Case: 15-1499 Document: 110 Page: 1 Filed: 05/19/2015

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 RESPONSE OF PLAINTIFFS-APPELLANTS AMGEN INC. AND AMGEN MANUFACTURING LIMITED REGARDING BOND FOR INJUNCTION PENDING APPEAL

NICHOLAS GROOMBRIDGE ERIC ALAN STONE JENNIFER H. WU JENNIFER GORDON PETER SANDEL MICHAEL T. WU ARIELLE K. LINSEY PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP 1285 Avenue of the Americas

New York, New York 10019

(212) 373-3000

VERNON M. WINTERS ALEXANDER D. BAXTER SIDLEY AUSTIN LLP 555 California Street, Suite 2000

San Francisco, California 94104

(415) 772-1200

WENDY A. WHITEFORD LOIS M. KWASIGROCH KIMBERLIN L. MORLEY

AMGEN INC.

One Amgen Center Drive

Thousand Oaks, California 91320

(805) 447-1000

Attorneys for Plaintiffs-Appellants

Case: 15-1499 Document: 110 Page: 2 Filed: 05/19/2015

#### **CERTIFICATE OF INTEREST**

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:

Nicholas Groombridge
Eric Alan Stone
Jennifer H. Wu
Jennifer Gordon
Peter Sandel
Michael T. Wu
Arielle K. Linsey
PAUL, WEISS, RIFKIND, WHARTON
& GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

Vernon M. Winters Alexander D. Baxter SIDLEY AUSTIN LLP 555 California Street, Suite 2000 San Francisco, CA 94104 (415) 772-1200

Wendy A. Whiteford Lois M. Kwasigroch Kimberlin L. Morley AMGEN INC. One Amgen Center Drive Thousand Oaks, CA 91320 (805) 447-1000

/s/ Nicholas Groombridge

Case: 15-1499 Document: 110 Page: 3 Filed: 05/19/2015

#### **TABLE OF CONTENTS**

		<b>Page</b>
TAE	BLE OF AUTHORITIES	ii
INT	RODUCTION	1
I.	Sandoz's Proposed Bond is Excessive and Speculative	2
II.	Amgen's Proposed Bond Would Adequately Protect Sandoz	7
III.	Calculation of an Appropriate Daily Bond Amount	10

#### **CONFIDENTIAL MATERIAL OMITTED**

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 this response. Specifically, the material omitted on pages 1, 3-7, and 9-10 contains references to Sandoz's confidential information regarding sales, revenue, cost, and profit forecasts.

Case: 15-1499 Document: 110 Page: 4 Filed: 05/19/2015

### **TABLE OF AUTHORITIES**

CASES	<u>Page(s)</u>
CVI/Beta Ventures, Inc. v. Custom Optical Frames, Inc., 893 F. Supp. 508 (D. Md. 1995)	2
Int'l Equity Invs., Inc. v. Opportunity Equity Partners Ltd., 441 F. Supp. 2d 552 (S.D.N.Y. 2006)	2
Mead Johnson & Co. v. Abbott Labs., 201 F.3d 883 (7th Cir. 2000)	7

Case: 15-1499 onfidential Material Redacted 05/19/2015

#### **INTRODUCTION**

Sandoz wildly overstates the bond needed to protect it from the effects of a later-vacated injunction. The Court should reject Sandoz's inflated number.

Instead, Amgen respectfully submits that, if any bond is appropriate, the bond should track Sandoz's internal forecasts, and should be posted in stages, with the first tranche of million (or per day) to be posted now, covering Sandoz's expected sales revenue during ZARXIO<sup>®</sup>'s first three months on the market. If the Court has not resolved this appeal by the end of August in its merits opinion and subsequent mandate, then on September 1, 2015, Amgen would post a second tranche of million (or per day) to cover the next three-month period. Those amounts, taken from Sandoz's own projections, fully protect Sandoz, while affording the Court the opportunity to give this appeal—which presents significant issues of first impression—the appropriate attention.

Stepping back for a moment, Sandoz's submission implies that Sandoz accepted the risk that it would lose per day when it chose not to provide its Biologics License Application and manufacturing information to Amgen the BPCIA. That number cannot be supported by rational business decision-making. Nor can it be supported by the law, the record, or mathematics. Sandoz arrives at this oversized bond request by front-loading hoped-for profits over the next four and a half years, by awarding itself an unjustified premium for a supposedly lost

Case: 15-1499 Document: 110 Page: 6 Filed: 05/19/2015

first-mover-advantage, and by adding an arbitrary 20% cushion to "err on the high side." (Sandoz Br. at 9-10.)

If any bond is appropriate, the bond should be sufficient to ensure that Sandoz can be placed in the position it would have occupied had there been no injunction pending appeal. Amgen's proposal does that, by using Sandoz's projections for its sales revenue over the likely period of time for the injunction, and crediting Sandoz's assertion that "[a]ny bond should protect" Sandoz for losses "after June 1, 2015, because those losses are attributable to the injunction." (Sandoz Br. at 7.) A revenue-based calculation is less susceptible to arbitrary inflation and conjecture than is Sandoz's proposal—that Amgen post a bond now encompassing Sandoz's projected profits out to 2020.

