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No. 01-1151

IN THE
United States Court of Appeals
FOR THE FEDERAL CIRCUIT

FILED
U.S. COURT OF APPEALS FOR
THE FEDERAL CIRCUIT

FEB 12 2001

JAN HORBALY
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RANBAXY PHARMACEUTICALS INC.,

Defendant-Appellant,

v.

GLAXO GROUP LIMITED and
GLAXO WELLCOME, INC.,

Plaintiffs-Appellees.

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United States Court of Appeals
For the Federal Circuit

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY IN CIVIL ACTION NO. 00-5172,
JUDGE MARY LITTLE COOPER

**REPLY BRIEF OF DEFENDANT-APPELLANT
RANBAXY PHARMACEUTICALS INC.**

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February 12, 2001

CERTIFICATE OF INTEREST

Counsel for the Appellant Ranbaxy Pharmaceuticals Inc. certifies the following:

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

Ranbaxy Pharmaceuticals 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 me is:

Not Applicable

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:

Ranbaxy Pharmaceuticals Inc. is a wholly-owned subsidiary of Ranbaxy [Holdings] UK Ltd. which is a wholly-owned subsidiary of Ranbaxy Netherlands B.V. which is a wholly-owned subsidiary of Ranbaxy Laboratories Limited.

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 agency or are expected to appear in this Court are:

Knobbe, Martens, Olson & Bear, LLP; Darrell L. Olson; William R. Zimmerman; Mathews, Collins, Shepherd & Gould, P.A.; and Ronald Gould.

Date: 4/2/01

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In attempting to defend the district court's erroneous claim construction, Glaxo completely ignores the prosecution history, which shows that the claim scope Glaxo now seeks is exactly the claim scope it surrendered to obtain the '181 patent. Glaxo originally sought a claim directed to cefuroxime axetil in "substantially amorphous form," which Glaxo admits includes 10% crystalline material. In response to a rejection, Glaxo cancelled that claim and accepted narrower claims directed to the preferred subset of amorphous cefuroxime axetil "essentially free from crystalline material." Thus, the "essentially free from crystalline material" limitation at issue must specify a crystalline content at least less than 10%.

This construction is entirely consistent with the ordinary meaning of the claim language and with the express definition that Glaxo set forth in its priority document, which defines the crystalline content as "undetectable" by X-ray crystallography. Glaxo's own internal documents prepared contemporaneously with the filing of the patent application state that crystalline material is detectable at 5% and 10% levels using this method.

In direct contradiction to this evidence, Glaxo convinced the district court to adopt a claim construction which encompasses unspecified and unknowable amounts of crystalline material assessed by a bioavailability

standard not set forth in the intrinsic evidence. Glaxo then convinced the district court to use Glaxo's commercial product as the standard by which to assess bioavailability. Glaxo's attempt to cover any product that is bioequivalent to its commercial product is impermissible and is contrary to all of the intrinsic evidence.

Moreover, Glaxo mischaracterizes the crystalline cefuroxime axetil in Ranbaxy's antibiotic as an inert component that serves no meaningful purpose. However, the uncontroverted evidence shows, and the district court found, that the crystalline material in Ranbaxy's product is not an inert component, but rather is a necessary component that delivers the active moiety cefuroxime to the patient.

In short, the district court's claim construction is contrary to all of the intrinsic evidence. When properly construed, the claims of the '181 patent cannot cover Ranbaxy's cefuroxime axetil antibiotic. Thus, the preliminary injunction must be vacated.

**I. GLAXO'S ATTEMPT TO SUSTAIN THE DISTRICT COURT'S
ERRONEOUS CLAIM CONSTRUCTION MUST FAIL**

**A. The Prosecution History Refutes The Premise Of Glaxo's Claim
Construction**

**1. The '181 patent does not use "substantially" and
"essentially" synonymously**

Glaxo's attempt to sustain the district court's erroneous claim construction is premised on equating the phrases "substantially amorphous form" and "essentially free from crystalline material." Glaxo contends that the terms "substantially" and "essentially" are used synonymously in the patent. Glaxo Br. at 37. Glaxo's contention is incorrect.

The prosecution history of the '181 patent unequivocally shows that the terms "substantially" and "essentially" are not used synonymously in the patent. The prosecution history further shows that, in response to a rejection by the Examiner, Glaxo surrendered claim coverage for the embodiment of cefuroxime axetil in "substantially amorphous form," instead accepting claim coverage only for the narrower, preferred subset of cefuroxime axetil which is "essentially free from crystalline material." Tellingly, despite

Ranbaxy having raised these points on appeal, Glaxo fails to respond to this important evidence. Ranbaxy Br. 42-47.

Originally-filed Claims 1, 4 and 9 recite:

1. Cefuroxime axetil in highly pure, substantially amorphous form.
4. The product of claim 1 essentially free from crystalline material.
9. A method of combatting bacterial infections of the human or animal body which comprises administering to the said body orally or rectally an effective amount of a highly pure substantially amorphous form of cefuroxime axetil.

JA 728 (emphases added). By statute, “a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed.” 35 U.S.C. § 112, ¶ 4 (emphasis added); see *Desper Prods., Inc. v. QSound Labs, Inc.*, 157 F.3d 1325, 1338 n.5, 48 U.S.P.Q.2d 1088, 1097 n.5 (Fed. Cir. 1998) (dependent claims “necessarily must be narrower than the independent claims” from which they depend). Originally-filed dependent Claim 4 complies with these statutory requirements by referencing originally-filed independent Claim 1

and specifying a further limitation — “essentially free from crystalline material.”

