United States District Court,
E.D. Virginia, Richmond Division.

LUPIN LIMITED,
Plaintiff.
v.
ABBOTT LABORATORIES, and Astellas Pharma, Inc,
Defendants.
Abbott Laboratories, and Astellas Pharma, Inc,
Counterclaim Plaintiffs.
v.
Lupin Limited, and Lupin Pharmaceuticals, Inc,
Counterclaim Defendants.

Civil Action No. 3:06cv400

April 27, 2007.

Background: Potential manufacturer of generic version of crystalline form of antibiotic cefdinir sought declaration that its product did not infringe patent for antibiotic. Inventor and its affiliate filed counterclaims against manufacturer, alleging its product infringed patent.

Holdings: The District Court, Payne, J., held that:
(1) inventor patented only form that parties referred to as "Crystal A" to the exclusion both of "Crystal B," which was disclosed in Japanese priority application, and of any forms of cefdinir disclosed prior patent, and "Crystal A" was not only the preferred embodiment or subset of patent's invention;
(2) term "shows," in specification describing crystalline which shows the peaks at diffraction angles, required the display of a powder X-ray diffraction (PXRD) pattern which demonstrated existence of the relevant peaks to a scientifically acceptable degree of certainty;
(3) "peaks," existed at a PXRD angle that corresponded to an intensity measurement greater than measurements attributable to "noise," if that angle was immediately preceded by and immediately followed by PXRD angle with a lower intensity measurement;
(4) term "about" encompassed measurement errors inherently associated with PXRD testing; and
(5) claims were product-by-process claims.

Claims construed.

4,935,507. Construed.

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MEMORANDUM OPINION

PAYNE**, District Judge.**

This matter is before the Court on the construction of U.S. Patent No. 4,935,507 ("'507 patent"). The '507 patent relates to the antibiotic cefdinir in its crystalline form. The parties dispute the scope of the '507 patent and, specifically, whether it encompasses only one particular form of crystalline cefdinir.

BACKGROUND

Cefdinir is an effective antibiotic which, in its crystalline form, has worldwide sales exceeding $600 million per year. Cefdinir's inventor, Astellas Pharma, Inc. ("Astellas"), has secured, in the United States, two patents for cefdinir. According to Astellas, the first, U.S. Patent No. 4,559,334 ("'334 patent"), covers a crystalline-like amorphous form of cefdinir. The ' 334 patent was issued in 1985. Its term was extended and is set to expire on May 6, 2007. The '507 patent, the patent-in-suit, does not expire until December 4, 2011 and covers only some form, or forms, of the crystalline cefdinir which is on the market today. FN1

FN1. Astellas received a patent term extension (PTE) for the '507 patent on January 19, 2001. Without that PTE, the '507 patent would expire on August 8, 2008. Whether the '507 patent's PTE is enforceable is disputed by the parties, and will be addressed in a separate memorandum opinion.

One of the cefdinir forms indisputably covered by the '507 patent is Onmicef(R), the branded crystalline cefdinir product and marketed by Abbott Laboratories ("Abbott"). After the expiration of the '334 patent, Lupin Limited ("Lupin") hopes to produce and market a generic form of crystalline cefdinir to compete with Omnicef(R), and seeks a declaration that its product "has not infringed, does not infringe, and will not infringe any valid and enforceable claim of" the '507 patent. (Compl. for Declaratory J. at 1.) Abbott and Astellas each have filed counterclaims against Lupin, alleging that Lupin's crystalline cefdinir product infringes the '507 patent. (Dockets No. 18 and 21.) The first step in resolving this infringement dispute requires the Court to construe the claims of the '507 patent.

The specification of the '507 patent explains that Astellas developed the invention claimed in the '507 patent because the cefdinir forms disclosed in the '334 patent have somewhat limited use as a marketable antibiotic. Indeed, shortly after obtaining the '334 patent, Astellas discovered at least two crystalline forms of cefdinir featuring certain qualities that make the drug more marketable and, therefore, more valuable. FN2 Unsurprisingly, Astellas sought to patent the new crystalline forms. In 1987, Astellas filed a patent application in Japan ("the Japanese priority application" or "'199 Application") seeking explicitly to claim the two newly-discovered crystalline forms of cefdinir, which Astellas labeled "Crystal A" and "Crystal B."

See Japanese Patent Application No. 62-206199 at 1-2 (filed Aug. 19, 1987). FN3 One year later, Astellas filed a similar patent application in the United States and claimed priority to the patent application filed in Japan the year before. FN4 *See* United States Patent Application No. 07/229,489 (filed Aug. 8, 1988). The patent application filed in the United States eventually became, with a few changes, the ' 507 patent.

FN2. The '507 patent's specification describes the products disclosed in the '334 patent as "amorphous" or "crystalline like," but not as "crystalline," which is the preferred form of cefdinir. U.S. Patent No. 4,935,507 col.1 ll.27-28 (filed Aug. 8, 1988).

FN3. References to the Japanese Priority Application are references to the English translation of that document provided by Abbott and Astellas. (*See* Abbott Laboratories' and Astellas Pharma, Inc.'s Mem. in Supp. of Their Proposed Claim Construction Ex. 3.)

FN4. The Japanese priority application is, therefore, included in the '507 patent's file wrapper and is part of its prosecution history.