#### I. Sandoz's Proposed Bond is Excessive and Speculative

Sandoz must demonstrate an appropriate amount for a bond. Speculative harm warrants no bond at all. "Claims based upon speculation or conjecture, including claims for profits from a business contemplated but not established, will not support an award of damages on the [Rule 65(c)] bond." *CVI/Beta Ventures, Inc. v. Custom Optical Frames, Inc.*, 893 F. Supp. 508, 525 (D. Md. 1995), *aff'd*, 92 F.3d 1203 (Fed. Cir.1996) (nonprecedential); *Int'l Equity Invs., Inc. v. Opportunity Equity Partners Ltd.*, 441 F. Supp. 2d 552, 565-566 (S.D.N.Y. 2006) (a court is not required to order a bond for "claimed economic damages that are no

Case: 15-1499 onfidential Material Redacted 05/19/2015

more than speculative"), aff'd, 246 F. App'x 73 (2d Cir. 2007) (nonprecedential).

Sandoz initially argues that a bond should cover three categories of damages: its lost sales, expenses it has already paid and will not be able to use if enjoined, and the impact of other biosimilar competitors entering the filgrastim market. (Sandoz Br. at 3.) To create an impression that a lot of Sandoz's future earnings are at stake, Sandoz throws datum after datum at the Court, including: million in net sales for 2015 and 2016, "gross profit" of \$ million, million in damages for an injunction of up to 410 days, \$ million in lost profits through May 2016, \$ million in lost profits from 2015 to 2020, \$ million in "infrastructure costs" in 2015 and \$ million in the first three months of 2016, "stranded investments" of \$ million, \$ of "unusable inventory," and so on. (Id. at 3, 5, 6, 9.) Many of these figures overlap with each other. For example, the \$ million that Sandoz calls "lost profits" is actually gross profits, i.e., sales revenue minus cost of goods sold, without deduction for salaries and fixed costs. The \$ million "lost profits" figure, while encompassing the same time period, appears to be some other calculation, the basis for which Sandoz and its expert do not reveal.

Ultimately, however, Sandoz relies on only two numbers: (i) its expert's calculation of "\$ million in damages for an injunction of up to 410 days," which equals \$ per day and which Sandoz says includes lost profits,

sunken costs, and the impact of biosimilar competition, and (ii) a 20% adjustment up from that number to "err on the high side." (*Id.* at 9.) That gets Sandoz to per day, which it rounds up to \$460,000 per day "for simplicity," for a total of \$179,400,000 over 390 days. (*Id.* at 10 & n. 4.)

Sandoz's number wildly overstates the amount Sandoz actually has at stake here, and should be rejected.

#### 390 Days Is Far Longer Than Needed to Issue a Merits Opinion:

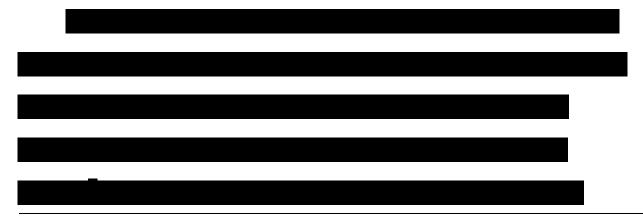
Sandoz suggests that the Court may take a year to issue an opinion on the merits, and thus asks Amgen to post a bond that covers 390 days of Sandoz's purported losses. (*Id.* at 10.) This is baseless. In recent cases with expedited briefing, as is the case here, the Court's average time from oral argument to an opinion on the merits was 58 days and the median time was 61 days.<sup>1</sup> Thus, the Court should not order a bond based on a 390-day calculation.

\_

Amgen has identified sixteen expedited cases: *AstraZeneca LP v. Breath Ltd.* (Appeal No. 15-1335) (3 days from oral argument to opinion on the merits); *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.* (Appeal No. 15-1139) (117 days); *CGI Federal v. United States* (Appeal No. 14-5143) (35 days); *Smith & Nephew Inc. v. Arthrex, Inc.* (Appeal No. 14-1729) (72 days); *Antares Pharma Inc. v. Medac Pharma Inc.* (Appeal No. 14-1648) (70 days); *Ferring B.V. v. Watson Labs., Inc.* (Appeal No. 14-1377) (73 days); *VirtualAgility Inc. v. Salesforce.com, Inc.* (Appeal No. 14-1232) (121 days); *Vascular Solutions, Inc. v. Boston Scientific Corp.* (Appeal No. 14-1185) (7 days); *Endo Pharms. Inc. v. Roxane Labs., Inc.* (Appeal No. 13-1662) (81 days); *GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.* (Appeal No. 13-1662) (48 days); *Shire Dev., LLC v. Watson Pharms., Inc.* (Appeal No. 13-1409) (116 days); *Lupin Atlantis Holdings v. Mylan Inc.* (Appeal No. 13-1141) (6 days); *Apple Inc. v. Samsung Elecs. Co.* 

Sandoz Improperly Distributes Damages: Sandoz calculates a daily bond amount by dividing by 390 its supposed damages from now until 2020, a period of four and a half years. That ignores reality. ZARXIO® will be new to the United States market and, like other new biological products, its uptake will grow over time. Sandoz's own internal projections demonstrate this. Sandoz's forecasted gross sales for June 2015 (\$ million) are a fraction of those in December 2015 (\$ million). See Olson Decl. Ex. A. By equating each of the next 390 days, Sandoz ignores the ramp-up that would occur in the real world, and "protects" itself from damages it would not incur, if ever, until long after this appeal is over.

