Appeal No. 2015-1499

United States Court of Appeals

for the

Federal Circuit

AMGEN INC., AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellants,

– v. –

SANDOZ INC.,

Defendant-Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA IN CASE NO. 3:14-CV-04741-RS, JUDGE RICHARD SEEBORG

NON-CONFIDENTIAL REPLY BRIEF FOR PLAINTIFFS-APPELLANTS AMGEN INC. AND AMGEN MANUFACTURING LIMITED IN SUPPORT OF EMERGENCY MOTION FOR INJUNCTION PENDING APPEAL

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April 28, 2015

CERTIFICATE OF INTEREST

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

   AMGEN INC. and AMGEN MANUFACTURING LTD.

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 LTD.

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 partners or associates that appeared for the party now represented by me in the trial court or are expected to appear in this Court are:

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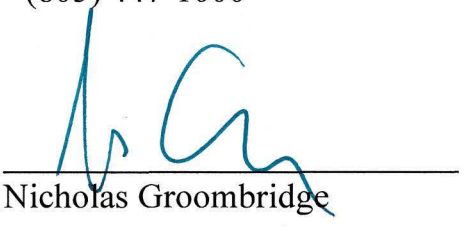

Nicholas Groombridge

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CONFIDENTIAL MATERIAL

Pursuant to Federal Circuit Rule 27(m), materials that were designated as confidential pursuant to the district court's Protective Order have been redacted from the non-confidential version of the reply brief. Specifically, the material omitted on pages 7 and 8 contains references to Amgen's confidential information regarding pricing strategy; and the material omitted on pages 1, 7, 9, 10 contains references to Sandoz's confidential information regarding pricing strategy and marketing and sales strategy.

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INTRODUCTION

Sandoz had a choice: apply for FDA approval of its biological product under the traditional pathway, 42 U.S.C. § 262(a), supported by its own clinical data, or apply under the BPCIA's abbreviated pathway, 42 U.S.C. § 262(k), referencing Amgen's license for its filgrastim product and accepting the obligations set forth in the BPCIA. Sandoz chose the BPCIA's abbreviated pathway, but then refused to comply with BPCIA provisions in § 262(*l*) that protect Amgen's rights as the RPS. Sandoz nevertheless pressed on with its § 262(k) application, securing an FDA "biosimilar" license. It is now poised to introduce its biosimilar competitor to Amgen's NEUPOGEN® product as soon as May 11, 2015. There is no dispute that [redacted]. The price erosion and other harms that Amgen will suffer are irreparable and immediate. Amgen's motion seeks to maintain the status quo until this Court has rendered a decision in Amgen's appeal. The injunction will be short: briefing is complete and argument is scheduled for June 3, 2015. Amgen respectfully requests this injunction to preserve this Court's ability to issue meaningful relief.

I. Amgen is Likely to Succeed on the Merits

A. Subsection (*l*)(2)(A) is Mandatory

Subsection 42 U.S.C. § 262(*l*)(2)(A), enacted with the BPCIA's abbreviated approval pathway, requires the Applicant to provide its BLA and manufacturing

information to the RPS. The statute includes the mandatory command "shall," and Congress described non-provision of that information as "fail[ure]" and the information itself as "required." Mot. at 10-11. None of Sandoz's arguments shows otherwise.

In § 262, Congress set forth two alternative pathways for FDA approval of biologic products. A Biologics License Application must be submitted under either §262(a) or (k). *See* 42 U.S.C. § 262(a)(1); (k)(1). While approval under § 262(a) requires the submission of independent clinical trial data, a subsection (k) Applicant may rely on the clinical trial data and approval of a previously approved product, the "reference product." *See* 42 U.S.C. § 262(a)(2)(C), (i)(4), and (k)(2)(A)(i). The choice between subsections (a) and (k) has consequences: "when a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the [RPS] . . . confidential access to the information required to be produced pursuant to paragraph (2)." 42 U.S.C. § 262(*l*)(1)(B)(i) (emphasis added).

Sandoz argues that the BPCIA provides the Applicant with different a choice: the choice to engage in part, all, or none of the patent-exchange process. It argues that the use of "shall" in § 262(*l*)(2)(A) denotes only a condition precedent to engaging in the next step of the patent-exchange process. Opp. at 10. That construction affords no help to Sandoz, which omits that § 262(*l*)(2)(A) itself has a

condition precedent that has been satisfied, obligating Sandoz to provide Amgen with a copy of its BLA and manufacturing information: "Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review . . ." 42 U.S.C. § 262(*l*)(2)(A). It is undisputed that Sandoz received such notice from FDA on July 7, 2014. And the subsection continues in mandatory language: "the subsection (k) applicant—(A) shall provide to the" RPS a copy of its BLA and manufacturing information (emphasis added). Thus, the § 262(*l*)(2)(A) disclosure became a mandatory obligation that Sandoz was required to fulfill within 20 days, but deliberately did not fulfill.

Sandoz further argues that "shall" cannot be mandatory because Congress contemplated that the parties might fail to comply. The fact that Congress may have contemplated bad behavior and set forth a consequence does not suggest that Congress permitted such behavior. Nor is Sandoz correct that for "each subsection (*l*) step [that] begins with 'shall,' the BPCIA contemplates that the applicant or sponsor might not pursue the patent-exchange to completion and expressly provides the consequences for not doing so." *Id*. at 9 (citing to A2050-51). Sandoz omits the "shall" commands in § 262(*l*)(3)(A)(ii), (*l*)(3)(B)(iii), (*l*)(3)(C), and (*l*)(8)(C), none of which has any corresponding "consequence."

Finally, to blunt the impact of the "shall" in § 262(*l*)(2)(A), Sandoz analogizes to the "shall" in § 262(*l*)(6)—the RPS "shall bring an action for patent

infringement"—which Sandoz says must be optional. *Id*. at 11. The statute proves Sandoz wrong. Subsection 262(*l*)(6) commands that suit be brought, and that it be brought within 30 days. If an Applicant is harmed by an RPS's failure to meet that obligation, the Applicant can seek relief to remedy that harm.

B. A Subsection (k) Applicant May Not Provide Effective Notice of Commercial Marketing Before Licensure

Amgen showed that the 180 days' notice of commercial marketing required by § 262(*l*)(8)(A) may not be given until the FDA has licensed the biosimilar. The statute refers to the commercial marketing of a "product licensed," whereas in every other instance the statute refers to the "product that is the subject of the subsection (k) application." Mot. at 12-13.

Sandoz argues that notice can be given before licensure because § 262(*l*)(8)(A) refers to notice being given by the "'subsection (k) *applicant*'—not the 'holder' of an approved application." Opp. at 12 (emphasis in original). But Sandoz omits that "subsection (k) applicant" is a defined term: Subsection (*l*) begins by stating the "person that submits an application under subsection (k)" is "referred to in this subsection as 'the subsection (k) applicant.'" 42 U.S.C. § 262(*l*)(1)(A). Congress's use of that defined term in § 262(*l*)(8)(A) signifies nothing about the timing of notice, only who has to give that notice: the Applicant. Sandoz also argues that Congress used "product licensed" to recognize that a product may not be marketed until it is licensed. Opp. at 12. That would be just as

true if Congress had said "product that is the subject of the subsection (k) application," however.

Finally, Sandoz argues that requiring notice after licensure would give the RPS an extra six months of market exclusivity, the functional equivalent of an "automatic, bondless six-month inunction." *Id.* at 13. Sandoz is incorrect. Nothing in the BPCIA provides market exclusivity, only data exclusivity. Any party may seek approval of a copy of the reference product under subsection (a), supported by clinical trial data, as Teva did with its filgrastim product, GRANIX®. And the 180-day period serves a very different function—providing time to bring a preliminary injunction—as is demonstrated by the statutory structure. The 180-day notice provision is provided in subsection (*l*)(8)(A). The very next subsection, (*l*)(8)(B), provides that the RPS can bring a motion for a preliminary injunction on patents that were identified but not selected for immediate litigation.