Whereas the Japanese priority application sought explicitly to claim the forms of cefdinir called Crystal A and Crystal B, the claims of the '507 patent are worded more generally, and read as follows:

What we claim is:

1. Crystalline 7-[2-(2-aminothiazol-4-yl) -2-hydroxyiminoacetamido]-3-vinyl-3-cephem4-carboxylic acid (syn isomer) FN5 which shows the peaks at the diffraction angles shown in the following table in its x-ray diffraction pattern:

FN5. The parties agree that the term "crystalline 7-[2-(2-aminothiazol-4-yl)-2 -hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer)" may be read as "crystalline cefdinir." References to "cefdinir" are references to the chemical compound described by the chemical name that follows the word "crystalline" in Claim 1 of the '507 patent.

diffraction angle ((deg.))
about 14.7
about 17.8
about 21.5
about 22.0
about 23.4
about 24.5
about 28.1

2. Crystalline 7-[2-(2-aminothiazol-4-yl) -2-hydroxyiminoacetamido]-3-vinyl-3-cephem4-carboxylic acid (syn isomer) which is obtainable by acidifying a solution containing 7-(2-(2-aminothiazol-4-yl)-2-

hydroxyiminoacetamido)-3-vinyl-3-cephem4-carboxylic acid (syn isomer) at room temperature or under warming.
3. Crystalline substance of claim 2, wherein a solution containing 7-[2-(2-aminothiazol-4-yl)2 -hydroxyiminoacetamido]-3-vinyl-3-cephem4-carboxylic acid (syn isomer) is an aqueous solution of an alkali metal salt of said compound.

4. Crystalline substance of claim 3, wherein the acidifying of the solution is carried out at the temperature from room temperature to 40 (deg.) C. at the pH from 1 to 4.

5. Crystalline 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) which is obtainable by dissolving 7-(2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido)-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) in an alcohol, continuing to stir the solution slowly under warming, then cooling the solution to room temperature and allowing the solution to stand.

U.S. Patent No. 4,935,507 col.16 ll.12-50 (filed Aug. 8, 1988).
Although the claims of the '507 patent do not use the terms Crystal A or Crystal B, Lupin argues that the '507 patent's claims must be limited to Crystal A because the specification declares the invention of the '507 patent to be Crystal A. Moreover, Lupin points out, the specification addresses itself exclusively to touting the benefits of, and reciting the processes for preparing, Crystal A. Finally, Lupin argues that the '507 patent's prosecution history confirms that Astellas patented only Crystal A to the exclusion both of Crystal B, which was disclosed in the Japanese priority application, and of any forms of cefdinir disclosed in the '334 patent. Astellas and Abbott disagree, and contend that Crystal A is only the preferred embodiment of the '507 patent's invention, and that the patent's claims are not limited to Crystal A.

To support their different constructions of the '507 patent, the parties have focused on the proper interpretation of three claim terms: "crystalline," "show the peaks," and "about." As a general matter, Lupin seeks a restrictive reading of those three terms that would explicitly or practically limit the scope of the '507 patent to Crystal A. On the other hand, Abbott and Astellas generally urge a broader reading of those three terms that would potentially expand the patent's reach beyond Crystal A.

The parties also dispute the proper reading of Claims 2-5. Lupin argues that they should be construed to be process claims or, alternatively, limited to Crystal A if construed to be product-by-process claims. Abbott and Astellas contend that Claims 2-5 are clearly product-by-process claims that, like Claim 1, are not necessarily limited to Crystal A alone.

DISCUSSION

[1] [2] [3] [4] The construction of patent claims is a matter of law for the court. Markman v. Westview Instruments, Inc., 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). It is axiomatic in patent law that "the claims of a patent define the invention to which the patentee is entitled the right to exclude." Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1115 (Fed.Cir.2004). Therefore, "the words of a claim 'are generally given their ordinary and customary meaning.' " Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed.Cir.2005) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996)). The ordinary and customary meaning of a claim term is the meaning it would have to a person of ordinary skill in the art. Id. at 1313.

[5] [6] Importantly, however, the claims "do not stand alone." Id. at 1315. Indeed, the person of ordinary

skill in the art is deemed to have read the claims, and, specifically, a disputed claim term, "not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Id. Because the claims and the specification are part of a "fully integrated written instrument," Markman v. Westview Instruments, Inc., 52 F.3d 967, 978 (Fed.Cir.1995), the specification is "the single best guide to the meaning of a disputed term," Vitronics, 90 F.3d at 1582. In fact, "[u]sually, it is dispositive." Vitronics, 90 F.3d at 1582.

[7] That said, courts, in construing claim terms, must be careful not to read limitations from the specification into the claims. Phillips, 415 F.3d at 1323. In that regard, the Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." Id. That is not to say, however, that the claims of a patent are never limited in scope to the embodiment or embodiments described in the specification. After reading the specification it will become clear, on most occasions, "whether the patentee is setting out specific examples of the invention ... or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive." Id. While there may be some cases in which the specification does not clarify the scope of a claim term, courts should make their best effort to construe claims in light of the specification rather than divorce the claim language from the specification entirely. Id. at 1323-24.

[8] [9] Courts also may consider the patent's prosecution history when construingclaim terms. A patent's prosecution history is part of the "intrinsic evidence" (along with the language of the patent itself), and "consists of the complete record of the proceedings before the Patent and Trademark Office (PTO)." Id. at 1317. While the prosecution history is less useful than the specification for claim construction purposes, it "can often inform the meaning of claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claims scope narrower than it would otherwise be." Id.

[10] Finally, it also is permissible to consider extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Markman, 52 F.3d at 980. The Federal Circuit has warned, however, that extrinsic evidence is "less reliable than the patent and its prosecution history" in construing claim terms, and "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." Phillips, 415 F.3d at 1318-19. In particular, a court risks interpreting disputed claim terms far too expansively if it focuses on extrinsic evidence rather than the specification, which might explicitly or implicitly circumscribe the terms used in the claims. Id. at 1321.

The foregoing precepts will govern the construction of the '507 patent, beginning with the term "crystalline."

