, Sanofi and Regeneron's accused PCSK9 inhibitor (Praluent®) was approved by the FDA and launched commercially before Amgen's own PCSK9 inhibitor product (Repatha®).[123]

While some of the Best Practice recommendations from the BPCIA discussion above apply in the context of branded biologic patent litigation as well (as discussed below), the factual differences between the two may drive important legal differences, particularly in the consideration of injunctive relief.

### 1. "At Risk" Launch and Preliminary Injunctive Relief

In instances where the accused infringer decides to launch at risk, the patent holder could file for a preliminary injunction to try to block the launch. To be successful, the patent holder must establish (1) a likelihood of success on the merits; (2) irreparable harm in the absence of preliminary relief; (3)

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120 Among those differences, of course, the statutory framework of the BPCIA for resolving patent disputes is entirely inapplicable to biologic patent litigation.

121 *See* Sandoz Inc. v. Amgen Inc., 773 F.3d 1274, 1279 (Fed. Cir. 2014) ("We are aware of no decision in which we have found a case or controversy when the only activity that would create exposure to potential infringement liability was a future activity requiring an FDA approval that had not yet been sought.").

122 For instance, differences in dosage form, routes of administration, or the demonstration through Phase IV clinical trials of not unexpected clinical endpoints.

123 *See* Amgen Inc. v. Sanofi, 227 F. Supp.3d 333 (D. Del. 2017).

that the balance of the hardships tips in the branded company's favor; and (4) that a preliminary injunction would not disserve the public interest.

The substantive issues in an innovator-versus-innovator case are likely to be somewhat different than in a BPCIA action. Given that the accused product is unlikely to be based on the patent holder's reference product, infringement may require proof beyond the defendant's regulatory submission and internal documents. In addition, the development of the accused product is likely to be relevant to multiple issues, for example enablement.[124] The asserted patents may have claims that are not limited to the structure or use of a specific composition, for example claims directed to therapeutic agents that act on a particular biological pathway or bind to a functionally defined target, and this in turn will inform the invalidity arguments.[125] Further, the commercial situation is likely to be more complex in that economic harm to the patent holder may be driven by factors other than price. Taken together, these considerations mean that for purposes of a preliminary injunction, discovery may well be both more important and wider ranging than in a BPCIA case.

There are also likely to be different timing factors at play. The BPCIA provides for an elaborate exchange of information before litigation is commenced[126] and has a built-in 180-day notice provision precisely to allow time for orderly resolution of any preliminary injunction request.[127] While a biosimilar applicant can elect not to engage in the information exchange,[128] in practice this has been rare. By contrast, in an innovator-versus-innovator dispute, there is no cognate to the BPCIA information exchange and no mechanism for advance notice of commercial launch. On the contrary, the accused infringer is likely to view its launch plans as a matter of confidential business strategy and may very well be reluctant to share them with a competitor. The timing issues may be more complex than a simple binary division between pre- and post-launch. For example, it is possible that an expanded label approving a new indication for an already-marketed product might be the cause of irreparable harm to the patent holder.[129] Indeed, as noted above, the accused product may already be on the market before litigation is even commenced, for example where the patent in question is not granted until after market entry by the accused infringer. In that situation, the patent holder will have to decide whether to seek a preliminary injunction given that the accused infringer will almost certainly argue that an injunction would change rather than preserve the status quo.

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124 *See*, *e.g.*, AbbVie Deutschland GmbH & Co. v Jannsen Biotech, Inc., 759 F.3d 1285, 1300 (Fed. Cir. 2014); Amgen Inc. v. Sanofi, 872 F.3d 1367, 1373–75 (Fed. Cir. 2017) (evidence of development of accused product was relevant to enablement, and the erroneous exclusion of such evidence required a new trial).

125 *E.g.*, Amgen Inc. v. Sanofi, 987 F.3d 1080, 1087 (Fed. Cir. 2021) ("While functional claim limitations are not necessarily precluded in claims that meet the enablement requirement, such limitations pose high hurdles in fulfilling the enablement requirement for claims with broad functional language.").