Glaxo’s contention that “substantially” and “essentially” are used synonymously in the patent cannot be correct because, contrary to statute, originally-filed Claims 1 and 4 would then have had exactly the same scope. *See* 35 U.S.C. § 112, ¶ 4. Rather, originally-filed independent Claim 1 specifies the embodiment of cefuroxime axetil in “substantially amorphous form” and originally-filed dependent Claim 4 specifies a narrower, preferred subset of that embodiment, which is “essentially free from crystalline material.” JA 67 (col. 2, ll. 23-40) (explaining that the “essentially free” embodiment is a preferred subset of the “substantially amorphous form” embodiment). Therefore, “essentially free from crystalline material” means containing less crystalline material than cefuroxime axetil in “substantially amorphous form.”

2. **Glaxo surrendered claim coverage for cefuroxime axetil in “substantially amorphous form”**

Not only are “substantially” and “essentially” not synonymous in the context of the patent, but Glaxo also surrendered cefuroxime axetil in

“substantially amorphous form” in order to obtain the patent. Glaxo cannot now construe the claims to recover this surrendered subject matter.

In the first Office Action, the Examiner rejected all of Glaxo’s originally-filed claims as indefinite:

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite

It is not definite what is particularly included or excluded by the term “highly pure, substantially amorphous form”. . . . It is also not clear how much crystalline material is permitted. Dependent claim 4 specifies a product which is essentially free from crystalline material. The cefuroxime axetil as employed in the method of claim 9 is further mixed with other materials.

JA 786. In this rejection, the Examiner stated that the phrase “substantially amorphous form,” as used in independent Claims 1 and 9, failed to adequately specify a level of crystalline material, while the phrase “essentially free from crystalline material” in dependent Claim 4 did adequately specify a level of crystalline material. The Examiner’s rejection flatly contradicts Glaxo’s contention that “substantially” and “essentially” are synonymous.

In response to the Examiner's rejection, Glaxo cancelled originally-filed Claims 1 and 4 and substituted new Claim 10, which recites:

10. Cefuroxime axetil in amorphous form essentially free from crystalline material, which contains less than 5% m/m of impurities other than residual solvents and less than 6% m/m of residual solvents.

JA 801 (emphasis added); *see* JA 801-03. By canceling Claim 1 directed to cefuroxime axetil in "substantially amorphous form" and substituting therefor Claim 10 directed to the narrower, preferred subset of cefuroxime axetil which is "essentially free from crystalline material," Glaxo surrendered claim coverage for the "substantially amorphous form" embodiment. *See Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1378-79, 49 U.S.P.Q.2d 1065, 1068-69 (Fed. Cir. 1998); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1572-73, 43 U.S.P.Q.2d 1398, 1409-10 (Fed. Cir. 1997).

Glaxo's surrender is further evidenced by its amendment of independent Claim 9 to depend from Claim 10, which recites the "essentially free from crystalline material" limitation. JA 802, 804 ("Claim 9 has been amended to be dependent upon Claim 10."). Independent Claim 10

ultimately issued as Claim 1 of the '181 patent after further amendments not relevant to this appeal. *Compare* JA 801 with JA 73. Claim 9 issued as dependent Claim 7 without further amendment. *Compare* JA 728, 802 with JA 73.

By attempting to equate “substantially” and “essentially,” Glaxo seeks to construe the claims of the '181 patent to recover the very claim scope that it surrendered — cefuroxime axetil in “substantially amorphous form.” As discussed in detail in I(C)(3), *infra*, Glaxo defined its “substantially amorphous form” embodiment as including 10% crystalline content. Having acquiesced in the Examiner’s indefiniteness rejection and amended the claims to cover only the narrower, preferred subset of cefuroxime “essentially free from crystalline material,” Glaxo cannot now construe the claims so as to regain the subject matter it surrendered, i.e., 10% or more crystalline content. *See Spectrum*, 164 F.3d at 1378-79, 49 U.S.P.Q.2d at 1068-69; *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576, 34 U.S.P.Q.2d 1673, 1677 (Fed. Cir. 1995) (“Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers.”). Glaxo cannot now challenge the necessity of that surrender. *See Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1356, 48 U.S.P.Q.2d 1674,

1678 (Fed. Cir. 1998) (a patentee “may not both make the amendment and then challenge its necessity in a subsequent infringement action on the allowed claim”).

B. Glaxo Incorrectly Construes The Disputed Claim Limitation To Have A Meaning Other Than Its Ordinary Meaning

1. “Essentially free from crystalline material” has an ordinary meaning

Claim 1 of the ‘181 patent, the only independent claim, recites:

Cefuroxime axetil in amorphous form essentially free from crystalline material, and having a purity of at least 95% aside from residual solvents.

JA 73 (emphasis added). The plain meaning of the claim language specifies the compound cefuroxime axetil in one specific physical form, the amorphous form, and further specifies that the compound is “essentially free from crystalline material,” the other physical form.

Glaxo submitted, and the district court relied upon, a dictionary definition that defines “essentially” to mean “fundamentally” and that defines “essential” to mean “belonging to or being a part of the essence of something.” JA 27, 1707. Based on these definitions, the “essentially free

from crystalline material” limitation requires that the claimed amorphous cefuroxime axetil be “fundamentally” free from crystalline material, or that the “essence” of the claimed amorphous cefuroxime axetil is that it is “free from crystalline material.” Ranbaxy Br. at 21-24. Simply put, the ordinary and accustomed meaning of the “essentially free from crystalline material” limitation is to exclude virtually all crystalline material. *See K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1362-63, 52 U.S.P.Q.2d 1001, 1004 (Fed. Cir. 1999); *Johnson Worldwide Assocs. v. Zebco Corp.*, 175 F.3d 985, 989, 50 U.S.P.Q.2d 1607, 1610 (Fed. Cir. 1999).