A. "Crystalline"

1. The Claim Language

[11] The term "crystalline" is used in all five claims in the '507 patent. The parties are in general agreement that "crystalline" ordinarily means "of or made up of crystals." (Claim Construction Br. of Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Lupin Br.") at 7.) "Crystals" are distinctive because their molecules or atoms are uniformly arranged. (Abbott Laboratories' and Astellas Pharma, Inc.'s Mem. in Supp. of Their Proposed Claim Construction ("Abbott and Astellas Br.") at 12.) Therefore, the parties agree that, under the ordinary meaning of "crystalline," a compound in its crystalline form exhibits uniformly arranged molecules or atoms.

That, however, is not the end of the matter because Claim 1 is naturally read to claim a form of crystalline cefdinir which displays certain characteristics. Specifically, the text claims "[c]rystalline cefdinir which shows the peaks" at certain powder X-ray diffraction (PXRD) angles. '507 Patent col.1 ll.12-15. The peaks at those PXRD angles are what distinguish the '507 patent's invention from other crystalline forms of cefdinir. Similarly, Claims 2-5 claim crystalline cefdinir which is obtainable by certain process steps, and those steps serve further to define the '507 patent's invention.

Lupin argues that "crystalline," in the context of that patent's claims, must be read to mean "Crystal A as explained in the specification." FN6 First, Lupin argues that the specification implicitly defined "crystalline" to mean "Crystal A" and explicitly described Crystal A as "the present invention." Second, Lupin argues that the ' 507 patent's prosecution history confirms that Crystal A constitutes the full extent of that patent's invention. Abbott and Astellas argue, on the other hand, that the specification and prosecution history disclose nothing that requires the Court to limit the ordinary meaning of "crystalline," and that Crystal A is merely the preferred embodiment of the ' 507 patent's invention.

FN6. Although the parties dispute the meaning of "crystalline" within the claims, the purpose of defining "crystalline" is to establish scope of "crystalline cefdinir" as described in the claims.

2. The Specification

Abbott and Astellas urge the Court not to give any effect to the specification in the '507 patent and to confine the inquiry to the accepted meaning of the term "crystalline." (*See* Abbott and Astellas Br. at 5.) As noted above, however, the Federal Circuit has warned against divorcing the claims language from the specification, and instructs courts to refer to the specification in seeking to define disputed claim terms. Indeed, it is appropriate to consider the specification even where the disputed claim term has an agreed-upon general meaning, as is the case here. For example, in Astrazeneca AB v. Mutual Pharmaceutical Co., the Federal Circuit relied on the specification to narrow the construction of the term, "solubilizer," a term with a generally-accepted meaning, to "surfactant," one particular type of solubilizer. 384 F.3d 1333, 1341 (Fed.Cir.2004). The Federal Circuit reached that conclusion because, in the specification, the patentee had stated that "solubilizer" meant, in the context of that patent, "surfactant," and because the patentee had "clearly disavow[ed]" non-surfactant solubilizers in the language of the specification. Id. at 1339-40. Given the Federal Circuit's reasoning in Astrazeneca, the Court risks misconstruing the term "crystalline cefdinir" if it turns a blind eye to the '507 patent's specification and focuses only on the word "crystalline" as it appears in text of the claims.

Moreover, the Federal Circuit has construed patents in such a way that "the embodiments of the invention set forth in the specification constituted the invention itself, in spite of claim language that could, in the abstract, be interpreted more broadly." Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 907 (Fed.Cir.2004) (citing Biogen, Inc. v. Berlex Labs., Inc., 318 F.3d 1132, 1139-40 (Fed.Cir.2003); Watts v. XL Sys., Inc., 232 F.3d 877, 882-83 (Fed.Cir.2000); Cultor Corp. v. A.E. Staley Mfg. Co., 224 F.3d 1328, 1331 (Fed.Cir.2000); Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1301-02 (Fed.Cir.1999); Gen. Am. Transp. Corp. v. Cryo-Trans, Inc., 93 F.3d 766, 770 (Fed.Cir.1996); Modine Mfg. Co. v. U.S. Int'l Trade Comm'n, 75 F.3d 1545, 1550-51 (Fed.Cir.1996)). Of course, those decisions do not require a patent's scope to be limited in all cases to the particular embodiments disclosed in the specification, but there certainly are instances in which the specification makes "clear that the invention was limited to a particular

structure" disclosed in the specification. Id. at 908. Here, the Court has a duty to decide whether the specification plays such a role in the '507 patent.

[12] [13] There are no talismanic words to indicate whether an embodiment in a specification constitutes the extent of the invention or is merely an example. Sometimes, the specification operates to circumscribe broadly written claims because it contains express limiting definitions and language disclaiming other embodiments. *See* id. at 907. But, neither explicit definitions nor explicit disclaimers are necessary, and claims also may be coextensive with a particular embodiment simply because the inventor affirmatively, and clearly, described the invention to be a particular embodiment disclosed in the specification. *See* Toro, 199 F.3d at 1300-02. Accordingly, the Federal Circuit states the basic guiding principle as follows: although the claims are not necessarily limited to the preferred embodiment of the invention, "neither do the claims enlarge what is patented beyond what the inventor has described as the invention." Netword, LLC v. Centraal Corp., 242 F.3d 1347, 1352 (Fed.Cir.2001).