Lost Profits Are the Wrong Measure of Damages: Sandoz seeks to have Amgen post a bond to cover both Sandoz's lost profits and Sandoz's "stranded" costs, such as employee salary, marketing materials, and supposedly unusable drug product. That is the wrong approach, for two reasons.



(Appeal No. 12-1507) (52 days); Butamax(TM) Advanced Biofuels LLC v. Gevo, Inc. (Appeal No. 12-1490) (7 days); Sanofi-Aventis Deutschland GmbH v. Genentech, Inc. (Appeal No. 12-1454) (122 days); and Allergan, Inc. v. Watson Labs., Inc. (Appeal No. 12-1310) (4 days).

Case: 15-1498 on Focument: 110 rage: 10 actied: 05/19/2015

Second, separating "profits" and "expenses" risks double-counting, and it is not clear from Sandoz's "profit" calculations what expenses are included or excluded. The simpler approach, which Amgen applies below, is to have the bond cover revenue: the amount of money that Sandoz projects it would have received from customers after discounts and rebates.

If Sandoz is protected against losing that revenue by a bond, and can prove damages, then it may use the lost revenue recovered from the bond to pay its costs, just as it would have done in the but-for world in which there was no injunction. Awarding Sandoz more money than it would have received absent an injunction would be an undue windfall.

Other Biosimilar Competitors Do Not Change the Analysis: Sandoz says that it should be compensated for the loss of first-mover advantage, because other biosimilar competitors will enter the market during the injunction period. Its \$179 million figure supposedly reflects the impact of this competition. There is no such impact. Sandoz is not the first competitor to Amgen in the filgrastim market;

Case: 15-1498 on Focument: 1110 Page: 11 acfiled: 05/19/2015

Teva's GRANIX® product has been on the market since 2013. Furthermore, Sandoz's \$179 million figure is highly speculative, resting on cascading assumptions that: (i) Sandoz continues to lose profits until 2020, a calculation based on assumptions about a five-competitor market over four years; (ii) Apotex's filgrastim product is approved by FDA and launches in the fourth quarter of 2015; (iii) Hospira files a BLA, gets approval, and launches its own filgrastim product before June, 2016; and (iv) this Court decides this appeal after June, 2016. Basing a bond on this parade of hypotheticals would be improper speculation.

There Is No Basis For a 20% Cushion: Sandoz's baseline daily calculation of \$ is improper for the reasons above. Sandoz then inflates that by 20%, to "err on the high side." (Sandoz Br. at 9-10.) There is no basis for that inflation. The only case Sandoz cites (*id.*), *Mead Johnson & Co. v. Abbott Labs.*, 201 F.3d 883, 888 (7th Cir. 2000), says nothing about a 20% increase, or any increase, above calculated possible losses.

#### II. Amgen's Proposed Bond Would Adequately Protect Sandoz

The Court's order asked the parties to specify "what amount of a bond, if any, should be posted for each day that the injunction is in place." (Dkt. No. 105 at 2.) Given that ZARXIO® is a new product, that the injunction is expected to be short, and that Amgen has sufficient resources to pay any damages award, the Court could fairly conclude that no bond is needed. If the Court is inclined to

order Amgen to post a bond, however, Amgen submits the bond should reflect the revenue Sandoz forecasts that it would have received during the injunction period.

The Length of the Injunction Pending Appeal: When considering a well-established product with a proven track record, using a daily-rate bond might make the length of an injunction of secondary importance. Here, however, where Sandoz is introducing a new product with a projected non-linear sales curve, the estimated length of the injunction materially affects the total harm to Sandoz that might accrue if it is later determined that the injunction was wrongly granted.

In the expedited appeals that Amgen has been able to identify, *see supra* n.1, this Court has averaged 58 days from oral argument to an opinion on the merits, with 75% of those opinions issued within three months after the oral argument. No case took even remotely close to the 390 days that Sandoz predicts. Amgen therefore respectfully submits that a daily bond rate should be calculated using Sandoz's projected revenue for the first three months that ZARXIO® would be on the market. If the Court has not resolved the appeal in a merits opinion and subsequent mandate when those three months end, Amgen would then post a second bond to cover the next three months, using Sandoz's projections for that second three-month period. This would equitably protect Sandoz and afford the Court flexibility to take the time it wishes to resolve this important appeal.

