United States Court of Appeals for the Federal Circuit

01-1329

BAYER AG and BAYER CORPORATION,

Plaintiffs-Appellants,

v.

BIOVAIL CORPORATION,

Defendant-Appellee,

and

ELAN CORPORATION, PLC and ELAN PHARMA, LTD.,

Defendants-Appellees,

and

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellee.

01-1330

BAYER AG and BAYER CORPORATION,

Plaintiffs-Appellants,

v.

ELAN PHARMACEUTICAL RESEARCH CORPORATION
and ELAN CORPORATION, PLC,

Defendants-Appellees.

Rudolf E. Hutz, Connolly Bove Lodge & Hutz LLP, of Wilmington, Delaware, argued for plaintiffs-appellants. With him on the brief were Jeffrey B. Bove, Mary W. Bourke, and William E. McShane.

Gary N. Frischling, Irell & Manella LLP, of Los Angeles, California, argued for defendants-appellees. With him on the brief for Elan Corporation, PLC, et al., were Richard M. Birnholz, Flavio Rose, Nicola J. Bird. Also on the brief for defendant-appellee Biovail Corporation was Eric C. Cohen, Welsh & Katz, of Chicago, Illinois; on the brief for defendant-appellee Teva Pharmaceuticals USA, Inc., was Frederick H. Rein, Goodwin Procter LLP, of New York, New York.

Appealed from: U.S. District Court for the Northern District of Georgia

Senior Judge William C. O'Kelley

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DECIDED: February 7, 2002

Before MICHEL, FRIEDMAN, and RADER, Circuit Judges.

RADER, Circuit Judge.

Bayer brought two separate actions in the United States District Court for the Northern District of Georgia asserting that Elan Pharmaceuticals Research Corp. (Elan) infringed U.S. Patent No. 5,264,446 (the '446 patent). The first action asserted that Elan infringed by filing an abbreviated new drug application (ANDA) with the Food and Drug Administration (FDA) seeking approval of a 60 mg generic version of the invention claimed in the '446 patent. The second action asserted infringement in Elan's marketing of a commercial 30 mg generic version. On summary judgment, the district court collaterally estopped Bayer from pursuing either action based on the court's previous finding of non-infringement in a related 30 mg ANDA infringement case. Because the district court erred in finding that it had necessarily and sufficiently construed the claims of the '446 patent in the 30 mg ANDA infringement case, this court vacates and remands both cases.

I.

In 1999, Bayer filed two lawsuits under 35 U.S.C. § 271(e)(2)(A) against Elan for infringement of the '446 patent. Bayer alleged that Elan infringed the '446 patent by filing ANDAs seeking FDA approval of the generic version of Bayer's 30 mg and 60 mg Adalat (R) (CC), a high blood pressure drug. Later that year, the district court resolved the 30 mg ANDA case in favor of Elan on a summary judgment of non-infringement. In 2000, this court affirmed that judgment. Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 54 USPQ2d 1710 (Fed. Cir. 2000). In 2000, Bayer also filed a third suit against Elan, Biovail Corp., and Teva Pharmaceuticals USA, Inc. (collectively Elan) under 35 U.S.C. § 271(a). In that case, Bayer argued that Elan's actual 30 mg generic commercial product infringed the '446 patent. The 60 mg ANDA case and the 30 mg commercial case are now on appeal before this court. The primary issue is whether collateral estoppel bars Bayer at the summary judgment phase in its two actions in light of the previous summary judgment of non-infringement in the 30 mg ANDA case.

The '446 patent claims a pharmaceutical composition, as well as a method for treating hypertension with that composition. The composition comprises crystals of nifedipine (a coronary vasodilator) with a specific surface area (SSA) of 1 – 4 m^2/g. SSA is important to the invention. SSA is the total surface area of all individual crystals per unit weight. SSA is generally inversely proportional to particle size – the larger the particles, the smaller the SSA. [BB 6, n.1] Bayer discovered that solid compositions comprising nifedipine drug crystals with a lower SSA unexpectedly demonstrated high solubility and good bio-availability. '446 patent, col. 3, ll. 47-58. Claims 1 and 4 claim this inventive feature. Claim 1 of the '446 patent reads (emphasis added):

> A solid pharmaceutical composition comprising as the active ingredient an effective amount of nifedipine crystals with a specific surface area of 1.0 to 4 m^2/g, in admixture with a solid diluent, to result in a sustained release of nifedipine.

