No. 2007-1280

United States Court of Appeals for the Federal Circuit

AVENTIS PHARMA S.A. AND AVENTIS PHARMACEUTICALS, INC.,

Plaintiffs-Appellants,

V.

AMPHASTAR PHARMACEUTICALS, INC.,

Defendant-Appellee,

AND

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellee.

Appeal From the United States District Court
for the Central District of California in Case No. 03-CV-887,
Senior Judge Mariana R. Pfaelzer

BRIEF OF *AMICUS CURIAE* SANDOZ, INC. REQUESTING AFFIRMANCE IN SUPPORT OF DEFENDANT-APPELLEES

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CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae*, Sandoz, Inc., pursuant to Rule 47.4 of the Rules of this Court, certifies the following:

1. The full name of every party or amicus represented by this firm is:

SANDOZ, INC.

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 this firm is:

N/A.

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

   Sandoz, Inc. is ultimately wholly owned by Novartis AG, which trades on the New York Stock Exchange (NYSE), under ticker symbol (NVS).

   There are no publicly held companies between Sandoz, Inc. and Novartis AG.

4. **The names of all law firms and the partners or associates that appeared for the party or amicus now represented by this firm in the trial court or agency or are expected to appear in this court are:**

   Meredith Martin Addy, Glen P. Belvis, Kelly J. Eberspecher, Richard D. Watkins, and C. Noel Kaman of BRINKS HOFER GILSON & LIONE.

August 30, 2007

Meredith Martin Addy

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I. INTEREST OF *AMICUS CURIAE*[1]

Sandoz, Inc. ("Sandoz"), a leader in the generic pharmaceuticals industry and one of the largest manufacturers and distributors of generic pharmaceuticals in the United States, is seeking approval from the United States Food and Drug Administration ("FDA") to market a generic version of enoxaparin based on its abbreviated new drug applications ("ANDAs"). Aventis S.A. and Aventis Pharmaceuticals, Inc. (collectively, "Aventis") allege that by filing these ANDAs Sandoz infringes the patents at issue on appeal.[2]

Desperate to maintain its exclusivity on enoxaparin, Aventis continues enforce its alleged patent rights. Even after this Court held Aventis made "material omissions" during prosecution, Aventis sued Sandoz. *E.g., Aventis Pharma S.A. v. Sandoz, Inc.*, No. 06-cv-4858 (C. D. Cal. filed August 4, 2006) (ANDA No. 77-857). Then, *after* the district court entered its final judgment

[1] The parties _____to the filing of this brief. No party authored the brief in whole or in part or contributed monetarily to its preparation or submission.

[2] The patents on appeal, U.S. Patent No. 5,389,618 (the "'618 patent") and U.S. Reissue Patent No. 38,743 (the "'743 patent", collectively, the "enoxaparin patents"), are at issue in the *Aventis v. Sandoz* cases.

of unenforceability, Aventis sued Sandoz *again*. *Aventis Pharma S.A. v. Sandoz, Inc.*, No. 07-cv-3658 (C.D. Cal. filed June 6, 2007) (ANDA No. 78-660). Yet, Sandoz is not a party to this appeal.

Aventis recognizes Sandoz's interest in this appeal by acknowledging that this appeal may affect the district court cases pending against Sandoz. Brief of Plaintiffs-Appellants at iv, "Statement of Related Cases," *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, No. 2007-1280 (Fed. Cir. filed June 25, 2007) ("*BlueBr.*").

II. SUMMARY OF THE ARGUMENT

None of the parties here dispute the standard for finding inequitable conduct; none of the parties call for the law to be changed. Aventis merely argues the facts. Yet, the facts here show a pattern of omissions and misstatements to the PTO — a pattern of conduct that Aventis continues at the district court through new litigations and correspondence to the FDA. Aventis's pattern of conduct harms the public because, in its attempt to keep generic enoxaparin off the market, Aventis failed to plead before the district court and failed to inform the agency about the unenforceable status of the patent it asserts. This conduct is not appropriate, especially in light of the high standard of review Aventis faces before this Court.

III. ARGUMENT

A. The District Court Did Not Abuse Its Discretion By Finding Aventis Committed Inequitable Conduct

Aventis faces substantial obstacles on appeal. To succeed, Aventis must ultimately show that the district court abused its discretion.[3] Aventis cannot, and does not, contest the high materiality of its omission of the dosage information before the PTO. *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 176 Fed. Appx. 117, 120, 122-23 (Fed. Cir. 2006); *see also* A7-8, 29, 38-39, 42. Nor is Aventis likely to overcome the district court's credibility determinations. *See Schinzing v. Mid-States Stainless, Inc.*, 415 F.3d 807, 813 (Fed. Cir. 2005), *cert. denied*, 546 U.S. 1173, 126 S.Ct. 1337 (2006); *ARedBr.* at 24-25; *TRedBr.* at 35-36. In addition to those obstacles, Aventis fails to identify any legal error of the district court.

