Appeal No. 2016-2179

United States Court of Appeals

for the

Federal Circuit

AMGEN INC., AMGEN MANUFACTURING, LIMITED,

Plaintiffs-Appellants,

– v. –

HOSPIRA, INC.,

Defendant-Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE IN CASE NO. 1:15-CV-00839-RGA, JUDGE RICHARD G. ANDREWS

BRIEF FOR PLAINTIFFS-APPELLANTS AMGEN INC. AND AMGEN MANUFACTURING, LIMITED

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September 12, 2016

SECOND AMENDED CERTIFICATE OF INTEREST

1. The full name of every party represented by me is:

   AMGEN INC. and AMGEN MANUFACTURING, LIMITED

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

   AMGEN INC. and AMGEN MANUFACTURING, LIMITED

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are:

   AMGEN INC.

4. The names of all law firms and the principals or associates that appeared for the party now represented by me in the trial court or are expected to appear in this Court (and who have not or will not enter an appearance in this case) are:

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Date: September 12, 2016

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TABLE OF CONTENTS

Page

TABLE OF CONTENTS (CONTINUED)

Page

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES (CONTINUED)

Page(s)

Statutes

TABLE OF AUTHORITIES (CONTINUED)

Page(s)

Rules

Other Authorities

TABLE OF AUTHORITIES (CONTINUED)

Page(s)

STATEMENT OF RELATED CASES

No other appeal in or from this civil action was previously before this or any other appellate court, and counsel is not aware of any pending case that will directly affect or be directly affected by this Court's decision in the pending appeal.

This appeal relies on this Court's interpretation of 42 U.S.C. § 262(*l*)(2)(A) in *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015). That decision is currently the subject of pending petitions for a writ of certiorari before the Supreme Court of the United States. *Sandoz Inc. v. Amgen Inc.*, No. 15-1039; *Amgen Inc. v. Sandoz Inc.*, No. 15-1195.

JURISDICTIONAL STATEMENT

The district court has subject-matter jurisdiction over this case under 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202.

This Court has jurisdiction over this appeal under 28 U.S.C. § 1295(a)(1) and the collateral-order doctrine. *Cohen v. Beneficial Indus. Loan Corp.*, 337 U.S. 541, 546-47 (1949). Alternatively, this Court has jurisdiction under the All Writs Act, 28 U.S.C. § 1651(a).

Amgen timely appealed under 28 U.S.C. § 2107 and Fed. R. App. P. 4(a) on June 3, 2016, within 30 days of the district court's May 4, 2016 Order. (Appx764-766.)

STATEMENT OF THE ISSUES

1. Whether, in a patent-infringement action pursuant to the Biologics Price Competition and Innovation Act ("BPCIA"), the district court erred by holding that "information that describes the process or processes used to manufacture the biological product that is the subject of" the Applicant's subsection (k) application, 42 U.S.C. § 262(*l*)(2)(A), may properly be shielded from discovery, in light of this Court's holding in *Amgen Inc. v. Sandoz Inc.* that where a subsection (k) applicant ("Applicant") does not provide that information during the information-exchange period of the BPCIA, the reference product sponsor ("RPS") can bring an infringement suit against the Applicant and "can access the required information through discovery," 794 F.3d 1347, 1356 (Fed. Cir. 2015).

2. Whether this Court has jurisdiction under the collateral-order doctrine or the All Writs Act, 28 U.S.C. § 1651(a), to review the first post-*Sandoz* decision of a district court denying an RPS access, through discovery in an infringement suit, to the manufacturing information that the Applicant refused to disclose during the BPCIA information-exchange period as set forth in 42 U.S.C. § 262(*l*)(2)(A), thereby denying the RPS the sole remedy that this Court has held is available to it for the Applicant's failed disclosure: a patent-infringement action before the Applicant commences commercial marketing of the biosimilar.

STATEMENT OF THE CASE

This is an appeal from the district court's Order (Appx1-42) denying Amgen's motion to compel production of information "that describes the process or processes used to manufacture the biological product" that is the subject of Hospira's abbreviated Biologics License Application ("aBLA"). 42 U.S.C. § 262(*l*)(2)(A).

Hospira submitted an application to FDA under the BPCIA's abbreviated, subsection 262(k) pathway, seeking approval of a biosimilar version of Amgen's biological product EPOGEN®. (Appx204-231 at Appx215 ¶ 37.) On March 3, 2015, Hospira provided Amgen with its aBLA, but did not provide "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application," 42 U.S.C. § 262(*l*)(2)(A). (Appx216-217 ¶¶ 43-44.) Amgen asked repeatedly for a subset of such information—specifically, information describing the components of the cell-culture medium that Hospira uses in the process of manufacturing its biosimilar product—explaining that subparagraph 262(*l*)(2)(A) required Hospira to disclose that information so that Amgen could determine whether certain claims for patent infringement could reasonably be asserted. (Appx699-700, Appx702-703, Appx705-706.) Hospira refused to provide its cell-culture information. (Appx708, Appx710.)

Amgen thereafter filed this patent-infringement suit against Hospira in the United States District Court for the District of Delaware. (Appx150-178.) Amgen sued on only the patents it had previously identified to Hospira using the standard set forth in the BPCIA and based on Hospira's aBLA: patents for which Amgen "believe[d] a claim of patent infringement could reasonably be asserted," 42 U.S.C. § 262(*l*)(3)(A). (Appx172-175 ¶¶ 92-112.) Accordingly, Amgen did not file suit on any of its cell-culture patents, as to which Hospira had refused to provide the information required by subparagraph 262(*l*)(2)(A). Amgen then sought the withheld cell-culture manufacturing information in discovery, stating its intention to use that information to evaluate whether the making, using, selling, offering for sale, or importation of Hospira's proposed biosimilar product would infringe one or more claims of Amgen's cell-culture patents. (Appx773-775, Appx806-807, Appx752-753.) When Hospira again refused to provide the information, Amgen moved to compel its production. (Appx715-717, Appx732-739, Appx694-697.)

The district court denied Amgen's motion, holding that if the information is not relevant to the two patents on which Amgen had filed suit, Amgen could not obtain that information to determine whether it could assert its cell-culture patents. (Appx39-40.) Although this Court stated in *Amgen v. Sandoz* that once an RPS brings an infringement suit under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C.

§ 271(e)(2)(C)(ii) "it can access the required information through discovery," 794 F.3d at 1356—that is, the aBLA and also the manufacturing information that Hospira refused to provide—the district court held that *Sandoz* was not "on point." (Appx39-40 at 39:24-40:2.) The district court acknowledged that if *Sandoz* were "on point" it "would be controlling." (*Id.*)

Amgen appealed on June 3, 2016, relying on the collateral-order doctrine. (Appx764-765; Dkt. 7 at 2.) On June 8, 2016, Hospira moved to dismiss Amgen's appeal for lack of jurisdiction. (Dkt. 13.) On August 12, 2016, this Court denied that motion and directed the parties to brief the Court's jurisdiction, under the collateral-order doctrine and under the All Writs Act, 28 U.S.C. § 1651(a), as part of the merits briefing. (Dkt. 16 at 3.)

STATEMENT OF THE FACTS

A. Amgen's EPOGEN® (epoetin alfa) Product

Amgen discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry. (Appx204 ¶ 3.)

Its first such therapeutic product was EPOGEN® (epoetin alfa), a recombinantly produced biologic protein that stimulates the production of red blood cells and is used to treat anemia. (Appx207-208 ¶ 19.) In 1989, Amgen obtained FDA approval for EPOGEN® under the traditional biologics regulatory pathway of 42 U.S.C. § 262(a) (Appx209-210 ¶ 24), committing significant resources to satisfying FDA's requirements to prove that EPOGEN® "is safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I). EPOGEN® was initially approved for use in treating anemia due to chronic kidney failure; subsequent approvals followed for treating anemia induced by certain chemotherapies and anti-viral therapies, and to decrease the need for transfusion in connection with certain surgeries. (Appx209-210 ¶ 24.)

B. Hospira's aBLA for Biosimilar Epogen®

In December 2014, Hospira filed an aBLA under the BPCIA's abbreviated pathway of 42 U.S.C. § 262(k) for approval of its biosimilar epoetin product, designating Amgen's EPOGEN® as the reference product. (Appx215 ¶ 37.) On

February 23, 2015, Hospira notified Amgen that its aBLA had "recently been accepted for filing by FDA." (Appx216 ¶ 40.) FDA has not yet approved Hospira's aBLA.

C. The Parties' Information Exchange Under the BPCIA

This Court has considered the BPCIA, and the information-exchange obligations of an Applicant and an RPS, in two prior cases: *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1351-52 (Fed. Cir. 2015), and *Amgen Inc. v. Apotex Inc.*, --- F.3d ---, 2016 WL 3606770, at *2-4 (Fed. Cir. July 5, 2016). Rather than repeating this Court's descriptions of the information-exchange process, Amgen describes the process as it occurred here.

After FDA accepted Hospira's aBLA for review, Hospira provided a copy of its aBLA to Amgen on March 3, 2015 (Appx216 ¶ 43). *See* 42 U.S.C. § 262(*l*)(2)(A); *Sandoz*, 794 F.3d at 1352, 1354-57; *Apotex*, 2016 WL 3606770, at *2. Although subparagraph 262(*l*)(2)(A) specifies that the Applicant's disclosure include the aBLA and "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application," Hospira provided no manufacturing information beyond that in the aBLA itself. (Appx217 ¶ 44.)

Amgen reviewed Hospira's aBLA and found that it did not fully describe the processes that Hospira uses to manufacture its biosimilar product. (Appx699-700.)

Because Amgen has patents to methods of manufacturing using different compositions of cell-culture media, and because subparagraph 262(*l*)(2)(A) encompasses disclosure of such manufacturing information by the Applicant so that the RPS can determine whether it has a reasonable basis to assert infringement of one or more of its manufacturing patents, Amgen identified the deficiency in Hospira's subparagraph 262(*l*)(2)(A) disclosure and asked Hospira to provide specific information about the composition of the cell-culture medium that Hospira uses to manufacture its biosimilar product. Amgen asked three times. (Appx699-700, Appx702-703, Appx705-706.) Hospira refused. (Appx708, Appx710.)

The BPCIA provides that after receipt of the Applicant's subparagraph 262(*l*)(2)(A) disclosure—specifically calling out both the "application," i.e., the aBLA, and the other "information," i.e., describing manufacturing processes—the RPS then prepares a list of all patents "for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted" against the "making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(*l*)(3)(A); *Sandoz*, 794 F.3d at 1352, 1354-57; *Apotex*, 2016 WL 3606770, at *2. Despite Hospira having failed to provide the information required by, and thus having failed to comply with, subparagraph 262(*l*)(2)(A) (Appx702-703), on

May 1, 2015, Amgen proceeded to identify for Hospira a list of patents in accordance with the deadline and standard set forth in subparagraph 262(*l*)(3)(A), i.e. patents for which Amgen believes a claim of patent infringement could reasonably be asserted based on the only information then provided by Hospira, its aBLA. (Appx1001-1002.) Having not received the information about Hospira's cell-culture manufacturing processes, despite a statutory obligation and repeated requests from Amgen for it, Amgen could not form a belief as to whether a claim of patent infringement could reasonably be asserted for those patents—the standard for listing in accordance with subparagraph 262(*l*)(3)(A).

On September 18, 2015, Amgen filed a patent-infringement suit against Hospira in the United States Court for the District of Delaware, asserting infringement under 35 U.S.C. § 271(e)(2)(C) and 271(a) of U.S. Patent No. 5,856,298, and infringement under 35 U.S.C. § 271(a) of U.S. Patent No. 5,756,349 (Appx172-175 ¶¶ 92-112; *see* Appx225-228 ¶¶ 86-106), both of which had been included on Amgen's May 1, 2015 list of patents (Appx1001-1002).

D. Amgen Sought Cell-Culture Information in Discovery

Amgen's complaint included a count directed to Hospira's failure to produce its cell-culture information in compliance with subparagraph 262(*l*)(2)(A). (Appx171-172 ¶¶ 86-91.) At that time, this Court's decision in *Amgen v. Sandoz*—

in which the Court held that the BPCIA does not grant "a procedural right to compel compliance with the disclosure requirement of paragraph (*l*)(2)(A)," 794 F.3d at 1356—was the subject of pending petitions for en banc rehearing. Sandoz's Petition for Rehearing En Banc, *Amgen Inc. v. Sandoz Inc.*, No. 15-1499 (Fed. Cir. Aug. 20, 2015), Dkt. 119; Amgen's Petition for Rehearing En Banc, *Amgen Inc. v. Sandoz Inc.*, No. 15-1499 (Fed. Cir. Aug. 20, 2015), Dkt. 118.

When this Court denied en banc review of that decision, *see* Order Denying Petitions, *Amgen Inc. v. Sandoz Inc.,* No. 15-1499 (Fed. Cir. Oct. 16, 2015), Dkt. 162, Amgen filed an Amended Complaint on November 6, 2015 (Appx204-230). Amgen removed the count that sought injunctive relief to compel Hospira to provide its cell-culture manufacturing information, but retained the factual allegations detailing Hospira's refusal to provide that information. (Appx217-219 ¶¶ 44-53.) Amgen expressly stated its intention to rely on this Court's ruling in *Sandoz* to remedy Hospira's non-compliance with subparagraph 262(*l*)(2)(A) (Appx206 ¶ 12, Appx217-219 ¶¶ 44-53) as provided for by this Court: after a sponsor brings an infringement suit under the BPCIA under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii), "it can access the required [subparagraph 262(*l*)(2)(A)] information through discovery." *Sandoz*, 794 F.3d at 1356. Amgen also provided notice that, if appropriate, it would "seek to assert

additional patents following eventual receipt of Hospira's manufacturing information to be produced in discovery." (Appx219 ¶ 52.)

Amgen thus served discovery requests on Hospira seeking the composition of the cell-culture medium used in Hospira's process of manufacturing its biosimilar to Amgen's Epogen®. (Appx773-775, Appx806-807.) Hospira again refused to provide the information. (Appx715-717, Appx732-739.)

E. The Opinion Below Denying Amgen Discovery

On May 2, 2016, Amgen moved to compel Hospira to produce information regarding the composition of its cell-culture medium. (Appx694-697.) On May 4, 2016, the district court heard argument on that motion. (Appx1-42.)

The district court held that Amgen is not entitled to discover the cell-culture information in order to determine whether Amgen has additional patents to assert against Hospira's manufacture of its biosimilar product. (Appx39-40 at 39:22-40:13.) The district court reviewed this Court's *Sandoz* decision again during oral argument, and concluded: "I don't think the *Amgen v. Sandoz* Federal Circuit case is really on point for—not only—it would be controlling, obviously, if it were on point, but it's not on point. I don't think that really impacts this at all." (Appx39-40 at 39:24-40:2.) Referring to the December 2015 amendments to the Federal Rules of Civil Procedure governing discovery, the court stated, "And, I think, looking for the cell culture medium so you can consider about asserting other

patents, it's, basically, what in the pre-amendment, you know, before December, what we just called the fishing expedition, is they're even less favored after the amendments than they were before." (Appx40 at ll. 3-7.)

The district court also addressed a "narrower ground" for discovery of the cell-culture information, its potential relevance to a method-of-manufacture claim in one of the patents-in-suit, which requires cells to be cultured "under suitable nutrient conditions." (Appx6-7 at 6:15-7:1, Appx27 at ll. 3-8, Appx40 at ll. 15-19.) As permitted by the district court, Hospira informed Amgen that it will not dispute infringement of that claim limitation, and, thus, the "narrower ground" affords Amgen no basis to discover the cell-culture information that Hospira has withheld. (Dkt. 13 at 4 n.2; Appx40 at ll. 11-19, Appx997-1000.)

Consequently, unless this Court reverses the district court's ruling, Hospira may succeed in evading detection of infringement first by withholding information describing its processes of manufacture, even though that information is called for under subparagraph 262(*l*)(2)(A), and then by refusing to produce that information in discovery on the basis that Amgen has not sued on the very patents for which provision of that information is intended to facilitate suit.

F. This Appeal and Hospira's Motion to Dismiss It

Amgen timely filed its Notice of Appeal on June 3, 2016 (Appx764-765), and this Court docketed the appeal on June 7, 2016 (Dkt. 1). On July 8, 2016,

Hospira moved to dismiss the appeal for want of jurisdiction, addressing the "collateral order" exception to the final-judgment rule. (Dkt. 13.) The parties briefed the applicability of that exception.

On August 12, 2016, the Court denied Hospira's motion, holding as follows:

> Upon review of the papers submitted, the court deems it the proper course to deny the motion to dismiss and for the parties to address in their briefs the merits and also whether this court has jurisdiction pursuant to the collateral order doctrine or under the All Writs Act, 28 U.S.C. § 1651(a).

(Dkt. 16 at 3.)

SUMMARY OF THE ARGUMENT

This appeal presents an important question of law for BPCIA cases: where an Applicant fails to provide information required under subparagraph 262(*l*)(2)(A) of the BPCIA, and the RPS sues for patent infringement and seeks to access that information through discovery, is the information properly shielded from discovery unless it is relevant to a patent already in suit? In *Amgen Inc. v. Sandoz Inc.*, the Court held that once the RPS brings a patent-infringement suit against the Applicant, "it can access the required information through discovery." 794 F.3d 1347, 1351 (Fed. Cir. 2015). By denying Amgen access to information about the processes used to manufacture Hospira's biosimilar product, the district court erred. Amgen respectfully requests that this Court correct that error of law under the collateral-order doctrine or by writ of mandamus.