Claim 4 reads (emphasis added):

> In a method for treating hypertension by administering an effective amount therefor of nifedipine crystals to a patient, the improvement comprising employing nifedipine crystals having a specific surface area of 1.0 to 4 m^2/g, in admixture with a solid diluent, to result in a sustained release of nifedipine.

The 30 mg ANDA case

On March 16, 1999, the district court granted Elan's motion for summary judgment that the 30 mg ANDA did not infringe the '446 patent. Bayer AG v. Elan Pharm. Research Corp., 64 F. Supp. 2d 1295 (N.D. Ga. 1999). On May 12, 2000, this court affirmed that judgment. Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 54 USPQ2d 1710 (Fed. Cir. 2000). This court observed that Elan amended its ANDA specification to cover nifedipine crystals with a SSA of at least 5 m^2/g, measured no more than five business days before tablet manufacture. Id. at 1246. This court also noted: "Significantly, Bayer does not allege that within five working days, the nifedipine's SSA will decrease from 5

m^2/g to a literally infringing size of 4 m^2/g or less. Therefore, under the ANDA specification, Elan cannot literally infringe the '446 patent." Id. at 1249.

This court also faulted Bayer's reliance in its infringement analysis on a biobatch featured as test data in Elan's ANDA because ANDA applicants have immunity from allegations of infringement for testing necessary to prepare an ANDA. This court also noted that Elan's 30 mg ANDA specification defined its product to avoid infringement (i.e., testing nifedipine crystals outside the claimed SSA range), in contrast with the ANDA specification at issue in Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 42 USPQ2d 1257 (Fed. Cir. 1997) (the ANDA specification did not test compounds specifically outside the claims). Id. at 1249, 1250. This court also held that prosecution history estoppel prevented Bayer from capturing a SSA above 4 m^2/g because Bayer had amended its SSA range limitation from 0.5 – 6 m^2/g to 1 – 4 m^2/g during prosecution. Thus, Bayer could not assert infringement under the doctrine of equivalents. Id. at 1251, 1252. Accordingly, this court upheld the judgment that Elan's 30 mg ANDA did not infringe the '446 patent.

The 60 mg ANDA case

On September 24, 1999, Bayer filed the 60 mg ANDA case with the district court, one of the two cases now on appeal. Elan argued that this court's affirmance of non-infringement in the 30 mg ANDA case estopped Bayer from pursuing the 60 mg ANDA case. Elan argued that the relevant issue in the two actions was identical, namely, whether Elan would likely make a product that literally infringes the '446 patent upon approval of its ANDA.

Bayer responded that collateral estoppel did not apply. Specifically, Bayer asserted that the district court in the 30 mg ANDA case erroneously limited the '446 patent claims to measure only the SSA of starting raw material nifedipine, and not the SSA of nifedipine in the manufactured tablet. Bayer AG v. Elan Pharm. Research Corp., No. 2:99-CV-167-WCO, slip op. at 14-15 (N.D. Ga. Mar. 21, 2001) (60 mg ANDA Summary Judgment Order). To support this assertion, Bayer submitted new and previously unavailable evidence showing that Elan's commercial tablets made under the 30 mg ANDA likely would infringe the '446 patent. Id. at 6, 7. Bayer also requested full discovery of Elan's entire 60 mg ANDA specifications and related materials, arguing that its new evidence of infringement justified discovery to verify that "those specifications 'define' a hypothetical product which cannot under any circumstances infringe," such as during manufacture. Bayer AG v. Elan Pharm. Research Corp., No. 2:99-CV-167-WCO, slip op. at 8-9 (N.D. Ga. Jan. 29, 2001) (60 mg ANDA Discovery Order).