Sandoz's Projected Revenue During the Next Six Months: Amgen suggests that any bond should be based not on Sandoz's lost profits but on predicted lost revenue. That would account for the sales staff salaries, unusable inventory, marketing materials, and other "stranded costs" Sandoz identifies, but avoid the risk of double-counting these expenses inherent in deciding what portion of revenue is actually "profit." If Sandoz receives as damages the revenue those costs would have generated, it is not harmed by having incurred the costs.

Calculating lost revenue can be complicated, because biological products have both a Wholesale Acquisition Cost and, for established products, an Average Sales Prices reflecting often-substantial discounts and rebates. A proper measure for this bond is the amount Sandoz would have collected from its customers, after discounts and rebates. Sandoz itself calculates that number by multiplying its forecasted sales volume by its Wholesale Acquisition Cost and then applying a Gross-to-Net or "GTN" reduction, which for ZARXIO<sup>®</sup> is % for 2015 and % for 2016. (Sandel Decl. Exs. 1, 2, and 3.) Amgen proposes to adopt Sandoz's calculation. Using the gross sales reflected in Exhibit A to Sandoz's Olson Declaration, and applying Sandoz's GTN reduction, net revenues for ZARXIO<sup>®</sup> would be \$ million for the first month on the market, \$ second month, \$ million for the third month, \$ month, \$ million for the fifth month, and \$ million for the six month. That

### Case: 15-1498 on Focument: 110 Page: 14 actied: 05/19/2015

these revenues total \$ million for ZARXIO®'s first six months on the market further confirms how far off base Sandoz is in seeking a \$179 million bond.<sup>2</sup>

#### III. Calculation of an Appropriate Daily Bond Amount

That three-month inflection point coincides well with the Court's historical time to decide expedited-briefing cases. Amgen therefore proposes to divide any bond into two three-month tranches, as follows:

<u>June 1, 2015 to August 31, 2015</u>:

\$ million (total), or daily

September 1, 2015 to November 30, 2015: \$ million (total), or daily

If the Court imposes a bond using these data, Amgen would propose to post a bond for the full amount of the first three-month period in response to the Court's order. If, by September 1, 2015, the Court has not resolved this appeal, Amgen would then post the second bond, in a higher amount to reflect what Sandoz predicted would be its higher sales in its fourth through sixth months on the market.

<sup>&</sup>lt;sup>2</sup> These data actually tilt a bit in Sandoz's favor: the first-month figures reflect preorders. Sandoz presumably has not accepted any pre-orders, since it has been stipulating not to launch ZARXIO<sup>®</sup> since before it received FDA approval on March 6, 2015. Removing pre-orders from Sandoz's forecasts, however, would require speculation. Amgen therefore adopts Sandoz's calculations as-is.

Dated: May 19, 2015 Respectfully submitted,

/s/ Nicholas Groombridge
Nicholas Groombridge
Eric Alan Stone
Jennifer H. Wu
Jennifer Gordon
Peter Sandel
Michael T. Wu
Arielle K. Linsey
PAUL, WEISS, RIFKIND, WHARTON
& GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

Vernon M. Winters Alexander D. Baxter SIDLEY AUSTIN LLP 555 California Street, Suite 2000 San Francisco, CA 94104 (415) 772-1200

Wendy A. Whiteford Lois M. Kwasigroch Kimberlin L. Morley AMGEN INC. One Amgen Center Drive Thousand Oaks, CA 91320 (805) 447-1000

Attorneys for Plaintiffs-Appellants

**EXHIBITS IN SUPPORT OF RESPONSE** 

### **INDEX OF EXHIBITS**

Ex.	Description	Date Filed	Appendix No.
	Declaration of Peter Sandel in Support of Response of Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Limited Regarding Bond for Injunction Pending Appeal		
1.	Deposition Transcript of Alexander Thole, Sandoz Inc.'s Executive Director of Oncology Sales and Marketing, dated February 26, 2015 (selected pages)		
2.	Exhibit 27 to the deposition of Alexander Thole: a document produced by Sandoz Inc. bearing production number SDZ(56)0201442		
3.	Exhibit 28 to the deposition of Alexander Thole: a document produced by Sandoz Inc. bearing production number SDZ(56)0201358.		

Case: 15-1499 Document: 110 Page: 18 Filed: 05/19/2015

#### **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

#### DECLARATION OF PETER SANDEL IN SUPPORT OF RESPONSE OF PLAINTIFFS-APPELLANTS AMGEN INC. AND AMGEN MANUFACTURING LIMITED REGARDING BOND FOR INJUNCTION PENDING APPEAL

- I, Peter Sandel, declare and state as follows:
- 1. I am an attorney admitted to the bar of this Court, and a counsel 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 Declaration, and if called upon as a witness, I could and would testify competently as to these facts.

Case: 15-1499 Document: 110 Page: 19 Filed: 05/19/2015

2. Attached hereto as Exhibit 1is a true and correct copy of excerpts from the February 26, 2015, deposition transcript of Alexander Thole in *Amgen Inc. v. Sandoz Inc.*, No. 3:14-CV-04741-RS (N.D. Cal.) (the "District Court Action").