The BPCIA was intended to strike a balance between "innovation and consumer interests." *Sandoz*, 794 F.3d at 1351. One aspect of that balance was the creation of "a unique and elaborate process for information exchange between the biosimilar applicant and the RPS to resolve patent disputes." *Id.* at 1352. Under that process, "the biosimilar applicant grants the RPS confidential access to its aBLA and the manufacturing information regarding the biosimilar product no later than 20 days after the FDA accepts its application for review." *Id.* (citing 42 U.S.C. § 262(*l*)(1)-(2)). The Court separated the "aBLA" and "the manufacturing

information" in that sentence just as the BPCIA itself does: The Applicant's disclosure obligation extends past its aBLA to "other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A).

After the Applicant provides both "the application" and the manufacturing "information" called for by subparagraph 262(*l*)(2)(A), the RPS provides a list of patents, including manufacturing patents, for which it believes a claim of patent infringement "could reasonably be asserted." *Id.* § 262(*l*)(3)(A); *Sandoz*, 794 F.3d at 1356 n.3. As Judge Newman noted, manufacturing-process patents "may be highly material" for biosimilars, and "were so recognized during enactment" of the BPCIA by Congress. *Sandoz*, 794 F.3d at 1364 (Newman, J., dissenting).

In *Sandoz*, the Court held that where an Applicant fails to provide the information required by subparagraph 262(*l*)(2)(A), the RPS's only remedies are those based on patent infringement. *See* 794 F.3d at 1356. Once the RPS brings a declaratory judgment action or a patent-infringement suit, the RPS may "access the required information through discovery":

> Notably, both 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) are premised on a claim of patent infringement, and the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A). Once the RPS brings an infringement suit under those two provisions, it can access the required information through discovery.

Id.

Here, Hospira refused Amgen's requests for information about the cell-culture medium Hospira uses in the manufacture of its biosimilar product, information that may show infringement of some of Amgen's portfolio of cell-culture process patents. (Appx699-700, Appx702-703, Appx705-706, Appx708, Appx710.) Following this Court's holding in *Sandoz*, Amgen sued Hospira for infringement of two patents other than its cell-culture patents and, having been denied information about Hospira's cell-culture processes under subparagraph 262(*l*)(2)(A), sought the cell-culture manufacturing information from Hospira in discovery. (Appx773-775, Appx806-807, Appx752-753.) Hospira again refused to provide the information, and the district court denied Amgen's motion to compel. (Appx39-40 at 39:22-40:13.)

In allowing an Applicant to refuse to disclose "information that describes the process or processes used to manufacture the biological product that is the subject of" the subsection (k) application, 42 U.S.C. § 262(*l*)(2)(A), the district court erred. That error threatens to undermine the entire balance of the BPCIA as construed by this Court in *Sandoz*. If Applicants cannot be compelled to provide their manufacturing information under the information-exchange provisions of the BPCIA, as this Court held, and if Applicants may further refuse to provide that information in discovery, as the district court held, then an Applicant could avoid suit on process patents forever. The RPS might never have the information needed

to form a good-faith belief about whether a claim of patent infringement could be asserted under a process patent, and thus the technical act of infringement created by the BPCIA—which extends to only patents the RPS believes "'could reasonably be asserted' with respect to the biosimilar product at issue"—would not be satisfied. *Amgen Inc. v. Apotex Inc.*, No. 2016-1308, 2016 WL 3606770, at *4 (Fed. Cir. July 5, 2016); *see also* 35 U.S.C. § 271(e)(2)(C)(ii).

Hospira offers three arguments to defend its refusal to produce, in discovery, information about the process by which it manufactures its biosimilar product.

First, Hospira says that this Court's decision in *Sandoz* does not mean what it says. Hospira denigrates as "specious" Amgen's argument that it is entitled to access manufacturing information in discovery, and dismisses this part of the Court's *Sandoz* decision as gratuitous: Hospira describes the Court as "merely" having "mentioned in passing that once the RPS brings a patent infringement lawsuit it can access information through discovery." (Dkt. 15 at 7.)

The Court's decision that such required information is available through discovery was hardly "in passing." One of the key points of dispute in that case was whether discovery was an adequate alternative to the disclosure provisions of subsection 262(*l*). Sandoz stressed that disclosure of the aBLA and manufacturing information under paragraph 262(*l*)(2) was not required because the RPS could obtain this material through discovery. Brief for Sandoz, *Amgen Inc. v. Sandoz*

Inc., No. 15-1499 (Fed. Cir. Apr. 21, 2015), Dkt. 69, 2015 WL 1926147, at *5-6, 13, 23, 33, 62; Sandoz Inc.'s Opposition to Emergency Motion for Injunction Pending Appeal, *Amgen Inc. v. Sandoz Inc.*, No. 15-1499 (Fed. Cir. Apr. 24, 2015), Dkt. 83, at 9, 18; Oral Argument at 33:52-34:19, 36:26-38:20, 38:29-40:28, *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir. June 3, 2015), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/15-1499/all; Sandoz's Response to Amgen's Petition for Rehearing En Banc, *Amgen Inc. v. Sandoz Inc.*, No. 15-1499 (Fed. Cir. Sept. 8, 2015), Dkt. 156, at 7. The Court itself framed the parties' dispute as whether discovery is an adequate alternative to the statutory information exchange. *See Sandoz*, 794 F.3d at 1355. And that is how this Court has understood its ruling in *Sandoz*. Judge Newman dissented "from the court's holding that this activity is not required because the Sponsor might file an infringement suit in which it might learn this information though discovery." *Id.* at 1363 (Newman, J., dissenting). And the Court's order denying Hospira's motion to dismiss this appeal reiterated the RPS's right as recognized in *Sandoz* to "access 'the required information' through discovery." (Dkt. 16 at 2.)

Second, Hospira says that Amgen was required to list its cell-culture patents under subparagraph 262(*l*)(3)(A) and—having not done so—is barred from suing Hospira on those patents with respect to this biosimilar product by 35 U.S.C. § 271(e)(6)(C). (Appx22 at ll. 19-25; Appx23 at ll. 16-21.) That is incorrect. That

limitation applies to only "a patent that should have been included in" the RPS's subparagraph 262(*l*)(3)(A) list but "was not timely included in such list." 35 U.S.C. § 271(e)(6)(C). Because Hospira failed to provide its cell-culture manufacturing information—which Amgen requested repeatedly, before any obligation to list those patents under subparagraph 262(*l*)(3)(A) could have come due—Amgen had no obligation to list its cell-culture manufacturing patents, if any patents at all, under subparagraph 262(*l*)(3)(A). The RPS's obligation is expressly conditioned on receipt of the Applicant's "application and information" under subparagraph 262(*l*)(2)(A). 42 U.S.C. § 262(*l*)(3)(A). Moreover, listing a patent under subparagraph 262(*l*)(3)(A) is expressly conditioned on forming a belief that a claim of infringement could "reasonably be asserted"; if an Applicant refuses to provide the information from which such a belief could be formed, the patent cannot be properly listed, and 35 U.S.C. § 271(e)(6) does not bar the RPS from asserting that patent.

Third, and relatedly, Hospira argues that the scope of Rule 26 prohibits discovery of information that would tend to prove or disprove infringement of unasserted patents. Implicitly, Hospira argues that Amgen should have sued Hospira on Amgen's entire portfolio of cell-culture patents and then sought discovery to find out which, if any, of those patents are infringed. That cannot be what the BPCIA contemplates, or what this Court intended in *Sandoz*. Indeed, in

Apotex the Court recognized that the hallmark of a technical act of infringement under the BPCIA is the RPS's belief that a claim of infringement could reasonably be asserted. *See* 2016 WL 3606770, at *4. If an Applicant refuses to disclose its manufacturing information, the RPS may never know that one or more of its process patents is implicated or, even if the RPS suspects that such a patent may be implicated, whether it is reasonable to assert the process patent. The RPS should not have to risk Rule 11 sanctions or accusations of anticompetitive behavior by suing on patents that may or may not be infringed, only to then take discovery to find out whether the lawsuit was justified.

In holding otherwise, the district court erred. That error is ripe for review under the collateral-order doctrine or by writ of mandamus.

The Collateral-Order Doctrine provides appellate jurisdiction over orders that "[1] conclusively determine the disputed question, [2] resolve an important issue completely separate from the merits of the action, and [3] [are] effectively unreviewable on appeal from a final judgment." *Apple Inc. v. Samsung Elecs. Co.*, 727 F.3d 1214, 1220 (Fed. Cir. 2013). The first prong is uncontested: Hospira does not dispute that the district court's order conclusively determined the question of whether Amgen may obtain Hospira's cell-culture manufacturing information through discovery. The importance of the issue is clear, as this is the first district-court ruling after *Sandoz* to address the RPS's ability to access the Applicant's

manufacturing information in discovery where the Applicant refused to provide it in accordance with subparagraph 262(*l*)(2)(A). This issue is separate from the merits; the district court refused to order disclosure of this information precisely because the information is not relevant to the patents that are in suit. And there can be no effective appellate review after a final judgment: by the time the trial on the patents-in-suit is concluded, an appeal is prosecuted and decided, and the case is remanded to the district court, Hospira could have begun marketing its product, without Amgen having received the manufacturing information that the BPCIA affords an RPS so that infringement suits and preliminary-injunction practice can precede marketing of the biosimilar.

The All Writs Act, alternatively, permits this Court to issue a writ of mandamus to correct the district court's clearly erroneous legal ruling. Although Amgen did not frame this appeal as a petition for a writ of mandamus, the Court has the power to convert the appeal into such a petition, and the Court's Order denying Hospira's motion to dismiss directed the parties to brief the applicability of that relief. (Dkt. 16 at 3.)

In that regard, Amgen notes that this is not the kind of ordinary discovery dispute in which mandamus is inappropriate and in which the district court's discovery rulings are reviewed only for abuse of the court's discretion. This debate is not about whether the requested information is cumulative, or privileged,

or burdensome to produce. Hospira did not make any of those arguments. Instead, the district court ruled purely as a matter of law, holding that where an RPS has requested information "that describes the process or processes used to manufacture the product that is the subject of" the subsection (k) application—i.e., information that the RPS was entitled to receive pursuant to subparagraph 262(*l*)(2)(A)—the Applicant cannot be compelled to provide that information in discovery unless it also happens to be relevant to the patents in suit.

That holding misunderstood this Court's decision in *Sandoz*, and threatens to undermine the balance that Congress struck. The Court can remedy that clear error by writ of mandamus.

ARGUMENT

I. The District Court Erred in Interpreting the BPCIA To Allow Hospira To Shield from Discovery the Manufacturing Information Required Under Subparagraph 262(*l*)(2)(A)

This appeal presents a legal issue about the correct interpretation of the BPCIA, 42 U.S.C. § 262(*l*)(2)(A), under this Court's ruling in *Amgen v. Sandoz*. The Court reviews the district court's statutory interpretation of the BPCIA *de novo*. *See Sandoz*, 794 F.3d at 1354 (citing *Qantas Airways Ltd. v. United States*, 62 F.3d 385, 387 (Fed. Cir. 1995)). The district court's decision is not reviewed under the abuse-of-discretion standard because the decision turns solely on interpretation of the BPCIA and this Court's decision in *Sandoz*.

A. This Court's Decision in *Sandoz* Holds That an RPS May Obtain Through Discovery the Information Required Under Subparagraph 262(*l*)(2)(A)

The Court's decisions in *Sandoz* and *Apotex* review the history and structure of the information-exchange provisions of the BPCIA. *See Amgen Inc. v. Apotex Inc.*, No. 2016-1308, 2016 WL 3606770, at *4 (Fed. Cir. July 5, 2016); *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1351-53 (Fed. Cir. 2015). In relevant part, subparagraph 262(*l*)(2)(A) provides that the Applicant shall disclose both its aBLA and information about the processes used to manufacture its proposed biosimilar product:

> (2) Subsection (k) application information
>
> Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—
>
> (A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and
>
> (B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

42 U.S.C. § 262(*l*)(2) (emphasis added). The BPCIA treats the aBLA and the manufacturing information equally and in tandem, referring to them as the "application and information." *See* 42 U.S.C. § 262(*l*)(3)(A), (*l*)(9)(A), (*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii).

After the RPS receives the Applicant's aBLA and its manufacturing information, the RPS provides a list of patents for which it reasonably believes a claim of infringement could be asserted:

> (3) List and description of patents. –
>
> (A) List by reference product sponsor. – Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant –
>
> a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor . . . with respect to the reference product, if a person not licensed by the reference

> product sponsor engaged in the making, using, offering for sale, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application.

42 U.S.C. § 262(*l*)(3)(A) (emphasis added). The inclusion of the word "making" ensures that paragraph 262(*l*)(3) "does not exclude process patents." *Sandoz*, 794 F.3d at 1356 n.3.

This Court held in *Sandoz* that if the Applicant refuses to provide the subparagraph 262(*l*)(2)(A) information, the RPS may not seek injunctive relief to compel the Applicant to follow that part of the BPCIA's information-exchange process, but may bring an infringement suit or a declaratory-judgment action and "access the required information through discovery." 794 F.3d at 1356.[1]

Here, while Hospira provided Amgen with a copy of its aBLA, Hospira refused to provide the other manufacturing information required under subparagraph 262(*l*)(2)(A), specifically other information that describes the components of the cell-culture medium used in Hospira's manufacturing process.

[1] *Sandoz* remains controlling law, although Amgen respectfully submits that the Court erred in holding that an RPS's sole remedy for an Applicant's failure to provide the required subparagraph 262(*l*)(2)(A) information is a patent-infringement lawsuit. Amgen has conditionally cross-petitioned the Supreme Court for a writ of certiorari to review this aspect of the *Sandoz* decision if the Supreme Court accepts Sandoz's petition to review other, here-unrelated aspects of the *Sandoz* decision regarding notice of commercial marketing under paragraph 262(*l*)(8). The Supreme Court has called for the views of the Solicitor General with respect to both petitions, which remain pending. *Sandoz Inc. v. Amgen Inc.*, No. 15-1039 (June 20, 2016); *Amgen Inc. v. Sandoz Inc.*, No. 15-1195 (June 20, 2016).

To be clear, the discretionary provision of subparagraph 262(*l*)(2)(B) does not apply here; what Amgen requested, and what Hospira refused to provide, is information within the scope of subparagraph 262(*l*)(2)(A), "information that describes the product or processes used to manufacture the product that is the subject of" Hospira's aBLA, not subparagraph 262(*l*)(2)(B), "additional information requested by or on behalf of the" RPS.

When Hospira failed to comply with its disclosure obligations, Amgen filed an infringement action on two patents for which Hospira's aBLA disclosed sufficient information to support a lawsuit: the '298 Patent under 35 U.S.C. § 271(a) and (e)(2)(C) and the '349 Patent under 35 U.S.C. § 271(a). (Appx172-175 ¶¶ 92-112; *see* Appx225-228 ¶¶ 86-106.) And Amgen sought in discovery the cell-culture-medium information required under subparagraph 262(*l*)(2)(A). (Appx773-775, Appx806-807.)

B. The District Court Erred in Limiting the Scope of *Sandoz* to Discovery of Manufacturing Information Relevant to the Patents Already in Suit

Amgen followed the path this Court described in *Sandoz*, yet the district court refused to compel production of subparagraph 262(*l*)(2)(A) manufacturing information because that information was not relevant to the patents on which Amgen had already filed suit. The district court stated that *Sandoz* is "not on point" and that Amgen was on a "fishing expedition" not permitted by Rule 26 of

the Federal Rules of Civil Procedure. (Appx39-40 at 39:24-40:7.) In so holding, and in interpreting the BPCIA and *Sandoz* to allow Hospira to shield from discovery information that describes the process or processes used to manufacture Hospira's proposed biosimilar, the district court erred.

The effect of the district court's decision is to deny the RPS an opportunity to evaluate whether to assert—and possibly deny it the ability to assert—manufacturing patents where, as here, the Applicant refuses to disclose the manufacturing information in the pre-litigation, BPCIA exchange and then shields it from production during discovery. As Amgen told this Court in *Sandoz*, the BPCIA does not permit the Applicant to "unlawfully evade[] the detection of process patent infringement" by refusing to provide the required information. 794 F.3d at 1355. That is the case here. By providing only its aBLA and refusing to provide the manufacturing information equally required under subparagraph 262(*l*)(2)(A), Hospira deprived Amgen of its right to fully evaluate its patent portfolio.

Because this Court has held that the only remedy for a violation of subparagraph 262(*l*)(2)(A) is for the RPS to file a patent-infringement lawsuit, discovery of the required manufacturing information must be available during such a lawsuit. Otherwise, the Applicant could indefinitely escape liability for infringement of process patents, and unilaterally control the patents for which an

infringement lawsuit is brought, by selectively disclosing some, but not all, of the information required to be disclosed under the BPCIA.

Indeed, under Hospira's reasoning, an Applicant could withhold "required information" under subparagraph 262(*l*)(2)(A) altogether, potentially preventing an RPS from ever assessing the infringement of its full portfolio of patents. That cannot be correct; the very purpose of subsection 262(*l*) is the identification and resolution of patent disputes through an exchange of information, negotiation, and, if necessary, litigation. *See Apotex*, 2016 WL 3606770, at *2-3. Nor does it reflect the balance that the BPCIA sought to achieve. The Applicant can determine what manufacturing patents the RPS holds through searches of the United States Patent and Trademark Office's public databases; the RPS, on the other hand, has no means to discover which of its manufacturing-process patents the Applicant infringes, other than pursuant to the BPCIA itself or, as this Court held in *Sandoz*, in discovery in a patent-infringement suit.