126 42 U.S.C. § 262(l)(2)–(6).

127 42 U.S.C. § 262(l)(8)(A) and (B).

128 Sandoz Inc. v. Amgen Inc., 582 U.S. __, 137 S. Ct. 1664, 1675 (2017).

129 *See*, *e.g.*, Baxalta Inc. v. Genentech, Inc., No. 17-509-TBD, Document 262 (D. Del. Aug. 7, 2018), Opinion and Order at 16 n.3 (holding preliminary injunction timely brought where it "was filed well in advance of the expected approval" for the patient population that would be the subject of the injunction, even though the accused product was already approved for a different patient population).

In view of the foregoing considerations, it is important that the parties and the court focus early in the case on whether a preliminary injunction may be sought. If a motion for a preliminary injunction is filed simultaneously with the complaint, the parties should confer on these issues and attempt to present a joint scheduling and discovery proposal to the court as soon as possible. In some cases, however, a preliminary injunction will only be sought later in the case, for example when the defendant is close to receiving FDA approval. In that situation, it will be important for the parties to address whether the plaintiff intends to seek a preliminary injunction and, if so, when. A recurring issue is whether the defendant should be required to provide advance notice of its commercial launch. As noted above, most defendants will view that information as commercially sensitive. Without advance notice, however, the patent holder may feel it has no choice but to make an emergency request for injunctive relief when it becomes clear a launch is imminent or has actually happened, with concomitant disruption to the court's schedule and resources. Injunction proceedings are likely to be more efficient and fairer to all if the parties can investigate and brief the issues in an orderly fashion, and the court has adequate time to consider them fully, without the urgency resulting from a pressure of a launch or one that has just occurred. Thus a common practice is for the parties to agree, or the court to require, that the accused infringer provide a certain amount of notice prior to any launch. Often, the notice period is on the order of 30 or 60 days. Where there may be a launch during the pendency of the litigation and the patent holder is contemplating a preliminary injunction, it is strongly recommended that the parties address these considerations with the court at the initial case management conference, including a discussion of whether and how much advance notice of launch should be required. Thus, Best Practices 18, 19 and 20 apply to this branded biologic patent litigation context, although unlike in BPCIA litigation, they will not be impacted by the existence of a Notice of Commercial Marketing. Rather, they arise and should be addressed after the patent holder decides that it will seek to prevent the launch of the new product or seek to remove a new product from the marketplace.

As noted above, to obtain preliminary injunctive relief, the patent holder must satisfy the usual four-factor test. In the context of innovator-versus-innovator cases, the public interest factor may warrant more consideration than would be usual in an ANDA or BPCIA case. As in all patent cases, there is a public interest in protection of intellectual property rights, and this is especially true in the biopharmaceutical field, where the level of investment necessary to bring new treatments to market is very high.[130] But where a differentiated product is accused of infringement, the public interest in enforcing valid patent rights must be weighed against a potentially competing public interest in not disserving patient care. Because the products are differentiated, it is likely that some physicians will consider the accused product preferable for at least some patients. It is also possible that the patent holder does not market a directly comparable product notwithstanding the scope of its patents. Given these considerations, litigants may well present evidence—for example in the form of declarations or live testimony from physicians—on the extent to which the accused product provides a treatment benefit that would be adversely affected by an injunction; in this situation, a court will be required to make factual findings on this issue pursuant to Federal Rule of Civil Procedure 52(a)(2).

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130 *E.g.*, Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1362 (Fed. Cir. 2008) ("The statutory period of exclusivity reflects the congressional balance of interests, and warrants weight in considering the public interest.").