- 3. Attached hereto as Exhibit 2 is a true and correct copy of the document marked as Exhibit 27 at the February 26, 2015 deposition of Alexander Thole in the District Court Action. The document is titled "BioPharma Strat Plan GTN Workbook Zarxio 2016 Projected GTN" and was produced in native form by Sandoz Inc. ("Sandoz") bearing the production number SDZ(56)0201442.
- 4. Attached hereto as Exhibit 3 is a true and correct copy of the document marked as Exhibit 28 at the February 26, 2015 deposition of Alexander Thole in the District Court Action. The document is titled "BioPharma GTN Workbook Zarxio 2015 Projected GTN" and was produced in native form by Sandoz bearing the production number SDZ(56)0201358.
- 5. Exhibits 1, 2, and 3 contain sales projections, cost and profit estimates that Sandoz designated as highly confidential in the District Court Action. For this reason, Amgen is submitting the publicly filed versions of Exhibits 1, 2, and 3 in redacted form.

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

Executed on May 19, 2015 in New York, New York.

Peter Sandel

**EXHIBIT 1** 

## HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY ALEXANDER THOLE - 2/26/2015

Page 271

1	time is 3:30. This concludes tape	03:30:54
2	number five. We're off the record.	03:30:57
3		03:30:58
4	(A recess was taken at this time.)	03:30:58
5		03:41:45
6	THE VIDEO OPERATOR: The	03:41:50
7	time is 3:41. This is the start of	03:41:50
8	tape number six. We're on the record.	03:41:53
9	BY MR. STONE:	03:41:57
10	Q. Mr. Thole, I'm going to print out	03:41:57
11	two I'm going to mark two spreadsheet	03:41:59
12	printouts, one as Exhibit 27, and the other is	03:42:05
13	Exhibit 28. They were produced respectively as	03:42:09
14	SDZ(56)201442 and 201358. I'm going to hand	03:42:13
15	them both to you and my first question in the	03:42:23
16	first instance as to each of them is have you	03:42:25
17	ever seen them before. The answer might be no.	03:42:28
18	Aside from your preparation for your	03:42:31
19	deposition.	03:42:32
20	A. Okay.	03:43:41
21		03:43:41
22	(Spreadsheet Bates SDZ(56)0201442	03:43:41
23	marked Exhibit 27 and Spreadsheet Bates	03:43:41
24	SDZ(56)0201353 marked Exhibit 28 for	03:43:41
25	identification.)	03:43:41

Merrill Corporation

### Case: 15-1499 on Focument: 1/10 e Page: 23 ac Filed: 05/19/2015

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY ALEXANDER THOLE - 2/26/2015

	-	1
1		03:43:41
2	BY MR. STONE:	03:43:41
3	Q. So with respect to Exhibit 27, the	03:43:42
4	larger of the two in terms of its print format,	03:43:44
5	have you ever seen that before today aside from	03:43:47
6	your deposition preparation?	03:43:49
7	A. Yes.	03:43:51
8	Q. And what is this document?	03:43:52
9	A. This is a gross to net analysis for	03:43:53
10	the strat plan.	03:43:55
11	Q. A gross to net analysis for the	03:43:58
12	strategic plan?	03:44:00
13	A. Yes.	03:44:01
14	Q.	03:44:02
15		03:44:07
16	A. I don't know where you are looking	03:44:09
17	at.	03:44:10
18	Q. Fair enough. Let me direct you to	03:44:10
19	the second page of the document.	03:44:12
20	A. Yes.	03:44:13
21	Q. A page entitled biopharma strat	03:44:15
22	plan GTN workbook, Zarxio. Do you see that?	03:44:16
23	A. Yes.	03:44:19
24	Q. And GTN there is gross to net?	03:44:19
25	A. Correct.	03:44:23

## Case: 15-1499 on Focument: 1/10 Page: 24 actied: 05/19/2015

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY ALEXANDER THOLE - 2/26/2015

1		-	
	1	Q. And directing you to the page, the	03:44:23
	2	little table at the top of this page, total	03:44:26
	3	G-N, am I correct that that's total gross to	03:44:29
	4	net?	03:44:34
	5	A. Correct.	03:44:34
	6	Q.	03:44:35
	7	A.	03:44:36
	8	Q.	03:44:36
	9		03:44:40
	10	A.	03:44:42
	11		03:44:44
	12	Q.	03:44:46
	13		03:44:49
	14		03:44:53
	15	A.	03:44:56
	16	Q.	03:44:57
	17		03:44:58
	18	A.	03:44:58
	19		03:45:00
	20	Q. Okay. And that is the relation,	03:45:00
	21	God bless you, total gross to net is the	03:45:05
	22	relationship between the WAC price and the net	03:45:08
	23	price after discounts?	03:45:11
	24	A. After discounts, distribution	03:45:14
	25	expense.	03:45:16
		<del>-</del>	

## Case: 15-1490 onfidential Material Redacted: 05/19/2015

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY ALEXANDER THOLE - 2/26/2015