C. Subsection 262(*l*)(9) is Not the Exclusive Remedy for Failure to Comply with Subsections 262(*l*)(2)(A) or (*l*)(8)

Amgen explained how the district court had erred in finding that a declaratory judgment under § 262(*l*)(9)(C) was the exclusive remedy for an Applicant's failure to provide the required information or proper notice. Mot. at 13-15. Sandoz does not defend that finding. Instead, Sandoz argues that Amgen's exclusive remedy for Sandoz's failure to provide its application and manufacturing information is an infringement suit under § 271(e)(2)(C)(ii), limited to the

remedies provided in § 271(e)(4). Opp. at 13-14. But nothing in the BPCIA says that an infringement suit is the sole procedural device available where an Applicant violates the statute, and § 271(e)(4) provides the exclusive remedies "for an act of infringement," not for failing to provide the required information by § 262(*l*)(2)(A). 35 U.S.C. § 271(e)(4) (emphasis added).

Sandoz argues there should be no implied federal cause of action to compel compliance with the BPCIA (Opp. at 15), citing *Alexander v. Sandoval*, 532 U.S. 275 (2001). But Sandoz itself brought three counterclaims seeking declarations that its conduct under the BPCIA is lawful. Mot. at A0006. Those counterclaims necessarily require a cognizable claim that an RPS could bring under the BPCIA to remedy the conduct in which Sandoz engaged, if that conduct is indeed unlawful. Otherwise, Sandoz's counterclaims presented no justiciable case or controversy. Sandoz cannot now argue that the BPCIA forecloses a federal remedy.

II. Amgen Faces Irreparable Harm Without an Injunction Pending Appeal

A. The Harm Amgen Seeks to Avoid by this Injunction is Not Predicated on Patent Infringement

Sandoz argues that there can be no irreparable harm without a showing of patent infringement. Opp. at 16-17. Not so. Amgen has been and will be irreparably harmed if Sandoz's product enters the market without affording Amgen the process due it under the BPCIA. By refusing to provide the required BLA and manufacturing information, Sandoz converted Amgen's property and is poised to

compete directly with Amgen. Sandoz materially prejudiced Amgen, depriving it of the time—up to 230 days—and information needed to detect Sandoz's infringement and commence a § 262(*l*)(6) action. By refusing to provide 180-day advance notice after FDA licensure, Sandoz further denied Amgen the statutory period to seek a preliminary injunction on the licensed product.

B. Amgen Will Suffer Price Erosion and Loss of Goodwill

Sandoz does not dispute that it will [redacted] NEUPOGEN®. Sandoz nevertheless argues that price erosion is speculative and unfounded. First, Sandoz says that Amgen's witnesses testified only that Amgen "might" or "may" have to lower prices. Opp. at 17. But when those witnesses testified, it was still unclear whether Sandoz would price ZARXIO® above, at parity with, or below NEUPOGEN®. Mot. at A0478. Sandoz had said publicly it might price at parity. Ex. 16 at A0591. It was only later that [redacted] NEUPOGEN® (Mot. at A1444; Mot. at A1682-83), confirming the price erosion and loss of goodwill that Amgen will suffer. Mot. at A0477-79; Mot. at A0516-17.

Finally, Sandoz suggests that Amgen's internal forecasts show that Amgen planned to [redacted], despite the launch of ZARXIO®. But Sandoz omits that those same documents show that Amgen also [redacted]. Ex. 17 at A1999-2000; Ex. 18 at A1996-

97. Indeed, internal forecasting documents state the "[redacted]" Ex. 18 at A1997. Sandoz also omits that the planned [redacted]. *Id*. at A1996 ([redacted]).

C. Amgen Faces Patent Uncertainty

Sandoz suggests that Amgen's assertion that, without the BLA, it was "impossible for Amgen to determine which of its patents read on the manufacture of Sandoz's product" is belied by the fact that Amgen was able to bring an action for patent infringement. Opp. at 18 (quoting Mot. at 18). Sandoz omits that the patent Amgen was able to assert is directed to methods of treatment, not methods of manufacturing. Mot. at A0072. Amgen has more than 400 manufacturing patents, but could not assess potential infringement of those patents without disclosure of Sandoz's BLA and manufacturing information as required by § 262(*l*)(2)(A). Mot. at 18.

D. Amgen Did Not Delay in Seeking Relief

Sandoz accuses Amgen of taking too long to obtain Sandoz's BLA and to sue, suggesting that Sandoz timely offered its BLA and Amgen refused. There is no issue of delay here: the district court made no findings of delay. Moreover, Sandoz omits that (i) Amgen consistently stated it was ready to receive Sandoz's

BLA and manufacturing information under the confidentiality provisions set forth in the BPCIA; and (ii) Sandoz's offer for confidential access was limited to the BLA, did not include "such other information that describes the process or processes used" as required by § 262(*l*)(2)(A), and would have precluded Amgen from bringing suit under 35 U.S.C. § 271(e) or 271(g). Ex. 19 at A1465-68; Ex. 20 at A1484; Opp. at A1481-82, A1505-07. That Amgen instead insisted on the rights provided to it by the BPCIA itself is hardly a basis for accusations of delay.

III. Scope of Injunction and Bond Amount

Sandoz attempts to limit the scope of any injunction pending appeal to California, and to "shipping its product to customers in commercial quantities." Opp. at 20. That is, Sandoz wants to promote, market, offer to sell, and even sell ZARXIO® while an injunction is in place, as long as it does not actually ship the product. But the harm to Amgen is not limited to Sandoz's shipment of product. Price erosion, for example, will begin as soon as Sandoz begins promoting, marketing, offering to sell, and selling [redacted] Nor is the harm limited to California. While *Allergan Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350 (Fed. Cir. 2013), cited by Sandoz, limited an injunction based on violation of California's Unfair Competition Law to the state of California, it placed no such territorial restrictions on common law conversion claims, which Amgen has pleaded here.

Sandoz's suggestion that the bond be set at [redacted] is excessive and without merit. That estimate is predicated on an injunction lasting at least 410 days, while Amgen here seeks an injunction only until the resolution of this appeal, in which briefing will be complete today and oral argument will be held on June 3, 2015. Sandoz's [redacted] figure also assumes that Sandoz would have launched on [redacted] which it already agreed not to do and did not do, and—inexplicably—assumes damages through 2020. Opp. at A1063.

Amgen respectfully suggests that the bond for this injunction should be set at [redacted]. That amount would be more than adequate to cover net sales revenue for ZARXIO® through August 2015, and is based on Sandoz's own sales forecasts (Ex. 21 at A2014), revised to account for commercial sales beginning on May 11, 2015, the date to which Sandoz agreed to stay off the market absent an injunction.

CONCLUSION

For the foregoing reasons, Amgen respectfully requests that the Court enjoin Sandoz from marketing, selling, offering for sale, or importing into the United States its ZARXIO® biosimilar product during this appeal.