Amgen notes that in *Sandoz*, the Court stated that the RPS may access the required information in discovery after filing a patent-infringement action under 35 U.S.C. § 271(e)(2)(C)(ii)—the technical act of infringement where an Applicant "fails to provide the application and information required" under subparagraph 262(*l*)(2)(A)—and 42 U.S.C. § 262(*l*)(9)(C)—the limitation on declaratory-judgment actions where the Applicant fails to provide that same information. 794

F.3d at 1355-56. Amgen brought patent-infringement claims under 35 U.S.C. § 271(e)(2)(C) and 271(a), but did not seek a declaratory judgment of infringement. That is a distinction without a difference, however. What the Court in *Sandoz* addressed was the need to file suit to seek discovery. Indeed, Sandoz itself refused to provide any subparagraph-262(*l*)(2)(A) material, withholding its aBLA as well as any additional manufacturing information, but after Amgen sued under California state law and brought a patent-infringement claim on only a method-of-treatment patent, discovery of the subparagraph 262(*l*)(2)(A) information was not limited to that portion of the required disclosure that was relevant to the method-of-treatment patent, nor did this Court suggest that it should have been. The holding of *Sandoz* applies to Applicants like Sandoz that fail to disclose any of the required information, and to Applicants like Hospira that disclose some, but not all, of the required information. In each instance, if the RPS sues for patent infringement, the Applicant cannot shield from discovery the information it was required to disclose under subparagraph 262(*l*)(2)(A).

Hospira has made three arguments in defense of its refusal to produce, and hence the district court's denial of Amgen's motion to compel production of, Hospira's cell-culture manufacturing information. Each fails.

1. The Court's Discussion in *Sandoz* Was Not Merely an "In Passing" Observation

Hospira dismisses the holding of *Sandoz* as an in-passing, gratuitous reference, describing the Court as having "merely mentioned in passing that once the RPS brings a patent infringement lawsuit it can access information through discovery." (Dkt. 15 at 7.) That sentence was hardly delivered "in passing." One of the key points of dispute in *Sandoz* was whether discovery was an adequate alternative to the disclosure provisions of subsection 262(*l*). The Court resolved that dispute by holding that discovery was an appropriate means to access information the Applicant failed to provide during the statutory information exchange.

Thus, the district court in *Sandoz* interpreted the BPCIA as permitting a "reference product sponsor who believes it may have an infringement claim" to "file suit to access the biosimilarity BLA, manufacturing process, and other relevant information via discovery." *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741-RS, 2015 WL 1264756, at *7 n.6 (N.D. Cal. Mar. 19, 2015).

On appeal, this Court framed the parties' position as a dispute about whether an Applicant may avoid disclosure of the required information and evade detection of process-patent infringement, or whether an RPS may access that information in discovery:

> Amgen argues that, by refusing to provide the required information, a subsection (k) applicant unlawfully evades the detection of process patent infringement and avoids an immediate infringement action under § 262(*l*)(6).
>
> . . . . .
>
> Sandoz also responds that, under the BPCIA, if a subsection (k) applicant does not disclose the information under paragraph (*l*)(2)(A), then the sponsor may file an infringement suit under paragraph (*l*)(9)(C) and obtain the information in discovery, which Amgen has done.

Sandoz, 794 F.3d at 1355. Consistent with its position in the district court, in this Court Sandoz stressed repeatedly that disclosure of the aBLA and manufacturing information under paragraph 262(*l*)(2) was not required because the RPS could obtain this material through discovery. Brief for Sandoz, *Amgen Inc. v. Sandoz Inc.*, No. 15-1499 (Fed. Cir. Apr. 21, 2015), Dkt. 69, 2015 WL 1926147, at *5-6, 13, 23, 33, 62; Sandoz Inc.'s Opposition to Emergency Motion for Injunction Pending Appeal, *Amgen Inc. v. Sandoz Inc.*, No. 15-1499 (Fed. Cir. Apr. 24, 2015), Dkt. 83, at 9, 18; Oral Argument at 33:52-34:19, 36:26-38:20, 38:29-40:28, *Amgen Inc. v. Sandoz Inc.*, No. 2015-1499 (Fed. Cir. June 3, 2015), *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/15-1499/all. Indeed, after the panel decided the case and Amgen petitioned for rehearing en banc, Sandoz described the panel's opinion as permitting the RPS to access this information in discovery: "As the panel recognized, '[o]nce the [sponsor] brings an infringement suit under those two provisions, it can access the required information through

discovery.'" Sandoz's Response to Amgen's Petition for Rehearing En Banc, *Amgen Inc. v. Sandoz Inc.*, No. 15-1499 (Fed. Cir. Sept. 8, 2015), Dkt. 156, at 7.

That is how this Court itself has characterized the *Sandoz* decision. Judge Newman's dissent began: "I respectfully dissent from the court's holding that this activity is not required because the Sponsor might file an infringement suit in which it might learn this information through discovery." *Sandoz*, 794 F.3d at 1363 (Newman, J., dissenting). And in the Court's order denying Hospira's motion to dismiss this appeal, the Court concluded its discussion of the existing law by reiterating the RPS's right to access the subparagraph 262(*l*)(2)(A) information in discovery:

> Under 42 U.S.C. § 262(*l*)(2)(A), an applicant seeking regulatory approval of a biosimilar product must provide to the reference product sponsor a copy of the biosimilar application and 'such other information that describes the process or processes used to manufacture the biological product that is the subject of such application' within 20 days of the FDA having accepted the biosimilar application. The parties then exchange a list of patents that would be the subject of an immediate infringement action. *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1352 (Fed. Cir. 2015) "[F]ailing to disclose the required information under paragraph (*l*)(2)(A) is [under 35 U.S.C. § 271(e)(2)(C)(ii)] an artificial 'act of infringement' of 'a patent that could be identified' pursuant to paragraph (*l*)(3)(A)(i)." *Id.* at 1356. Once the reference product sponsor brings an infringement suit, it can access "the required information" through discovery. *Id.*

(Dkt. 16 at 2 (emphasis added).) Hospira cannot escape its obligations under the BPCIA by mischaracterizing the holding of *Sandoz* as a judicial aside.

2. Amgen Was Not Required To List Its Cell-Culture Patents Under Subparagraph 262(*l*)(3)(A) and Is Not Barred From Suit

Hospira has argued in the district court that Amgen is barred from suing on its cell-culture patents because Amgen did not list those patents under subparagraph 262(*l*)(3)(A). (Appx22 at ll. 19-25; Appx23 at ll. 16-21, Appx758-761 at Appx759.) Hospira misreads the statute. The prohibition against an RPS suing on a patent that it did not list under subparagraph 262(*l*)(3)(A) is expressly limited to patents "that should have been included" in that list but were "not timely included." 35 U.S.C. § 271(e)(6)(C). That provision cannot reach Amgen's cell-culture manufacturing patents, because Hospira did not satisfy the condition precedent to that obligation: providing the "application and information required" under subparagraph 262(*l*)(2)(A). 42 U.S.C. § 262(*l*)(3)(A) (emphasis added).

That is an essential component of the BPCIA process. The prohibition in subparagraph 271(e)(6)(C) is draconian: the RPS is forever barred from suing the Applicant over the biosimilar product for each patent shown not to have been timely listed in the RPS's subparagraph 262(*l*)(3)(A) list. In *Apotex*, this Court explained that this provision is "evidently designed to reinforce the reference product sponsor's incentives to follow the distinctive Biologics Act's patent process where the Applicant has launched that process." 2016 WL 3606770, at *4.

By refusing to provide the information about the cell-culture medium it uses to manufacture its biosimilar product, Hospira prevented Amgen from listing its cell-culture patents. The BPCIA provides that an RPS may list a patent only where it "believes a claim of patent infringement could reasonably be asserted." 42 U.S.C. § 262(*l*)(3)(A) (emphasis added). The Applicant provides its manufacturing information so that the RPS can make that determination. If an Applicant could refuse to provide the information required for an RPS to assess potential patent infringement, and then rely on the limitation in 35 U.S.C. § 271(e)(6)(C) to bar the RPS from suing on those patents for which it could not assess infringement, then an Applicant could escape liability for patent infringement simply by refusing to disclose anything at all. That flouts the BPCIA's text, its purpose, and the Court's decision in *Sandoz*.

By limiting the RPS's subparagraph 262(*l*)(3)(A) list to only those patents it believes could reasonably be asserted after receipt of the Applicant's aBLA and manufacturing information, Congress benefitted Applicants. Within just 60 days of receiving the RPS's patent list, the Applicant must respond, for each listed patent, with "a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the [Applicant] that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application." 42 U.S.C.

§ 262(*l*)(3)(B). If an RPS could list all patents that theoretically could be infringed, without limitation to those which it had a good-faith basis to believe would be infringed, an RPS could inundate the Applicant with listed patents and make compliance with subparagraph 262(*l*)(3)(B) in only 60 days extremely difficult.

3. Federal Rule of Civil Procedure 26 Does Not Bar Amgen From Discovering Hospira's Withheld Information

Hospira contends that Rule 26 of the Federal Rules of Civil Procedure prohibits discovery of its cell-culture information, because that information is not relevant to the patents in suit or within the scope of "proportional" discovery. Based on Hospira's characterization of the issue, the district court concluded that Amgen's request for Hospira's cell-culture information was a "fishing expedition" to determine whether to assert additional patents, specifically citing the December 2015 amendments to the Federal Rules of Civil Procedure that limited the scope of discovery. (Appx40 at ll. 3-7.) This misreads this Court's decision in *Sandoz*.

Amgen asked Hospira three times to provide its cell-culture information so that Amgen could assess whether any of its cell-culture patents met the standard for listing patents under subparagraph 262(*l*)(3)(A). (Appx699-700, Appx702-703, Appx705-706.) Hospira refused. (Appx708, Appx710.) Reversing the information flow provided for by the statute, and depriving Amgen of the ability to make a determination that the BPCIA vests in the RPS, Hospira said that Amgen

should simply list its cell-culture patents, and only then would Hospira tell Amgen whether Hospira infringed those patents. (Appx708; Appx22-23 at 22:20-23:21; Appx759.)

Then, when Hospira refused to provide that information, Amgen sought to access that information in discovery. (Appx773-775, Appx806-807, Appx752-753.) That the information bears not on the patents-in-suit but on other patents as to which Hospira kept Amgen ignorant does not mean that this is a "fishing expedition." On the contrary, what Amgen did is exactly what this Court held in *Sandoz* that an RPS should do.

To be clear, Hospira's cell-culture information would have been relevant to one of the patents-in-suit. But when the district court held that Hospira would have to produce that information if it contested infringement under the applicable claim of the patent-in-suit—the "narrower ground" for disclosure that the court addressed (Appx40 at ll. 11-19)—Hospira decided not to contest infringement so that it could continue to shield its cell-culture information from disclosure (*see* Appx997-1000). Besides showing the extent to which Hospira is willing to go to avoid producing this information, this also shows that Hospira itself contrived its "fishing expedition" argument.

Worse, implicit in Hospira's "fishing expedition" argument is that Hospira would produce the cell-culture information if Amgen had sued on its cell-culture

patents. Essentially, Hospira argues, and the district court held, that Amgen should have sued first and taken discovery later. If that were the law, it would put RPSs in a terrible position. An Applicant could withhold the information that an RPS needed to form a good-faith basis as to whether a claim of infringement under a patent is "reasonable," a belief that is an essential element of the relevant act of infringement under the BPCIA, 35 U.S.C. § 271(e)(2)(C)(ii); *see Apotex*, 2016 WL 3606770, at *4. If discovery revealed that there was no basis to have sued on that patent, the RPS could face a motion for sanctions under Rule 11 or an allegation of anticompetitive conduct.

The risk of Rule 11 sanctions or antitrust counterclaims is not hypothetical. Innovators have faced Rule 11 motions for suing a generic-drug maker and only then taking discovery to find out whether the patent applied. In *Hoffmann-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1361-62 (Fed. Cir. 2000), the plaintiff sought manufacturing information from the generic manufacturer in order to assess whether to assert a manufacturing patent, and then sued on that patent when the generic refused to provide the information. The generic sought Rule 11 sanctions. *Hoffmann-La Roche*, 213 F.3d at 1362. While this Court affirmed the district court's denial of sanctions in that case, *see id.* at 1365-66, what matters is that sanctions were sought at all. The BPCIA should not be construed to require an RPS to accept the risk of Rule 11 sanctions in order to perfect its remedy for an

Applicant's failure to comply with subparagraph 262(*l*)(2)(A) in the first instance. Likewise, in the *Apotex* case, Apotex asserted antitrust counterclaims accusing Amgen of "sham litigation" on the patents in suit. Apotex's Corrected Counterclaims, *Amgen Inc. v.Apotex Inc.*, Case No. 15-61631-CIV-COHN (S.D. Fla. Oct. 23, 2016), Dkt. 47, ¶¶ 51-100. While Apotex ultimately withdrew those counterclaims before trial, that they existed at all confirms the risks that Sponsors face in asserting patents against biosimilar makers.

Nothing in *Sandoz* suggests that the ability to "access the required information in discovery" turns on the RPS filing suit on the very patents to which the discovery might be relevant. All that is required is that an RPS file a patent-infringement suit related to the product that is the subject of the Applicant's subsection (k) application, or the use or manufacture of that product. Once it does so, it is entitled to receive all of the subparagraph 262(*l*)(2)(A) information in discovery. *See Sandoz*, 749 F.3d at 1356.

Nor is there any proportionality concern under Rule 26 here. Amgen's request is as narrowly tailored as possible, seeking only the specific information that Hospira is known to have withheld: information regarding the composition of the specific cell-culture medium it uses to manufacture the specific biosimilar product at issue. Although Hospira's disclosure obligations span the full scope of subparagraph 262(*l*)(2)(A), Amgen has not requested that Hospira produce every

document in its possession regarding its manufacturing methods, or even every document regarding its cell-culture medium. In fact, Hospira's counsel admitted that Amgen seeks what amounts to mere "scraps of paper." (Appx603 at l. 8.) Hospira has not made any argument about burden, or cumulativeness, or privilege, or any of the factors that would go into a proportionality analysis. Indeed, Hospira agrees it would produce this information if Amgen first sued on its cell-culture patents.

Finally, it is worth noting that a prior biosimilar bill—one that did not become law—would not have required an Applicant to provide the RPS with a copy of its aBLA or manufacturing information prior to the RPS asserting an infringement claim. *See* H.R. 1427, 111th Cong. (2009), *available at* https://www.congress.gov/111/bills/hr1427/ BILLS-111hr1427ih.pdf. That bill was criticized for not permitting an RPS to determine whether there exists a good-faith basis under Rule 11 from which to assert infringement. *See Biologics and Biosimilars: Balancing Incentives for Innovation*, *Hearing Before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 197, 208 (2009) (statement of Teresa Stanek Rea, President of the American Intellectual Property Law Association), *available at* https://judiciary.house.gov/_files/hearings/printers/111th/111-73_51014.PDF. And that same bill would have imposed a more broad requirement than does 42 U.S.C.

§ 262(*l*)(3)(A) as enacted, in that it would have required the RPS to list not only those patents for which a claim of infringement reasonably could be asserted, but all patents that the RPS "believes in good faith relate to the reference product," H.R. 1427 at 31 (emphasis added), including all manufacturing patents "regardless of whether that method or process is used to manufacture the reference product." *Id.* The "related to" standard, too, was criticized, *see Biologics and Biosimilars: Balancing Incentives for Innovation* at 206-07 (statement of Ms. Stanek Rea), and was not included in the final BPCIA.

II. This Court Has Jurisdiction Over This Appeal

In declaring that *Sandoz* was not "on point" and in refusing Amgen access through discovery to the manufacturing information that Hospira had refused to provide under subparagraph 262(*l*)(2)(A), the district court committed legal error. That error is not about the scope of discovery in one specific case, but about how an RPS may "access the required information through discovery" where an Applicant refuses to provide it under the BPCIA's information-exchange process. *Sandoz*, 794 F.3d at 1356. If uncorrected, the district court's error will create precedent that an Applicant can, by its obstinacy or guile, "unlawfully evade[] the detection of process patent infringement," including by selectively withholding some but not all of the required information. *Id.* at 1355. This Court has

jurisdiction to correct that error under the collateral-order doctrine or, alternatively, the All Writs Act.

A. The Collateral-Order Doctrine Provides Appellate Jurisdiction Over This Important Issue of Law That Is Completely Separate from the Merits of the Action

The collateral-order doctrine provides appellate jurisdiction over orders that "[1] conclusively determine the disputed question, [2] resolve an important issue completely separate from the merits of the action, and [3] [are] effectively unreviewable on appeal from a final judgment." *Apple Inc. v. Samsung Elecs. Co.*, 727 F.3d 1214, 1220 (Fed. Cir. 2013). Since the Supreme Court first articulated the collateral-order doctrine in *Cohen v. Beneficial Industrial Loan Corp*., 337 U.S. 541 (1949), it has applied the doctrine to permit appeals of a variety of orders, from those denying qualified immunity, *Mitchell v. Forsyth*, 472 U.S. 511, 530 (1985), to those denying Westfall Act certification and substitution, *Osborn v. Haley*, 549 U.S. 225, 238-39 (2007), and in forma pauperis status, *Roberts v. United States Dist. Court*, 339 U.S. 844, 845 (1950).

The collateral-order doctrine gives this Court jurisdiction to review the district court's order. All three factors are satisfied.

First, Hospira does not dispute that the district court's ruling conclusively determined the disputed question of whether Hospira needs to produce the

manufacturing information it failed to disclose to Amgen as part of its subparagraph (*l*)(2)(A) disclosure. (Dkt. 13 at 12 n.4.)

Second, the district court's order resolved an important issue separate from the merits of the action: whether Amgen may obtain, through discovery, information about the process or processes used to manufacture Hospira's proposed biologic product that does not bear on the patents-in-suit but may permit Amgen to assert additional patents.

The importance of the issue is clear, as it may influence the way other district courts interpret this Court's *Sandoz* decision. If Hospira can withhold in discovery information that it was expressly required to provide under subparagraph 262(*l*)(2)(A) of the BPCIA's information-exchange process, then Hospira and future Applicants will be able to evade detection of process-patent infringement and deny Amgen and other RPSs the ability to protect their patent rights. Or, Amgen and other RPSs will have to risk Rule 11 sanctions to sue on patents for which there is real uncertainty as to whether there is infringement, only to then learn through discovery that they should not have filed suit in the first place. That is exactly the result that subparagraph 262(*l*)(2)(A) is designed to avoid, and why the BPCIA refers to provision of the aBLA and manufacturing information as "required."