Here, Astellas described its invention as "Crystal A." At the outset of the '507 patent's specification, Astellas represented that "[t]he present invention relates to novel crystalline" cefdinir. '507 Patent col.1 ll.6-8. Astellas went on to explain the invention by stating that "[a]fter an intensive study, the inventors of the present invention succeeded in obtaining the compound (I) as a special crystalline form, i.e. Crystal A and completed the present invention, which is explained in detail as follows." FN7 Id. col.1 ll.34-39. The term "i.e.," of course, means "that is," and Astellas specified the special form of crystalline cefdinir that it had invented by defining it with the phrase "i.e. [that is] Crystal A." Thus, in plain language, Astellas explained that its "present invention" was a "special crystalline form" of cefdinir which Astellas called "Crystal A." FN8 Astellas then went on to explain "the present invention ... in detail." Id. col.1 ll.37-38. The ensuing explanation occupies the next fifteen and one-half columns of the sixteen-column patent, and references only Crystal A.

FN7. According to the '507 patent's specification, "the compound (I)" is "cefdinir." '507 Patent col.1 ll.9-10.

FN8. Abbott and Astellas offer a slightly different, but very strained, reading of this sentence, which is discussed briefly below.

Astellas and Abbott argue that the references to Crystal A in the specification merely articulate the preferred embodiment of an invention that might encompass multiple forms of crystalline cefdinir. The linchpin of their argument is that Crystal A is only a subset of the "present invention." Abbott and Astellas contend that Crystal A is so described in the patent by the phrase "Crystal A of the compound (I) of the present invention," which appears several places in the specification.FN9 (*See* Abbott Laboratories' and Astellas Pharma, Inc.'s Response Memorandum to Lupin's Proposed Claim Construction ("Abbott and Astellas Response Br.") at 4.)

FN9. It first appears in column 2, lines 15-17, and reappears several times thereafter in the specification.

If read in the way Abbott and Astellas propose, that somewhat awkward language is inconsistent with the antecedent language in the specification which, as explained above, describes the '507 patent's invention as Crystal A. Moreover, when the patent explains "the present invention ... in detail," and then describes only

Crystal A, the patent offers no indication that the invention is not also explained in its entirety. Indeed, the descriptions of Crystal A in the specification, when compared with the claims, confirm that Crystal A is, in fact, coextensive with "the present invention."

First, in column 1 of the specification, Astellas explains that "Crystal A of the compound (I) shows its distinguishing peaks" at the very same seven PXRD angles which define the '507 patent's invention in Claim 1. '507 Patent col.1 ll.51-62, col.16 ll.19-27. Logically, therefore, if Crystal A is "distinguished" by those seven peaks, any form of crystalline cefdinir which displays peaks at the seven diffraction angles listed in Claim 1 is "distinguished" as Crystal A.FN10 Had Astellas intended, in the chart found in column 1, to distinguish Crystal A from other forms of crystalline cefdinir that also fall within the scope of Claim 1, it would have listed, at a minimum, an eighth peak associated only with Crystal A. However, by listing in column 1 only the same seven "distinguishing" peaks featured in Claim 1, Astellas confirmed that Crystal A was synonymous with the invention listed in Claim 1.

FN10. "Distinguishing" is defined as: "serving to separate or set apart from others in nature, character, or quality." *Webster's Third New International Dictionary* 659 (2002).

Second, and importantly, that interpretation of "crystalline cefdinir" is also appropriate in the context of Claims 2-5. *See* Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed.Cir.2001) ("a claim term should be construed consistently with its appearance in other places in the same claim or in other claims of the same patent"). As is discussed in greater detail below, Claims 2-5 define the '507 patent's invention according to the processes that may be used to obtain it. *See* '507 Patent col.16 ll.29-50. The process steps detailed in those claims correspond with the processes for making Crystal A disclosed in the specification under the heading "The Process For Preparing Crystal A of The Compound (I)." *See* id. col.2 ll.13-42; Laird Decl. para. 43. Moreover, those same process steps were used in the Japanese priority application to distinguish between preparations of Crystal A and Crystal B. *See* '199 Application col.6 ll.1-25; Laird Decl. para. 45; *see also* Glaxo Group Ltd. v. Ranbaxy Pharmaceuticals, Inc., 262 F.3d 1333, 1337 (Fed.Cir.2001) (citing foreign priority application in claim construction analysis where priority application was part of patent's file wrapper). Therefore, Claims 2-5, like Claim 1, define "Crystal A," and, accordingly, one is justified in reading "crystalline cefdinir" to mean "Crystal A" throughout the claims.FN11

FN11. This is true even though "crystalline" is used somewhat differently in Claims 3 and 4 than in Claims 1, 2, and 5. In Claims 1, 2, and 5, "crystalline" is followed by the chemical name for cefdinir. ' 507 Patent col.16 ll.13, 29, 43. In Claims 3 and 4, "crystalline" is followed by the word "substance." Id. at col.16 ll.35, 40. However, Claims 3 and 4 are dependant on Claim 2, so if Crystal A is described in Claim 2, it must be described in Claims 3 and 4. *See* 3 Donald Chisum, *Chisum on Patents* s. 8.06[5], at 8-254 (2002). Moreover, in light of the specification, the only crystalline product which is described by the claims is Crystal A, so whether it is "crystalline cefdinir" or a "crystalline substance," the crystalline product described in the claims can only be Crystal A.

However, by defining "crystalline," as used in Claims 1-5, to mean "Crystal A," the Court is not affirmatively defining Crystal A to be anything other than what the claims say it is.FN12 Abbott and Astellas seem to be particularly concerned that, by defining "crystalline" to mean "Crystal A" within the context of the claims, the Court will substitute the descriptions of "Crystal A" found in the specification (or elsewhere) for the descriptions found in the claims. There, of course, is no reason or justification for so

construing "Crystal A," which is amply defined by the claims language itself.