Dated: April 28, 2015

Respectfully submitted,

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SUPPLEMENTAL EXHIBITS IN SUPPORT OF REPLY MOTION

INDEX OF SUPPLEMENTAL EXHIBITS

Ex.	Description	Date Filed	Appendix No.
	Supplemental Declaration of Jennifer H. Wu in Support of Plaintiffs-Appellants' Reply Brief in Support of Emergency Motion for an Injunction Pending Appeal		
16.	Exhibit 4 to Winters Declaration in Support of Amgen's Motion for a Preliminary Injunction: Derrick Gingery, *ODAC Asks Sandoz if Biosimilar Price Is Right*, THE PINK SHEET DAILY (Jan. 7, 2015) [Dkt. No. 56-10]	2/5/2015	A0591-93
17.	Exhibit C to Baxter Declaration in Support of Amgen's Motion for an Injunction Pending Appeal: Excerpts from Amgen's U.S. G-CSF 2014 LRP [Dkt. No. 107-12] [Confidential]	3/24/2015	A1999-2000
18.	Exhibit B to Baxter Declaration in Support of Amgen's Motion for an Injunction Pending Appeal: Excerpts from Amgen's OBU Q4 14' QBR Review [Dkt. No. 107-10] [Confidential]	3/24/2015	A1995-97
19.	Wu Declaration in Support of Amgen's Preliminary Injunction Reply [Dkt. No. 83-5]	3/6/2015	A1464-70
20.	Exhibit 3 to Wu Declaration in Support of Amgen's Preliminary Injunction Reply: Amgen's July25, 2014 Letter [Dkt. No. 83-8]	3/6/2015	A1484-85
21.	Exhibit E to Baxter Declaration in Support of Amgen's Motion for an Injunction Pending Appeal [Dkt. No. 107-16] [Confidential]	3/24/2015	A2014

Appeal No. 2015-1499

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMGEN INC., AMGEN MANUFACTURING LTD.,

Plaintiffs-Appellants,

v.

SANDOZ INC.,

Defendant-Appellee.

Appeal from the United States District Court for the Northern District of California in Case No. 3:14-CV-04741, Judge Richard Seeborg

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SUPPLEMENTAL DECLARATION OF JENNIFER H. WU IN SUPPORT OF PLAINTIFFS-APPELLANTS' REPLY BRIEF IN SUPPORT OF EMERGENCY MOTION FOR AN INJUNCTION PENDING APPEAL

I, Jennifer H. Wu, declare and state as follows:

1. I am an attorney admitted to the bar of this Court, and a partner of the law firm, Paul, Weiss, Rifkind, Wharton & Garrison LLP. I am one of the attorneys of record in Appeal No. 2015-1499 for Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing, Limited (together, "Amgen"). I have personal knowledge of the facts set forth in this Supplemental Declaration, and if called upon as a witness, I could and would testify competently as to these facts.

2. Attached hereto as Exhibit 16 is a true and correct copy of Exhibit 4 to Winters Declaration in Support of Amgen's Motion for Preliminary Injunction (Dkt. No. 56-10) dated February 5, 2015 from *Amgen Inc. v. Sandoz Inc.*, No. 3:14-CV-04741-RS (N.D. Cal.) (the "District Court Action"). This is an article entitled "ODAC Asks Sandoz If Biosimilar Price Is Right" published in THE PINK SHEET DAILY on January 7, 2015.

3. Attached hereto as Exhibit 17 is a true and correct copy of Exhibit C to Baxter Declaration in Support of Amgen's Motion for an Injunction Pending Appeal (Dkt. No. 107-12) dated March 24, 2015 from the District Court Action. This contains excerpts of a document produced by Amgen bearing the production numbers AMG-NEUP-00002697-746.

4. Attached hereto as Exhibit 18 is a true and correct copy of Exhibit B to Baxter Declaration in Support of Amgen's Motion for an Injunction Pending Appeal (Dkt. No. 107-10) dated March 24, 2015 from the District Court Action. This contains excerpts of a document produced by Amgen bearing the production numbers AMG-NEUP-00002616-83.

5. Attached hereto as Exhibit 19 is a true and correct copy of the Wu Declaration in Support of Amgen's Reply Supporting its Preliminary Injunction Motion (Dkt. No. 83-5) dated March 6, 2015 from the District Court Action.

6. Attached hereto as Exhibit 20 is a true and correct copy of excerpts of Exhibit 3 to Wu Declaration in Support of Amgen's Reply Supporting its Preliminary Injunction Motion (Dkt. No. 83-8) dated March 6, 2015 from the District Court Action. This is a letter from Amgen to Defendant-Appellee Sandoz Inc. ("Sandoz") dated July 25, 2014.

7. Attached hereto as Exhibit 21 is a true and correct copy of Exhibit E to Baxter Declaration in Support of Amgen's Motion for an Injunction Pending Appeal (Dkt. No. 107-16) dated March 24, 2015 from the District Court Action. This contains an excerpt of a document produced by Sandoz bearing the production number SDZ(56)0201442.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on April 28, 2015 in New York, New York.

Jennifer H. Wu

EXHIBIT 16

2 of 7 DOCUMENTS

The Pink Sheet Daily

January 7, 2015

SECTION: Vol. 15 No. 10

LENGTH: 922 words

HEADLINE: ODAC Asks **Sandoz** If Biosimilar Price Is Right

BODY:

Among the most striking differences seen between a typical advisory committee meeting and FDA's first for a 351(k) application was a somewhat extensive discussion of pricing.

Specifically, **Sandoz Inc.** was asked whether its filgrastim biosimilar, if approved, would help lower costs.

FDA decisions cannot take price into account, and the agency usually avoids such discussions if they come up during the advisory committee meetings.

Agency officials did not interrupt the discussion of the "elephant in the room that nobody acknowledges," as Oncologic Drugs Advisory Committee member James Liebmann put it during the Jan. 7 meeting. But the answers **Sandoz** gave were not definitive.

Sandoz argued during the meeting at which its biosimilar to **Amgen Inc.** 's *Neupogen* was considered that consumer and payer costs would be lower. But **Sandoz** would not state it would price the product, which has the proposed trade name *Zarxio* , below Neupogen.

Some models have estimated price reductions of 20% to 30% once biosimilars enter the market.

"We can't say that the price would be less because in some situations the price will be at parity because of other relative terms that will come into existence that's there," said Mark McCamish, **Sandoz** global head of biopharmaceuticals and oncology injectables development. "Price is a relatively complex situation."

Committee members voted unanimously to recommend approval of Zarxio for all five Neupogen indications (*see related story*, "**Sandozs** Biosimilar Filgrastim Sails Through FDA Panel" "The Pink Sheet Daily" Jan. 7, 2015).

ODAC agreed with FDA review staff that there were no clinically meaningful differences that would raise concerns ("**Sandozs** Biosimilar Filgrastim Highly Similar To Neupogen FDA Staff Say" "The Pink Sheet Daily" Jan. 5, 2015).

McCamish and other executives of companies looking to enter the biosimilar market have argued price will not be the only issue involved, indicating that rebates could be higher, which would affect the overall cost.

Sandoz in particular said it would not make the same pricing mistake with Zarxio that it made with *Omnitrope* (somatropin [rDNA origin]), a 505(b)(2) follow-on biologic. The company priced it too low, which hindered sales ("Biosimilar Pricing **Sandoz** Vows Not To Make emOmnitropeem Mistake With Filgrastim" "The Pink Sheet" Dec. 22, 2014).

FDA officials did not speak during the pricing discussion at the committee meeting. The agency said in a statement issued after the meeting that it generally doesn't stop discussions "that occur during the natural course of a meeting if a committee member brings something up."

Comments about the potential for cost savings also emerged during the open public hearing session. Representatives of a number of advocacy groups and patients argued in favor of allowing biosimilars on the market because of the potential for cost reductions.

But the extended conversation among committee members may be another signal of the difference in how biosimilar advisory committee meetings may function compared to those for new drugs. Cost may become a more regular discussion topic, even if it does not play a part in the agency's ultimate approval decision.