2. **Glaxo’s attempt to deviate from the ordinary meaning is unsupported**

In contrast to the ordinary meaning, Glaxo and the district court construe the “essentially free from crystalline material” limitation to mean “free from an amount of crystalline cefuroxime axetil which materially detracts from the bioavailability of the amorphous cefuroxime axetil.” Glaxo Opp. at 39; *see* JA 26-27, 28, 37-38, 40. This construction fails to give the disputed claim language its ordinary meaning. Moreover, this claim

construction cannot be correct because it is based completely on faulty premises.¹

Glaxo begins by merely citing to its proffered dictionary definitions of “essentially” and “essential.” Glaxo Opp. at 36. However, these definitions, standing alone, fail to address the remainder of the disputed claim limitation, “free from crystalline material.” Glaxo makes no attempt to use the dictionary definitions in conjunction with the remaining language of the claim limitation to set forth the ordinary meaning. When the dictionary definitions are coupled with the remaining language of the claim limitation, it is evident that the ordinary meaning of “essentially free from crystalline material” is to exclude virtually all crystalline material. Thus, Glaxo’s recitation of the dictionary definitions confirms the ordinary meaning of the claim language and does not support Glaxo’s proposed claim construction.

After merely reciting the dictionary definitions, Glaxo contends that these definitions accord with precedent construing the phrases “essentially

¹ While Glaxo states that this Court reviews “application of the patent claim to the accused product” under an abuse of discretion standard, Glaxo Opp. at 28-29, this Court reviews the issue of claim construction *de novo*. See *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 1380, 54 U.S.P.Q.2d 1086, 1088-89 (Fed. Cir. 2000); *Novo Nordisk of N. Am., Inc. v. Genentech, Inc.*, 77 F.3d 1364, 1368, 37 U.S.P.Q.2d 1773, 1776 (Fed. Cir. 1996).

free', and synonym expressions such as 'consisting essentially of,' 'substantially,' and 'substantially free.'" *Id.*; *see id.* at 37 (stating that Claim 7 of the patent "uses 'substantially' and 'essentially' as synonyms"), 38 ("a substantially amorphous form of cefuroxime axetil, a form essentially free of crystalline material"). Glaxo provides no support for its contention, and the prosecution history shows that "substantially" and "essentially" are not synonymous in the context of the patent. *See I(A)(1), supra.* Thus, Glaxo's reliance on precedent construing the phrase "substantially" is misplaced.²

Likewise, Glaxo cites no precedent to support equating "essentially free" with the recognized transitional phrase "consisting essentially of." "Essentially free from crystalline material" is not a recognized transitional phrase, nor is it used as a transitional phrase in the '181 patent. Rather, this limitation is a negative limitation specifying what is not included in the

² Glaxo's reliance on *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 47 U.S.P.Q.2d 1705 (Fed. Cir. 1998) is misplaced for additional reasons. In *Johns Hopkins*, this Court construed "substantially free of mature lymphoid and myeloid cells" to permit "no more than 10%" of the recited cells because this was the only embodiment disclosed in the patent and the prosecution history did not alter this construction. *Id.* at 1354-56, 47 U.S.P.Q.2d at 1714-15. In contrast, the '181 patent discloses two distinct embodiments, and the prosecution history clearly shows that Glaxo only obtained claim coverage for the narrower, preferred embodiment. Thus, *Johns Hopkins* fails to support Glaxo's claim construction.

claimed subject matter — more than a negligible amount of crystalline material.³ *Ranbaxy Br.* at 26-28; *see In re Wakefield*, 422 F.2d 897, 904, 164 U.S.P.Q. 636, 641 (C.C.P.A. 1970); *Manual of Patent Examining Procedures* § 2173.05(i) (7th ed. 2000). Thus, Glaxo's leap from the dictionary definitions to precedent construing the transitional phrase "consisting essentially of" is utterly unsupported.

In contrast to the irrelevant precedent relied upon by Glaxo, in *In re Marosi*, 710 F.2d 799, 218 U.S.P.Q. 289 (Fed. Cir. 1983), this Court construed the claim phrase "essentially free of alkali metal." *See id.* at 801, 218 U.S.P.Q. at 292. Based upon a definition provided in the written description, this Court held that "essentially free of" permits the presence of the material at issue only as an "unavoidable impurit[y]." *Id.* at 802-03, 218

³ Relying upon *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 36 U.S.P.Q.2d 1225 (Fed. Cir. 1995), Glaxo suggests that "essentially free from crystalline material" is a "performance characteristic." In *Pall*, the claim recited a "skinless" filtration membrane. The evidence established that "skinless" was understood in the art to describe how the membrane impeded flow, and the patent specification set forth several tests for assessing this functional characteristic to determine if a membrane was "skinless." *Id.* at 1216-17, 36 U.S.P.Q.2d at 1228. Unlike in *Pall*, there is no evidence to suggest that the "essentially free from crystalline material" limitation at issue here describes a function and is therefore a performance characteristic of the claimed compound. Thus, Glaxo's reliance upon *Pall* is misplaced.

U.S.P.Q. at 292. This construction accords with the ordinary meaning of “essentially free from.” Thus, the relevant precedent further refutes Glaxo’s proposed claim construction.

After citing to the dictionary definitions and inapposite precedent, Glaxo leaps to the totally unsupported claim construction of “essentially free from crystalline material” to mean “free of an amount of crystalline cefuroxime axetil which materially detracts from the bioavailability of the amorphous cefuroxime axetil.” Glaxo Opp. at 39; see JA 26-27, 28, 37-38, 40. Neither the dictionary definitions nor the precedent cited by Glaxo support this unfounded leap. Indeed, Glaxo’s proposed claim construction contradicts both the ordinary meaning of the claim language and the intrinsic evidence.