FN12. The claims explicitly define what Crystal A *is*, but only implicitly define what it *is not*. At this juncture, it is neither necessary nor appropriate to decide whether any known forms of cefdinir are necessarily excluded from the scope of the '507 patent's claims as a consequence of defining the '507 patent's invention to be Crystal A. The Court notes that, as argued by Lupin, the '507 patent's specification quite clearly distinguishes the '507 patent's invention (Crystal A) from the forms of cefdinir disclosed in the '334 patent. '507 Patent col.1 ll.24-34. However, determining the consequences of that difference is not necessary to the task of construing the claims at issue.

Abbott and Astellas also contend that "crystalline" cannot be "Crystal A" because they have discovered, experimentally, a non-Crystal A form of crystalline cefdinir which displays peaks at "about" (this term will be discussed below) the seven PXRD angles listed in Claim 1. (*See* Abbott and Astellas Br. at 8.) This argument rests on the assumption that Crystal A is not actually defined by the claims in the '507 patent. As explained above, the '507 patent defines Crystal A by certain processes (Claims 2-5) and according to the seven peaks listed in Claim 1. Therefore, any subsequently discovered crystalline form of cefdinir that features the seven peaks in Claim 1 is, by definition, Crystal A, and not something else. FN13

FN13. The specification itself makes a similar point when it explains that " *any crystal* of the compound (I) which shows substantially the same diffraction pattern ... is identified as Crystal A of the compound (I)." '507 Patent col.1 ll.68-col.2 l.2 (emphasis added).

In sum, a close reading of the '507 patent's specification discloses Crystal A to be the patent's invention. Moreover, the specification defines "crystalline" as used in the context of the claims, to mean "Crystal A." FN14

FN14. Again, however, Crystal A is affirmatively defined only according to the language of Claims 1-5. The construction of "crystalline" herein does not carry with it any affirmative descriptions of "Crystal A" which do not appear in the claims themselves.

3. The Prosecution History

The Japanese priority application already has been referenced once above and, indeed, that document, along with the rest of the '507 patent's prosecution history, confirms that "crystalline," as used in the claims, means "Crystal A." Not only does the prosecution history focus exclusively on Crystal A, but it also assists in interpreting some of the awkward language contained in the '507 patent's specification.

First, much of the language in the Japanese priority application closely resembles, and therefore helps to clarify, the language of the '507 patent. For example, as explained in multiple places above, the following sentence appears in the '507 patent: "After an intensive study, the inventors of the present invention succeeded in obtaining the compound (I) as a special crystalline form, i.e. Crystal A and completed the present invention, which is explained in detail as follows." '507 Patent col.1 ll.34-38. In the Japanese priority application, that sentence reads: "After an intensive study, the inventors of the present invention succeeded in obtaining the novel Crystal A and Crystal B of [cefdinir] as disclosed hereinafter and

completed the present invention." '199 Application col.3 ll.22-27. According to Abbott and Astellas, that sentence, as written in the '507 patent, cannot be read, based on its plain language, to announce Crystal A as "the present invention." *See* Markman Hearing Tr. 38-40, Mar. 8, 2007 (arguing that the word "special" prevents one from concluding that "Crystal A" is synonymous with "the present invention"). However that sentence, as it appears in the Japanese priority application, can be read clearly to define Crystals A and B as "the present invention." Such a reading is permitted because Astellas explicitly claimed only Crystals A and B in the Japanese priority application. Therefore, in that context, "the present invention" in the Japanese priority application could be nothing more than Crystals A and B. Where that sentence is repeated, nearly verbatim, in the '507 patent, a person of ordinary skill in the art is justified in reading it to announce Crystal A as "the present invention" (rather than a subset of the invention), even if, as Abbott and Astellas contend, such a reading is not compelled by the plain language of the sentence alone. (*See* Laird Decl. para. 28.)

Similarly, the following, rather awkward, language appears in several places in the '507 patent's specification: "Crystal A of the compound (I) of the present invention." *See, e.g.,* '507 Patent col.2 l.16, col.3 ll.15-16. As noted above, Astellas and Abbott argue that, in the context of the '507 patent alone, that sentence may be read to indicate that Crystal A is a subset of "the present invention." However, where that same term is used in the Japanese priority application-"Crystal A and Crystal B of [cefdinir] of the present invention"-it is clear that the products which precede "the present invention" cannot be a subset of "the present invention" but are, in fact, the extent of "the present invention." '199 Application col.3 ll.30-32. Because that term is repeated in the '507 patent, it is logical to read it, too, as announcing Crystal A to be the extent of "the present invention." (*See* Laird Decl. para. 29.)

The significance of the clause "of the present invention" is further clarified by reading a letter written by Astellas to the patent examiner. ' 507 Patent File History, 10/27/89 Response (Paper No. 6). In that letter, Astellas touted the benefits of " *the* crystalline *product* of *the* present invention." Id. at 4 (emphasis added). In the context of that letter, "the crystalline product" is written in the singular form, and is quite clearly the extent of "the present invention;" therefore, it is permissible to infer that the word "of," when preceding "the present invention," was not necessarily an indicator of subset to Astellas. That being the case, a person of ordinary skill in the art would be justified in reading "Crystal A of the compound (I) of the present invention" to mean that Crystal A is the invention of the ' 507 patent, and not merely a preferred embodiment (or subset).

Finally, the rest of the prosecution history, like the '507 patent itself, mentions only Crystal A when touting the benefits of the invention claimed in the '507 patent. While there is no explicit declaration that Crystal A "is the present invention," there is language, referenced above, indicating that "the present invention" is comprised of only one "crystalline product," and not multiple crystalline products, as Abbott and Astellas now urge. Id. at 4, 7 (using phrases such as "the crystalline product of the present invention" and "a novel crystalline form," indicating that the invention constitutes a single form or product). Given that language, the prosecution history's exclusive focus on Crystal A bolsters the conclusion that Crystal A is "the crystalline product of the present invention" and that, therefore, "crystalline," as used in the '507 patent's claims, means "Crystal A."