That the relevant law is new—both the BPCIA and this Court's decision in *Sandoz*—underscores why interlocutory review under the collateral-order doctrine is appropriate. In *Mohawk Industries, Inc. v. Carpenter*, the Supreme Court held that disclosure orders adverse to the attorney-client privilege do not qualify for collateral-order review in part because "[m]ost district court rulings on these matters involve the routine application of settled legal principles. They are unlikely to be reversed on appeal, particularly when they rest on factual determinations for which appellate deference is the norm." 558 U.S. 100, 110 (2009). In contrast, the Court found in *Nixon v. Fitzgerald* that collateral-order review was appropriate where the issues "present a 'serious and unsettled'" question. 457 U.S. 731, 742 (1982). This appeal presents the first decision of a district court applying this Court's holding in *Sandoz* that where an Applicant fails to provide its aBLA or manufacturing information under subparagraph 262(*l*)(2)(A), the RPS may sue for patent infringement and "access the required information through discovery." 794 F.3d at 1356. By clarifying how *Sandoz* is to be construed in BPCIA cases, this Court will give guidance to Applicants, Sponsors, and the district courts regarding Applicants' disclosure obligations under the statute.

That this issue is separate from the merits is also clear. While Hospira argues that this Court must "resolve the question of whether the documents

requested by Amgen were relevant to its current claims" and that to do so "this Court would necessarily have to consider Amgen's claims against Hospira and reach some conclusion as to the relative importance of the discovered material" (Dkt. 13 at 16 (citation and internal quotation marks omitted)), this argument evaporated along with the now-abandoned "narrower ground" that the district court considered. When Hospira admitted infringement of the claim limitation to which this information might be relevant, any connection of the requested discovery to the merits of the patents-in-suit was severed. There is no need to determine—in this Court or in the district court—whether the cell-culture information is relevant to Amgen's current patent claims.

Third, the district court's order will not be effectively reviewable on appeal from final judgment. If the district court's order cannot be reviewed until the appeal from a trial on the two patents-in-suit, Hospira's biosimilar may have been licensed by FDA, 180 days' notice of commercial marketing may have been provided, *see Apotex*, 2016 WL 3606770, at *6, and Hospira may have begun commercial marketing 180 days thereafter, long before this Court has an opportunity to review the order denying Amgen access to Hospira's cell-culture information.

That runs afoul of a fundamental purpose of the BPCIA: "to allow infringement suits based on a biosimilar application prior to FDA approval and

prior to marketing of the biological product." *Sandoz*, 794 F.3d at 1352 (emphasis added). It imperils the Applicant's ability to assert manufacturing patents in the 180-day window after legally-effective notice of commercial marketing, which, as this Court held in *Sandoz* and confirmed in *Apotex*, is intended to "'provide[] a defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product.'" *Apotex*, 2016 WL 3606770, at *5 (quoting *Sandoz*, 794 F.3d at 1358). Moreover, if an Applicant could refuse to produce certain manufacturing information and thereby foreclose inclusion of related patents in a paragraph 262(*l*)(6) lawsuit, the Applicant could game the system to try to escape the mandatory injunction available in some such lawsuits, *see* 35 U.S.C. § 271(e)(4)(D). By affecting which patents are in the (*l*)(6) lawsuit, the Applicant could even affect the length of exclusivity awarded to the first biosimilar Applicant to demonstrate that its product meets the "interchangeability" requirements of subsection 262(k), where the length of that interchangeability can depend on whether a patent-infringement lawsuit is or is not a "paragraph (*l*)(6) lawsuit." *See* 42 U.S.C. § 262(k)(6)(B)(i), (B)(ii), (C)(i).

Hospira's only answer is to cite a litany of cases holding that discovery orders are not ordinarily appealable under the collateral-order doctrine. Those cases hold that where a district court wrongly precludes discovery of important evidence, the case can be re-tried on remand after an appeal from a final judgment.

That argument does not fit the undisputed facts of this case, however. Amgen is not seeking the cell-culture information to use as proof of infringement at the trial of the patents already in suit, and thus the familiar principle of allowing the trial to occur and addressing discovery rulings on post-trial appeal is inapposite here.

Further, the touchstone of the collateral-order doctrine is not whether an issue could in theory be reviewed on appeal after final judgment, but whether the issue can be effectively reviewed on appeal after final judgment. For example, this Court has found that an order unsealing confidential information is appealable under the collateral-order doctrine because once the "parties' confidential information is made publicly available, it cannot be made secret again." *Apple*, 727 F.3d at 1220; *see also Virginia Dep't of State Police v. Washington Post*, 386 F.3d 567, 574 n.4 (4th Cir. 2004) ("[A]n order unsealing district court documents is an appealable collateral order . . . ."). Likewise, courts routinely find that orders denying claims of absolute, qualified, and sovereign immunity are appealable under the collateral-order doctrine because these immunities provide immunity from suit, and if the protected party must first stand trial before appealing denial of immunity, the party would effectively lose its immunity. *Puerto Rico Aqueduct & Sewer Auth. v. Metcalf & Eddy, Inc.*, 506 U.S. 139, 147 (1993) (sovereign immunity under the Eleventh Amendment); *Mitchell v. Forsyth*, 472 U.S. 511, 524-30 (1985) (qualified immunity); *Nixon*, 457 U.S. at 742 (absolute immunity).

For the foregoing reasons, this Court has jurisdiction under the collateral-order doctrine.

B. Alternatively, the Court Has Jurisdiction Under the All Writs Act To Issue a Writ of Mandamus

In its order denying Hospira's motion to dismiss this appeal, the Court ordered the parties to "address in their briefs . . . whether this court has jurisdiction pursuant to the collateral-order doctrine or under the All Writs Act, 28 U.S.C. § 1651(a)." (Dkt. 16 at 3.) If this Court were to find that it does not have jurisdiction under the collateral-order doctrine, issuing a writ of mandamus to reverse the district court would be well within the Court's discretion. The Court has the power to "'treat as a petition for a writ'" an "'attempted appeal from an order that is not appealable.'" *In re Cuozzo Speed Techs.*, *LLC*, 793 F.3d 1268, 1275 & n.5 (Fed. Cir. 2015) (quoting 16 Charles Alan Wright, Arthur R. Miller, Edward H. Cooper, *Federal Prac. & Proc.* § 3932.1 (3d ed. 2012)), *aff'd sub. nom Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131 (2016); *see also GTNX, Inc. v. INTTRA, Inc.*, 789 F.3d 1309, 1312 (Fed. Cir. 2015).

As an initial matter, Amgen did not frame this appeal under the All Writs Act or as one seeking a writ of mandamus. Amgen asserts this argument in response to the Court's invitation to the parties to brief the applicability of the All Writs Act. Amgen is cognizant, however, of the Court's recent statement "discourag[ing] the practice" of a party, on its own initiative, asking for its appeal

to be converted to a writ of mandamus, *Apple Inc. v. Samsung Elec. Co.*, Case No. 15-1857 (Fed. Cir. June 1, 2016), Dkt. 75, at 9, given the different procedural requirements for a petition for a writ of mandamus. Amgen has therefore attempted to keep this brief substantially shorter than the 14,000 words allowed for an ordinary, non-mandamus appeal.

The All Writs Act allows federal courts to "issue all writs necessary or appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law." 28 U.S.C. § 1651(a). The Act "is a residual source of authority to issue writs which are not otherwise provided for by statute." *Cox v. West*, 149 F.3d 1360, 1363 (Fed. Cir. 1998) (citing *Pa. Bureau of Corr. v. U.S. Marshals Serv.*, 474 U.S. 34, 43 (1985)).

One of those writs is the writ of mandamus, available "when there has been a clear abuse of discretion or usurpation of judicial authority in the grant or denial of the order." *In re Queen's Univ. at Kingston*, 820 F.3d 1287, 1291 (Fed. Cir. 2016) (quoting *Connaught Lab., Inc. v. SmithKline Beecham P.L.C.*, 165 F.3d 1368, 1370 (Fed. Cir. 1999)). "To prevail, a petitioner must establish that it has no other adequate means to attain the desired relief and that its right to issuance of the writ is 'clear and indisputable.'" *Id.* (quoting *Cheney v. U.S. Dist. Court for D.C.*, 542 U.S. 367, 380-81 (2004)).

Here, if this Court were to find that the collateral-order doctrine does not provide appellate jurisdiction, Amgen would have no other adequate means to attain relief. Amgen would lose its right to receive Hospira's cell-culture manufacturing information in order to assess that information in determining whether to enforce its cell-culture patents before Hospira launches its biosimilar product. And Amgen has a "clear and indisputable" right to the issuance of such a writ, because the district court committed reversible legal error in interpreting, and failing to apply, this Court's ruling in *Sandoz*. A central purpose of the BPCIA, this Court has held, is to resolve patent-infringement disputes before a biosimilar product enters the market, *Apotex*, 2016 WL 3606770, at *5; *Sandoz*, 794 F.3d at 1358, yet the district court here has prevented Amgen from even obtaining the information Amgen is seeking to use in deciding whether to assert its cell-culture patents.

Even if this were the garden-variety discovery dispute that Hospira describes—a dispute about burden, or privilege, or the like—a writ of mandamus would be appropriate. This Court has stated that mandamus may "be appropriate in certain cases to further supervisory or instructional goals where issues are unsettled and important." *In re Queen's Univ.*, 820 F.3d at 1291 (quoting *In re Nintendo Co.*, 544 F. App'x 934, 936 (Fed. Cir. 2013) (nonprecedential)). While *Sandoz* appeared to settle the issue of whether an RPS may access the Applicant's

aBLA or manufacturing information in discovery where it is not provided in the BPCIA information-exchange process, the district court held that *Sandoz* was not even "on point" when Amgen sought to do exactly what this Court described: bring an infringement suit and seek discovery of the information required by subparagraph 262(*l*)(2)(A). The issue is indisputably important and, at least as the district court and Hospira read *Sandoz*, unsettled.

The Court can issue a writ of mandamus to correct the district court's error and hold that an RPS has a right to "access . . . through discovery," *Sandoz*, 794 F.3d at 1356, the "information that describes the process or processes used to manufacture the biological product that is the subject of" the Applicant's application, 42 U.S.C. § 262(*l*)(2)(A), irrespective of the specific patents on which the RPS files its infringement suit.

CONCLUSION

For the foregoing reasons, this Court should reverse the district court's May 4, 2016 ruling and remand to the district court for an order compelling Hospira to provide discovery of the information Hospira withheld under 42 U.S.C. § 262(*l*)(2)(A) and for further proceedings.

Date: September 12, 2016

Respectfully submitted,

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ADDENDUM

INDEX TO ADDENDUM

§ 257a. Transferred

CODIFICATION

Section, Pub. L. 91–513, title I, § 4, Oct. 27, 1970, 84 Stat. 1241; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695, which related to medical treatment of narcotics addiction, was transferred to section 290bb–2a of this title.

§ 258. Repealed. Pub. L. 106–310, div. B, title XXXIV, § 3405(a), Oct. 17, 2000, 114 Stat. 1221

Section, acts July 1, 1944, ch. 373, title III, § 342, 58 Stat. 699; 1953 Reorg. Plan No. 1, §§ 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 91–513, title I, § 2(a)(2)(A), Oct. 27, 1970, 84 Stat. 1240; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695, related to employment, establishment of industries, plants, etc., sale of commodities, and disposition of proceeds.

§ 258a. Transferred

CODIFICATION

Section, act July 8, 1947, ch. 210, title II, § 201, 61 Stat. 269, which related to transfer of balances in working capital fund, narcotic hospitals, to surplus fund, was transferred and is set out as a note under section 290aa of this title.

§§ 259 to 261a. Repealed. Pub. L. 106–310, div. B, title XXXIV, § 3405(a), Oct. 17, 2000, 114 Stat. 1221

Section 259, acts July 1, 1944, ch. 373, title III, § 343, 58 Stat. 699; Pub. L. 91–513, title I, § 2(a)(2)(A), (3), (4), Oct. 27, 1970, 84 Stat. 1240; Pub. L. 92–293, § 3, May 11, 1972, 86 Stat. 136; Pub. L. 98–473, title II, § 232(b), Oct. 12, 1984, 98 Stat. 2031, related to convict addicts or other persons with drug abuse or drug dependence problems.

Section 260, acts July 1, 1944, ch. 373, title III, § 344, 58 Stat. 701; June 25, 1948, ch. 654, § 5, 62 Stat. 1018; July 24, 1956, ch. 676, title III, § 302(b), 70 Stat. 622; Pub. L. 91–513, title I, § 2(a)(2)(A), (3), (4), Oct. 27, 1970, 84 Stat. 1240, related to addicts and persons with drug abuse or drug dependence problems.

Section 260a, act July 1, 1944, ch. 373, title III, § 345, as added May 8, 1954, ch. 195, § 2, 68 Stat. 79; amended July 24, 1956, ch. 676, title III, § 302(c), 70 Stat. 622; Pub. L. 91–358, title I, § 155(c)(32), July 29, 1970, 84 Stat. 572, related to admission of addicts committed from District of Columbia.

Section 261, acts July 1, 1944, ch. 373, title III, § 346, formerly § 345, 58 Stat. 701; renumbered § 346, May 8, 1954, ch. 195, § 2, 68 Stat. 79; amended Pub. L. 91–513, title I, § 2(a)(2)(A), (5), Oct. 27, 1970, 84 Stat. 1240, related to penalties for introducing prohibited articles and substances into hospitals and escaping from, or aiding and abetting escape from hospitals.

Section 261a, act July 1, 1944, ch. 373, title III, § 347, as added May 8, 1954, ch. 195, § 4, 68 Stat. 80; amended Pub. L. 91–513, title I, § 2(a)(4), Oct. 27, 1970, 84 Stat. 1240, related to release of patients and determination by Surgeon General.

PART F—LICENSING OF BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES

SUBPART 1—BIOLOGICAL PRODUCTS

§ 262. Regulation of biological products

(a) Biologics license

(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and

(B) each package of the biological product is plainly marked with—

(i) the proper name of the biological product contained in the package;

(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

(iii) the expiration date of the biological product.

(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355c].

(C) The Secretary shall approve a biologics license application—

(i) on the basis of a demonstration that—

(I) the biological product that is the subject of the application is safe, pure, and potent; and

(II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and

(ii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c) of this section.

(D) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING; RISK EVALUATION AND MITIGATION STRATEGY.—A person that submits an application for a license under this paragraph is subject to sections 505(*o*), 505(p), and 505–1 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(*o*), (p), 355–1].

(3) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).

(b) Falsely labeling or marking package or container; altering label or mark

No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.

(c) Inspection of establishment for propagation and preparation

Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any biological product.

(d) Recall of product presenting imminent hazard; violations

(1) Upon a determination that a batch, lot, or other quantity of a product licensed under this section presents an imminent or substantial hazard to the public health, the Secretary shall issue an order immediately ordering the recall of such batch, lot, or other quantity of such product. An order under this paragraph shall be issued in accordance with section 554 of title 5.

(2) Any violation of paragraph (1) shall subject the violator to a civil penalty of up to $100,000 per day of violation. The amount of a civil penalty under this paragraph shall, effective December 1 of each year beginning 1 year after the effective date of this paragraph, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest ⅒ of 1 percent. For purposes of this paragraph, the term ''base quarter'', as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.

(e) Interference with officers

No person shall interfere with any officer, agent, or employee of the Service in the performance of any duty imposed upon him by this section or by regulations made by authority thereof.

(f) Penalties for offenses

Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a fine not exceeding $500 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

(g) Construction with other laws

Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(h) Exportation of partially processed biological products

A partially processed biological product which—

(1) is not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;

(2) is not intended for sale in the United States; and

(3) is intended for further manufacture into final dosage form outside the United States,

shall be subject to no restriction on the export of the product under this chapter or the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et. seq.] if the product is manufactured, processed, packaged, and held in conformity with current good manufacturing practice requirements or meets international manufacturing standards as certified by an international standards organization recognized by the Secretary and meets the requirements of section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)).

(i) "Biological product" defined

In this section:

(1) The term ''biological product'' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(2) The term ''biosimilar'' or ''biosimilarity'', in reference to a biological product that is the subject of an application under subsection (k), means—

(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(3) The term ''interchangeable'' or ''interchangeability'', in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

(4) The term ''reference product'' means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).

(j) Application of Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], including the requirements under sections 505(*o*), 505(p), and 505–1 of such Act [21 U.S.C. 355(*o*), (p), 355–1], applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act.

(k) Licensure of biological products as biosimilar or interchangeable

(1) In general

Any person may submit an application for licensure of a biological product under this subsection.

(2) Content

(A) In general

(i) Required information

An application submitted under this subsection shall include information demonstrating that—

(I) the biological product is biosimilar to a reference product based upon data derived from—

(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

(bb) animal studies (including the assessment of toxicity); and

(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended

to be used and for which licensure is sought for the biological product;

(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

(ii) Determination by Secretary

The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

(iii) Additional information

An application submitted under this subsection—

(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

(II) may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product.

(B) Interchangeability

An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

(3) Evaluation by Secretary

Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if—

(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

(i) is biosimilar to the reference product; or

(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(4) Safety standards for determining interchangeability

Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

(A) the biological product—

(i) is biosimilar to the reference product; and

(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

(5) General rules

(A) One reference product per application

A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

(B) Review

An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

(C) Risk evaluation and mitigation strategies

The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

(6) Exclusivity for first interchangeable biological product

Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (*l*)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (*l*)(6).