The district court did not address claim construction in this new 60 mg ANDA case. Rather, finding Elan's ANDA specifications for the 60 mg product identical in relevant parts to those for the 30 mg product, the district court determined: "[T]he issue of whether Elan will likely make a product that literally infringes Bayer's '446 patent under these circumstances was previously decided in the 30 mg ANDA case." 60 mg ANDA Summary

Judgment Order, slip op. at 17. The district court also noted that collateral estoppel required an analysis of "whether Bayer can prove infringement of the '446 patent's '1.0 to 4 m^2/g' surface area requirement when Elan's specifications require Elan to use nifedipine greater than 5 m^2/g . . . and when Elan's supplier AWD's [Arzneimittelwerk Dresden GmbH's] specifications require that it only sell nifedipine with a surface area more than 4.7 m^2/g." 60 mg ANDA Discovery Order, slip op. at 11. This analysis, according to the district court, required examination of the decisions in the 30 mg ANDA case, the 60 mg ANDA SSA specifications, and AWD's SSA specifications, but not evidence of nifedipine SSA in the commercial tablet. Id. at 11-12. With these findings and conclusions, the district court dismissed Bayer's discovery request and granted Elan's motion for summary judgment of non-infringement based on collateral estoppel.

The 30 mg commercial case

On May 8, 2000, Bayer filed the 30 mg commercial case, the second of the two cases now on appeal. In this case, Bayer argued before the district court that it had obtained samples of the commercial 30 mg tablets Elan released on the market after final FDA approval of its 30 mg ANDA. As in the 60 mg ANDA case, Bayer submitted evidence that the SSA of those nifedipine tablets fell within the 1 – 4 m^2/g range recited in the '446 patent. Bayer AG v. Biovail Corp., No. 2:00-CV-128-WCO, slip op. at 12 (N.D. Ga. Mar. 27, 2001) (30 mg Commercial Summary Judgment Order). In this case, however, unlike either the 30 mg or 60 mg ANDA cases, where allegations of infringement were based on ANDA specifications and "hypothetical" compositions for future marketing, Bayer proffered evidence of actual infringement by the commercial product.

The district court determined that:

> [W]hile this court did not "expressly" articulate a construction of the '446 patent [in the 30 mg ANDA case] . . . the court found that a BET measurement of SSA of at least 5 m^2/g measured on the starting material

> avoids infringement. . . . [Thus], the court had to necessarily construe the '446 claims as applied to the BET measurements made on the batch of starting raw material.

30 mg Commercial Summary Judgment Order, slip op. at 12. Regarding Bayer's new evidence, the district court opined:

> [W]hile Bayer's final commercial tablets were not in existence when the court ruled . . . in the first action, it is unclear why Bayer chose not to present any actual SSA measurements taken from any finished tablets, including any of its own tablets or from Elan's biobatch. . . . If Bayer had a basis to believe that Elan could comply with its specifications and nevertheless infringe, its opportunity to pursue that theory fully was in the 30 mg ANDA case. It is also unclear why Bayer chose not to pursue on appeal its assertion that SSA declines over time and that the appropriate time for measurement is after tableting. . . . Notably, Bayer did not suggest to the Federal Circuit that it had extracted nifedipine from Elan's biobatch tablets nor did Bayer argue that the nifedipine crystals should be measured after tableting.

Id. at 16-17. Based on its inherent claim construction in the 30 mg ANDA case and Bayer's failure to supply evidence that Elan changed its ANDA specifications, the district court concluded that Bayer did not show a genuine issue of material fact on infringement in the 30 mg commercial case.

Bayer also requested discovery in the 30 mg commercial case of Elan compliance with its ANDA raw material specifications, and, assuming Elan did comply, the cause of the reduction in SSA in the Elan commercial tablets that Bayer tested. Id. at 20. The district court found that Bayer's discovery requests mistakenly assumed that measurements of nifedipine SSA in the commercial tablet were evidence of literal infringement. This assumption, the district court noted, was contrary to the inherent claim construction in the 30 mg ANDA case limiting the measurements to raw starting materials. Id. at 23. Thus, the court denied Bayer's motion for discovery, and granted Elan's motion for summary judgment for non-infringement based on collateral estoppel. Id. at 24.

In sum, in both the 60 mg ANDA and the 30 mg commercial cases, the district court granted Elan's motions for summary judgment of non-infringement based on collateral estoppel in light of the 30 mg ANDA case and denied Bayer's motions for additional discovery. Bayer appeals the district court's decisions in both cases. This court has jurisdiction under 28 U.S.C. § 1295(a)(1).

II.