In sum, the '507 patent's specification and prosecution history, read carefully together with the claims, announce "Crystal A" as the '507 patent' s invention. Considering that evidence, a person of ordinary skill in the art would read the word "crystalline," as used in the claims, to mean "Crystal A as outlined in the specification."

B. "Shows the Peaks"

The parties have taken considerable pains to define "shows the peaks," in part because of the Court's repeated inquiries. The parties' have, at various times, focused both on the phrase as a whole and on the individual words which comprise it. Because each of the individual words has received special attention from the parties, they will be addressed separately below.

1. "Shows"

[14] According to Lupin, "shows" requires a graphical PXRD display, like the one found in Figure 1 of the '507 patent, that would render peaks visible to the human eye. (*See* Lupin Br. at 13.) Abbott and Astellas, on the other hand, argue that "shows" is not limited to the graphical display of a PXRD pattern and, instead, includes any data display that demonstrates the existence of peaks in PXRD pattern. (*See* Abbott and Astellas Response Br. at 15.) The '507 patent's specification confirms that the definition of "shows" offered by Abbott and Astellas is the most correct one.

To begin, the language of Claim 1 limits "shows" to some display of a "powder X-ray diffraction pattern." *See* '507 Patent col.16 ll.15-17. However, the patent's specification"shows" those PXRD patterns in two different ways. For example, the specification displays two charts which list the numerical values of PXRD angles and relative intensity figures that correspond to Crystal A. Id. col.12 ll.48-69, col.13 l.66-col.14 l.17. In those charts, the "powder X-ray diffraction pattern of ... Crystal A was *shown,*" even though no graphically-depicted peaks were visible. Id. col.12 l.49, col.13 l.67 (emphasis added). Such peaks are visible, however, in Figure 1, where Crystal A's peaks are also "shown" in a graphical display. Id. col.1 ll.64-66. Thus, because the '507 patent's specification "shows" PXRD peaks in two different ways, the Court cannot justify construing "shows," as used in Claim 1, to require any single method of "showing." FN15

FN15. This reading of "shows" is fully consistent with the plain meaning of the word "show" as defined by *Webster's Third New International Dictionary* (2002). None of the many definitions of the word requires visibility to the eye alone.

In Glaxo, Inc. v. TorPharm, Inc., 153 F.3d 1366 (Fed.Cir.1998), the Federal Circuit addressed the meaning of the word "showing" in a somewhat similar factual situation. There, the court required that the relevant peaks be demonstrated to "an acceptable degree of certainty" either "visually or by other appropriate means of data display." Glaxo, 153 F.3d at 1374. Given the uses of "show" in the '507 patent's specification, the same definition can be adopted here.FN16 Therefore, the Court holds that "shows" requires the display of a PXRD pattern which demonstrates the existence of the relevant peaks to a scientifically acceptable degree of certainty either visually or by other appropriate means of data display.

FN16. Glaxo involved an infrared spectrum, not PXRD, but the definition of "showing" used by the Federal Circuit in that case is appropriate on these facts as well. *See* Glaxo, 153 F.3d at 1374.

2. "The"

The word "the" in "shows the peaks" is significant primarily because the position advanced by Abbott and Astellas essentially reads the word "the" out of the phrase entirely, thereby rendering "shows the peaks" identical to "shows peaks." Such a reading would seem to be unacceptable because claims, no less than

statutes, should be interpreted to avoid superfluity. *See* Kraft Foods, Inc. v. International Trading Co., 203 F.3d 1362, 1370 (Fed.Cir.2000). Moreover, definite articles, like "the," which particularize the subjects they precede, cannot be read as if they are indefinite articles, like "any." NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282, 1306 (Fed.Cir.2005) (citing Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1356 (Fed.Cir.2003)). However, after a careful reading of the context in which "shows the peaks" is used, the Court is unable to ascribe any significance to the word "the" which would permit the Court to assign material limitations to the word "peaks."

The phrase "shows the peaks" appears in the following sentence from Claim 1 of the '507 patent: "Crystalline [cefdinir] which shows the peaks at the diffraction angles shown in the following table in its powder X-ray diffraction pattern." '507 Patent col.16 ll.13-17. A fair reading of the position advanced by Abbott and Astellas would allow them to allege infringement whenever any peaks (which are defined below) exist at the PXRD angles listed in Claim 1, so the phrase "shows the peaks" could be replaced, under their claim construction, with "shows peaks." Lupin argues that "the" cannot be rendered meaningless, and that "the peaks" must refer to some particular peaks. (*See* Supplemental Claim Construction Br. of Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Lupin Supplemental Br.") at 4-8.) Those peaks, according to Lupin, are the most intense peaks displayed in Figure 1 and in the charts found in columns 12 and 14 of the '507 patent's specification. Id. As Lupin points out, the most intense peaks in those displays correspond directly to the PXRD angles listed in Claim 1. Accordingly, Lupin argues that the term "the peaks" requires some absolute or relative intensity limitation on the peaks that would be found at the PXRD diffraction angles listed in Claim 1.

Abbott and Astellas argue that "the" in "the peaks" has no such significance. To the contrary, Abbott and Astellas argue that "the" is required "for grammatical accuracy and consistency, since the claim recited 'crystalline [cefdinir] which shows *the* peaks ... shown in *the* following table.' " (Abbott Laboratories' and Astellas Pharma's Mem. Supporting Their Proposed Construction of the Word "Peaks" ("Abbott and Astellas Supplemental Br.") at 11 (emphasis in original).) For that reason, Abbott and Astellas contend that "the" may not be used as a vehicle for importing intensity requirements on the peaks listed in Claim 1.