		1
1	Q. Are rebates included within	03:45:18
2	discounts for that purpose?	03:45:22
3	A. Yes.	03:45:24
4	Q.	03:45:24
5		03:45:27
6	MR. OLSON: Could we put	03:45:31
7	this aside? Is that a different	03:45:32
8	question?	03:45:33
9	MR. STONE: Leave it there,	03:45:35
10	but it is not a question related to	03:45:35
11	this document. Withdrawn.	03:45:37
12		03:45:40
13		03:45:42
14		03:45:44
15	THE WITNESS:	03:45:45
16		03:45:46
17	BY MR. STONE:	03:45:46
18	Q.	03:45:47
19		03:45:49
20		03:45:51
21		03:45:55
22	A. I'm not sure I understand the	03:45:59
23	question.	03:46:00
24	Q.	03:46:01
25		03:46:02
-		-

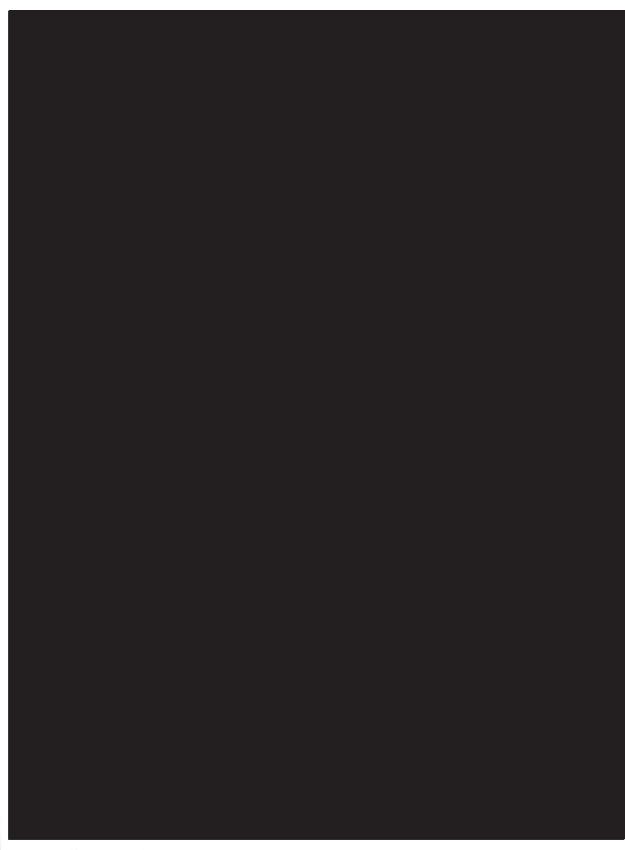
## HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY ALEXANDER THOLE - 2/26/2015

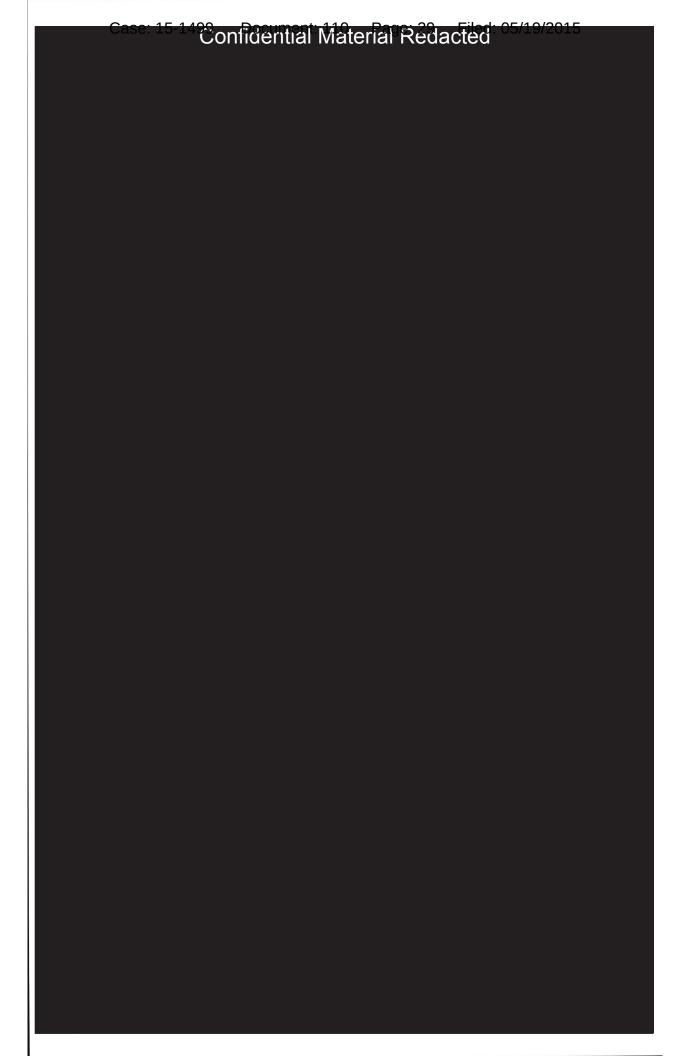
1	or not.	03:47:46
2	Q. Right. Looking at the second	03:47:46
3	document.	03:47:48
4	A. Uh-huh.	03:47:49
5	Q. Exhibit 28, have you ever seen this	03:47:51
6	before prior to your preparation for your	03:47:52
7	deposition?	03:47:54
8	A. Yes.	03:47:54
9	Q. And what is this?	03:47:54
10	A. This is the biopharma gross to net	03:47:57
11	workbook for Zarxio for 2015.	03:47:59
12	Q. Oh, I see the previous one was	03:48:04
13	2016?	03:48:06
14	A. Through '20.	03:48:07
15	Q. Got it. I want to go back to the	03:48:08
16	ODAC meeting for a moment. Do you know whether	03:48:18
17	any materials were provided to Mr. McCamish in	03:48:22
18	advance of the ODAC meeting to prepare him for	03:48:25
19	it?	03:48:29
20	A. Yes.	03:48:34
21	Q. What was provided to him?	03:48:36
22	A. I don't know the full range of	03:48:38
23	materials.	03:48:40
24	Q. Do you know whether he received any	03:48:41
25	materials that talked about pricing?	03:48:44