Moreover, Claim 1 of the patent does not contain any reference, whatsoever, to bioavailability, nor does the patent provide any standard by which to assess bioavailability. As discussed in detail in II(B), *infra*, Glaxo’s proposed claim construction impermissibly attempts to cover any product that is bioequivalent to its commercial product. The intrinsic evidence provides no support for such a construction. The language of Claim 1 should properly be construed in accord with its ordinary meaning to

specify the amorphous physical form of the compound cefuroxime axetil containing “fundamentally” no crystalline material.

C. **Glaxo Cannot Avoid The Definition Of “Essentially Free From Crystalline Material” Clearly Set Forth In The Prosecution History**

1. **Glaxo expressly defined the disputed claim limitation in the prosecution history**

Glaxo deliberately and expressly defined “essentially free from crystalline material” in the United Kingdom Patent Application from which the ‘181 patent claims priority. Properly interpreted, Glaxo’s express definition is consistent with the ordinary meaning of the claim language, but is contrary to Glaxo’s proposed claim construction, which the district court adopted.

The ‘181 patent claims priority to United Kingdom Patent Application No. 8222019. JA 64. This Application became part of the prosecution history of the ‘181 patent, and thus the intrinsic evidence, when Glaxo submitted it to the Patent Office in making its claim of priority. Ranbaxy Br. at 29-33; JA 28-31.

Glaxo deliberately and expressly defined “essentially free from crystalline material” in the United Kingdom Application:

The cefuroxime 1-acetoxethyl ester in accordance with the invention is preferably essentially free from crystalline material, by which we mean that any amount of crystalline material which may be present is so low as to be undetectable by X-ray crystallography, i.e. that an X-ray photograph of a sample of the compound shows no rings. The crystalline content of such a sample may be presumed to be zero for all practical purposes.

JA 797, 845 (emphases added); *see* JA 841-55 (complete priority document); *see also* *K-2*, 191 F.3d at 1363, 52 U.S.P.Q.2d at 1004 (“a different meaning clearly and deliberately set forth in the intrinsic materials — the written description or the prosecution history — will control”); *Hockerson-Halberstadt, Inc. v. Converse Inc.*, 183 F.3d 1369, 1375, 51 U.S.P.Q.2d 1518, 1522 (Fed. Cir. 1999); *In re Paulsen*, 30 F.3d 1475, 1480, 31 U.S.P.Q.2d 1671, 1674 (Fed. Cir. 1994) (an express definition set forth “with reasonable clarity, deliberateness, and precision” will control). Glaxo admits that this definition is made “[a]s clearly as words can be used.”

Glaxo Opp. at 40. Thus, the disputed claim language precludes the presence of crystalline cefuroxime axetil that is detectable using X-ray crystallography.

In making its claim of priority, Glaxo made no effort to disavow this express definition of "essentially free from crystalline material," despite having ample opportunity to do so during prosecution. Thus, Glaxo cannot now disavow its express definition.

2. **Glaxo's attempt to use unsupported testimony to reinterpret its express definition is impermissible**

Unable to jettison this express definition, Glaxo attempts to use unsupported testimony from one of its employees to reinterpret the definition. However, Glaxo's own pre-suit, internal documents, prepared contemporaneously with the filing of the '181 patent, contradict the unsupported testimony upon which Glaxo relies.

As acknowledged by the district court, a November 3, 1983 Glaxo report concludes that 10% crystalline cefuroxime axetil was detectable using Debye-Scherrer X-ray photography at the time the patent application was filed. JA 32, 1652; *see* JA 1646-84 (1983 Glaxo report); *see also* *Schering Corp. v. Amgen, Inc.*, 222 F.3d 1347, 1353, 55 U.S.P.Q.2d 1650, 1654-55

(Fed. Cir. 2000) (claims are construed as they would be understood at the time the patent application was filed). Even Glaxo's own employee, Robert Lancaster, admits that "[t]his report also concluded that detection levels of crystalline cefuroxime axetil by Debye-Scherrer X-ray photography was about 10%." JA 1641 (Lancaster Decl., ¶ 8) (emphasis added).

The 1983 Glaxo report, in fact, shows in multiple instances that crystalline cefuroxime axetil was detectable at even lower levels, i.e., at 5%, using Debye-Scherrer X-ray photography. The report states that "Isomer A (II) was visible at the 5% level." JA 1650 (emphasis added). Table II of the report shows that 5-10% crystalline material was detectable in Sample No. JSC 3726 C. JA 1653. Even the district court acknowledged "that the report in two places refers to the detection of crystalline material constituting 5% of the sample." JA 32 n.9. Thus, Glaxo's own evidence, documented contemporaneously with the filing of the patent application, shows that at that time 5% crystalline cefuroxime axetil was detectable using Debye-Scherrer X-ray photography.

Despite acknowledging that Glaxo's own 1983 report concludes that 10% crystalline material was detectable and without mentioning that the report shows that 5% crystalline material was detectable, Lancaster opines

that photographs, which are not part of the report and which were taken by Glaxo scientists in 1982-83, show that “[i]f there is reasonably good sample preparation and film processing the detection level is about 10 to 15% crystalline material.” JA 1640 (Lancaster Decl., ¶ 7). Thus, Lancaster’s seventeen-year after-the-fact opinion based on miscellaneous photographs taken by someone else and not included in the report contradicts the very Glaxo report on which he also opines. Lancaster provides no explanation for this inconsistency.

Glaxo also fails to explain this discrepancy, and yet contends that Lancaster’s opinion establishes that the detection limit for crystalline cefuroxime axetil using Debye-Scherrer X-ray photography “exceeds 10% even for ideal sample preparation and film exposure.” Glaxo Opp. at 21. Glaxo then expands this threshold still further to 10-15%. *Id.* These detection thresholds are not supported by Lancaster’s inconsistent declaration or the extrinsic evidence upon which it is based. They simply represent Glaxo’s litigation-driven effort to reinterpret the express definition in the prosecution history in a transparent attempt to broaden the definition.