This court reviews a grant of summary judgment without deference. Johns Hopkins Univ. v. Cellpro, Inc., 152 F.3d 1342, 1353, 47 USPQ2d 1705, 1713 (Fed. Cir. 1998) (citing Conroy v. Reebok Int'l, 14 F.3d 1570, 1575, 29 USPQ2d 1373, 1377 (Fed. Cir. 1994)). This court must decide for itself "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). In this process, this court draws all justifiable inferences in the nonmovant's favor. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986).

Because the application of collateral estoppel is not a matter within the exclusive jurisdiction of this court, this court applies the law of the circuit in which the district court sits, Pharmacia & Upjohn Co. v. Mylan Pharms., Inc., 170 F.3d 1373, 1381 n.4, 50 USPQ2d 1033, 1040 n.4 (Fed. Cir. 1999), the Eleventh Circuit in this case. In the Eleventh Circuit, "[w]hether collateral estoppel is available is a mixed question of law and fact in which the legal issues predominate. The question of its availability is subject to our de novo review." In re McWhorter, 887 F.2d 1564, 1566 (11th Cir. 1989) (quoting Davis & Cox v. Summa Corp., 751 F.2d 1507, 1519 (9th Cir. 1985)).

Collateral estoppel forecloses re-litigation of an issue of fact or law where an identical issue has been fully litigated and decided in a prior suit. Grosz v. City of Miami Beach, Fla., 82 F.3d 1005, 1006 (11th Cir. 1996). Collateral estoppel requires four showings:

> (1) the issue at stake was identical to the one involved in the prior litigation; (2) the issue had been actually litigated in the prior suit; (3) the determination of the issue in the prior litigation was a critical and necessary part of the judgment in that action; and (4) the party against whom the earlier decision is asserted had a full and fair opportunity to litigate the issue in the earlier proceeding.

In re McWhorter, 887 F.2d at 1566 (citing I.A. Durbin, Inc. v. Jefferson Nat'l Bank, 793 F.2d 1541, 1549 (11th Cir. 1986)).

A.

The 60 mg ANDA case presents an issue very similar to the one resolved in the prior 30 mg ANDA suit. Both ANDA suits require examination of nearly identical ANDA specifications – presumably identical in that the nifedipine raw material must have a SSA of at least 5 m^2/g, as measured no more than five business days before tablet manufacture. Both suits address whether those nearly identical ANDA specifications infringe the '446 patent under 35 U.S.C. § 271(e)(2)(A). In both cases, the focus "is on 'what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred.'" Bayer, 212 F.3d at 1248 (quoting Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569, 42 USPQ2d 1257, 1263 (Fed. Cir. 1997)).

While the legal issues are facially similar, the factual evidence proffered in the 60 mg ANDA case differs from the evidence in the 30 mg ANDA case. See In re McWhorter, 887 F.2d at 1568 (finding an application of collateral estoppel improper because "[t]he previous litigation did not address [an] additional inference [of fact], and thus the issue now before the court is not identical to the previously litigated issue"). In the 30 mg ANDA case, Elan provided evidence that its supplier "requirements [did] not allow the sale of nifedipine under 4.7 m^2/g to customers for use in products sold in the U.S." and "a certified test of the nifedipine used in its batch of tablets show[ed] a SSA of 6.15 m^2/g." Bayer, 64 F. Supp. 2d at 1300. Bayer did not, presumably because at that time it could not, provide evidence of infringement by the ANDA tablet in the 30 mg ANDA case. As noted correctly by the district court at that time:

> [I]t is not enough for Bayer to suggest that the accused product may be infringing at some point in the future. The relevant test is whether Elan's drug, if put on the market, would infringe Bayer's patent. . . . [T]he patentee

> has the burden of showing that the product that Elan would likely sell following FDA approval would likely infringe its patent. Here, Bayer has offered no such evidence. Bayer's unsubstantiated assertions can not form the basis for a literal infringement claim.

Id. (citations omitted). In other words, neither party in the 30 mg ANDA case submitted evidence that the commercial product – as distinct from the raw starting material for that product – would include nifedipine crystals with a specific surface area within the claimed range of 1.0 to 4 m^2/g. Consequently, based on Elan's raw material evidence alone, the district court properly granted summary judgment of non-infringement on Elan's 30 mg ANDA.