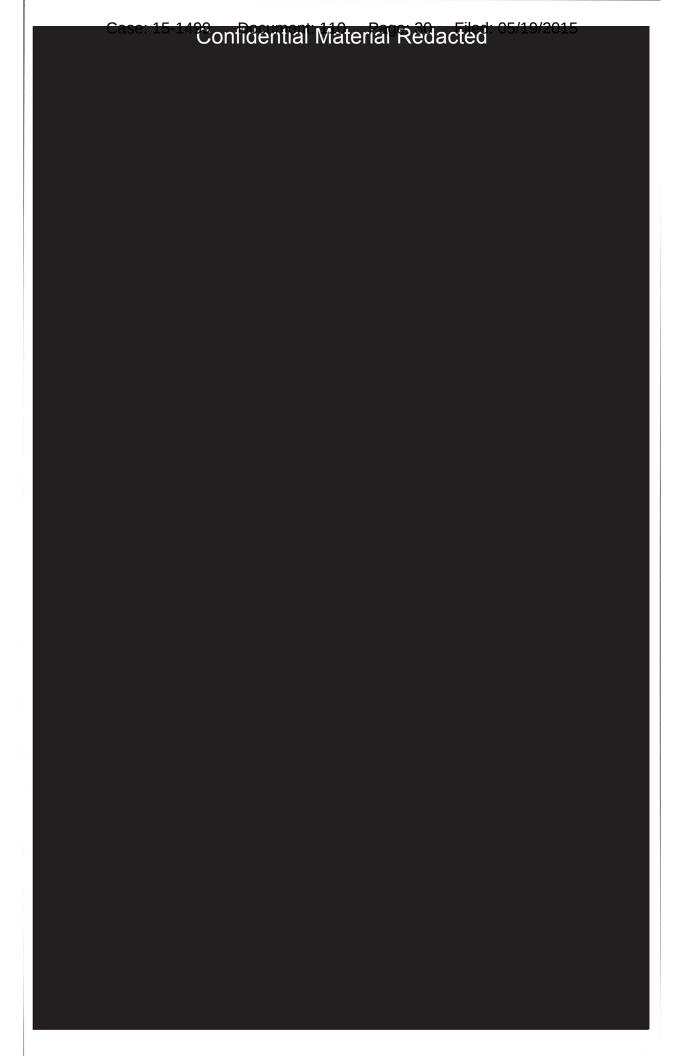
**EXHIBIT 2** 

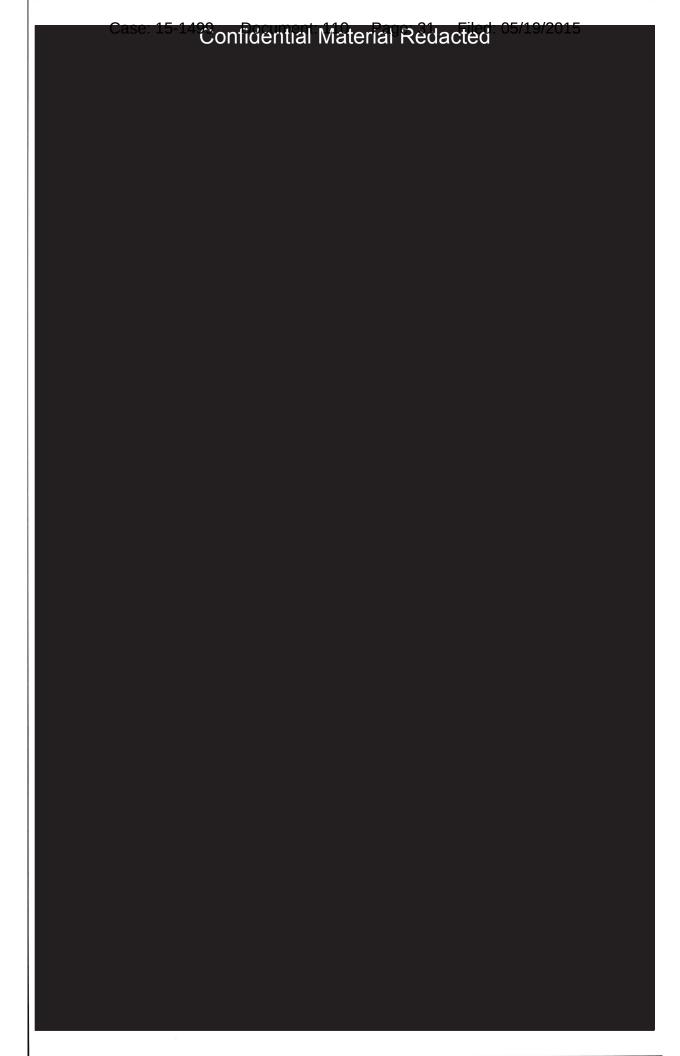
Case: 15-1498 on Focument: 110 terral Redacted: 05/19/2015