How advisory committees would handle various aspects of a biosimilar application has been an issue potential sponsors were anticipating as the filgrastim meeting approached ("Biosimilar Sponsors Offer Advisory Committee Primer" "The Pink Sheet" Dec. 22, 2014).

Sandoz Initiates Discussion During Presentation

Sandoz broached the pricing issue when consultant Louis Weiner, chairman of the Georgetown University Medical Center Department of Oncology, suggested during a presentation on the clinical perspective for biosimilar use that the products would lower costs and spur competition.

Liebmann, an assistant professor at the University of Massachusetts Department of Medicine, said he was pleased the issue emerged and noted it has not been acknowledged in previous advisory committee meetings.

He asked **Sandoz** officials directly: "Is the consultant correct? Would this really bring down cost?"

The question drew some laughter from the crowd. McCamish said experience with the product in Europe - where it was approved for marketing in 2009 - showed that costs fell.

"There has been a substantial increase in the use so we are addressing access, and there has been a substantial reduction in cost because of the competition that's there," McCamish said.

But Liebmann pushed for a more direct answer, saying European pricing models are different from the U.S. and may not be relevant.

"The point of my question was that I was hoping that the sponsor would address it," he said. "You could simply say 'Yes we're going to price it less than Neupogen.' And if you're honest that would be delightful."

Price Parity, Lower Cost

McCamish said mechanisms in place such as rebates will help patients save money.

"The cost will be less to the consumer, to the payer, to the health care economy," he said. "It has to be; otherwise it doesn't make sense."

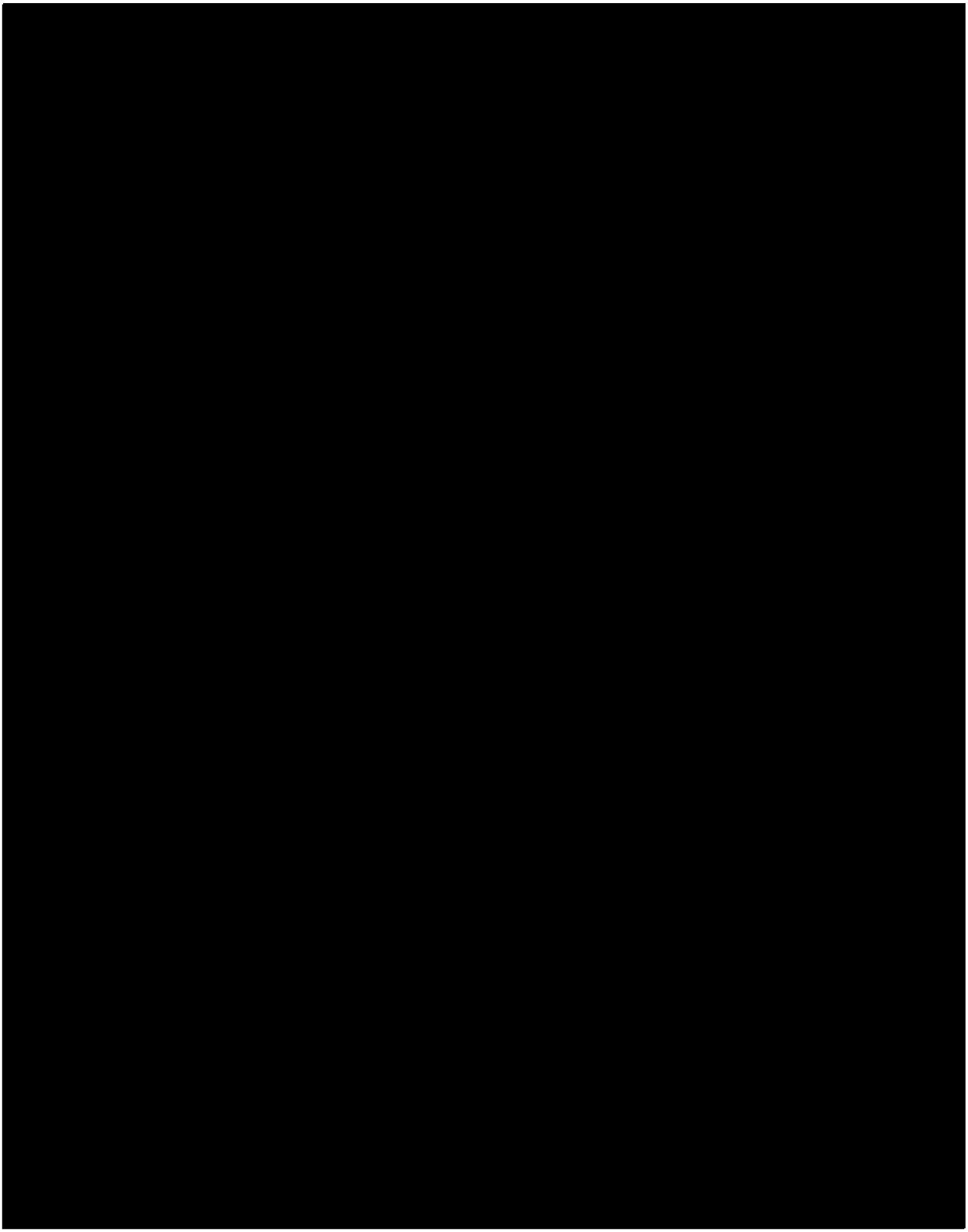
Sandoz's filgrastim 351(k) submission is the first to reach the advisory committee stage. It also was the first to be publicly disclosed as filed ("**Sandoz** emNeupogenem Biosimilar Heads To **ODAC** Cmte May Be Students As Much As Advisors" "The Pink Sheet Daily" Dec. 8, 2014).

Since **Sandoz's** announcement, two other companies have stated they have submitted biosimilar applications ("Apotex Biosimilar Goes To FDA But May Enter Crowded Market" "The Pink Sheet Daily" Dec. 17, 2014).