Rather, focusing on the facts, Aventis merely argues that the district court "clearly erred by holding that Dr. Uzan intended to deceive the PTO."

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[3] Pursuant to FED. R. CIV. P. 29(4), Sandoz relies on Amphastar's and Teva's recitation of the standard of review. *Brief of Defendant-Appellee Amphastar Pharmaceuticals., Inc.* at 23 ("*ARedBr.*"), and *Brief of Defendant-Appellee Teva Pharmaceuticals USA, Inc.* at 29 ("*TRedBr.*"), *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, No. 2007-1280 (Fed. Cir., filed Aug. 21, 2007).

BlueBr. at 45. Indeed, Aventis seeks to overcome the district court's holding of unenforceability by relying on evidence that allegedly establishes that Dr. Uzan's half-life comparisons, which relied on undisclosed different doses of the compared compositions, were "scientifically" reasonable and therefore his omission was only inadvertent. *Blue Br.* at 4-5. Yet, that argument cannot withstand scrutiny.

In this case, the judge provided a thorough, 40-page opinion, issued after entertaining pre-trial motions, considering the trial briefs of the parties, conducting a 4-day bench trial, and considering the parties' the post-trial arguments, all on the issue of intent. In that opinion, the court held that "clear and convincing evidence adduced at trial independently reestablishes – and substantially strengthens – those earlier inferences of intent" to deceive the PTO. A39. Thus,

> "[b]ut for Dr. Uzan's intentional omissions, the probability is high that the '618 patent would not have issued. The '618 patent must therefore be found to be unenforceable on the ground of inequitable conduct."

A42.

According to the court, "Dr. Uzan's [clinical relevance] explanation suffers from a total absence of indicia of credibility." A40. The court based its findings on the fact that:

(1) Dr. Uzan's clinical relevance justifications for his omission clearly are unrelated to patentability while

(2) Dr. Uzan's omission clearly relates to patentability.

A14, 20, 21, 22 n.11, 23, 35, 36, 39.

Aventis's argument that the court erred by focusing solely on the anticipation rejection, *BlueBr.* 4, 5, 32, is simply a distraction; the court focused on whether the evidence demonstrated that Dr. Uzan intended to deceive the PTO about the *patentability* of the claimed compositions. A22, 25, 39; *see also ARedBr.* at 31-32 40; *TRedBr.* at 48-53. Indeed, the district court properly found that Dr. Uzan intended to deceive the PTO that the claimed compounds were patentable, when they were not. A14, 20, 21, 22, n.11, 23, 35, 36, 39; *see also Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1366-67 (Fed. Cir. 2007) (finding intent to deceive the PTO because omitted test data "related to 'the heart of the question that bedeviled the examiner: the nature of the difference between [the claimed oil and the prior art oil.]'").

1. Aventis Misstates The Intent Inquiry

According to Aventis, "resolving Dr. Uzan's intent turns on whether he used his different-dose comparison to demonstrate clinical advantage or compositional difference." *BlueBr*. at 20. But that is not the test. Rather, the proper test is whether Dr. Uzan should have known that the **PTO** would view his omissions as **material to the patentability** of the claimed compositions.

Because Dr. Uzan should have known this,[4] the court properly found Dr. Uzan intended to deceive the PTO. *Cargill,* 476 F.3d at 1366-67; *see also Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997) ("[i]ntent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the patent application.").

a. Dr. Uzan's Clinical Relevance Justifications Are Insufficient To Show Lack Of Intent Because They Are Unrelated To Patentability

Contrary to Aventis's arguments, intent to deceive does not turn on whether one's actions are "scientifically reasonable," "clinically relevant," or even consistent with "standard practice in the field of the invention." *BlueBr.* at 2, 11, 13, 15, 37, 45-47. None of those has anything to with whether Dr. Uzan intended to deceive the PTO. *Cargill*, 476 F.3d at 1366-67.