In the 60 mg ANDA case, by contrast, Bayer introduced evidence of actual infringement by a commercial tablet made under the specifications of an allegedly identical ANDA (because the 30 mg and 60 mg ANDAs must be identical in relevant part for collateral estoppel to apply). Unlike the 30 mg ANDA case, Bayer submitted a declaration by Professor Markus Antonietti that Elan's 30 mg commercial tablet contained nifedipine crystals with a specific surface area of 1.0 to 4 m^2/g. According to his declaration, Professor Antonietti performed a "gradient separation method" and an "isopycnic separation method" to determine the nifedipine SSA in the commercial tablets. Using those two methods, he discovered the SSA in the tablets to be, on average, 3.32 m^2/g and 3.40 m^2/g, respectively.

Even assuming Elan strictly follows its 60 mg ANDA (presumably identical in relevant part to the 30 mg ANDA) in making a commercial tablet, Professor Antonietti's declaration raises a legitimate question as to whether Elan will likely make a 60 mg product that literally infringes Bayer's '446 patent upon approval of the ANDA. This question – the fundamental question in the 60 mg ANDA infringement case – requires claim construction of the terms "effective amount of nifedipine crystals with a specific

surface area of 1.0 to 4 m^2/g" in composition claim 1, and "employing nifedipine crystals having a specific surface area of 1.0 to 4 m^2/g" in method claim 4.

If those claim terms apply only to the SSA of raw material nifedipine crystals, as measured by the BET method before tablet manufacture, Professor Antonietti's declaration regarding the nifedipine SSA in the commercial tablets is irrelevant to the 60 mg ANDA infringement analysis. In other words, under that claim construction, as long as the 30 mg and 60 mg ANDAs are identical in relevant part, collateral estoppel principles will dictate summary judgment of non-infringement, as the district court determined. If, however, those claim terms also encompass SSA of nifedipine recovered from manufactured tablets, as measured by BET or another method, the district court must consider Professor Antonietti's declaration in its 60 mg ANDA infringement analysis. Bayer, 212 F.3d at 1249 ("[I]t is proper for the court to consider the ANDA itself, materials submitted by the ANDA applicant in support of the ANDA, and any other relevant evidence submitted by the applicant or patent holder.") (emphasis added).

In the 30 mg commercial case, the district court asserted that it had necessarily construed "nifedipine crystals with a specific surface area of 1.0 to 4 m^2/g" in the 30 mg ANDA case to mean only BET measurements on starting raw material. 30 mg Commercial Summary Judgment Order, slip op. at 12. The district court further reasoned that this circuit had affirmed that construction. Id. The district court's opinion in the 30 mg ANDA case, however, merely stated: "The only measurement methods taught in the '446 patent are BET measurements made on the batch of starting material." Bayer, 64 F. Supp. 2d at 1300. This single sentence, especially without any express reference to claim construction, is a sandy foundation upon which to build a multi-storied collateral estoppel building.

Moreover, despite the district court's suggestion to the contrary, this court did not construe the claims nor affirm a claim construction in the 30 mg ANDA case. Rather, this court merely stated that Elan's testing biobatch was irrelevant, and that Bayer did not allege that within 5 days of manufacture the nifedipine's SSA would decrease to a size of 4 m^2/g or less. This court did say, "[i]n short, the only drug Elan can produce upon approval of the ANDA at issue is a drug that does not literally infringe the '446 patent." Bayer, 212 F.3d at 1250. This statement, however, did not construe the claims nor assume a particular claim construction. Because neither party raised the issue of whether the tablets after manufacture would infringe, this court did not address whether the claims would include such tablets, even assuming Elan complied with its ANDA specification. Thus, neither the district court nor this court in the 30 mg ANDA case conducted a complete and binding claim construction of the relevant terms, either expressly or implicitly.

This court notes that the claims themselves do not indicate a measurement method for SSA, nor whether the SSA requirement applies only to raw starting material as distinguished from manufactured tablets. As found by the district court in the 30 mg ANDA case, the '446 specification states that "[t]he specific surface are[a] is measured by the gas absorption method (BET method; see S. Brunauer: The absorption of Gases and Vapours, Princeton (1945))." '446 patent, col. 3, ll. 44-46. In addition, the examples in the specification discussing nifedipine SSAs only refer to drug crystals before final preparation of the composition. '446 patent, col. 4, l. 52 – col. 5, l. 28. The specification does not disclose SSA measurements on the claimed composition in tablets. Elan also submitted evidence that Bayer supplied only BET method measurements on nifedipine raw material during prosecution of the '446 patent, even though Bayer allegedly conducted measurements on tablets before the patent issued.