For purposes of this paragraph, the term ''final court decision'' means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

(7) Exclusivity for reference product

(A) Effective date of biosimilar application approval

Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

(B) Filing period

An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

(C) First licensure

Subparagraphs (A) and (B) shall not apply to a license for or approval of—

(i) a supplement for the biological product that is the reference product; or

(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

(8) Guidance documents

(A) In general

The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 371(h)] with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

(B) Public comment

(i) In general

The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

(ii) Input regarding most valuable guidance

The Secretary shall establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

(C) No requirement for application consideration

The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

(D) Requirement for product class-specific guidance

If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

(E) Certain product classes

(i) Guidance

The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

(ii) Modification or reversal

The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

(iii) No effect on ability to deny license

Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

(*l*) Patents

(1) Confidential access to subsection (k) application

(A) Application of paragraph

Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the ''subsection (k) applicant'') and the sponsor of the application for the reference product (referred to in this subsection as the ''reference product sponsor''), the provisions

of this paragraph shall apply to the exchange of information described in this subsection.

(B) In general

(i) Provision of confidential information

When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the ''confidential information'').

(ii) Recipients of information

The persons described in this clause are the following:

(I) Outside counsel

One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the ''outside counsel''), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(II) In-house counsel

One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(iii) Patent owner access

A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his or her agreement to be subject to the confidentiality provisions set forth in this paragraph, including those under clause (ii).

(C) Limitation on disclosure

No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

(D) Use of confidential information

Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

(E) Ownership of confidential information

The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

(F) Effect of infringement action

In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy such information, it will confirm destruction in writing to the subsection (k) applicant.

(G) Rule of construction

Nothing in this paragraph shall be construed—

(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

(ii) as an agreement or admission by the subsection (k) applicant with respect to the competency, relevance, or materiality of any confidential information.

(H) Effect of violation

The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

(2) Subsection (k) application information

Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted

to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

(3) List and description of patents

(A) List by reference product sponsor

Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

(B) List and description by subsection (k) applicant

Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

(C) Description by reference product sponsor

Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

(4) Patent resolution negotiations

(A) In general

After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6).

(B) Failure to reach agreement

If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

(5) Patent resolution if no agreement

(A) Number of patents

The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

(B) Exchange of patent lists

(i) In general

On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—

(I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and

(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

(ii) Number of patents listed by reference product sponsor

(I) In general

Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

(II) Exception

If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

(6) Immediate patent infringement action

(A) Action if agreement on patent list

If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

(B) Action if no agreement on patent list

If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

(C) Notification and publication of complaint

(i) Notification to Secretary

Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

(ii) Publication by Secretary

The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

(7) Newly issued or licensed patents

In the case of a patent that—

(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

(8) Notice of commercial marketing and preliminary injunction

(A) Notice of commercial marketing

The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

(B) Preliminary injunction

After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

(ii) not included, as applicable, on—

(I) the list of patents described in paragraph (4); or

(II) the lists of patents described in paragraph (5)(B).

(C) Reasonable cooperation

If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

(9) Limitation on declaratory judgment action

(A) Subsection (k) application provided

If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

(B) Subsequent failure to act by subsection (k) applicant

If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement,

validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(C) Subsection (k) application not provided

If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

(m) Pediatric studies

(1) Application of certain provisions

The provisions of subsections (a), (d), (e), (f), (i), (j), (k), (*l*), (p), and (q) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(a), (d), (e), (f), (i), (j), (k), (*l*), (p), (q)] shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(b), (c)].

(2) Market exclusivity for new biological products

If, prior to approval of an application that is submitted under subsection (a), the Secretary determines that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(3)]—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526[1] [21 U.S.C. 360bb] for a rare disease or condition, the period for such biological product referred to in section 527(a)[1] [21 U.S.C. 360cc(a)] is deemed to be 7 years and 6 months rather than 7 years.

(3) Market exclusivity for already-marketed biological products

If the Secretary determines that information relating to the use of a licensed biological product in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(3)]—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526[1] [21 U.S.C. 360bb] for a rare disease or condition, the period for such biological product referred to in section 527(a)[1] [21 U.S.C. 360cc(a)] is deemed to be 7 years and 6 months rather than 7 years.

(4) Exception

The Secretary shall not extend a period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(3)[1] [21 U.S.C. 355a(d)(3)] is made later than 9 months prior to the expiration of such period.

(July 1, 1944, ch. 373, title III, § 351, 58 Stat. 702; 1953 Reorg. Plan No. 1, §§ 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 85–881, § 2, Sept. 2, 1958, 72 Stat. 1704; Pub. L. 91–515, title II, § 291, Oct. 30, 1970, 84 Stat. 1308; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 99–660, title I, § 105(a), title III, § 315, Nov. 14, 1986, 100 Stat. 3751, 3783; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 104–134, title II, §§ 2102(d)(2), 2104, Apr. 26, 1996, 110 Stat. 1321–319, 1321–320; Pub. L. 105–115, title I, § 123(a)–(d), (g), Nov. 21, 1997, 111 Stat. 2323, 2324; Pub. L. 108–155, § 2(b)(3), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 110–85, title IX, § 901(c), Sept. 27, 2007, 121 Stat. 939; Pub. L. 111–148, title VII, § 7002(a), (b), (g)(1), Mar. 23, 2010, 124 Stat. 804, 814, 819.)

REFERENCES IN TEXT

The effective date of this paragraph, referred to in subsec. (d)(2), is the effective date of section 315 of Pub. L. 99–660 which added subsec. (d)(2). See Effective Date of 1986 Amendment note set out below.

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (g), (h), (j), and (k)(5)(C), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Sections 526, 527(a), and 505A(d)(3), referred to in subsec. (m)(2)(B), (3)(B), (4), probably mean sections 526, 527(a), and 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act, act June 25, 1938, ch. 675, which are classified to sections 360bb, 360cc(a), and 355a(d)(3), respectively, of Title 21, Food and Drugs.

AMENDMENTS

2010—Subsec. (a)(1)(A). Pub. L. 111–148, § 7002(a)(1), inserted ''under this subsection or subsection (k)'' after ''biologics license''.

Subsec. (i). Pub. L. 111–148, § 7002(b), substituted ''In this section:'' for ''In this section,'', designated remainder of existing provisions as par. (1), substituted ''The term'' for ''the term'', inserted ''protein (except any chemically synthesized polypeptide),'' after ''allergenic product,'', and added pars. (2) to (4).

Subsecs. (k), (*l*). Pub. L. 111–148, § 7002(a)(2), added subsecs. (k) and (*l*).

[1] See References in Text note below.

Case: 16-2179 Document: 28 Page: 71 Filed: 09/12/2016

Subsec. (m). Pub. L. 111–148, §7002(g)(1), added subsec. (m).

2007—Subsec. (a)(2)(D). Pub. L. 110–85, §901(c)(1), added subpar. (D).

Subsec. (j). Pub. L. 110–85, §901(c)(2), inserted '', including the requirements under sections 505(*o*), 505(p), and 505–1 of such Act,'' after ''and Cosmetic Act''.

2003—Subsec. (a)(2)(B), (C). Pub. L. 108–155 added subpar. (B) and redesignated former subpar. (B) as (C).

1997—Subsec. (a). Pub. L. 105–115, §123(a)(1), amended subsec. (a) generally. Prior to amendment, subsec. (a) related to intrastate and interstate traffic in biological products and suspension or revocation of licenses as affecting prior sales.

Subsec. (b). Pub. L. 105–115, §123(b), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: ''No person shall falsely label or mark any package or container of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid; nor alter any label or mark on any package or container of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid so as to falsify such label or mark.''

Subsec. (c). Pub. L. 105–115, §123(c), substituted ''biological product.'' for ''virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession.''

Subsec. (d). Pub. L. 105–115, §123(a)(2), designated par. (2) as subsec. (d), redesignated subpars. (A) and (B) of par. (2) as pars. (1) and (2), respectively, in par. (2), substituted ''Any violation of paragraph (1)'' for ''Any violation of subparagraph (A)'' and substituted ''this paragraph'' for ''this subparagraph'' wherever appearing, and struck out former par. (1) which read as follows: ''Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations and all licenses issued for the maintenance of establishments for the propagation or manufacture and preparation, in any foreign country, of any such products for sale, barter, or exchange in any State or possession shall be issued upon condition that the licensees will permit the inspection of their establishments in accordance with subsection (c) of this section.''

Subsec. (i). Pub. L. 105–115, §123(d), added subsec. (i).

Subsec. (j). Pub. L. 105–115, §123(g), added subsec. (j).

1996—Subsec. (h). Pub. L. 104–134, §2104, amended subsec. (h) generally, revising and restating former provisions, which also related to exportation of partially processed biological products.

Subsec. (h)(1)(A). Pub. L. 104–134, §2102(d)(2), substituted ''in a country listed under section 802(b)(1)'' for ''in a country listed under section 802(b)(A)'' and ''to a country listed under section 802(b)(1)'' for ''to a country listed under section 802(b)(4)''.

1992—Subsec. (c). Pub. L. 102–300, which directed substitution of ''Health and Human Services'' for ''Health, Education, and Welfare'', could not be executed because the words ''Health, Education, and Welfare'' did not appear in original statutory text. Previously, references to Department and Secretary of Health and Human Services were substituted for references to Federal Security Agency and its Administrator pursuant to provisions cited in Transfer of Functions note below.

1986—Subsec. (d). Pub. L. 99–660, §315, designated existing provisions as par. (1) and added par. (2).

Subsec. (h). Pub. L. 99–660, §105(a), added subsec. (h).

1970—Subsecs. (a) to (c). Pub. L. 91–515 inserted ''vaccine, blood, blood component or derivative, allergenic product,'' after ''antitoxin'' wherever appearing.

1958—Subsec. (d). Pub. L. 85–881 struck out ''made jointly by the Surgeon General, the Surgeon General of the Army, and the Surgeon General of the Navy, and approved by the Secretary'' after ''regulations'' in first sentence.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 110–85 effective 180 days after Sept. 27, 2007, see section 909 of Pub. L. 110–85, set out as a note under section 331 of Title 21, Food and Drugs.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–155 effective Dec. 3, 2003, except as otherwise provided, see section 4 of Pub. L. 108–155, set out as an Effective Date note under section 355c of Title 21, Food and Drugs.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105–115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as a note under section 321 of Title 21, Food and Drugs.

EFFECTIVE DATE OF 1986 AMENDMENT

Section 105(b) of Pub. L. 99–660 provided that: ''Paragraph (1) of section 351(h) of the Public Health Service Act [former subsec. (h)(1) of this section] as added by subsection (a) shall take effect upon the expiration of 90 days after the date of the enactment of this Act [Nov. 14, 1986].''

Amendment by section 315 of Pub. L. 99–660 effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary of Health and Human Services by section 509(b) of Pub. L. 96–88 which is classified to section 3508(b) of Title 20, Education.

References to Secretary and Department of Health, Education, and Welfare substituted for references to Federal Security Administrator and Federal Security Agency, respectively, pursuant to Reorg. Plan No. 1 of 1953, §5, set out as a note under section 3501 of this title, which transferred all functions of Federal Security Administrator to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency to Department of Health, Education, and Welfare. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953. Secretary and Department of Health, Education, and Welfare redesignated Secretary and Department of Health and Human Services by section 509(b) of Pub. L. 96–88 which is classified to section 3508(b) of Title 20.

PRODUCTS PREVIOUSLY APPROVED UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Pub. L. 111–148, title VII, §7002(e), Mar. 23, 2010, 124 Stat. 817, provided that:

''(1) REQUIREMENT TO FOLLOW SECTION 351.—Except as provided in paragraph (2), an application for a biological product shall be submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

''(2) EXCEPTION.—An application for a biological product may be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if—

''(A) such biological product is in a product class for which a biological product in such product class is the subject of an application approved under such section 505 not later than the date of enactment of this Act [Mar. 23, 2010]; and

''(B) such application—

''(i) has been submitted to the Secretary of Health and Human Services (referred to in this subtitle [subtitle A (§§ 7001–7003) of title VII of Pub. L. 111–148, see Short Title of 2010 Amendment note under section 201 of this title] as the 'Secretary') before the date of enactment of this Act; or

''(ii) is submitted to the Secretary not later than the date that is 10 years after the date of enactment of this Act.

''(3) LIMITATION.—Notwithstanding paragraph (2), an application for a biological product may not be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if there is another biological product approved under subsection (a) of section 351 of the Public Health Service Act [42 U.S.C. 262] that could be a reference product with respect to such application (within the meaning of such section 351) if such application were submitted under subsection (k) of such section 351.

''(4) DEEMED APPROVED UNDER SECTION 351.—An approved application for a biological product under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) shall be deemed to be a license for the biological product under such section 351 on the date that is 10 years after the date of enactment of this Act.

''(5) DEFINITIONS.—For purposes of this subsection, the term 'biological product' has the meaning given such term under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).''

COSTS OF REVIEWING BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS

Pub. L. 111–148, title VII, § 7002(f)(3)(B), (C), Mar. 23, 2010, 124 Stat. 818, 819, provided that:

''(B) EVALUATION OF COSTS OF REVIEWING BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS.—During the period beginning on the date of enactment of this Act [Mar. 23, 2010] and ending on October 1, 2010, the Secretary [of Health and Human Services] shall collect and evaluate data regarding the costs of reviewing applications for biological products submitted under section 351(k) of the Public Health Service Act [42 U.S.C. 262(k)] (as added by this Act) during such period.

''(C) AUDIT.—

''(i) IN GENERAL.—On the date that is 2 years after first receiving a user fee applicable to an application for a biological product under section 351(k) of the Public Health Service Act [42 U.S.C. 262(k)] (as added by this Act), and on a biennial basis thereafter until October 1, 2013, the Secretary shall perform an audit of the costs of reviewing such applications under such section 351(k). Such an audit shall compare—

''(I) the costs of reviewing such applications under such section 351(k) to the amount of the user fee applicable to such applications; and

''(II)(aa) such ratio determined under subclause (I); to

''(bb) the ratio of the costs of reviewing applications for biological products under section 351(a) of such Act [42 U.S.C. 262(a)] (as amended by this Act) to the amount of the user fee applicable to such applications under such section 351(a).

''(ii) ALTERATION OF USER FEE.—If the audit performed under clause (i) indicates that the ratios compared under subclause (II) of such clause differ by more than 5 percent, then the Secretary shall alter the user fee applicable to applications submitted under such section 351(k) [42 U.S.C. 262(k)] to more appropriately account for the costs of reviewing such applications.

''(iii) ACCOUNTING STANDARDS.—The Secretary shall perform an audit under clause (i) in conformance with the accounting principles, standards, and requirements prescribed by the Comptroller General of the United States under section 3511 of title 31, United State Code, to ensure the validity of any potential variability.''

LICENSING OF ORPHAN PRODUCTS

Pub. L. 111–148, title VII, § 7002(h), Mar. 23, 2010, 124 Stat. 821, provided that: ''If a reference product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act) has been designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for a rare disease or condition, a biological product seeking approval for such disease or condition under subsection (k) of such section 351 as biosimilar to, or interchangeable with, such reference product may be licensed by the Secretary [of Health and Human Services] only after the expiration for such reference product of the later of—

''(1) the 7-year period described in section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)); and

''(2) the 12-year period described in subsection (k)(7) of such section 351.''

SAVINGS GENERATED BY 2010 AMENDMENT

Pub. L. 111–148, title VII, § 7003, Mar. 23, 2010, 124 Stat. 821, provided that:

''(a) DETERMINATION.—The Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, shall for each fiscal year determine the amount of savings to the Federal Government as a result of the enactment of this subtitle [subtitle A (§§ 7001–7003) of title VII of Pub. L. 111–148, see Short Title of 2010 Amendment note under section 201 of this title].

''(b) USE.—Notwithstanding any other provision of this subtitle (or an amendment made by this subtitle), the savings to the Federal Government generated as a result of the enactment of this subtitle shall be used for deficit reduction.''

ENHANCED PENALTIES AND CONTROL OF BIOLOGICAL AGENTS

Pub. L. 104–132, title V, § 511, Apr. 24, 1996, 110 Stat. 1284, as amended by Pub. L. 107–188, title II, § 204, June 12, 2002, 116 Stat. 647, provided that:

''(a) FINDINGS.—The Congress finds that—

''(1) certain biological agents have the potential to pose a severe threat to public health and safety;

''(2) such biological agents can be used as weapons by individuals or organizations for the purpose of domestic or international terrorism or for other criminal purposes;

''(3) the transfer and possession of potentially hazardous biological agents should be regulated to protect public health and safety; and

''(4) efforts to protect the public from exposure to such agents should ensure that individuals and groups with legitimate objectives continue to have access to such agents for clinical and research purposes.

''(b) CRIMINAL ENFORCEMENT.—[Amended sections 175, 177, and 178 of Title 18, Crimes and Criminal Procedure.]

''(c) TERRORISM.—[Amended section 2332a of Title 18.]''

§ 262a. Enhanced control of dangerous biological agents and toxins

(a) Regulatory control of certain biological agents and toxins

(1) List of biological agents and toxins

(A) In general

The Secretary shall by regulation establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety.

make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners.

(July 19, 1952, ch. 950, 66 Stat. 810; Pub. L. 103–465, title V, § 533(b)(3), Dec. 8, 1994, 108 Stat. 4989.)

HISTORICAL AND REVISION NOTES

This section states a condition in existing law not expressed in the existing statutes.

AMENDMENTS

1994—Pub. L. 103–465 substituted ''use, offer to sell, or sell'' for ''use or sell'' and inserted ''within the United States, or import the patented invention into the United States,'' after ''invention''.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–465 effective on date that is one year after date on which the WTO Agreement enters into force with respect to the United States [Jan. 1, 1995], with provisions relating to earliest filed patent application, see section 534(a), (b)(3) of Pub. L. 103–465, set out as a note under section 154 of this title.