Aventis's attempts to excuse its material omission by offering clinical relevance justifications must fail. Aventis argues Dr. Uzan could not have the requisite intent to deceive the PTO because Dr. Uzan reasonably based his

[4] As a scientist, Dr. Uzan would have known that concealing the dosage data was a highly material omission. Aventis's own expert testified such an omission was "scientifically unreasonable." A37.

different-dose half-life comparison on his awareness of other studies and "real-world assessments." *BlueBr.* at 9-11, 13. Yet a closer examination reveals the opposite. Some of Dr. Uzan's clinical relevance justifications are simply misleading:

- Allegedly, Dr. Uzan "made exactly the same kinds of [different-dose half-life] comparisons" that were made in "contemporary publications." *BlueBr.* at 12.

  But: Unlike Dr. Uzan's comparisons, every "contemporaneous publication" *explicitly disclosed the dosages compared. TRedBr* at 42-43.

- Dr. Uzan's "aim . . . was to compare clinically relevant doses." *BlueBr.* at 13.

  But: "there was no evidence that 60 mg was the 'clinically relevant dose' for the prior art" composition. *ARedBr.* at 5-6, n.1, 2.

While other justifications are unrelated to patentability:

- Allegedly, the 40 mg dose "was the clinically relevant dose (i.e. the dose with the best efficacy-safety ratio) for the most challenging indication (i.e. prevention of [deep vein thrombosis] DVT in high-risk surgery)." *BlueBr.* at 13.

  But: The patents never disclose that only certain doses are clinically relevant, nor that only certain doses are useful only for certain applications. *ARedBr.* at 8. Nor are the claims limited to any dose or use. A255-56, 268-69

  Further, Dr. Uzan omits from his declarations that: Only the 40 mg dose of the claimed composition compared to the 60 mg dose of the prior art composition showed a statistically significant difference; other comparisons between 60 mg of the prior art

composition and doses of the claimed compound did not show any significant difference. A28.

- Aventis argues Dr. Uzan did not choose the 60 mg dose of the claimed compound for his comparison because it "'induced some bleeding' in patients undergoing high-risk surgery." *BlueBr.* at 14.

  But: The '618 patent represents that every dose may induce bleeding: "the mixtures thereby obtained have a favorable ratio of the fractions of high to those of low molecular weights, which endows them with the requisite antithrombotic properties with but slight risk of hemorrhagic effect." *ARedBr.* at 8; A252, col. 3, ll 31-35.

Thus, the district court aptly rejected Dr. Uzan's argument that he selected the 40 mg dose based on its clinical relevance. Other clinically relevant doses were known to Dr. Uzan, A31, and he offered no convincing reason why those doses would be inappropriate in a half-life comparison designed to demonstrate patentability. Further, that "[o]nly the 40 mg dose showed a statistically significant difference" compared with the prior art, "gives rise to the natural inference" that Dr. Uzan intended to deceive the PTO about the existence of a statistically significant difference where none existed.[5] A28.

[5] This finding of the court sufficiently rebuts evidence of good faith. *See Cargill,* 476 F.3d at 1368 ("Indeed, self-serving manipulation of highly material evidence can hardly be called 'good faith.'").

b. While Dr. Uzan's Clinical Relevance Justifications Are Unrelated To Patentability, His Omission Clearly Relates To Patentability.

The district court was not misled by Aventis's clinical relevance justifications:

> Dr. Uzan's clinical justifications – as he and Aventis have stated them – are implausible ***under the circumstances of the '618 prosecution*** and, in that context, fail to persuade the Court that the comparison between different doses was reasonable."

A14 (second emphasis added). According to the PTO, during prosecution, Aventis bore the burden of "explaining the data in any declaration they proffer[ed] as evidence of non-obviousness." *Ex parte Ishizaka*, 24 USPQ2d 1621, 1624 (Bd. Pat. App. & Inter. 1992). That is, Aventis was required to inform the PTO how the allegedly statistically significant differences demonstrated by Dr. Uzan's clinically relevant different-dose half-life comparisons provided objective evidence of non-obviousness *commensurate in scope with the claims*. He utterly failed in this task.

Specifically, a showing of non-obviousness based on unexpected results must be reviewed to see if the results occur over the claimed range. *In re Peterson*, 315 F.3d 1325, 1329-31 (Fed. Cir. 2003) (affirming rejection because applicant failed to show unexpected results for the entire claimed range of

about 1-3% rhenium because no expected result occurred when rhenium was added at 1% or 3%).

The ’618 patent is not limited to any dose or use. A29. Yet, Dr. Uzan’s half-life comparisons are limited to demonstrating the non-obviousness of a single “clinically relevant” dose, selected based on its safety and efficacy for a single therapeutic indication — treatment of DVT in high-risk orthopedic surgeries.