By Derrick Gingery

LOAD-DATE: January 7, 2015

EXHIBIT 17



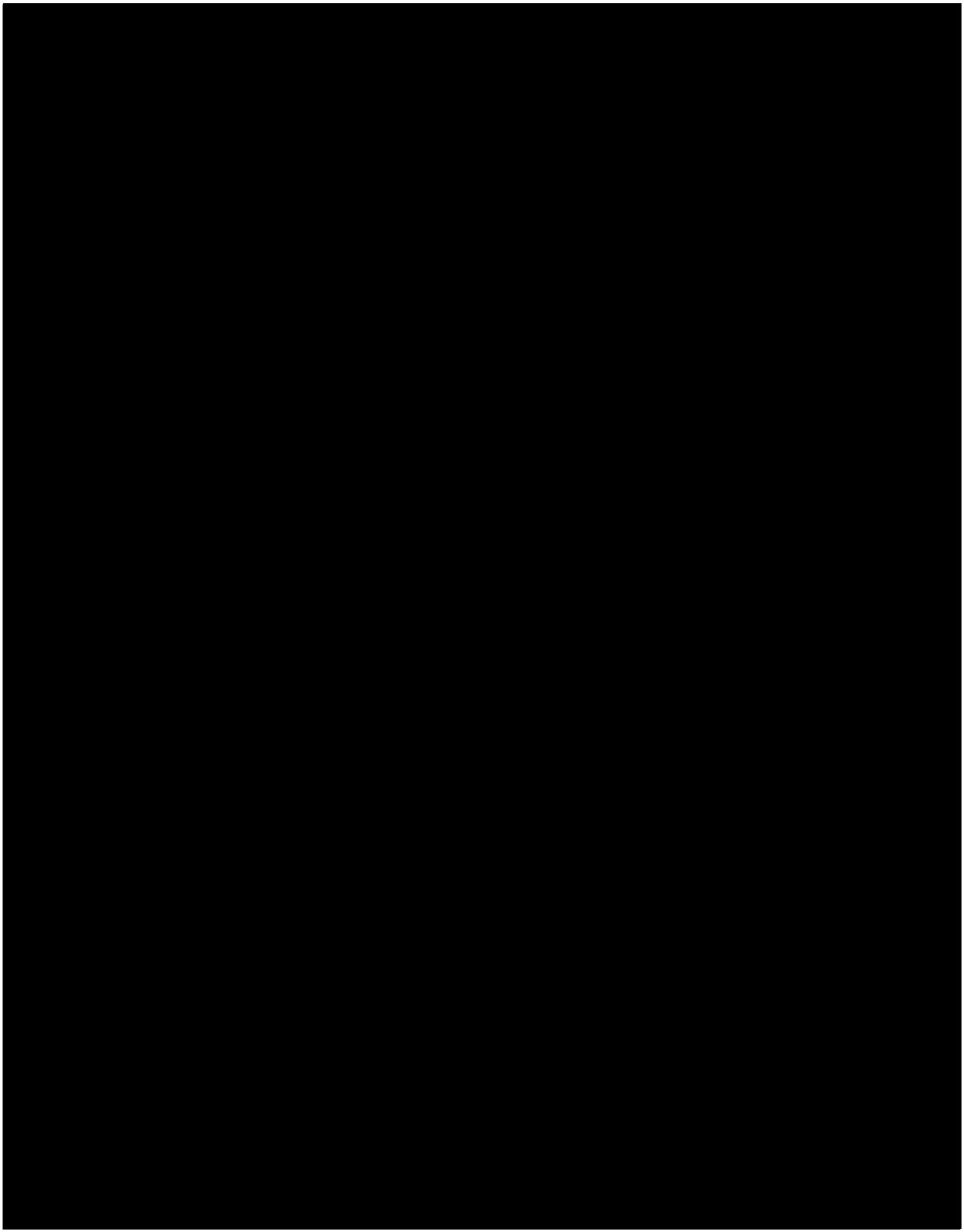
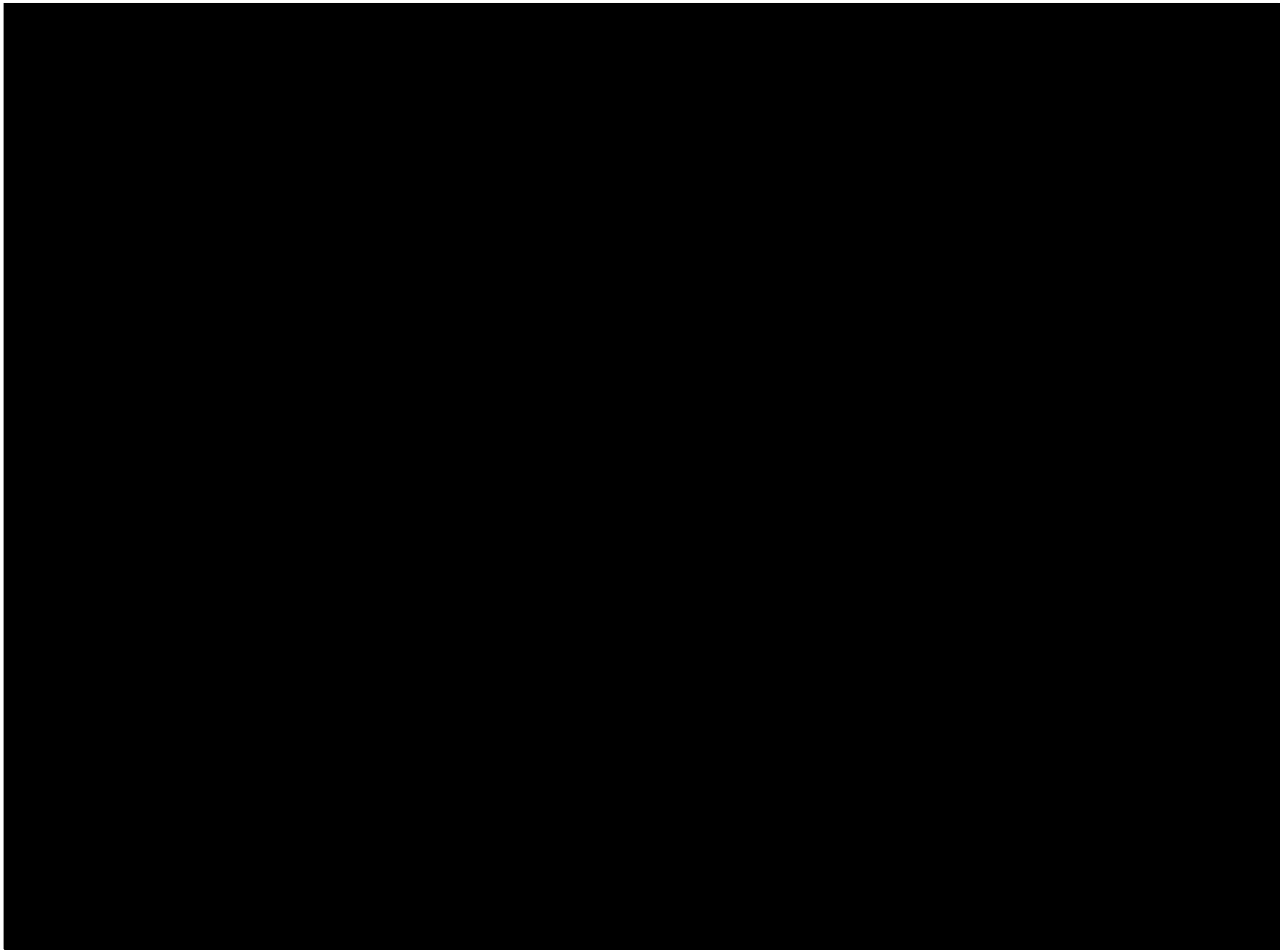
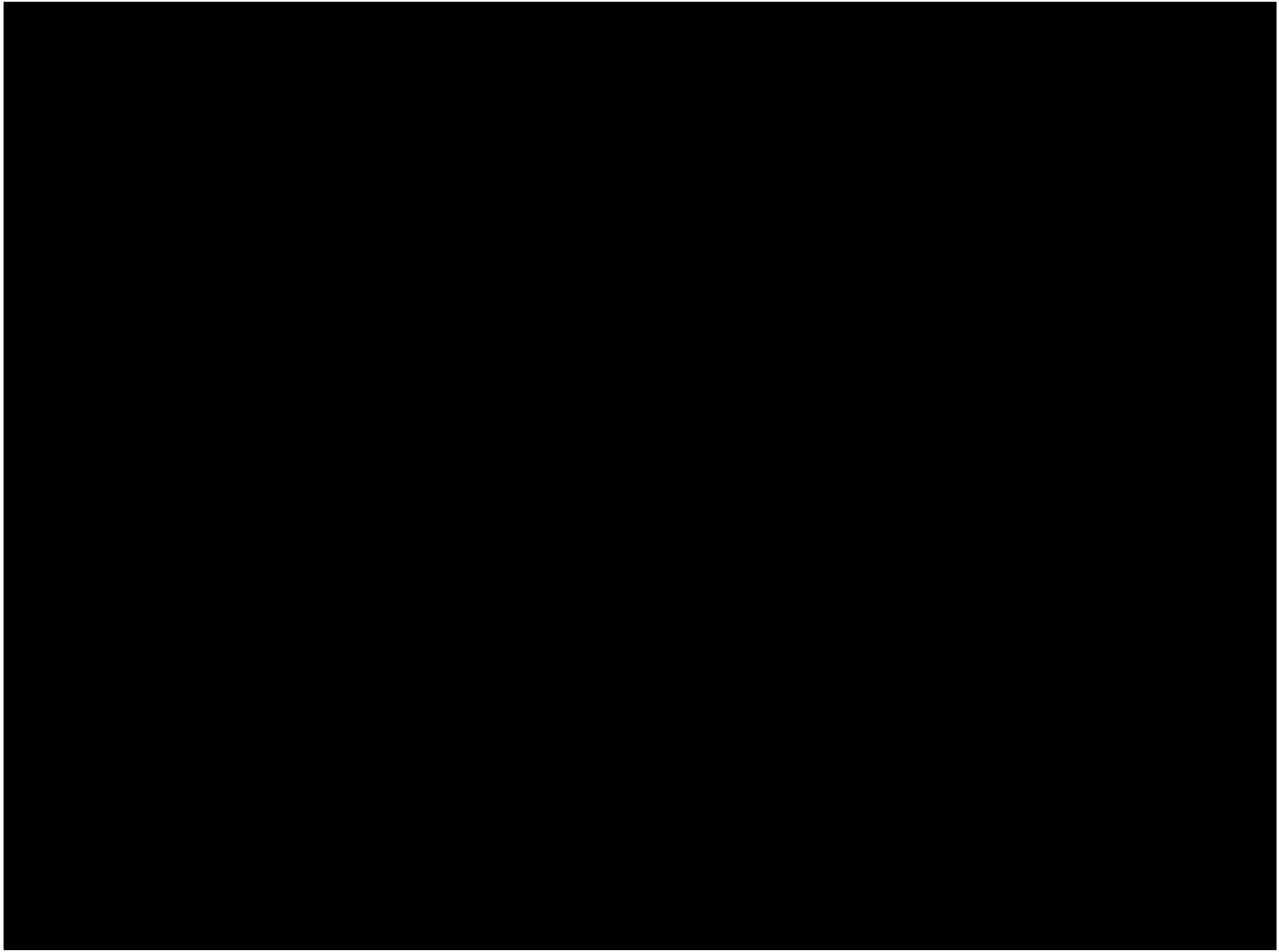