While the Court does not agree precisely with the argument made by Abbott and Astellas, it is not clear that "the" is as significant as Lupin contends. The reading given by Abbott and Astellas makes little sense because what is "shown in the following table" is not "the peaks" but, rather, "the diffraction angles." Therefore, "the peaks" is not required grammatically for the purposes cited by Abbott and Astellas. Nevertheless, it is not clear that "the peaks" does not refer simply to those peaks which exist at the diffraction angles listed in Claim 1. Therefore, the significance of "the" is not clear enough to require the limitations proposed by Lupin. Moreover, Astellas can be assumed to have intentionally excluded intensity limitations from Claim 1 because it included such limitations in parts of the specification and in the Japanese priority application. *See, e.g.,* '507 Patent col.12 ll.52-68, col.14 ll.1-17; '199 Application col.1 ll.16-38, col.2 ll.7-34. Given that inferred intent, the meaning of "the peaks" is certainly not clear enough to justify importing intensity requirements into Claim 1. Accordingly, the only limitations on the word peaks are those explained below.

3. "Peaks"

[15] The definition of "peaks" is critically important because the invention in Claim 1 is defined in terms of its peaks. The parties have proposed vastly different constructions of the word "peaks." Abbott and Astellas define "peaks" as "the locations of all numerical apexes of X-ray intensity at particular diffraction angles."

FN17 (Abbott and Astellas Supplemental Br. at 3.) Lupin, on the other hand, argues that "peaks" refers to the most intense features in the PXRD pattern, such that Crystal A, as described in the ' 507 patent's specification, can be readily identified and distinguished from other crystals. (*See* Lupin Supplemental Br. at 4-8.) Neither definition is appropriate, however, given the significance of "peaks" in the ' 507 patent.

FN17. Abbott and Astellas also describe a "peak" as "the apex of intensity for a given diffraction angle." (Abbott Laboratories' and Astellas Pharma's Resp. Mem. Supporting Their Proposed Construction of the Word "Peaks" ("Abbott and Astellas Supplemental Resp.") at 7.)

The word "peaks" is used only twice in the '507 patent. It is used first in the specification, where Crystal A is defined according to its "distinguishing peaks" located at the diffraction angles listed in column 1 of the specification. '507 Patent col.1 ll.51-62. As discussed above, those same angles are used to define the invention of the '507 patent (Crystal A) in Claim 1, where the word "peaks" occurs for the second time. Id. col.16 ll.15-27. The word "peaks" is not given any definition within the context of Claim 1, but its use in the specification offers some guidance for how it should be construed within the context of the claims. Specifically, the only "peaks" listed in the '507 patent correspond with distinctive features of significant intensity, which, as indicated by Figure 1, have obvious rises and falls before and after reaching a single apex. *See, e.g.,* id. col.12 ll.51-68, col.14 ll.1-17, fig. 1. For example, in Claim 1 and column 1 of the specification, the PXRD angles listed correspond with the seven most intense and pointed features in Figure 1 of the patent's specification. Similarly, the charts displayed in columns 12 and 14 of the specification, which mathematically describe "peaks," list no peak smaller than eight percent of the tallest listed peak's intensity.FN18 Thus, the construction of "peaks," as used in Claim 1, certainly cannot conflict with those descriptions of "peaks" in the ' 507 patent's specification.

FN18. Abbott and Astellas acknowledge that the charts in columns 12 and 14 list "peaks," even though the word "peaks" is not used in connection with those charts. (*See* Abbott and Astellas Br. at 15.)

With the specification and other considerations, which are discussed below, in mind, each party's definition of "peaks" presents problems. First, the definition proposed by Abbott and Astellas would allow for peaks that are nothing like the features displayed in Figure 1. Indeed, their definition eviscerates any limiting feature of the word "peaks." If a peak is merely the numerical apex at any given diffraction angle, then a "peak" would exist at each and every diffraction angle in a PXRD pattern (so long as that measured intensity is above the so-called background "noise"-a concept discussed below).FN19 Such an interpretation of "peaks" is nonsensical. Not only is it totally unrelated to the "peaks" identified in the specification, but it would fail to describe "distinguishing" features at all.

FN19. The definition of "peaks" submitted by Abbott and Astellas does not incorporate any concept of "noise," but a fair reading of the briefs submitted by Abbott and Astellas, combined with their proffered definition, indicates that a peak could exist only if the measured intensity at a particular diffraction angle rises above the so-called "noise." (*See* Abbott and Astellas Supplemental Resp. at 3.) Nevertheless, the '507 patent simply does not support a reading of "peaks" under which a "peak" would exist at every point of measured intensity above the background noise, and nothing in the record indicates that a person of ordinary skill in the art would accept such a definition of "peaks."

Lupin's definition suffers from a different problem. Lupin urges the Court to impose some PXRD intensity limitation on the word "peaks" as used in Claim 1. However, Claim 1 does not include any explicit intensity limitations, in contrast both to the charts in columns 12 and 14 of the specification and the claims in the Japanese priority application. '507 Patent col.12 ll.52-68, col.14 ll.1-17; '199 Application col.1 ll.16-38, col.2 ll. Moreover, nothing in the patent indicates that Crystal A is claimed only in its pure form. As even Lupin acknowledges, mixing Crystal A with other materials might cause the peaks featured in Figure 1 to have reduced absolute intensity in a PXRD pattern. (*See* Lupin Resp. Br. at 11.) Additionally, the record does not permit the conclusion that even the relative intensities of those peaks (their intensities with respect only to one another) would be unaffected if Crystal A were mixed with other materials. Therefore, any intensity requirement, whether absolute or relative, might unjustifiably limit the scope of the ' 507 patent to cover only the pure form of Crystal A.