Dr. Uzan never explains how his comparisons may be used to demonstrate patentability across the full scope of the claims. Instead Aventis argues that it is irrelevant to Dr. Uzan’s intent that the ’618 patent covers all doses and indications other than the prevention of DVT in high-risk surgery. *BlueBr.* at 37; A30. Aventis’s argument however, “ignores the broad coverage of the ’618 patent” and “fails to recognize that future approvals for additional indications were eminently foreseeable.” A30.

Aventis downplays the significance of the broad scope of the ’618 claims by relying on *In re Chupp,* 816 F.2d 643, 646 (Fed. Cir. 1987). *BlueBr*. at 38, 47-49, 53. The district court correctly found that case inapposite. A30. *Chupp* simply holds that evidence of unexpected results can rebut obviousness. *Chupp*, 816 F.2d at 646. Further, in *Chupp*, inequitable conduct was not even an issue. In contrast, here, it is undisputed that Dr. Uzan concealed “highly

material" information from the examiner. *Aventis*, 176 Fed. Appx. at 120, 122-23. Indeed, the district court properly declined to apply *Chupp* on the facts of this case because:

> Aventis' reliance on *Chupp* begs the question of whether the '618 LMWH is, in fact, superior to the EP '144 LMWH prior art in <u>any property</u> at <u>any dose</u> for <u>any indication</u> – and is sufficiently so to prove both compositional difference and ***nonobviousness***.

A30-A31 (final emphasis added).

Neither Aventis nor Dr. Uzan show how the half-life comparisons demonstrate patentability, much less how those comparisons, in view of their undisclosed limitations based on different dose comparisons, demonstrate patentability commensurate with the scope of the claims. As such, Dr. Uzan's comparisons fail to demonstrate any unexpected result sufficient for patentability.

2. The Court Correctly Focused On Patentability When It Found Dr. Uzan Intended To Deceive To PTO

Aventis misunderstands the district court's opinion when it takes issue with the court's finding that the different-dose half-life comparison could never demonstrate compositional difference. *See, e.g. ARedBr.* at 31-32, 40, *TRedBr.* at 48-53; *BlueBr.* at 4, 5, 32. The court did not make those findings simply in the anticipation context. Indeed, the court expressly rejected Aventis's reliance on *Chupp* precisely because it questioned whether Aventis's half-life

comparisons showed sufficient evidence of compositional difference **or nonobviousness**. A30-31. Thus, the court focused on whether the comparisons demonstrated any **patentable** difference, and did not limit its consideration to demonstration of compositional difference:

- "Note that the Court is not now considering the question of whether the compositions used in the various studies underlying Examine 6 are, in fact, chemically different. . . . Rather . . . the question of compositional difference . . . is question of law for the PTO – which is to say the issue is not compositional difference, but ***patentable*** compositional difference." A22, n.11 (emphasis added).

- The undisclosed dosage information is the "the fulcrum on which Aventis' entire case for ***patentability*** turned. ***Depending on the dose tested***, compositional difference was either possible to prove, or it was not; ***the difference in half-life either appeared significant, or it did not.***" A39 (emphases added).

- "Because Dr. Uzan must (and should) have known what experimental question he was answering and because Dr. Uzan clearly did know what experimental design he was using to do so, it is inconceivable that a scientist of Dr. Uzan's abilities could have simply overlooked the fundamental scientific mismatch between what his comparison was required to show, ***to satisfy the PTO,*** and what it could show, scientifically." A35 (emphasis added).

The district court did not simply rely on Aventis's omission when it found Aventis intended to deceive the PTO. Rather, the district court properly considered the evidence and concluded that clear and convincing evidence showed Dr. Uzan's omission directly related to the problem confronting the

PTO — whether the claimed compositions indeed were patentable in view of the prior art.

This Court has "never held that materiality is irrelevant to the question of intent." *Cargill,* 476 F.3d at 1367. Rather, the Court acknowledges that when an omission is highly material to patentability, it may be difficult to establish a lack of an intent to deceive the PTO. *Id.* citing *Critikon,* 120 F.3d at 1257. In fact, that occurred in *Cargill.* In that case, the Court considered a patent to an oil having an allegedly superior stability that was found unenforceable for inequitable conduct. *Cargill,* 476 F.3d at 1366. The "district court [had] found the omitted test data was related to 'the heart of the question that bedeviled the examiner: the nature of the difference between [the claimed oil and the prior art oil.]'" Based on that, this Court held it was proper to infer an intent to deceive the PTO. *Id.* at 1367. Indeed, on appeal, this Court acknowledged that "the repeated nature" of the PTO's rejection of the claims "demonstrates that the applicant should have been aware of the materiality of the omitted test data, and therefore, the district court properly considered it as significant circumstantial evidence of an intent to deceive the PTO about the evidence relevant to that application." *Id.* at 1366.