A further implication of the potentially unique benefits attributable to the accused product is whether and how any injunction should be tailored to prevent harm to patients. This tends to arise where the court finds the patent holder has met the other requirements for grant of a preliminary injunction, but that certain patients can only be treated, or can better be treated, with the accused product. Here again, a determination on this issue may require receipt of evidence from medical professionals, patients, or other witnesses, and consequent fact finding. All relevant facts should be clearly laid out to facilitate appellate review. The challenge for the court is how to balance the competing interests of patient well-being or public interest while protecting intellectual property rights. The court may wish to consider tailoring the scope of an injunction so as to permit continued supply of the accused product for at least those patients to whom it offers unique benefits. Sometimes this is conditioned on a certification by the defendant or prescribing physicians to verify that there is in fact a bona fide medical need for the product wherever it is to be used. However, this type of procedure can easily become cumbersome, perhaps to the point of being unworkable.[131] Another alternative that might be considered in appropriate circumstances is a numerical limit on the quantity of accused product that can be supplied, calculated to correspond to the amount of legitimate medical need, though this is something of a blunt instrument.

Another issue with respect to the scope of an injunction is whether and to what extent it should be crafted to avoid interfering with ongoing or future clinical trials. Such trials are very likely to be covered by the safe-harbor provision of 35 U.S.C. § 271(e)(1), and therefore exempted from infringement liability. However, care should be taken with the language of a proposed injunction to ensure that it does not arguably bar activities protected by the safe harbor. Also, there can be areas in which the law is unclear as to the applicability of the safe harbor, for example with respect to so-called continuing access programs that allow additional patients to be treated even after a trial has been fully enrolled. Because of the possibility of legitimate disagreement regarding the extent of the safe harbor, it is preferable for an injunction to be crafted with as much specificity as possible concerning what activities are prohibited, and to avoid defining those activities by reference to "infringement." Thus, Best Practice 24 above, which recommends tailoring the scope of any injunction to the acts of infringement, applies with equal force to branded biologic patent litigation, with particular reference to the scope of any preliminary injunction.

### 2. Permanent Injunctive Relief

Many of the same considerations addressed above also apply to the grant of a permanent injunction, particularly with respect to public interest. As a matter of procedure, it is important for the parties and the court to focus on how the factual record with respect to issues that are solely equitable in nature will be developed. Will evidence be presented in the form of live testimony or in written submissions, and if the latter, will there be an opportunity to cross-examine or otherwise contest factual assertions by the opposing party? Will the evidence be presented by the same witnesses who testify at trial, and to what extent will it overlap with other trial evidence? It is easy for this to be overlooked in the run-up to a trial and then present a challenge in the event of a decision in favor of the patent holder. As a matter of best practice, the issue should be addressed by the parties and the court in advance of trial, perhaps as early as the initial case management conference and in no event

[131] *E.g.*, Baxalta Inc. v. Genentech, Inc., No. 17-509-TBD, Document 262 (D. Del. Aug. 7, 2018), Opinion and Order at 7 n.2 ("The procedure for doctors to certify—and for Genentech to verify—that patients fall within the carveout is complicated and perhaps unworkable. But for purposes of resolving this motion, the Court will treat it as if it were able to be implemented.").

later than the final pretrial conference. A further complicating factor is that if the accused product has been marketed, or even merely stockpiled, the patent holder will likely seek damages and thus has the right to demand a jury. If the case is to be tried to a jury, it will be important for the court to separate issues that are solely equitable from issues of fact that affect the questions being resolved by the jury. The jury's decision on liability should not be influenced by the potential that the court may later issue an injunction. Thus, evidence uniquely relevant to injunction factors should be presented outside the presence of the jury. Alternatively, the court may decide to hold a separate evidentiary hearing on permanent injunction issues after liability has been determined. These concerns are addressed, in part, in Best Practices 21 to 23.

If a permanent injunction is to be issued against a product that is currently on the market, the court may wish to consider whether any transitional measures are appropriate to prevent disruption in the delivery of medical care. Where patients are currently being treated with a product that has been adjudicated to be infringing, an injunction could interfere with that treatment, particularly in the case of products that are used to treat chronic conditions. In those circumstances, the court may wish to consider whether an injunction will apply only to treatment-naïve patients, leaving the accused product on the market for those who are already receiving it.