Glaxo’s use of purportedly expert testimony to reinterpret extrinsic evidence developed by the patentee contemporaneously with the filing of the

patent is contrary to law. See *Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.*, 132 F.3d 701, 706, 45 U.S.P.Q.2d 1033, 1038 (Fed. Cir. 1998) (explaining that “after-the-fact ‘experts’ that played no part in the creation and prosecution of the patent” should “not be heard to inject a new meaning into terms”); *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1583-84, 39 U.S.P.Q.2d 1573, 1577-79 (Fed. Cir. 1996) (stating that extrinsic evidence cannot alter the public record and suggesting a preference for contemporaneous documentary evidence over after-the-fact testimony). The actual evidence requires no after-the-fact interpretation, much less the new inconsistent interpretation provided by Glaxo’s employee. Glaxo’s own extrinsic evidence, documented contemporaneously with the filing of the patent application, refutes Lancaster’s seventeen-year after-the-fact opinion regarding what that very evidence shows. This extrinsic evidence also refutes Glaxo’s further reinterpretation of Lancaster’s opinions in an attempt to broaden the definition it provided in the prosecution history.

3. The intrinsic evidence further belies Glaxo's attempt to reinterpret its express definition

Glaxo's attempt to reinterpret the definition in the prosecution history is also contrary to Example 22 of the '181 patent. This example shows that 10% crystalline cefuroxime axetil is detectable.

Example 22 recites that "X-ray crystallography revealed that the product was substantially amorphous with a small content of crystalline material." JA 71 (col. 10, ll. 26-28) (emphases added). During prosecution of two process patents relating to cefuroxime axetil, both of which claim priority to the same United Kingdom Application as the '181 patent, Glaxo represented to the Patent Office that the crystalline content of identical Example 22 is "estimated at about 10%" and "approximately 10%." JA 1230, 1244; see JA 71, 1218, 1225, 1232, 1239; Glaxo Opp. at 9, 41 n.28. Example 22 was not present in the United Kingdom Application, which contains Glaxo's express definition of "essentially free from crystalline material." Compare JA 841-55 with JA 71 (Example 22). Rather, Glaxo admits that "broadened Example 22 was added" when the application that matured into the '181 patent was filed. Glaxo Opp. at 41 n.28 (emphasis added).

The absence of Example 22 from the United Kingdom Application confirms that at the time Glaxo set forth its express definition of “essentially free from crystalline material,” it did not believe this definition encompassed compositions containing approximately 10% crystalline material. Rather, Glaxo’s definition encompassed the examples disclosed in the United Kingdom Application, which describe compositions containing less crystalline material than the 10% in “broadened Example 22.” Thus, Glaxo’s own admission contradicts its proffered reinterpretation of the express definition it provided.

Glaxo deliberately and expressly defined “essentially free from crystalline material” to mean a crystalline content that is “undetectable by X-ray crystallography.” JA 797, 845. Glaxo contends “that the reality here compels a determination of how much crystalline cefuroxime axetil comports with the no ring by Debye-Scherrer test.” Glaxo Opp. at 33. As shown by Glaxo’s own internal documents, 5% crystalline cefuroxime axetil was detectable, as was 10% crystalline material. JA 1650, 1652-53, 1640 (Lancaster Decl., ¶ 8). Thus, Glaxo’s express definition of “essentially free from crystalline material” must mean containing less than 5% crystalline

material, and cannot possibly encompass 10% crystalline material. This meaning accords with the ordinary meaning of the disputed claim language.

D. Glaxo Mischaracterizes The Written Description In Attempting To Support Its Proposed Claim Construction

Further attempting to support its proposed claim construction, Glaxo tries to deny that the written description of the '181 patent discloses two embodiments. Glaxo Opp. at 43-44. The written description belies Glaxo's contention:

According to one aspect of the present invention, there is provided cefuroxime axetil in highly pure, substantially amorphous form.

...

The cefuroxime axetil ester in accordance with the invention is preferably essentially free from crystalline material.

JA 67 (col. 2, ll. 23-40) (emphases added). This passage demonstrates that the written description sets forth two embodiments — cefuroxime axetil in “substantially amorphous form” and a narrower, preferred subset that is

“essentially free from crystalline material.”⁴ The narrower, preferred subset necessarily contains less crystalline cefuroxime axetil.

The disclosure of two embodiments in the written description is also consistent with originally-filed Claims 1 and 4, which attempted to claim each of these embodiments. As discussed, Glaxo surrendered claim coverage for cefuroxime axetil in “substantially amorphous form,” instead accepting claim coverage for only the narrower, preferred subset of cefuroxime axetil “essentially free from crystalline material.” See I(A), *supra*.

In the written description, Glaxo characterizes Example 22 as “substantially amorphous.” JA 71 (col. 10, ll. 27-28) (emphasis added). Glaxo has represented to the Patent Office during related prosecution that Example 22 contains “about 10%” and “approximately 10%” crystalline material. JA 1230, 1244; see JA 71, 1218, 1225, 1232, 1239; Glaxo Opp. at 9, 41 n.28. Glaxo has thus characterized cefuroxime axetil containing 10% crystalline cefuroxime axetil as “substantially amorphous.” Therefore, the

⁴ Elsewhere in the written description, pharmaceutical compositions which are disclosed as “essentially free from crystalline material” are identified as a “preferred embodiment.” JA 69 (col. 6, ll. 7-10).

narrower, preferred subset of cefuroxime axetil "essentially free from crystalline material" contains less than 10% crystalline cefuroxime axetil.