Just as in *Cargill,* here, the omitted dose information related to the heart of the question the PTO sought to answer: whether any statistically significant

differences existed between the claimed and prior art compounds. A39. Dr. Uzan knowingly compared the half-lives of the claimed and prior art compounds at different doses. A35. Yet, in the court's view:

> Dr. Uzan represented in his declarations to the PTO, in essence, that the claimed LMWH exhibited, ***at any dose***, a statistically significant increase in half-life over the [prior art], ***at any dose.***"

A36 (emphases added). Intent to deceive the PTO is usually inferred from the facts and circumstances surrounding the conduct at issue. *Impax Labs., Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1374-75 (Fed. Cir. 2006). Here, Dr. Uzan made broad representations in his declarations, even though ***only*** a comparison of 40 mg of the claimed composition with 60 mg of the prior art composition shows any statistically significant increase in half-life, and that dosage information was omitted. A28. This Court already found *that* omission to be "highly material." *Aventis*, 176 Fed. Appx. at 120, 122-23. Hence, the facts and circumstances lead to just one conclusion. Thus, this Court should affirm.

B. Aventis Continues To Act Improperly

Aventis asks this Court to erase the determination of inequitable conduct and to maintain its exclusivity. At the same time, however, Aventis proceeds before the district court and the FDA as if there was no final judgment of unenforceability. Aventis's actions put the public at risk of losing access to

generic alternatives because unnecessary lawsuits can create delays and raise the cost to bring a drug to market.

Although the district court entered final judgment on March 13, 2007, Aventis sued Sandoz on ANDA 78-660 on June 6, 2007. *Aventis Pharma S.A. v. Sandoz, Inc.*, No. 07-cv-3658, (C.D. Cal. filed June 6, 2007). Aventis's complaint states that the'743 patent was "lawfully issued," that "a claim of infringement of the RE '743 patent could reasonably be asserted," and does not refer to the judgment of unenforceability. Complaint For Patent Infringement at 2-3, *Aventis Pharma S.A. v. Sandoz, Inc.*, No. 07-cv-3658 (C.D. Cal. filed June 6, 2007) (ECF Pacer Dkt. No. 1).

On June 7, 2007, Aventis certified the new lawsuit at the FDA by asserting infringement but did not mention the judgment of unenforceability:

> We hereby certify that on June 6, 2007, Aventis filed a suit for patent infringement against Sandoz in the United States District Court for the Central District of California. Aventis alleges, among other things, that under 35 U.S.C. § 271(e)(2)(A) Sandoz's submission to the FDA of an ANDA to obtain approval for the commercial manufacture, use, or sale of enoxaparin sodium before the expiration of United States Reissue Patent No. 38,743 ***was an act that infringes United States Patent No. RE 38,743***.

(Letter to the FDA Re: Lovenox® enoxaparin sodium injectable vial, 300 mg / 3 ml, Abbreviated New Drug Application No. 78-660, Notification of Filing of Legal Action for Patent Infringement, dated June 7, 2007) (emphasis added).

By notifying the FDA of its complaint, Aventis obtained a 30-month stay of final FDA approval, preventing Sandoz from marketing its generic enoxaparin product.[6] 21 U.S.C. § 355(j)(4)(B)(iii).

Aventis should not be allowed to gain any further benefits from its unenforceable patents.

[6] Sandoz filed a motion seeking to dismiss Aventis's new complaint under Rules 12(b)(6) and (b)(1), FED. R. CIV. P., which was heard on August 20, 2007. Sandoz and Aventis are negotiating a stipulation regarding the 30-month stay of final FDA approval.

CONCLUSION

For the foregoing reasons, *amicus curiae* Sandoz respectfully requests that this Court affirm the district court's holding that the '618 and '743 patents are unenforceable due to inequitable conduct.

Dated: August 30, 2007

Respectfully submitted,

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Certificate of Service

I hereby certify that on this 30th day of August 2007, two bound copies of the foregoing BRIEF OF AMICUS CURIAE SANDOZ, INC. REQUESTING AFFIRMANCE IN SUPPORT OF DEFENDANT-APPELLEES were served via UPS, overnight delivery, to:

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I also hereby certify that on this 30th day of August 2007, twelve bound copies of the foregoing BRIEF OF AMICUS CURIAE SANDOZ, INC. REQUESTING AFFIRMANCE IN SUPPORT OF DEFENDANT-APPELLEES were filed via UPS, overnight delivery, to:

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