Notwithstanding this intrinsic evidence, "[t]he claim language, of course, defines the bounds of claim scope." York Prods., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572, 40 USPQ2d 1619, 1622 (Fed. Cir. 1996). While a court may look to the specification and prosecution history to interpret what a patentee meant by a word or phrase in a claim, extraneous limitations cannot be read into the claims from the specification or prosecution history. Burke, Inc. v. Bruno Indep. Living Aids, Inc., 183 F.3d 1334, 1340, 51 USPQ2d 1295, 1299 (Fed. Cir. 1999) (citing Intervet Am., Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1053, 12 USPQ2d 1474, 1476 (Fed. Cir. 1989) ("[T]his court has consistently adhered to the proposition that courts cannot alter what the patentee has chosen to claim as his invention, that limitations appearing in the specification will not be read into claims, and that interpreting what is meant by a word in a claim 'is not to be confused with adding an extraneous limitation appearing in the specification, which is improper.'") (quoting E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433, 7 USPQ2d 1129, 1131 (Fed. Cir. 1988))). In other words, a court may not read into a claim a limitation from a preferred embodiment, if that limitation is not present in the claim itself.

To construe the meaning of "nifedipine crystals with [or having] a specific surface area of 1.0 to 4 m^2/g," a court must consider what was known to one of ordinary skill in this art (SSA measurements on pharmaceuticals) at the time of filing, in addition to the claims, the specification, and the prosecution history. Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1561, 19 USPQ2d 1500, 1503 (Fed. Cir. 1991); Fonar Corp. v. Johnson & Johnson, 821 F.2d 627, 631, 3 USPQ2d 1109, 1112 (Fed. Cir. 1987) ("[e]xpert testimony, including evidence of how those skilled in the art would interpret the claims," applies in claim construction). The parties both agree that one of ordinary skill in this art understood the BET method for SSA measurements on raw material crystals at the time of filing in

1981.[*] The parties dispute, however, whether one of skill in the art would have known, based on the '446 patent and the prior art, how to perform an in-the-tablet SSA measurement on the nifedipine crystals, i.e., how to determine if manufactured tablets contain "nifedipine crystals with [or having] a specific surface area of 1.0 to 4 m^2/g," as of the effective filing date. In other words, the parties dispute whether, at the time of filing, the specification and prior art supported an interpretation of "nifedipine crystals with [or having] a specific surface area of 1.0 to 4 m^2/g" in the claims that includes nifedipine crystal SSA in the tablets after manufacture. See Union Oil Co. v. Atlantic Richfield Co., 208 F.3d 989, 997, 54 USPQ2d 1227, 1233 (Fed. Cir. 2000) (stating that "the Patent Act and this court's case law require only sufficient description to show one of skill in the refining art that the inventor possessed the claimed invention at the time of filing.").

As discussed above, the district court did not, either in the 30 mg ANDA case or the two cases now on appeal, address this claim construction issue. While claim construction is a matter of law reviewed without deference on appeal, Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456, 46 USPQ2d 1169, 1174 (Fed. Cir. 1998) (en banc), the district court in this case has yet to perform a comprehensive claim construction of the relevant terms based on a complete record. See CVI/Beta Ventures, Inc. v. Tura LP, 112 F.3d 1146, 1160 n.7, 42 USPQ2d 1577, 1587 n.7 (Fed. Cir. 1997) ("[U]nlike the earlier appeal [a preliminary injunction proceeding], this appeal required us to construe the asserted claims based upon the final and complete record in the case."). Therefore, it would be premature for this court to engage in its own claim construction without, for instance, evidence of the meaning of the terms to one of skill in the art at the time of invention. In sum, this court does not yet have a claim construction to review.

[*] The '446 patent application is the fifth in a series of continuation applications based on an original application filed on August 20, 1981.