In contrast to Example 22, Example 21 describes amorphous cefuroxime axetil with "< 1% crystalline material." JA 71 (col. 10, ll. 4-5). Example 21 is the only example in the patent that numerically quantifies the level of crystalline material.⁵

Glaxo inaccurately asserts that Ranbaxy is attempting to read a preferred embodiment from the written description into the claims. Although Glaxo disclosed two embodiments in the written description, Glaxo was only able to claim the narrower, preferred embodiment that is "essentially free from crystalline material." *See Novo Nordisk*, 77 F.3d at 1369-70 & n.8, 37 U.S.P.Q.2d at 1778 & n.8 (the patentee "wrote a broader disclosure, but settled for patent protection for its preferred embodiment" after the Examiner rejected the broader claims). Glaxo acquiesced to the Examiner's rejection of claims directed to the "substantially amorphous

⁵ Glaxo's attempt to characterize Example 18 as having 10-15% crystalline material is disingenuous. X-ray powder analysis of the cefuroxime axetil in Example 18 showed "the presence of a few crystals." JA 71 (col. 9, ll. 29-30). This "presence of a few crystals" is obviously less crystalline material than the "small content of crystalline material" in Example 22, which Glaxo characterized as 10% crystalline material. *Id.* (col. 10, ll. 27-28); Glaxo Opp. at 41 n.28.

form” embodiment, and surrendered this embodiment to obtain allowance of the patent. Thus, Ranbaxy is not attempting to import a limitation from the written description into the claims, but instead is merely preventing Glaxo from construing the claims to recover the broader embodiment it surrendered during prosecution. *See Desper*, 157 F.3d at 1340, 48 U.S.P.Q.2d at 1099 (“Post-hoc, litigation-inspired argument cannot be used to reclaim subject matter that the public record in the PTO clearly shows has been abandoned.”); *Southwall*, 54 F.3d at 1576, 34 U.S.P.Q.2d at 1676-77.

The intrinsic evidence and the extrinsic evidence contemporaneous with the filing of the ‘181 patent do not support Glaxo’s attempt to sustain the district court’s claim construction. The evidence shows that “essentially free from crystalline material” cannot properly be construed to encompass cefuroxime axetil containing 10% or more crystalline material.

II. RANBAXY’S CEFUROXIME AXETIL ANTIBIOTIC DOES NOT INFRINGE ANY CLAIM OF THE ‘181 PATENT

A. Glaxo Mischaracterizes Ranbaxy’s Cefuroxime Axetil Antibiotic

Without any evidentiary support, Glaxo mischaracterizes the crystalline cefuroxime axetil in Ranbaxy’s antibiotic as an inert component that serves no purpose and asserts that the amorphous cefuroxime axetil

provides all of the active moiety cefuroxime required to achieve bioequivalence. Glaxo Opp. at 14-15, 45, 46. The evidence directly contradicts Glaxo's mischaracterizations of Ranbaxy's antibiotic.

In addition to the function of the crystalline material in Ranbaxy's antibiotic being legally irrelevant,⁶ the uncontroverted evidence shows that "[i]n Ranbaxy's cefuroxime axetil antibiotic, both the crystalline cefuroxime axetil and the amorphous cefuroxime axetil deliver the active moiety, cefuroxime, to the patient." JA 673 (Ternyik Decl., ¶ 6); see JA 15, 41. The crystalline cefuroxime axetil in Ranbaxy's antibiotic is thus not an inert component, but rather is an active and necessary part of the antibiotic. JA 15, 41 (the district court found that the "crystalline material is an active component"), 673-74 (Ternyik Decl., ¶ 6), 883, 900, 914, 916, 942, 1029. Glaxo's assertion that the crystalline material does not affect the medicine is wrong. In Ranbaxy's antibiotic, the crystalline cefuroxime axetil is part of the medicine. JA 883, 900, 914, 916, 942, 1029. It delivers the drug

⁶ If Claim 1 were totally rewritten to recite an "antibiotic consisting essentially of substantially amorphous cefuroxime axetil," whether the crystalline form affects the basic characteristics of the antibiotic might have relevance. Here, however, the claim expressly excludes essentially all crystalline material and thus its affect on the compound has no relevance.

substance, the active moiety cefuroxime, to the patient and necessarily contributes to bioequivalence.

Ranbaxy did not add an inert component to amorphous cefuroxime axetil in an attempt to avoid infringement. What Ranbaxy did do is develop an antibiotic that uses both crystalline and amorphous cefuroxime axetil as active components to deliver the active moiety to the patient. Thus, Ranbaxy developed a new and useful antibiotic, while at the same time avoiding Glaxo's patent.

B. Both The District Court And Glaxo Erroneously Compare Ranbaxy's Antibiotic To Glaxo's Commercial Product

Under the erroneous claim construction proposed by Glaxo and adopted by the district court, whether Ranbaxy's antibiotic is "essentially free from crystalline material" is assessed based upon whether it contains "crystalline cefuroxime axetil that materially detracts from or affects the characteristics of the claimed invention." JA 37-38; *see* JA 26-27. However, the intrinsic evidence fails to delineate what the characteristics of the claimed invention are or what it means to materially detract from these characteristics. Given this absence of a standard, the district court

impermissibly chose "bioavailability" as the characteristic and then impermissibly used Glaxo's commercial product as the standard by which to assess this characteristic. JA 40-42. Glaxo repeats the district court's error by comparing Ranbaxy's antibiotic to Glaxo's commercial product, Cefitin[®]. Glaxo Opp. at 14-16, 45-46.