CHAPTER 27—GOVERNMENT INTERESTS IN PATENTS

AMENDMENTS

1965—Pub. L. 89–83, § 8, July 24, 1965, 79 Stat. 261, struck out item 266 ''Issue of patents without fees to Government employees''.

[§ 266. Repealed. Pub. L. 89–83, § 8, July 24, 1965, 79 Stat. 261]

Section, act July 19, 1952, ch. 950, § 1, 66 Stat. 811, provided for issuance of patents to government employees without fees.

EFFECTIVE DATE OF REPEAL

Repeal effective three months after July 24, 1965, see section 7(a) of Pub. L. 89–83, set out as an Effective Date of 1965 Amendment note under section 41 of this title.

§ 267. Time for taking action in Government applications

Notwithstanding the provisions of sections 133 and 151, the Director may extend the time for taking any action to three years, when an application has become the property of the United States and the head of the appropriate department or agency of the Government has certified to the Director that the invention disclosed therein is important to the armament or defense of the United States.

(July 19, 1952, ch. 950, 66 Stat. 811; Pub. L. 106–113, div. B, § 1000(a)(9) [title IV, § 4732(a)(10)(A)], Nov. 29, 1999, 113 Stat. 1536, 1501A–582; Pub. L. 107–273, div. C, title III, § 13206(b)(1)(B), Nov. 2, 2002, 116 Stat. 1906; Pub. L. 112–29, § 20(j), Sept. 16, 2011, 125 Stat. 335.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., § 37 (R.S. 4894, amended (1) Mar. 3, 1897, ch. 391, § 4, 29 Stat. 692, 693, (2) July 6, 1916, ch. 225, § 1, 39 Stat. 345, 347–8, (3) Mar. 2, 1927, ch. 273, § 1, 44 Stat. 1335, (4) Aug. 7, 1939, ch. 568, 53 Stat. 1264).

This provision, which appears as the last two sentences of the corresponding section of the present statute (see note to section 133) is made a separate section and rewritten in simpler form.

AMENDMENTS

2011—Pub. L. 112–29 struck out ''of this title'' after ''151''.

2002—Pub. L. 107–273 made technical correction to directory language of Pub. L. 106–113. See 1999 Amendment note below.

1999—Pub. L. 106–113, as amended by Pub. L. 107–273, substituted ''Director'' for ''Commissioner'' in two places.

EFFECTIVE DATE OF 2011 AMENDMENT

Amendment by section 20(j) of Pub. L. 112–29 effective upon the expiration of the 1-year period beginning on Sept. 16, 2011, and applicable to proceedings commenced on or after that effective date, see section 20(*l*) of Pub. L. 112–29, set out as a note under section 2 of this title.

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by Pub. L. 106–113 effective 4 months after Nov. 29, 1999, see section 1000(a)(9) [title IV, § 4731] of Pub. L. 106–113, set out as a note under section 1 of this title.

CHAPTER 28—INFRINGEMENT OF PATENTS

AMENDMENTS

2011—Pub. L. 112–29, § 5(b), Sept. 16, 2011, 125 Stat. 299, amended item 273 generally, substituting ''Defense to infringement based on prior commercial use'' for ''Defense to infringement based on earlier inventor''.

1999—Pub. L. 106–113, div. B, § 1000(a)(9) [title IV, § 4302(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–557, added item 273.

§ 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from

acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151–158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, or

(C)(i) with respect to a patent that is identified in the list of patents described in section 351(*l*)(3) of the Public Health Service Act (including as provided under section 351(*l*)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(*l*)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(*l*)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) 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.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

(i) that is identified, as applicable, in the list of patents described in section 351(*l*)(4) of the Public Health Service Act or the lists of patents described in section 351(*l*)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product—

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(*l*)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), 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.

(C) The owner of a patent that should have been included in the list described in section 351(*l*)(3)(A) of the Public Health Service Act, including as provided under section 351(*l*)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.

(f)(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

(h) As used in this section, the term ''whoever'' includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

(i) As used in this section, an ''offer for sale'' or an ''offer to sell'' by a person other than the patentee, or any designee of the patentee, is that in which the sale will occur before the expiration of the term of the patent.

(July 19, 1952, ch. 950, 66 Stat. 811; Pub. L. 98–417, title II, § 202, Sept. 24, 1984, 98 Stat. 1603; Pub. L. 98–622, title I, § 101(a), Nov. 8, 1984, 98 Stat. 3383; Pub. L. 100–418, title IX, § 9003, Aug. 23, 1988, 102 Stat. 1563; Pub. L. 100–670, title II, § 201(i), Nov. 16, 1988, 102 Stat. 3988; Pub. L. 100–703, title II, § 201, Nov. 19, 1988, 102 Stat. 4676; Pub. L. 102–560, § 2(a)(1), Oct. 28, 1992, 106 Stat. 4230; Pub. L. 103–465, title V, § 533(a), Dec. 8, 1994, 108 Stat. 4988; Pub. L. 108–173, title XI, § 1101(d), Dec. 8, 2003, 117 Stat. 2457; Pub. L. 111–148, title VII, § 7002(c)(1), Mar. 23, 2010, 124 Stat. 815.)

HISTORICAL AND REVISION NOTES

The first paragraph of this section is declaratory only, defining infringement.

Paragraphs (b) and (c) define and limit contributory infringement of a patent and paragraph (d) is ancillary to these paragraphs, see preliminary general description of bill. One who actively induces infringement as by aiding and abetting the same is liable as an infringer, and so is one who sells a component part of a patented invention or material or apparatus for use therein knowing the same to be especially made or especially adapted for use in the infringement of the patent except in the case of a staple article or commodity of commerce having other uses. A patentee is not deemed to have misused his patent solely by reason of doing anything authorized by the section.

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (e)(1), (2), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21, Food and Drugs. Sections 505 and 512 of the Act are classified to sections 355 and 360b, respectively, of Title 21. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Act of March 4, 1913, referred to in subsec. (e)(1), (2), is act Mar. 4, 1913, ch. 145, 37 Stat. 828. The provisions of such act relating to viruses, etc., applicable to domestic animals, popularly known as the Virus-Serum-Toxin Act, are contained in the eighth paragraph under the heading ''Bureau of Animal Industry'' of act Mar. 4, 1913, at 37 Stat. 832, and are classified generally to chapter 5 (§ 151 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 151 of Title 21 and Tables.

Section 351 of the Public Health Service Act, referred to in subsec. (e)(2)(C), (4)(D), (6)(A), (C), is classified to section 262 of Title 42, The Public Health and Welfare.

AMENDMENTS

2010—Subsec. (e)(2). Pub. L. 111–148, § 7002(c)(1)(A)(iv), substituted '', veterinary biological product, or biological product'' for ''or veterinary biological product'' in concluding provisions.

Subsec. (e)(2)(C). Pub. L. 111–148, § 7002(c)(1)(A)(i)–(iii), added subpar. (C).

Subsec. (e)(4). Pub. L. 111–148, §7002(c)(1)(B)(iv), substituted ''(C), and (D)'' for ''and (C)'' in concluding provisions.

Subsec. (e)(4)(B). Pub. L. 111–148, §7002(c)(1)(B)(i), substituted '', veterinary biological product, or biological product'' for ''or veterinary biological product'' and struck out ''and'' at end.

Subsec. (e)(4)(C). Pub. L. 111–148, §7002(c)(1)(B)(ii), substituted '', veterinary biological product, or biological product'' for ''or veterinary biological product'' and '', and'' for period at end.

Subsec. (e)(4)(D). Pub. L. 111–148, §7002(c)(1)(B)(iii), added subpar. (D).

Subsec. (e)(6). Pub. L. 111–148, §7002(c)(1)(C), added par. (6).

2003—Subsec. (e)(5). Pub. L. 108–173 added par. (5).

1994—Subsec. (a). Pub. L. 103–465, §533(a)(1), inserted '', offers to sell,'' after ''uses'' and ''or imports into the United States any patented invention'' after ''the United States''.

Subsec. (c). Pub. L. 103–465, §533(a)(2), substituted ''offers to sell or sells within the United States or imports into the United States'' for ''sells''.

Subsec. (e)(1). Pub. L. 103–465, §533(a)(3)(A), substituted ''offer to sell, or sell within the United States or import into the United States'' for ''or sell''.

Subsec. (e)(3). Pub. L. 103–465, §533(a)(3)(B), substituted ''offering to sell, or selling within the United States or importing into the United States'' for ''or selling''.

Subsec. (e)(4)(B), (C). Pub. L. 103–465, §533(a)(3)(C), (D), substituted ''offer to sell, or sale within the United States or importation into the United States'' for ''or sale''.

Subsec. (g). Pub. L. 103–465, §533(a)(4), substituted ''offers to sell, sells,'' for ''sells'', ''importation, offer to sell, sale,'' for ''importation, sale,'', and ''other use, offer to sell, or'' for ''other use or''.

Subsec. (i). Pub. L. 103–465, §533(a)(5), added subsec. (i).

1992—Subsec. (h). Pub. L. 102–560 added subsec. (h).

1988—Subsec. (d). Pub. L. 100–703 added cls. (4) and (5).

Subsec. (e)(1). Pub. L. 100–670, §201(i)(1), inserted ''which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques'' after ''March 4, 1913)'' and ''or veterinary biological products'' after ''sale of drugs''.

Subsec. (e)(2). Pub. L. 100–670, §201(i)(2), amended par. (2) generally. Prior to amendment, par. (2) read as follows: ''It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.''

Subsec. (e)(4). Pub. L. 100–670, §201(i)(3), inserted ''or veterinary biological product'' after ''drug'' in subpars. (A) to (C).

Subsec. (g). Pub. L. 100–418 added subsec. (g).

1984—Subsec. (e). Pub. L. 98–417 added subsec. (e).

Subsec. (f). Pub. L. 98–622 added subsec. (f).

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–465 effective on date that is one year after date on which the WTO Agreement enters into force with respect to the United States [Jan. 1, 1995], with provisions relating to earliest filed patent application, see section 534(a), (b)(3) of Pub. L. 103–465, set out as a note under section 154 of this title.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–560 effective with respect to violations that occur on or after Oct. 28, 1992, see section 4 of Pub. L. 102–560, set out as a note under section 2541 of Title 7, Agriculture.

EFFECTIVE DATE OF 1988 AMENDMENT

Pub. L. 100–703, title II, §202, Nov. 19, 1988, 102 Stat. 4676, provided that: ''The amendment made by this title [amending this section] shall apply only to cases filed on or after the date of the enactment of this Act [Nov. 19, 1988].''

Pub. L. 100–418, title IX, §9006, Aug. 23, 1988, 102 Stat. 1566, provided that:

''(a) IN GENERAL.—The amendments made by this subtitle [subtitle A (§§9001–9007) of title IX of Pub. L. 100–418, enacting section 295 of this title and amending this section and sections 154 and 287 of this title] take effect 6 months after the date of enactment of this Act [Aug. 23, 1988] and, subject to subsections (b) and (c), shall apply only with respect to products made or imported after the effective date of the amendments made by this subtitle.

''(b) EXCEPTIONS.—The amendments made by this subtitle shall not abridge or affect the right of any person or any successor in business of such person to continue to use, sell, or import any specific product already in substantial and continuous sale or use by such person in the United States on January 1, 1988, or for which substantial preparation by such person for such sale or use was made before such date, to the extent equitable for the protection of commercial investments made or business commenced in the United States before such date. This subsection shall not apply to any person or any successor in business of such person using, selling, or importing a product produced by a patented process that is the subject of a process patent enforcement action commenced before January 1, 1987, before the International Trade Commission, that is pending or in which an order has been entered.

''(c) RETENTION OF OTHER REMEDIES.—The amendments made by this subtitle shall not deprive a patent owner of any remedies available under subsections (a) through (f) of section 271 of title 35, United States Code, under section 337 of the Tariff Act of 1930 [19 U.S.C. 1337], or under any other provision of law.''

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98–622 applicable only to the supplying, or causing to be supplied, of any component or components of a patented invention after Nov. 8, 1984, see section 106(c) of Pub. L. 98–622, set out as a note under section 103 of this title.

REPORTS TO CONGRESS; EFFECT ON DOMESTIC INDUSTRIES OF PROCESS PATENT AMENDMENTS ACT OF 1988

Pub. L. 100–418, title IX, §9007, Aug. 23, 1988, 102 Stat. 1567, provided that the Secretary of Commerce was to make annual reports to Congress covering each of the successive five 1-year periods beginning 6 months after Aug. 23, 1988, on the effect of the amendments made by subtitle A (§§9001–9007) of title IX of Pub. L. 100–418, enacting section 295 of this title and amending sections 154, 271, and 287 of this title, on those domestic industries that submit complaints to the Department of Commerce alleging that their legitimate sources of supply have been adversely affected by the amendments.

§ 272. Temporary presence in the United States

The use of any invention in any vessel, aircraft or vehicle of any country which affords similar privileges to vessels, aircraft or vehicles of the United States, entering the United States temporarily or accidentally, shall not constitute infringement of any patent, if the invention is used exclusively for the needs of the vessel, aircraft or vehicle and is not offered for sale or sold in or used for the manufacture of anything to be sold in or exported from the United States.

(July 19, 1952, ch. 950, 66 Stat. 812; Pub. L. 103–465, title V, §533(b)(4), Dec. 8, 1994, 108 Stat. 4989.)

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

AMGEN INC., et al.,	:	CA NO. 15-839-RGA
	:	
Plaintiffs,	:	
	:	
v.	:	May 4, 2016
	:	
HOSPIRA, INC.,	:	
	:	
Defendant,	:	1:32 o'clock p.m.
.....:		

TRANSCRIPT OF DISCOVERY DISPUTE

BEFORE THE HONORABLE RICHARD G. ANDREWS

UNITED STATES DISTRICT JUDGE

APPEARANCES:

For Plaintiffs: MORRIS, NICHOLS, ARSHT & TUNNELL

BY: MARYELLEN NOREIKA, ESQ

-and-

	MARSHALL, GERSTEIN & BORUN LLP
	BY: JOHN R. LABBE, ESQ
For Defendant:	PROCTOR HEYMAN & ENERIO LLP
	BY: DOMINICK T. GATTUSO, ESQ
	-and-
	WILLKIE FARR & GALLAGHER LLP
	BY: THOMAS J. MELORO, ESQ
Court Reporter:	LEONARD A. DIBBS
	Official Court Reporter

P R O C E E D I N G S

(The proceedings occurred at 1:32 o'clock p.m. as follows:)

THE COURT: Good afternoon, everyone. Please be seated.

This is Amgen v. Hospira, Civil Action No. 15-839.

Ms. Noreika, good afternoon.

MS. NOREIKA: Good afternoon, your Honor.

I'm here representing the plaintiff with my co-counsel, John Labbe, from the Marshall Gerstein firm in Chicago.

THE COURT: All right.

MR. LABBE: Good afternoon, your Honor.

THE COURT: Good afternoon.

Nice to see your, Mr. Labbe.

Have I seen you before.

MR. LABBE: Yes. We were here for the Case Management Conference and argued the Motion to Dismiss. I was in Court for the Motion to Dismiss in February.

THE COURT: Okay. So maybe the question I should have asked is, have I heard you before?

MR. LABBE: Only briefly at the Case Management Conference.

THE COURT: Okay. All right.

Mr. Gattuso.

MR. GATTUSO: Good afternoon, your Honor.

I'm here with Tom Meloro from Willkie Farr.

MR. MELORO: Good afternoon, your honor.

THE COURT: Good afternoon, Mr. Meloro.

So I read your letters. And why don't we talk about the first thing first.

And why don't you start off, Mr. Labbe, with what exactly is it that you want to get from Hospira in terms of -- well, what is it that you want to get in the first request?

MR. LABBE: Your Honor, in our first request, we're seeking specific manufacturing information regarding the product in suit, and its manufacturing information that Hospira was required to provide to us under Paragraph(2)(a) of the BPCIA.

And under Amgen vs. Sandoz --

THE COURT: So this manufacturing information, I thought I saw something where they said something like, you want to get four products that went into their -- that were involved in, somehow or other, in their production of this biologic.

MR. LABBE: The specific information that we're seeking -- and this is one of reasons we don't think this is a fishing expedition is -- we've identified the specific information.

It's four components of their cell culture medium that we're requesting the complete ingredient list for.

And then --

THE COURT: So, cell culture medium, you know, my

knowledge of this if from 9th grade biology, that this is some kind of substance that the cell, or the precursor of the cell, exists when it's making the cell that is claimed in the patent?

MR. LABBE: That's correct, your Honor.

So the product here is a biologic, and it's a protein, and the protein is made in recombinant cells. And the cells are grown in a mixture. You might call it a soup. I think Mr. Meloro used that term in the past.

The cell culture medium is the medium in which the cells are grown. And, in the commercial process, they do this in large vats that are able to grow many cells at one time.

And, so, the cell culture medium is made up of particular components. And one thing that's --

THE COURT: And just give me like a for example kind of thing.

What kind of components would be in cell culture medium?

MR. LABBE: Well, the most common example would be amino acids. Amino acids are the building blocks of proteins. And there may be information about amino acids in the BLA, for example, but there is not complete information about everything, but other things that may be included in the cell culture medium.

THE COURT: So amino acids, things like amino acids would be in the cell culture medium.

And the reason -- and I only have the haziest knowledge of this -- for the reason why this is relevant to your patent claims is what?

MR. LABBE: It's potentially relevant to additional patents that Amgen owns.

THE COURT: Well, let's skip the additional patents, all right?

Is it relevant to the patents that you've actually asserted so far?

MR. LABBE: It may be relevant to one of the claims of the Lin patent. Claim 7 of the Lin patent that calls for a suitable cell culture conditions.

But I would like the opportunity to make the broader point here, though --

THE COURT: Well, I'll let you do that in a second.

Claim 7 of the Lin patent, because the element of that has something to do with the culture medium?