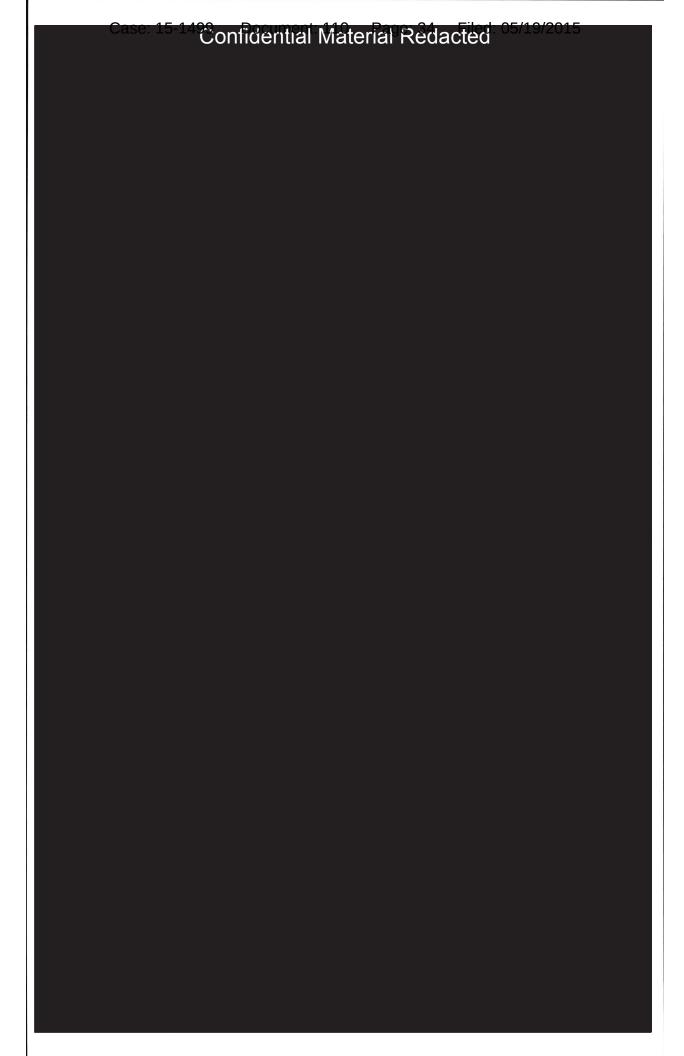






Case: 15-149 Confidential Material Redacted: 05/19/2015

Case: 15-14 Confidential Material Redacted 05/19/2015







**EXHIBIT 3** 

Case: 15-1498 on Focument: 110 terral Redacted: 05/19/2015



Case: 15-1499 Document: 110 Page: 39 Filed: 05/19/2015



Case: 15-1499 Confidential Material Redacted

Case: 15-1498 Confidential Material Redacted: 05/19/2015

Case: 15-1499 Document: 110 Page: 43 Filed: 05/19/2015

#### **CERTIFICATE OF SERVICE**

I hereby certify that on this 19th of May, 2015, I caused the foregoing Non-Confidential Response of Plaintiffs-Appellants Amgen, Inc. and Amgen Manufacturing Limited Regarding Bond 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 foregoing Non-Confidential Response of Plaintiffs-Appellants Amgen, Inc. and Amgen Manufacturing Limited Regarding Bond 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:

Deanne E. Maynard (dmaynard@mofo.com)
Marc A. Hearron
(mhearron@mofo.com)
Joseph R. Palmore
(jpalmore@mofo.com)
MORRISON & FOERSTER LLP
2000 Pennsylvania Ave., N.W.
Suite 6000
Washington, D.C. 20006

Rachel Krevans (rkrevans@mofo.com) MORRISON & FOERSTER LLP 425 Market Street San Francisco, CA 94105

> Maryna Sapyelkina Coupsel Press