The fact that the claim construction proposed by Glaxo and adopted by the district court fails to provide any standard in the intrinsic evidence by which to assess infringement confirms the error of this claim construction. *See Vitronics*, 90 F.3d at 1583, 39 U.S.P.Q.2d at 1577 (explaining that the public is entitled to ascertain the scope of the claims of a patent from the public record). Claim 1 contains no reference to bioavailability, nor does the intrinsic evidence delineate a bioavailability standard. Glaxo's Cefitin[®] certainly cannot be the standard by which infringement is assessed. *See Martin v. Barber*, 755 F.2d 1564, 1567, 225 U.S.P.Q. 233, 235 (Fed. Cir. 1985); *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1578, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984) ("Infringement is determined on the basis of the claims, not on the basis of a comparison with the patentee's commercial embodiment of the claimed invention."). However, this is

exactly the standard used by the district court and by Glaxo on appeal. JA 40-42.

Based on the following statement, the district court found, and Glaxo contends, that Ranbaxy's antibiotic is "essentially free from crystalline material":

Furthermore, Ranbaxy's dissolution and stability testing establishes that the percentage of crystalline and amorphous forms in its tablets (12% and 88%, respectively) does not adversely affect the identity, strength, quality, purity, potency and performance of the drug product. In particular, the percentage of crystalline component in Ranbaxy's tablets shows no adverse impact on the solubility or in-vivo characteristics of the drug product, since the drug product complies with the bioequivalence criteria.

JA 291; *see* JA 41-42. Contrary to the belief of the district court and Glaxo's assertion to this Court, this statement is irrelevant to the issue of infringement.

In an October 12, 2000 Fax Amendment, the FDA noted that Ranbaxy's antibiotic does not conform to the current United States Pharmacopoeia monographs for cefuroxime axetil and cefuroxime axetil tablets. JA 293-95 (Point B on JA 295), 1180-81 (monographs). In response, Ranbaxy acknowledged that its antibiotic does not conform to the monographs because it contains both crystalline and amorphous cefuroxime axetil. JA 286-92. Thus, both the FDA and Ranbaxy acknowledged that Ranbaxy's antibiotic, which contains both crystalline and amorphous cefuroxime axetil, differed from the monograph, which is based on Glaxo's Ceftin[®] and specifies cefuroxime axetil in amorphous form. *Id.*; JA 1165-67, 1180-81.

In explaining that the FDA could approve its ANDA despite the differences in physical form between the cefuroxime axetil in its antibiotic and the cefuroxime axetil monograph based on Ceftin[®], Ranbaxy made the statement quoted above, which appears under the heading "Ranbaxy's product is bioequivalent to the listed drug." JA 292; *see* JA 286-92. The quoted statement merely explains that although the cefuroxime axetil in Ranbaxy's antibiotic differs in physical form from the cefuroxime axetil in

the monograph and Ceftin[®], Ranbaxy's antibiotic is bioequivalent to Ceftin[®].

Thus, the statement relied upon by the district court and Glaxo compares Ranbaxy's antibiotic to Glaxo's Ceftin[®], a comparison that is irrelevant to the issue of infringement. *See Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423, 30 U.S.P.Q.2d 1285, 1289 (Fed. Cir. 1994) ("it is error for a court to compare in its infringement analysis the accused product or process with the patentee's commercial embodiment or other version of the product or process; the only proper comparison is with the claims of the patent"). If the statement is of any relevance, taken in context, it highlights the difference in physical form between Ranbaxy's antibiotic, which contains both crystalline and amorphous cefuroxime axetil, and Claim 1 of the '181 patent, which recites amorphous cefuroxime axetil to the virtual exclusion of the crystalline form.

Glaxo's proposed claim construction is a transparent attempt to cover any product that possibly could obtain FDA approval under an ANDA. In order to seek FDA approval to market a generic cefuroxime axetil antibiotic under an ANDA, the product must be shown to be bioequivalent to Ceftin[®].

However, under Glaxo's claim construction, such a product would necessarily infringe Claim 1. In Ranbaxy's correspondence with the FDA regarding Ranbaxy's ANDA, quoted approvingly by Glaxo, Ranbaxy reports that a drug product containing at least up to 20% crystalline and 80% amorphous cefuroxime axetil is bioequivalent to Ceftin[®]. JA 291. Thus, under Glaxo's erroneous construction, 20% (or more) crystalline content infringes Claim 1. Yet, to be consistent with the intrinsic evidence, Glaxo's proposed construction would require that 20% crystalline material be undetectable by X-ray crystallography, a result even Lancaster's unsupported opinions flatly contradict. The internal inconsistency of Glaxo's proposed claim construction further evidences its lack of merit.

C. **Ranbaxy's Antibiotic Is Not "Essentially Free From Crystalline Material"**

Independent Claim 1, the only independent claim, recites cefuroxime axetil "essentially free from crystalline material." JA 73. When properly construed, the disputed limitation cannot encompass compositions containing 10% crystalline cefuroxime axetil.

It is undisputed that the cefuroxime axetil antibiotic set forth in Ranbaxy's ANDA contains between 10-15% crystalline cefuroxime axetil. JA 15, 41, 673 (Ternyik Decl., ¶ 5), 895-97, 927-31, 1047, 1054. Ranbaxy's proposed antibiotic contains 12% crystalline cefuroxime axetil and 88% amorphous cefuroxime axetil. JA 15, 41, 673 (Ternyik Decl., ¶ 5), 1035, 1054. Because the cefuroxime axetil antibiotic set forth in Ranbaxy's ANDA and Ranbaxy's proposed commercial product are not "essentially free from crystalline material," when that limitation is properly construed, Ranbaxy does not literally infringe any claim of the '181 patent.⁷ Thus, the district court's conclusion regarding likelihood of success was erroneous.