MR. LABBE: Claim 7 of the Lin patent is a processing of producing erythropoietin comprising a step of culturing, under suitable nutrient conditions, vertebrate cells according to Claims 1, 2, 3, 4, 5, and 6.

THE COURT: And so, the suitable nutrient conditions, does that maybe include the culture medium?

MR. LABBE: Correct, your Honor. So the composition of the cell culture medium would certainly fall within the scope of

relevance, in our view, to that claim.

THE COURT: Okay. So that's your narrower argument.

You have a broader argument?

MR. LABBE: Your Honor, the broader argument is that the information is relevant to this case to the extent that this is a case that Amgen has brought under the BPCIA in an effort to resolve patent disputes regarding Hospira's product in advance of the launch of the product. And that's the entire purpose of the BPCIA.

We can't know for certain what information -- what the information says without reviewing the information, as is often the case with discovery.

THE COURT: But isn't the way that goes, is that they produced their aBLA, and then you reasonably assert the patents you think might be implicated by whatever it is they told you they were doing?

MR. LABBE: Well, that leads to one important point, your Honor. That Section (2)(a) of the statute says that they are to produce their application, and such other information that describes the process or processes used to manufacture a biological product.

And that's important here, because there's a distinction between the BPCIA and Hatch-Waxman.

Under Hatch-Waxman, you can only assert a 271(E) claim of infringement based on patents regarding the product, itself,

or methods of use of the product, but under the BPCIA you can also assert patents based on the manufacture of the product.

And this is the reason that it would, A, the information exchange process requires that the applicant provide the manufacturing information as well.

And then Amgen is required --

THE COURT: I'm sorry. You said "provide the manufacturing information."

The language of the statute, which you probably have in front of you --

MR. LABBE: Yes, I do.

THE COURT: -- but it's, essentially, the aBLA and other information, or something like that?

MR. LABBE: And such other information that describes the process or processes used to manufacture the biological product that is the subject of such application.

THE COURT: Okay.

MR. LABBE: So it, specifically, requires that the information regarding manufacturing be provided.

And we did raise this issue during the information exchange process. The first three exhibits are correspondence to Hospira during the information exchange process where we said that they should provide this information.

This would have been about year ago, because it's required under the BPCIA.

And you're correct, that Amgen is required to provide a list of patents that are reasonably believed Hospira would infringe. But it's a reasonableness requirement, it's not a speculation requirement, an uninformed speculation requirement.

Amgen is not required to list patents for which it lacks information. Amgen is entitled to the information and then it can list the patents. Under Hospira's reading of the statute, it would be able to prevent Amgen from ever reviewing the information.

THE COURT: And, I'm sorry, Mr. Labbe.

In terms of the aBLA, which I think I've heard Mr. Meloro, or one of his cohorts say is 700,000 pages, or some other ridiculous number, does it describe what goes into the cell culture medium?

MR. LABBE: It does to an extent, your Honor, yes, but it does not include the information that we've requested, the specific information regarding the four components. It identifies those four components, but it doesn't provide a complete ingredient list for those four components.

And that is what we've -- and they've never pointed to a place where that information is provided in the aBLA.

We said this in our letters to them that that information is lacking. And even though the BLA may be hundreds of thousands of pages, the fact remains that it lacks this specific manufacturing information, and the statute calls for

the manufacturing information to be provided so that Amgen can assess its patent portfolio.

But they're taking advantage of this abbreviated pathway. They should also be required to follow it.

And also Amgen v. Sandoz said that you couldn't have a cause of action based on a violation 2(A). It did say that Sandoz was required and had, in fact, produced the required information during discovery.

So you can't bring a cause of action based on 2(a). And then we have the separate 8(A) issue, and that's a different issue. We can't bring a cause of action under Amgen v. Sandoz based on a 2(A) violation, but we can receive the information during discovery.

And the Federal Circuit was -- expressed a concern about the fact that the applicant could keep the information secret forever, and prevent the reference product sponsor from evaluating its manufacturing patents.

And, in that case, the Federal Circuit found that it was sufficient that the information would be provided in discovery. And so, it didn't find that a concern only because the information would be provided in discovery.

If it's not provided in discovery, Amgen would never get the information, and the whole purpose of the information exchange process would be undermined.

THE COURT: All right.

THE COURT: Mr. Meloro?

MR. MELORO: Thank you, your Honor.

The argument that Amgen sets forth really falls in the end as an attempt to argue that the BPCIA trumps Rule 26 and relevance on the discovery standards.

Counsel mentioned a narrow argument and a broader argument.

The narrow argument, I don't even think Claim 7 of the Lin patent was mentioned in their letter, but suffice it to say, that simply identifying a claim limitation that refers to a -- not even the cell culture medium in those terms, culturing under suitable nutrient conditions, doesn't place in issue, directly or indirectly at this point in the case, the identity of the four components.

THE COURT: Well, you say that, but it doesn't seem to me on its face to be ridiculous for Mr. Labbe to say that the claim language implicates what is in the cell culture medium.

Is it ridiculous, what he's saying?

MR. MELORO: I wouldn't use --

THE COURT: You can use your own words.

MR. MELORO: I'm responding to the exact phraseology of the question.

The identity of those four components is not necessary nor relevant to the infringement allegation in the case. As a matter of fact, Amgen has already provided infringement

contentions without this information, so, clearly, they're able to do it.

We have not --

THE COURT: I take it one of the things that they have said is you infringe Claim 7?

MR. MELORO: I believe they have asserted Claim 7. I don't have the contentions in front of me.

We have not even engaged in a substantive discussion with Amgen as to whether or not there will be a contest of infringement of Claim 7. The issue has not been joined on that particular contention, as it was provided, nor whether if there is going to be a contest on infringement of Claim 7, whether the identities of these four components would have anything to do with it.

THE COURT: So I don't think it's real likely that in the next two weeks you're going to say, okay, we don't contest. We infringe Claim 7.

So it's not something where I'm going to say, okay, well, we're going to wait until you make up your mind on that, which, as we all know, might be a year from now, right? That's not really much a good dodge here, is it?

MR. MELORO: Well, if that were the difference in relevance in the case, and the Court were inclined to think that there was some relevance based on Claim 7, we'd go back and have a hard discussion with our client that there just hasn't been

the opportunity or need to have a discussion with Amgen on this.

We certainly have and are serving this week invalidity contentions on this '349 patent, and so, it's conceivable that the case could end up being an invalidity case, or at least as to Claim 7 being an invalidity case only.

We don't see that there is any relevance to these four components of the Claim 7 infringement case, but if there were a difference there, that's a discussion that we haven't had with Amgen.

On the broader BPCIA question, there is no indication in the statute that Congress intended that Rule 26 relevance be somehow circumvented.

THE COURT: Well, so, I -- I saw that argument in your papers, and I think I appreciate that argument.

And, I think, Mr. Labbe is really saying that you're circumventing the statutory purpose here, and so, regardless of what Congress might have thought, and I'm sure they never contemplated the intersection of this with the Discovery Rules, or the actual -- I mean maybe they did, actually. But in terms pf how you get these things if people didn't do what the statute envisioned.

Are you, by taking this tact, defeating the purpose here?

MR. MELORO: No. In fact, it was Amgen that defeated the purpose of the statute here, because Amgen was given the

information that's in the aBLA from Hospira. And, at that point, it had the opportunity to put in play whatever patents it wanted to put in play that it thought could -- that it believed the claim of patent infringement could reasonably be asserted, and that was initially to sue on those patents.

That was simply to just hand Hospira a list of those patents, at which point, it would have been incumbent upon Hospira to provide contentions of invalidity or non-infringement on those patents.

THE COURT: Why would -- one of the things that I was at least in the back of my mind thinking about was, why would Amgen narrowly assert patents, particularly when the standard, you know, seemed to allow -- allowed them assert the patents of 3(A), probably a lot more liberally than filing a lawsuit?

MR. MELORO: Without guessing as to their particular motives here, why someone in their position might, perhaps to try to intentionally conjure up a situation where not all information requested was provided, so that an argument could be made that 2(A) was violated.

And, although, counsel made the argument today that it is not possible to bring a lawsuit for a violation of 2(A), that's not the position that Amgen took at the beginning of this litigation. The original Complaint in this case had a cause of action for a violation 2(A).

THE COURT: But -- and the Sandoz case was decided

after that?

MR. MELORO: The Sandoz case was decided in the District Court beforehand.

MR. LABBE: The Federal Circuit denied en banc review between our original Complaint and our Amended Complaint, and that was the change of circumstances that caused you to drop the 2(A).

We think under the Amgen v. Sandoz case, as it stands today -- and our cert petition is pending, actually, but as it stands today, we didn't think we could bring that cause of action, but at the time of the original Complaint, an en banc petition was pending.

MR. MELORO: And so, in the original correspondence between the parties, which was about a year ago, clearly somebody in Amgen's shoes could have been thinking that they might want to have 2(A) cause of action available to them by asking for information and not getting the information.

THE COURT: Do you have any other theories?

MR. MELORO: There's a concept of potentially getting a second bite at the apple by wanting to come into court and asserting patents the way that the patent -- the so-called patent dance works. Not every patent on the 3(A) list automatically ends up in litigation.

THE COURT: Well, presumably, because part of it is, you could give them things that wouldn't cause them to think

that it was a good idea to go forward a particular patent.

MR. MELORO: Or, even if they wanted to go forward on a particular patent, there's a negotiation about the number of patents that would be included in the first-wave lawsuit that could, conceivably, result in the plaintiff not being able to assert all the patents that they would like to assert, even if they think they have good grounds to do that in a first-wave lawsuit.

THE COURT: Do you, Mr. Labbe, have anything to add as to why a company, in the position of Amgen, might be taking conservative approaches as to what to name in their 3(A) patent list?

MR. LABBE: Well, I think it does present the reference product sponsor. It puts Amgen on the horn of a dilemma, in some respects, because there have been cases in the Hatch/Waxman context, where the brand company has been found to have listed too many patents in the Orange Book. And so, it's a reasonableness standard.

Amgen is supposed to make a reason -- a determination of what patents would reasonably be asserted based on the information that's been provided. It can't make --

THE COURT: But isn't it the case, that -- because you were talking about Congressional intent -- Congressional policy -- didn't they want to get all of this stuff out in the air, open?

You said this multiple times.

MR. LABBE: Well, to us that's the reason that the -- that the information should be provided. And this notion that we were trying to cook up a dispute is not consistent with Amgen's activities.

THE COURT: Well, so, you know, I gave Mr. Meloro a chance to say various theories. I'm not so interested in that theory, because, frankly, you know, having the right to sue under 2(A) doesn't strike me as something that a rational company would say, yeah, well that's something we would like to work towards.

But I do -- but I am wondering when -- I am just wondering why, to the extent that everybody agrees part of goal here was to get things resolved, why a company like Amgen wouldn't be a reference sponsor, let's say, wouldn't be aggressive in saying, here's all the patents that we have that might cover this, and which then gives you the right to find out more stuff, and to make a better choice about which things to go forward on, right?

MR. LABBE: Well, a listing of the patents doesn't give Amgen a right to find out more information. It would find out their contentions, but it wouldn't require them to produce the information.

The production requirement is set forth in 2(A), and then Amgen is to make a determination, a reasonable

determination, not an uninformed determination.

Under what you're putting forth, your Honor, it would mean that Amgen would never be able to assess the information for itself.

Hospira could simply say, well, we don't infringe those patents for these reasons, and never have an opportunity to assess the underlying information.

What Congress intended is that the underlying information would be available to the reference product sponsor to evaluate. And let's keep in mind that the -- when we're talking about Congressional intent, and Rule 26 -- keep in mind we have Congressional intent, and we also have the Federal Circuit's decision in Amgen v. Sandoz, which forecloses the availability of -- at least as it stands right now, as the Court ruled -- we couldn't bring a private cause of action. We couldn't do anything else to get the information, but to bring an infringement suit, and seek the information in discovery.

And the Federal Circuit felt that that was a sufficient way of addressing the issue.

THE COURT: But the information in Amgen v. Sandoz, the Federal Circuit was talking about was actually, clearly, relevant to the claims that have been made, right?

MR. LABBE: It was not. It was not.

The only patent that had been asserted was a method of treatment patent. And, nevertheless, Sandoz produced its entire

BLA, and also produced additional manufacturing information.

The point of that really is that the Court in Amgen v. Sandoz, the Federal Circuit relied on that fact. The fact that the information was then made available in discovery. It relied on that fact to --

THE COURT: But the information that was made in discovery, what was important to the Federal Circuit was not that peripheral information had been made available, but the core information relating to even though one patent, right?

MR. LABBE: No. It was all the information was made available. The entire aBLA was provided.

The important thing for the Federal Circuit, it repeatedly referred to the information under 2(A) as required information.

And from the opinion, the Court appears sympathetic to the notion that the information needs to be provided, so that infringement can't go undetected.

And, in that case, Amgen was only able to sue on a method of treatment patent, and the Federal Circuit didn't suggest that discovery should be limited to discovery that would be relevant to a method of treatment patent. In fact, that is not what Sandoz did.

In its ruling, in its opinion, the Federal Circuit really focused on that. The information was then available in discovery through an infringement suit, so that the required

information would not be withheld forever. It would eventually be provided.

And, in fact, subsequently, Amgen has amended its Complaint that case to assert at least one additional patent after the Federal Circuit ruling, and discovery continued to progress in that case.

THE COURT: So, Mr. Labbe, what kind of patent, because, presumably, all the patents that Amgen has that could conceivably cover any of this. That's not a secret to somebody like Hospira.

There are ways for them to know what patents, at least according to the PTO, are assigned to you, correct?

MR. LABBE: That's correct, your Honor.

THE COURT: So what kind of patent do you have that might cover the amino acids and the like in the cell culture medium?

MR. LABBE: Well, there's a number of cell culture patents that Amgen owns, and they would require certain ingredients.

One, for example, would require the addition of caffeine to the cell culture medium that Amgen found that that was a way to promote the production of the protein in these cells, and a number of other patents of that nature that would call for, including additional ingredients, and --

THE COURT: And the description of the culture cell

culture medium that comes in the aBLA, isn't enough to tell you whether or not any of your patents are reasonably implicated?

MR. LABBE: Correct, your Honor, without knowing the entire list of ingredients of the cell culture medium.

So, for example, one of -- this is under a Protective Order, so I'm supposed to be careful about mentioning it, but --

THE COURT: Yes, yes. Pretend like everything you're going to say here is going to be on the public record and speak accordingly.

MR. LABBE: Okay. So, you know, one ingredient X. It is a -- it's a cell culture, it's a powder that is used in making a cell culture medium, and it is probably a commercially available powder, but the ingredient list is proprietary.

And we suspect that Hospira has the complete ingredient list and that they should provide it to us.

And what exactly is in that cell culture powder, product, we don't -- we don't know. That information is not provided. There's some information about it provided in the BLA, but it's not a complete ingredient that's provided in the BLA.

So we don't know with certainty whether there are additional patents of Amgen that are implicated. Maybe there aren't. I can't say that there are, but we don't know. We weren't able to form a belief one way or the other.

THE COURT: As a matter of curiosity, if you got the --

if you got what you were seeking from them, and you said, aha, we have a couple of cell culture patents that cover this exactly, would that mean that you would be moving to amend the Complaint here, or do you have to go to through some kind of other dance under the BPCIA, or what would happen next?

MR. LABBE: We would seek leave to amend, the Complaint, your Honor. I don't think it would call for any other process under the dance at this point, because this is information that should have been provided previously.

I mean, we could take that under advisement, if there were a process to go through, but I think it would just be a matter of whether it gives us a Rule 11 basis to seek leave to amend the Complaint at this point, if it was the purpose to go through the process that Hospira should have given us the information a year ago, and then we would have included it in the process at that time.

THE COURT: I understand your position.

Do you have a thought on that question?

MR. MELORO: Yes. A couple of thoughts.

First of all, a year ago Amgen had several choices, and Hospira would submit duties if they thought they had patents that could reasonably be asserted, even if they thought that there was still information they would like to see concerning those patents. And they should have listed the patents on the 3(A) list. That was their duty at that point.

Hospira also, in the correspondence, asked Amgen, specifically, when they asked for this information.

Hospira said, no, we've complied with the statute. We've given you aBLA, which describes the manufacturing process for the product. There is nothing more required.

But if there is something that you think you need to see to evaluate a specific patent, please let us know, so we can evaluate that.

And Amgen never responded to that. They never said, well, gee, here's something that we think might be implicated, but we just don't without knowing the ingredients of component X.

That's why we want the information. They stayed silent, and, presumably, we're fishing. I don't know. Maybe they were sandbagging, but they just never responded to that.

If Amgen were in a position where it got the information it's seeking now, and then sought leave to amend, Hospira would certainly oppose such a motion, and would move to dismiss such a claim on the grounds that those patent or patents should have been on the 3(A) list, and Amgen is barred by statute from asserting patents that were not on their 3(A) list.

THE COURT: Okay. Even though -- and I can't remember, maybe I'm confusing this with something else -- if somewhere down the road, let's assume in this particular case that we have right here, right now, ends up unfavorably to Amgen. And

somewhere down the road, you get whatever approvals you need -- well, obviously, not from me, but from somebody else, and you start selling your biologic -- they can then sue you for infringement upon some other theory that they haven't advanced here, right?

MR. MELORO: I don't believe Amgen can sue on patents that should have been on their 3(A) list.

THE COURT: Is that -- or is it only patents that come in -- that they get after?

MR. MELORO: If they have patents that are after invented, so to speak, or acquired, then we could be in a different situation. But I don't -- I don't get the sense that that's what we're talking about.

THE COURT: Well, I mean, that not what we're talking about right now, but I thought there was just some second round of --

MR. LABBE: Well, your Honor, the question raises a number of different issues. But just to focus on the should have been included point.