EXHIBIT 18





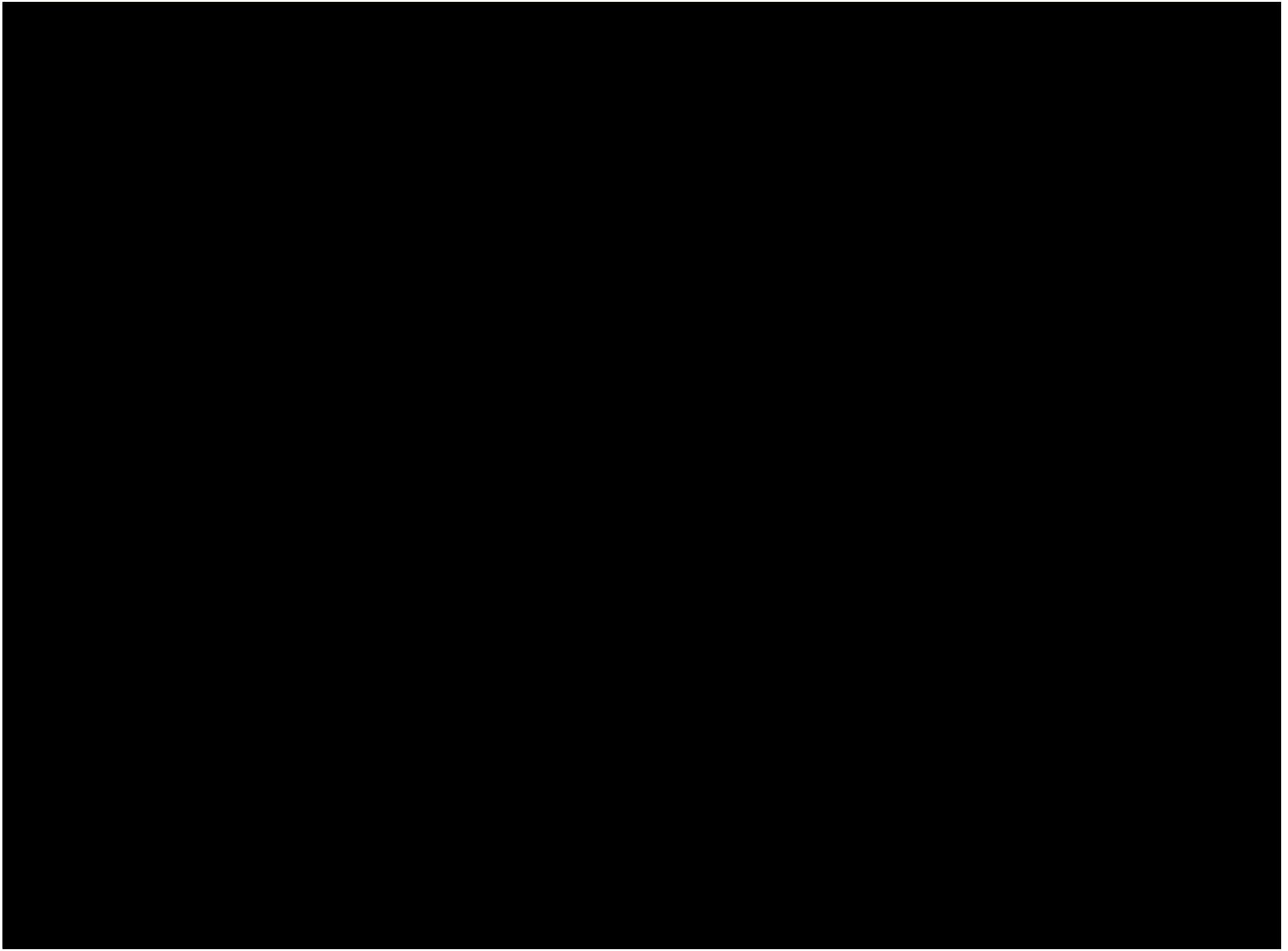


EXHIBIT 19

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, vs. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. 3:14-cv-04741-RS **DECLARATION OF JENNIFER H. WU IN SUPPORT OF AMGEN'S REPLY SUPPORTING ITS PRELIMINARY INJUNCTION MOTION**

I, Jennifer H. Wu, declare and state as follows:

1. I am a licensed attorney granted admission to practice *pro hac vice* in the above-captioned matter and a partner of the law firm Paul, Weiss, Rifkind, Wharton & Garrison LLP, attorneys of record for plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (together, "Amgen"). I have personal knowledge of the facts set forth in this Declaration, and if called upon as a witness, I could and would testify competently as to these facts.

2. On July 8, 2014, Sandoz sent Amgen a letter stating that Sandoz had filed an application for FDA approval of a biosimilar filgrastim product for which Amgen's Neupogen® is the reference product. Attached as **Exhibit 1** is a true and correct copy of that correspondence. Sandoz included with its letter an Offer of Confidential Access ("OCA"), which Sandoz characterized as "more generous than the BPCIA patent dispute resolution framework." (Wu Decl. Ex. 1, at 2.)