Where an injunction is tailored to permit some continued marketing by the adjudicated infringer, an issue arises as to how the patent holder should be compensated for such ongoing infringement. While there is a clear possibility of overlap with damages evidence, the issues are not identical. For example, if the prevailing patent holder was successful in obtaining an award of lost profits, it may be problematic to require payment of the same amount for continuing infringement, as to do so may deprive the infringer of any economic incentive to supply the infringing product, thus defeating the entire purpose of an exception to further the public interest. Again, the parties and the court should consider the issue of ongoing payment with or after a ruling on injunction, and any injunction decision should be stayed or have a transition that accommodates the fashioning of an ongoing royalty.

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**"DIALOGUE DESIGNED TO MOVE THE LAW FORWARD IN A REASONED AND JUST WAY."**

The Sedona Conference was founded in 1997 by Richard Braman in pursuit of his vision to move the law forward in a reasoned and just way. Richard's personal principles and beliefs became the guiding principles for The Sedona Conference: professionalism, civility, an open mind, respect for the beliefs of others, thoughtfulness, reflection, and a belief in a process based on civilized dialogue, not debate. Under Richard's guidance, The Sedona Conference has convened leading jurists, attorneys, academics, and experts, all of whom support the mission of the organization by their participation in conferences and the Sedona Conference Working Group Series (WGS). After a long and courageous battle with cancer, Richard passed away on June 9, 2014, but not before seeing The Sedona Conference grow into the leading nonpartisan, nonprofit research and educational institute dedicated to the advanced study of law and policy in the areas of complex litigation, antitrust law, and intellectual property rights.

The WGS was established to pursue in-depth study of tipping point issues in the areas of antitrust law, complex litigation, and intellectual property rights. It represents the evolution of The Sedona Conference from a forum for advanced dialogue to an open think tank confronting some of the most challenging issues faced by our legal system today.

A Sedona Working Group is created when a "tipping point" issue in the law is identified, and it has been determined that the bench and bar would benefit from neutral, nonpartisan principles, guidelines, best practices, or other commentaries. Working Group drafts are subjected to a peer review process involving members of the entire Working Group Series including—when possible—dialogue at one of our regular season conferences, resulting in authoritative, meaningful, and balanced final commentaries for publication and distribution.

The first Working Group was convened in October 2002 and was dedicated to the development of guidelines for electronic document retention and production. Its first publication, *The Sedona Principles: Best Practices Recommendations & Principles Addressing Electronic Document Production*, has been cited favorably in scores of court decisions, as well as by policy makers, professional associations, and legal academics. In the years since then, the publications of other Working Groups have had similar positive impact.

Any interested jurist, attorney, academic, consultant, or expert may join the Working Group Series. Members may participate in brainstorming groups, on drafting teams, and in Working Group dialogues. Membership also provides access to advance drafts of WGS output with the opportunity for early input. For further information and to join, visit the "Working Group Series" area of our website, https://thesedonaconference.org/wgs.

# *The Sedona Conference Working Group 10 on Patent Litigation Best Practice—List of Steering Committee Members and Judicial Advisors*

The Sedona Conference's Working Group 10 on Patent Litigation Best Practices Steering Committee Members and Judicial Advisors are listed below. Organizational information is included solely for purposes of identification.

The opinions expressed in publications of The Sedona Conference's Working Groups, unless otherwise attributed, represent consensus views of the Working Groups' members. They do not necessarily represent the views of any of the individual participants or their employers, clients, or any organizations to which they may belong, nor do they necessarily represent official positions of The Sedona Conference. Furthermore, the statements in each publication are solely those of the non-judicial members of the Working Group; they do not represent judicial endorsement of the opinions expressed or the practices recommended.

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