I think -- and I'll try to limit my answer to that -- in that to the extent that Mr. Meloro is referring to Section 271(E)(6)(c), to the extent that that provision of the Patent Act creates a bar of any kind, it only creates a bar for patents that Amgen should have listed on its 3(A) list.

And it can't be said that Amgen should have listed

patents for which it lacked sufficient information to have a reasonable belief that Hospira infringed.

The process that Mr. Meloro is describing --

THE COURT: But, I mean, presumably, that would be something that would be a question of fact to be figured out at some later time, right?

MR. LABBE: I agree with that, your Honor, that it could be an issue to be decided later, but it's just not that it's entirely foreclosed. It's a question of whether it's a patent that should have been included.

And we can't -- Amgen couldn't have included a patent for which it lacked information.

And Mr. Meloro was not entirely right earlier in saying that we didn't tell them why we wanted the information. We did say in our correspondence that Amgen owned cell culture patents, and that was the reason that we were seeking the information.

It's not that Amgen has to identify the patents, and then they tell us whether they infringe. They have to give us the manufacturing information so that Amgen can then assess it. That's the process that's set forth in the BPCIA.

It's true that we didn't follow the process that Mr. Meloro set forth, but that's not the process of the BPCIA. That's a process that Hospira proposed and doesn't comport with the process set forth in the statute where they give us, Amgen, the information to assess and make a determination based on a

reasonableness standard of which patents it should list on its 3(A) list.

MR. MELORO: May I respond, your Honor?

THE COURT: Yes.

MR. MELORO: In essence, I think what Amgen's position comes down to is a back-door private right of action on what they perceive to be a violation of Section (2)(A). Hospira complied with Section (2)(A).

Amgen is saying now they believe that Hospira didn't comply with Section (2)(A) as to these four components. They have no 2(A) cause of action, but that's essentially the gravamen of what they're trying to do under the rubric Rule 26.

THE COURT: Okay. And so, just to make sure that I know what I'm ruling on here, if I think of what I'm ruling on here is a list of ingredients for the four components in the cell culture medium or some variation of that.

That's what you're looking for, Mr. Labbe?

MR. LABBE: Yes, your Honor. It's most succinctly stated in our Interrogatory No. 1.

THE COURT: Well, if you are comfortable with that --

MR. LABBE: Yes.

THE COURT: -- I don't need to --

MR. LABBE: Yes.

THE COURT: And do you agree too if that's what it says?

MR. MELORO: I'm comfortable that we think we know what he is asking for.

THE COURT: All right.

What I'm going to do is this.

I'm going to say that within two weeks, on the basis of Claim 7 being asserted, it seems to me that it is relevant, it seems to me it's proportionate, so on the narrow ground you need to provide that information.

I'm going to take a break when we get through with the FDA, and go back and look at Amgen v. Sandoz, since I looked at it before, but to see -- because I'm inclined to give you an alternate ruling one way or the other on the broader ground, too, so that you can make whatever decisions are appropriate, okay?

MR. MELORO: Thank you, your Honor.

MR. LABBE: Okay, your Honor. Thank you.

THE COURT: All right.

So, the FDA correspondence.

And so, here, as I understand it, Amgen's position is Hospira should give you every single piece of paper of any kind between them and the FDA relating to any aspects of these biologics?

MR. LABBE: I think that's right, your Honor, with respect to the product that is the subject of their aBLA.

THE COURT: All right.

And Hospira has responded, we will provide you any FDA correspondence back and forth that relates to any -- essentially, to anything that's at issue, because of the assertion of the patents against the biologic product.

Is that -- does that accurately sum up what your two positions are?

MR. LABBE: More or less. I think their position is even narrower, in my view, and that it's not just relevant to the patent -- the patent lawsuit -- but it's relevant to the specific claims of the patent is their position.

THE COURT: Okay.

MR. LABBE: In other words, it's our view that it's relevant to the patent infringement suit. And it's their view that it's not relevant to the specific claims, and, therefore, not relevant.

THE COURT: Okay. I didn't see that in their letter.

Mr. Meloro, what's your position?

MR. MELORO: Our position is that we will provide anything in the correspondence that's relevant to the patent infringement claims in the case.

THE COURT: So, the patent infringement claims, that's ...

MR. MELORO: The subject matter of the patents, essentially.

So one patent relates to cells. The other patent

relates to what are called isoforms.

THE COURT: Okay. That's helpful.

And so, why is it that you should get every single piece of paper about unrelated aspects of the biologics? Is it, essentially, as I think you said, so you'll know when they're ready to launch?

MR. LABBE: That is one reason, your Honor. That's not a improper reason. Hospira suggested that's some improper reason.

There is a Protective Order in this case, and only limited people at Amgen would know the information. It's a proper purpose to know what the timing of the lawsuit needs to be.

There's other reasons.

We know that they received what's called a complete response letter from the FDA, and that they have to make an additional submission, which they're expected to make some time in the first half this year based on public information.

We don't know what will be in there. There may be amendments to the BLA. There may be changes to the manufacturing process.

THE COURT: Well, to the extent that they change the process, and that's relevant to this lawsuit, they're going to be, for sure, in their obligation to advise you, right? That's a duty to supplement kind of thing, right?

MR. LABBE: Yes, but we think the duty to supplement goes beyond that in this case. And there could be information that could implicate additional patents. It could implicate the timing of the case.

And we mentioned that this information, in our view, is routinely provided in Hatch-Waxman cases, and we say that only because for the same reasons it's relevant in those cases, it's relevant here, it's relevant regarding what types of rejections, what type of information they're receiving from the FDA. All of that is potentially relevant. It could be relevant to a potential defense in the case.

We -- they haven't answered the Complaint yet, but we expect them to assert a clinical trial exemption. There be could information about the manufacture of their lots of the products.

THE COURT: To the extent they assert particular defenses, you know, I think attributing to Mr. Meloro that right now he's just -- right now the only thing on the table is your infringement contentions. If they expand what is at issue here, presumably that expands what -- things that he might have to provide, if there is a discussion about experimental use, or whatever it was you said.

And you say it's standard in Hatch-Waxman to produce FDA correspondence, and I would say based on discovery disputes, that it's not certainly just accepted that a hundred percent of

FDA correspondence gets produced. And, if so, I don't know why I'm having so many discovery disputes over it.

The other thing is, even the discovery disputes I have, it strikes me that, in fact, the norm, as I would define it -- I will ask my Independent experts here in a minute -- the norm, I would define it is, yes, I think it is routine that some FDA correspondence gets provided back and forth, but I think it's not routine that it is a hundred percent.

But, in any event, Ms. Noreika or Mr. Gattuso, do you have any input on what the norm is?

MS. NOREIKA: In my experience, most of the FDA correspondence is provided, and there is not usually disputes. Disputes usually come up when you have situations where there's a question as to whether it's going to effect the timing of case, or whether they're going to be changes to the product that would impact, you know, the infringement allegations, or something like that.

I'm not sure what was brought to you, your Honor, but in my cases, it's usually just provided, and there is not much fight about it.

MR. GATTUSO: Judge, I think it's not always all. It's most. And you do see it more when there is a change of manufacturing process, or things like that, which will alter the posture of the case.

THE COURT: All right.

THE COURT: All right.

So what sort of things do you imagine happening, Mr. Meloro? What kind of correspondence do you imagine not producing?

MR. MELORO: Correspondence that is unrelated to the technical aspects of the product or the manufacturing process that have bearing on the patents.

So, if there were, for example, routine correspondence that indicated the progress of the application through the FDA, but had no substantive discussion of the product or the manufacturing process.

We're dealing with two expired patents. This is very different from a Hatch-Waxman case where the patents are enforced. There's usually a 30-month stay.

THE COURT: Well, when you say two expired patents, explain that.

MR. MELORO: Both of the patents-in-suit are expired in this case, and there is no 30-month stay.

So the usual concepts of expiration of the stay, and a potential at-risk launch, and the things that happened routinely in Hatch/Waxman cases are not at issue here.

THE COURT: Wait. Let me go back.

How can expired patents be asserted against you?

MR. LABBE: We can assert expired patents, your Honor, based on previous acts of infringement. And we're seeking

damages based on earlier acts of infringement prior to the expiration of the patents.

THE COURT: But if they -- if they get permission, or whatever it is they need to launch their biologic right now, these two patents couldn't stop them?

MR. LABBE: There's a possibility of some degree of injunctive relief based on prior infringement in terms of product that has been manufactured. Based -- if the product was manufactured and infringed under the patent, there's a possibility of injunctive relief to some extent, but it wouldn't -- it wouldn't prevent them forever, that's correct, your Honor.

We also --

THE COURT: Let me just go back.

When did the second of these two expire?

MR. LABBE: The second of two expired in January of this year.

THE COURT: How long, typically, does it take to culture cells and grow them? I mean, is that a long-drawn out process or is that something that happens every 24 hours?

MR. LABBE: I don't know how long it would take from start to finish to make a batch, your Honor. But I think since January they probably could have manufactured a batch of the product, if that's what you're asking?

THE COURT: So how would back and forth with the FDA effect -- so we're not, necessarily, talking about FDA

correspondence going forward. We're talking more about FDA correspondence that already occurred or, because I'm trying to wonder how -- like if they right now we want to change the way we manufacture things, maybe that -- I don't know whether that creates some separate duty to do something, but in relation to this suit, why do you care?

MR. LABBE: Well, we're talking about both, really.

They could amend the Complaint -- they could amend their BLA, rather, in a way that would implicate other Amgen patents, and we don't -- we would be completely in the dark about that.

THE COURT: Okay. But that doesn't seem to me like this lawsuit is really about other Amgen patents, right, it's about the two you asserted?

MR. LABBE: It is about the two that we have asserted, and that's based on the information that has been provided to us to date.

If they were to make a change to their BLA that would implicate other patents, Amgen should know about those patents as well. It should be provided as part of discovery.

THE COURT: And so, FDA correspondence you want, I take it's actually kind of a going-forward basis? I mean --

MR. LABBE: Correct, your Honor. We would seek the FDA correspondence on a going-forward basis for the reasons I've stated. For the -- there was a timing information --

THE COURT: Mr. Labbe, is that actually what's in dispute, not historical FDA correspondence, but stuff that has yet to occur?

MR. LABBE: Well, both items are in dispute. The only thing that we received from them is the BLA that they produced last February a year ago. Since February they haven't produced any other FDA information.

THE COURT: And so, this FDA response letter that you seem to be quite certain that they have received, and in which they have some duty to respond to, would that actually -- would that actually be -- I guess that could be relevant to your patent infringement, because it, perhaps, talks about something they were doing before your patents expired?

MR. LABBE: Correct, your Honor. It could be, yes. We don't know what was in the complete response letter. We don't know if they were -- if they were required to change their manufacturing process. Then, perhaps, nothing that they had already manufactured at the time the patents expired, would even be relevant any more, but we don't -- we don't know that. They haven't asserted that to us, but we don't have a way to even evaluate that.

THE COURT: All right.

And, Mr. Meloro, if the FDA correspondence, I guess if it talks about something you did during the -- or, in particular, this response letter -- and I'm not asking, because

I'm not entirely sure whether -- you don't even have to admit there is a response letter -- but let's assume, hypothetically, you got a response letter.

If there was something in it that talked about whatever you were doing directly either indirectly before the patents expired, you would produce that, right?

MR. MELORO: That's correct, your Honor. If it related to the subject matter of these patents, we would produce the information.

We haven't refused -- we did receive a letter from the FDA, that's been publicly-acknowledged by the company, and we haven't refused to produce that letter.

The reason we're before your Honor today is the line that we've drawn as to how we will decide what to produce from the FDA correspondence is what Amgen is unhappy about.

THE COURT: Okay. I think the usual balance of things here is pretty significantly in favor of Hospira here, because unlike the Hatch/Waxman cases that I see where there are legitimate timing issues that impact all aspects of the litigation, they don't really seem to be at issue here, because the two patents that are asserted, as I understand it, can't effectively -- you know, I can't see them as actually having much to do with whether or not Hospira can start -- or can launch its product, and market it, or whatever.

So I don't think the -- and so, even though I

appreciate the highest degrees of confidentiality and such, it seems to me that before you even order, or before you produce that, even though I'm quite confident everyone will live up to the Protective Order, that does seem to me to be very important information to Hospira.

And so, it seems to have, essentially, no relevance to the patents that are asserted. I think the line that Hospira has drawn is the right line.

MR. LABBE: Can I just add one thing, your Honor?

I mean, we do so on the pending 8(A) issue, and I know that's subject to a Motion to Dismiss right now, but were the Court to deny that Motion to Dismiss, the issue there is whether Hospira is giving the appropriate 180-day notice before it launches its product.

And there the timing of the information would be particularly relevant, because we're in the dark right now as to when they may get approval. We don't know if they've already filed their responses, a complete response letter or not, or when -- we just don't now anything other than what they have said publicly back in the fall.

So for that issue, we think it would be particularly relevant, and I haven't focused on that, because it's subject to the Motion to Dismiss.

I would just state that for the record.

THE COURT: Okay. And, I'm sorry, Mr. Labbe, just -- I

don't mind you mentioning that just a little more, because it's not in the forefront of my mind.

MR. LABBE: Yes. So the 8(A) issue, as I was referring to it, your Honor is, we have asserted a claim in the case that is subject to the Motion to Dismiss, saying that Hospira has violated the BPCIA by refusing to give 180-days notice prior to its commercial marketing.

Under the Amgen v. Sandoz case, such a notice can only be given after Hospira receives approval from the FDA. Under the Amgen v. Sandoz case, they're then required to wait a hundred and eighty days after approval before launching the product.

And so, that's an issue that's been raised.

THE COURT: But you would -- if they get the approval, do you learn that they've gotten the approval?

MR. LABBE: I don't know. It wouldn't be public information. They would, perhaps, announce that, but we wouldn't necessarily know that they've gotten approval. They might just launch.

Now, their position is that they don't have to give us the notice. And so, if they were able go forward with that position, we wouldn't know, and we wouldn't have an opportunity to seek an injunction to prevent the launch without their waiting the statutory 180 days, but I don't know of any way that Amgen would know, unless they made a press release about it.

THE COURT: Okay. Do --

MR. LABBE: It may, at some point, become a part of the FDA website. You wouldn't know when it's about to happen to be able to come to court and seek an injunction.

MR. MELORO: I'm not a FDA expert, but I do believe that the FDA posts approvals very promptly after they are issued.

THE COURT: So, in other words, to the extent that there is a concern about the timing of things, if the FDA gave you approval, you're saying it would be public knowledge, in your opinion?

MR. MELORO: That's my understanding.

THE COURT: All right. Okay.

Well, so, I'm going to stick with what I said about the FDA.

Let me just go off and take another look at Amgen v. Sandoz, and I will be back.

(A recess was taken at this time.)

(The proceedings continued after the recess as follows:)

THE COURT: Well, thank you for your patience.

So on the broader asserted basis for discovery, I'm going to deny plaintiffs' request.

I don't think the Amgen v. Sandoz Federal Circuit case is really on point for -- not only -- it would be controlling,

obviously, if it were on point, but it's not on point. I don't think that really impacts this at all.

And, I think, looking for the cell culture medium so you can consider about asserting other patents, it's, basically, what in the pre-amendment, you know, before December, what we just called the fishing expedition, is they're even less favored after the amendments than they were before.

So, to the extent that you're interested in assessing what other patents you might have had, I don't think this is the way to do it.

So I'm going to, on the broader grounds, deny it, but that will only come into play if the narrow grounds became moot for some reason, all right?

MR. MELORO: Thank you, your Honor.

Just for clarity, on the narrower ground, the Order at this point is that the information be produced in two weeks, if the Claim 7 infringement issue is still in play?

THE COURT: Right. It seems to me to be relevant to that.

MR. MELORO: Thank you, your Honor.

MR. LABBE: I understand the Court's ruling. It puts us in a somewhat difficult position.

If we're getting the discovery, it doesn't make any difference, but because we've dropped 2(A) claim, really, in reliance on the Amgen v. Sandoz decision, I think that's a issue

that we may -- Amgen may have reevaluate.

We'll take that under consideration as to whether there are any additional --

THE COURT: Okay. Let me just say, when we were taking the recess, my law clerk was pointing out, I was asking some of these questions that I was asking today at the oral argument.

You know, after we have oral argument, usually we decide how we're going to decide it, but it takes time to write it up.

And my law clerk reminded me that among other things, we weren't in a hurry to write that up, because we thought it -- the overall oral argument topics might be effected by the appeal from this Florida case in the Federal Circuit, which I think is on 8(A)?

MR. LABBE: Correct, your Honor.

THE COURT: Apparently, I was -- well, you obviously know this -- it was argued six weeks ago or something?

MR. LABBE: It was argued. That's right. That's about right, your Honor.

THE COURT: So we're probably not going to decide that until -- we would appreciate getting the benefit of whatever the Federal Circuit might have to say about that. Maybe it will be helpful, maybe it won't.

In terms of -- and so, is it -- is it the case, though, now this case is just is kind of just in more or less a hiatus,

because you are waiting for me to decide this thing, you said you haven't answered the Complaint?

MR. MELORO: With respect to a formal answer to the Complaint, I think it was the pending motion, but we do have a schedule in place, and the parties will move through fact discovery on the two expired patents, so we're not paused in that sense.

THE COURT: Okay. All right.

Thank you. That's another thing I couldn't remember.

All right.

Normally, the transcript here serves as the Order of the Court on these things.

If you need me any further, you know how to contact me.

MR. MELORO: Thank you, your Honor.

MR. LABBE: Thank you, your Honor.

THE COURT: Thank you very much.

(The proceedings adjourned at 1:18 o'clock p.m.)

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CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of September 2016, I caused the foregoing BRIEF OF PLAINTIFFS-APPELLANTS AMGEN INC. AND AMGEN MANUFACTURING, LIMITED to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the Court's CM/ECF system.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 28.1(e)(2) because it contains 10,880 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because the brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 with 14-point Times New Roman font.

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