III. THE DISTRICT COURT ERRED IN ISSUING A PRELIMINARY INJUNCTION AGAINST RANBAXY

Not only did the district court err in analyzing the likelihood of success factor, but this error also infected the court's assessment of the

⁷ Glaxo does not respond to Ranbaxy's arguments regarding prosecution history estoppel and infringement under the doctrine of equivalents. Thus, Glaxo does not challenge that prosecution history estoppel bars application of the doctrine of equivalents and that Ranbaxy's antibiotic does not infringe under the doctrine of equivalents.

remaining preliminary injunction factors in this declaratory judgment action.⁸ Ranbaxy Br. at 59-64.

Glaxo has already enjoyed the benefit of years of exclusivity over cefuroxime axetil by virtue of its '320 patent, which preceded the '181 patent and which covers the compound cefuroxime axetil regardless of its physical form. JA 856-64 (Claim 4 is directed to cefuroxime axetil). In fact, Glaxo extended its period of exclusivity by obtaining the maximum possible term extension for the '320 patent. JA 866-68. During this time, competitors could not market a cefuroxime axetil antibiotic to compete with Cefitin[®], which is covered by the '320 patent. JA 1199 (Glaxo marks the

⁸ Glaxo's Complaint for patent infringement asserts jurisdiction based on the Declaratory Judgment Act. JA 59-63. The parties do not dispute that declaratory judgment jurisdiction was proper in the district court, and that this Court properly has jurisdiction over this appeal. However, Glaxo asserts that jurisdiction was also based on 35 U.S.C. § 271(e)(2). Ranbaxy does not agree. Cefuroxime axetil, and certain other drug products, are exempted from the pre-market notification provisions of the Hatch-Waxman Act. See The Food and Drug Modernization Act of 1997, Pub. L. No. 105-115, § 125(d)(2), 111 Stat. 2321 (1997); *Marketing Exclusivity and Patent Provisions for Certain Antibiotic Drugs*, 65 Fed. Reg. 3623, 3624-26 (Jan. 24, 2000). Thus, the patent certification requirement, which is the artificial act of infringement that triggers jurisdiction under § 271(e)(2), cannot occur in this case. See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678, 110 S. Ct. 2683, 2692, 110 L. Ed. 2d 605 (1990). Jurisdiction under § 271(e)(2) does not exist in this case. This Court need not address jurisdiction under § 271(e)(2) given that the parties agree that declaratory judgment jurisdiction exists.

package insert for Ceftin[®] with the '320 patent number). The '320 patent has now expired and cefuroxime axetil has entered the public domain, except for the narrow physical form covered by the '181 patent — the amorphous form “essentially free from crystalline material.”

Ranbaxy's antibiotic does not utilize the specific physical form claimed in the '181 patent. Instead, Ranbaxy has developed an antibiotic that uses a combination of the physical forms of cefuroxime axetil which is now in the public domain.

Under the ANDA process, drug manufacturers benefit by gaining extended patent terms, while the public benefits by obtaining lower cost generic drugs more rapidly through ANDA approval. Glaxo has obtained its benefit by receiving the maximum possible extension for the '320 patent, covering cefuroxime axetil. The '320 patent has expired, and the public is now entitled to its benefit, a generic cefuroxime axetil antibiotic. Ranbaxy seeks to provide the public its benefit under the ANDA process. Ranbaxy Br. at 62-64. The public interest favors allowing Ranbaxy to launch this antibiotic.

IV. CONCLUSION

For the foregoing reasons, this Court should reject Glaxo's arguments and grant the relief originally requested by Ranbaxy on appeal. Ranbaxy Br. at 65-66.

Respectfully submitted,

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Dated: 2/12/01

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RANBAXY PHARMACEUTICALS INC.

**CERTIFICATE OF COMPLIANCE UNDER
FED. R. APP. P. 32(a)(7)(C)**

Defendant-Appellant Ranbaxy Pharmaceuticals Inc. submits its brief under Rules 32(a)(5)(A) and 32(a)(7)(B) of the Federal Rules of Appellate Procedure. As required by Rule 32(a)(7)(C), I hereby certify that Ranbaxy Pharmaceuticals Inc.'s Reply Brief complies with the type-volume limitation therein provided, and I further certify that Ranbaxy Pharmaceuticals Inc.'s brief contains approximately 6,820 words, including headings, footnotes and quotations.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 2/11/01

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RANBAXY PHARMACEUTICALS INC.

PROOF OF SERVICE BY OVERNIGHT COURIER

In Re: REPLY BRIEF OF DEFENDANT-APPELLANT
RANBAXY PHARMACEUTICALS INC.; No. 01-1151
Caption: Ranbaxy Pharmaceuticals Inc. vs. Glaxo Group Limited, et al.
Filed: IN THE FEDERAL CIRCUIT COURT OF APPEALS (via Federal Express)

STATE OF CALIFORNIA)
) ss:
COUNTY OF LOS ANGELES)

I am a citizen of the United States and a resident of or employed in the City and County of Los Angeles; I am over the age of eighteen years and not a party to the within action; my business address is: 350 South Figueroa Street, Suite 400, Los Angeles, California 90071. On this date, I served two copies of the above-entitled document on the persons interested in said action by placing sealed envelopes in the service of an overnight courier for next business day delivery, addressed as follows:

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NOTE: Defendant-Appellant files this brief pursuant to FRAP 25(a)(2) (B)(ii): "A brief or appendix is timely filed . . . if on or before the last day for filing, it is dispatched to a third-party commercial carrier for delivery to the clerk within 3 calendar days."

Additionally One copy of this brief was also faxed on this day to opposing counsel.

I certify (or declare) under penalty of perjury that the foregoing is true and correct. Service and court filing executed on February 12, 2001, at Los Angeles, California.



E. Gonzales