This court cannot affirm the district court's grant of summary judgment of non-infringement without a proper claim construction of the relevant claim limitations. Consequently, this court remands for that claim construction. After construing the claims, the district court may assess the need for further proceedings or discovery. In those proceedings, if required, the district court may ascertain the relevance of Professor Antonietti's declaration as well as other factual evidence with regard to "what the ANDA applicant will likely market if its [60 mg ANDA] application is approved." Bayer, 212 F.3d at 1248 (quoting Glaxo, 110 F.3d at 1569).

B.

As in the 60 mg ANDA case, this court cannot uphold a grant of summary judgment in the 30 mg commercial case based on collateral estoppel and an inherent claim construction in the 30 mg ANDA case. As noted before, the 30 mg ANDA case did not involve actual product tablets or a resolution of claim construction in that context. The 30 mg ANDA case only dealt with the SSA of raw material as recited in the ANDA specification. Neither the district court nor this court construed the claims in relation to actual tablets manufactured under the ANDA. Without this claim construction, this court cannot determine whether the 30 mg tablets infringe the '446 patent, irrespective of whether Elan followed the specifications of its 30 mg ANDA.

Moreover, in this 30 mg commercial case, in contrast with the ANDA cases, the "hypothetical inquiry" disappears. Rather, this case features an actual commercial product with actual test results from Bayer. This case, therefore, does not ask what Elan will likely market, but what Elan has actually marketed. In entering summary judgment on this case, the district court apparently drew inferences from Bayer's lack of proof about tablets in earlier cases: "[I]t is unclear why Bayer chose not to present any actual SSA measurements taken from any finished tablets, including any of its own tablets or from

Elan's biobatch." 30 mg Commercial Summary Judgment Order, slip op. at 16. In the context of an ANDA case, however, Bayer had little incentive to discuss or present evidence about actual tablets. SSA measurements on Bayer's own tablets, or tablets from Elan's biobatch, would have been, at best, only tangentially relevant to an ANDA infringement analysis. As noted by this court, "Elan's biobatch does not control the issue of infringement." Bayer, 212 F.3d at 1250. Moreover, because the 30 mg ANDA case focused only on the ANDA specification, the narrow issues of that case required Bayer to focus on the SSA of the nifedipine raw material, rather than tablets later manufactured under the approved ANDA. In fact, Bayer could not have possessed Elan's manufactured tablets during the 30 mg ANDA case. Thus, this court can draw no negative inferences from Bayer's failure to present evidence about tablets in the earlier ANDA proceeding.

In the 30 mg ANDA case, the district court also stated:

> The court's determination as to literal infringement does not leave Bayer without a remedy, however, should its fears [that the accused product infringes at some point in the future] prove merited. If Elan commences to manufacture a product with a SSA within the range claimed in Bayer's patent, Bayer may then bring an infringement action against Elan.

Bayer, 64 F. Supp. 2d at 1301 (emphasis added). On appeal in the 30 mg ANDA case, this court made note of that statement when it said: "The district court concluded by noting that Bayer could sue Elan for infringement if Elan begins manufacturing for commercial sale a product with a SSA within 1.0 to 4 m^2/g, as claimed by the '446 patent." Bayer, 212 F.3d at 1248 (emphasis added). Thus, the district court correctly recognizes that the 30 mg ANDA case itself does not collaterally estop Bayer from pursuing the 30 mg commercial case if the patent covers tablets and evidence shows that Elan's manufactured tablets have an SSA within the claimed range.

In sum, infringement under § 271(e)(2)(A) by submission of an ANDA is not synonymous with infringement under § 271(a) by a commercial product. Evidence of

actual infringement (contrasted with evidence of a "hypothetical" infringement) may differ in substance and may become available only after manufacture of the composition. Therefore, at a minimum, Bayer did not have a full and fair opportunity to litigate the issue of infringement by the commercial tablets because those tablets were not available until after ANDA approval. Because the 30 mg ANDA case cannot support collateral estoppel on this different 30 mg commercial case, this court also vacates this case and remands for further proceedings.

III.

This court vacates the judgments of non-infringement of the '446 patent in the 60 mg ANDA and the 30 mg commercial cases. Both cases are remanded to the district court for further proceedings, particularly to construe the claim terms "nifedipine crystals with a specific surface area of 1.0 to 4 m^2/g" in claim 1 and "nifedipine crystals having a specific surface area of 1.0 to 4 m^2/g" in claim 4.

COSTS

Each party shall bear its own costs.

VACATED AND REMANDED