3. The OCA that Sandoz proposed on July 8, 2014 differed from what the BPCIA requires. For example:

a. The OCA was limited to Sandoz's provision of the BLA. (Wu Decl. Ex. 1, at 3, OCA section 1.A.i.) The BPCIA, on the other hand, requires Sandoz also to 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).

b. The OCA would have allowed Sandoz to redact its BLA "to remove information of no relevance to any issue of patent infringement." (Wu Decl. Ex. 1, at 3, OCA section 1.A.ii.) The BPCIA does not provide for redaction, and instead requires Sandoz to provide a copy of its BLA and such other information that describes the process or processes used to manufacture the biological product that is the subject of the application. *See* 42 U.S.C. § 262(l)(2)(A).

c. The OCA would have allowed Amgen to use the BLA only "for the sole purpose of determining whether to bring an action under 35 U.S.C. §271(a), (b),

and/or(c) asserting one or more of its patents" against Sandoz's proposed biosimilar filgrastim product. Wu Decl. Ex. 1, at 3. Absent from that statutory list is 35 U.S.C. § 271(e) and (g). The BPCIA, on the other hand, would allow Amgen to review Sandoz's BLA and manufacturing information and assert claims under any appropriate statutory infringement provision, including sections 271(e) and (g).

d. The OCA would have limited Amgen's access to the BLA to "no more than two outside counsel." (Wu Decl. Ex. 1, at 3, OCA section 1.B.i.) The BPCIA has no such limit on outside counsel access; it permits "[o]ne or more" outside counsel attorneys to access the information provided that they not engage, formally or informally, in patent prosecution relevant to the reference product. 42 U.S.C. § 262(l)(1)(B)(ii)(I).

e. The OCA would have required Amgen to file suit within 60 days, and if Amgen did not file suit, to destroy within 30 days the entirety of Sandoz's confidential material. (Wu Decl. Ex. 1, at 5, OCA section D.1.) The BPCIA does not require bringing a lawsuit in 60 days. Instead, it provides 60 days for Amgen to identify the patents that could be infringed after Amgen has received the BLA and manufacturing information. 42 U.S.C. § 262(l)(3)(A). It is only after the parties have completed the exchange of patent lists and patent information in 42 U.S.C. § 262(l)(3)-(5) that Amgen shall bring an immediate patent infringement action under 42 U.S.C. § 262(l)(6).

4. On July 18, 2014, Amgen responded to Sandoz's OCA. Attached as **Exhibit 2** is a true and correct copy of that correspondence. Amgen said in its response that "Amgen is prepared to receive, without delay, the required disclosures from Sandoz subject to the confidentiality provisions set forth in 42 U.S.C. § 262(1)(1)(A)." (Wu Decl. Ex. 2, at 1.) Amgen also noted that Sandoz had 20 days from notification of FDA acceptance to provide its BLA and manufacturing information, and that it appeared that Sandoz was proposing to exchange information independent of, as opposed to satisfying, the provisions of 42 U.S.C. § 262(l). (*Id.*) Regarding Sandoz's confidentiality concerns, Amgen stated that it was

amenable to negotiating further terms of confidentiality to the extent the statute was silent, either prior to or concurrent with Sandoz's required disclosures, as time permits. (*Id.* at 2.)

5. On July 25, 2014, Amgen provided Sandoz with a proposed revision to Sandoz's July 8th OCA. Attached as **Exhibit 3** is a true and correct copy of that correspondence. Amgen's proposed revision followed the BPCIA's requirements: providing for mutual confidentiality protections, making clear that Sandoz would provide access to its BLA and manufacturing information, and allowing access to confidential information by one or more outside counsel attorneys and one in-house counsel attorney. *See* Wu Decl. Ex. 3, Confidential Access Agreement. Amgen reiterated that "Amgen is prepared to receive, without delay, the required disclosures from Sandoz subject to the confidentiality provisions set for[th] in 42 USC 262(1)(1)(A) as we negotiate any further confidentiality provisions." (*Id.* at 1.)

6. In a letter dated July 25, 2014, but which Amgen received after that date, Sandoz provided a Second Offer of Confidential Access ("Second OCA"). Attached as **Exhibit 4** is a true and correct copy of Sandoz's correspondence. In its cover letter to the Second OCA, Sandoz said that "After very careful consideration of the BPCIA confidentiality and information exchange provisions, Sandoz has chosen to use the flexibilities contained therein and has opted not to provide Amgen with Sandoz's biosimilar application within 20 days of the FDA's notification of acceptance." (Wu Decl. Ex. 4, at 2.) Sandoz's Second OCA was the same as its first OCA, except that Sandoz revised the Second OCA to allow Amgen to evaluate the BLA for the purpose of determining whether to bring a legal action asserting one or more of Amgen's patents. (*See id.* at 4.)

7. On August 22, 2014, Amgen sent Sandoz a follow-up letter asking for Sandoz's response to Amgen's proposed revision to Sandoz's July 8th OCA. Attached as **Exhibit 5** is a true and correct copy of that correspondence. In its letter, Amgen pointed out that both Sandoz's first OCA and Second OCA attempted to narrow the scope of Sandoz's disclosures compared to that set forth in 42 U.S.C. § 262(l)(2)(A), and that the first OCA attempted to limit the statutory bases of infringement that Amgen could consider in reviewing the narrowed scope of information to be provided by Sandoz. (Wu Decl. Ex. 5, at 1.) Amgen reconfirmed its

"readiness to receive Sandoz's disclosure in full compliance with the confidentiality provisions of the statute," offer "to negotiate further confidentiality protections," and provision of "proposed revisions to Sandoz's July 8th OCA for use within the statutory scheme. (*Id.* at 2.)

8. In a letter dated September 4, 2014, Sandoz responded. Attached as **Exhibit 6** is a true and correct copy of that correspondence. Sandoz's response said that it remained prepared to provide its BLA to Amgen under the terms of its Second OCA, and that if Amgen would not agree to terms of the Second OCA, then Amgen's next step under the BPCIA could be only filing a declaratory judgment action. (Wu Decl. Ex. 6, at 2.) Sandoz did not address whether Amgen's proposed revisions to the July 8th OCA were acceptable, did not offer to provide its manufacturing information to Amgen as required by the statute, and also did not agree to comply with the terms of the BPCIA. (*See id.* at 1-2.)

9. On January 7, 2015, the FDA's Oncologic Drugs Advisory Committee (ODAC) recommended approval of Sandoz's biosimilar filgrastim product. Attached as **Exhibit 7** is a true and correct copy of the ODAC's briefing document.

10. The trade press reported extensively on ODAC's positive recommendation. For example, attached as **Exhibit 8** is a true and correct copy of Bryan Koenig, "FDA Panel Supports Sandoz's Biosimilar Application on Neupogen," *FDAnews Drug Daily Bulletin* (Jan. 12, 2015); **Dkt. No. 56-7** is a true and correct copy of Shannon Firth, "FDA Advisory Committee Endorses Neupogen Biosimilar," *Public Health & Policy* (Jan. 8, 2015); and **Dkt. No. 56-10** is a true and correct copy of Derek Gingery, "ODAC Asks Sandoz If Biosimilar Price Is Right," *The Pink Sheet Daily* (Jan. 7, 2015).

11. On February 9, 2015, Sandoz agreed to provide five days' advance notice of Sandoz's launch. Attached as **Exhibit 9** is a true and correct copy of that correspondence.

12. On February 19, 2015, two weeks after the court's scheduling order (Dkt. No. 55), the parties stipulated to an alternate briefing schedule and Hearing date of March 13, 2015. (Dkt. No. 63.) Sandoz also agreed that it will not launch its biosimilar filgrastim product in the United States until the earlier of April 10, 2015, or a ruling in Sandoz's favor on Amgen's

preliminary injunction motion. (*Id.* at 2.) The Court granted the parties' request to extend the deadlines on Amgen's motion for preliminary injunction. (Dkt. No. 64.)

13. On February 12, 2015, Sandoz noticed the deposition of Stuart Watt for February 17, 2015. Attached as **Exhibit 10** is a true and correct copy of Sandoz's Notice of Deposition of Stuart Watt. Then on February 16, 2015, I received an email from Sandoz's counsel Anders Aannestad cancelling the deposition of Stuart Watt scheduled for the next day. Attached as **Exhibit 11** is a true and correct copy of this email. Sandoz did not thereafter seek to examine Mr. Watt.

14. On March 6, 2015, the FDA approved Sandoz's BLA dated May 8, 2014, received May 8, 2014, submitted under section 351(k) of the Public Health Service Act for Zarxio (filgrastim-sndz); and granted Sandoz U.S. License No. 2003 under the provisions of section 351(k) of the Public Health Service Act controlling the manufacture and sale of biological products. Attached as **Exhibit 12** is a true and correct copy of the FDA's BLA Approval to Sandoz, available at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/125553Orig1s000ltr.pdf.

15. I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed the 6th day of March, 2015, at New York, New York.

Jennifer H. Wu

ATTESTATION

I, Vernon M. Winters, am the ECF user whose user ID and password are being used to file the foregoing document. Pursuant to Civil Local Rule 5-1(i)(3), I hereby attest that concurrence in the filing of this document has been obtained from Jennifer H. Wu.

Dated: March 6, 2015

By: /s/ Vernon M. Winters

EXHIBIT 20

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Vice President Law
Intellectual Property and Litigation

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July 25, 2014

Sent Via Facsimile to (609) 627-8684
UPS Next Day Air

Robin Adelstein
Vice President, Legal IP & Compliance
General Counsel, N.A.
Sandoz, Inc.
506 Carnegie Center, Suite 400
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RE: Sandoz Inc.'s FDA Application for its Biosimilar Filgrastim Product

Dear Ms. Adelstein:

I refer to my letter to you of July 18, 2014 regarding your notification to Amgen that Sandoz has filed an application for FDA approval of a filgrastim biosimilar product for which Amgen's NEUPOGEN® is the reference product.

We now understand from a July 24, 2014 press release posted on the Novartis website (http://www.novartis.com/newsroom/media-releases/en/2014/1835571.shtml), that Sandoz's application has been accepted for review by the FDA.

In anticipation of the receipt of a copy of the application and such other information that describes the process or processes used to manufacture the product that is the subject of the application pursuant to 42 USC 262(l), I enclose for your consideration, a Confidential Access Agreement to provide additional protection for one another's information.

I will be out of the office next week, and in my absence, please contact Lois Kwasigroch so that she may answer any questions regarding the proposed agreement and to assist you in directing Sandoz's confidential information to the appropriate attorneys. Her contact information appears below.

As I indicated in my previous letter, Amgen is prepared to receive, without delay, the required disclosures from Sandoz subject to the confidentiality provisions set for in 42 USC 262(l)(1)(A) as we negotiate any further confidentiality provisions.

Finally, if you are represented by outside counsel and would prefer that our counsel deals directly with them, please let us know.

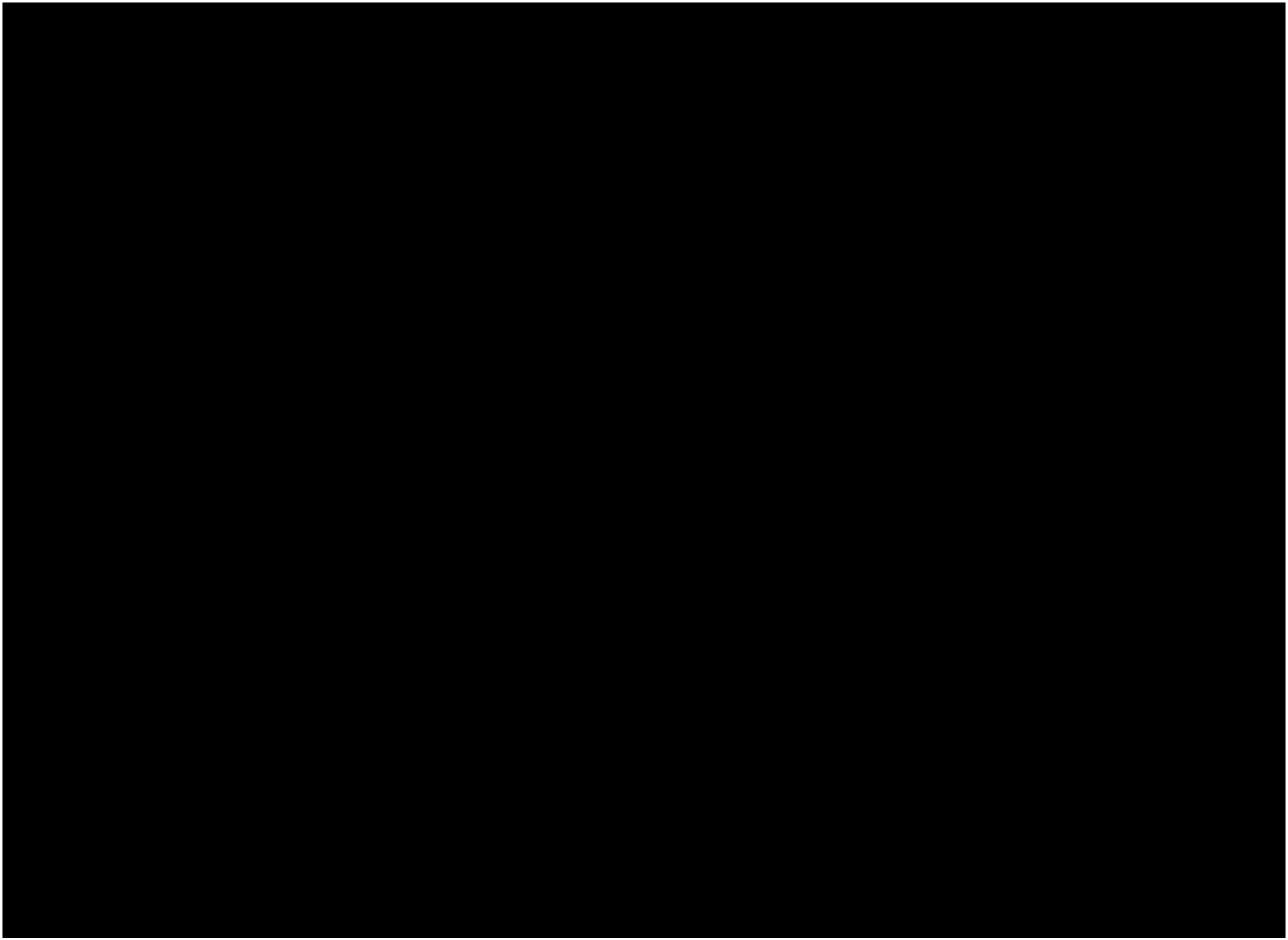
Sincerely,

WWhiteford /sp

Wendy A. Whiteford,
Vice President Law

cc: Lois Kwasigroch
Associate General Counsel
Lois.Kwasigroch@amgen.com
(805) 447-6265

EXHIBIT 21



CERTIFICATE OF SERVICE

I hereby certify that on this 28th of April, 2015, I caused the foregoing Non-Confidential Reply Brief of Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Ltd. in Support of Emergency Motion for Injunction Pending Appeal to be filed with the Clerk of the Court using the CM/ECF system. I also caused a true and correct copy of the Non-Confidential Reply Brief of Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Ltd. in Support of Emergency Motion for Injunction Pending Appeal to be electronically served on Defendant-Appellee Sandoz Inc.'s counsel of record, pursuant to agreement of the parties, as follows:

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