Because the definitions advanced by the parties are each deficient in some way, neither can be adopted. Even though those definitions are largely unhelpful, the expert reports submitted by the parties, along with the use of "peaks" in the '507 patent, provide a sufficient basis on which to construe the term "peaks." Indeed, the experts appear to be in general agreement about some basic features that signify a "peak" in a PXRD pattern. Dr. Atwood, the expert employed by Abbott and Astellas, says that peaks are defined by an apex, regardless of whether a peak has a broad or narrow base. (*See* Third Atwood Decl. para. 8.) Dr. Atwood also offers a graphical representation of a PXRD pattern which displays, visually, the sorts of features he considers to be peaks. (Id. para. 9.) Those peaks, like the peaks shown in Figure 1 of the '507 patent, are characterized by having a single apex surrounded on each side by a lower intensity value. Dr. Atwood is careful to point out that two "peaks" may share the same base, but he explains that they are still two separate "peaks" so long as they are distinguishable by their different apexes (surrounded on each side by a lower intensity value). (*See* id. para.para. 9-11.)

Dr. Atwood's description of peaks basically comports with the definition forwarded by Dr. Eli Shefter, Lupin's expert. Dr. Shefter explains that "[i]n its most basic sense, a 'peak' is defined as the highest point in a series where there are simultaneously visible lower points surrounding the highest point." (Shefter Decl. para. 17.) While he expands on that simple definition for purposes of accuracy, his definition at least requires an apex that is surrounded on each side by a point of lesser intensity. Like Dr. Atwood, Dr. Shefter also offers graphical depictions of peaks that are quite similar to the peaks seen in Figure 1 of the '507 patent. (Id. at para.para. 24-25.)

In perspective of the basic agreement between the experts from each side, the use of the word "peaks" in the '507 patent, considerations respecting the intensity of a "peak," and the way in which "peaks" has been discussed by the parties in their papers and at oral argument, the Court concludes that a "peak" corresponds at least to a PXRD angle with an intensity measurement that is immediately preceded by and immediately followed by a PXRD angle with a smaller intensity measurement. However, because of errors inherent in PXRD testing, that definition of "peaks" requires further refinement.

The parties and their experts have each concerned themselves with PXRD measurement errors commonly referred to as "noise." (*See* id. para. 20; Fourth Atwood Decl. para.para. 4-5.) Dr. Atwood describes "noise" as the random signal variation that is seen in the baseline of a PXRD pattern. (Fourth Atwood Decl. para. 4.) Dr. Shefter describes "noise" as "measurement errors" that result in "some random scattering" in a PXRD pattern. (Shefter Decl. para. 20.) The parties each agree that peaks must, at the very least, rise above this so-called "noise." (*See* Lupin Supplemental Br. at 5; Abbott and Astellas Supplemental Resp. at 3.) Therefore, a definition of "noise" is required. Based on the expert descriptions of "noise" and the use of "noise" by the

parties in their papers and at oral argument, the Court finds that the "noise" refers to those portions of a PXRD pattern produced by intrinsic measurement error, and which cannot be associated with a scientifically significant quantity of the material which is the subject of the PXRD test.

Accordingly, the Court holds that a peak exists at a PXRD angle that corresponds to an intensity measurement greater than measurements attributable to "noise," as defined above, if that angle is immediately preceded by and immediately followed by a PXRD angle with a lower intensity measurement.

C. "About"

[16] The parties have focused relatively little attention on the term "about," but disagree about its meaning nevertheless. The term "about" is important because it modifies the PXRD angles listed in Claim 1. '507 Patent col.16 ll.21-27. Therefore, a crystalline cefdinir product falls within the scope of Claim 1 even if it only exhibits peaks at "about" the PXRD angles listed in Claim 1. Lupin suggests that "about" simply allows for "some range of error intrinsic to the [PXRD] measurement itself." (Lupin Br. at 14.) Abbott and Astellas, on the other hand, urge that "about" be given its ordinary dictionary meaning, which is "approximately." (Abbott and Astellas Br. at 20.)

"About" is not defined anywhere in the patent or in the prosecution history, but its use in the specification offers some indication of its meaning. The PXRD angles listed in column 1, like the angles listed in Claim 1, are modified by the word "about." '507 Patent col.1 ll.56-26. Those angles are associated with Crystal A, and the peaks present at those angles are displayed in Figure 1. The specification notes, however, that Figure 1's "diffraction pattern is given only for reference and any crystal of the compound (I) which shows substantially the same diffraction pattern is identified as Crystal A of the compound (I)." Id. col.1 l.67-col.2 l.2. Because any form of crystalline cefdinir showing "substantially the same" PXRD pattern would be identified as Crystal A, the patent strongly indicates that the word "about" refers only to minor deviations from a PXRD angle.

Moreover, the parties' experts seem to agree that a person of ordinary skill in the art would also construe "about" fairly narrowly in the context of PXRD testing. *See* Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed.Cir.1995) (noting that the word "about" does not have a universal meaning in patent claims, and must be construed in its "technological and stylistic context"). Dr. Atwood says that " 'about' is intended to recognize that insignificant differences arise due to, among other factors, the type of equipment used to make the [PXRD] measurement, the care taken in making the measurement, and the number of samples measured." (Atwood Decl. para. 9.) Similarly, Dr. Trevor Laird, one of Lupin's experts, explains that "about" refers to "inherent and minor measurement variations associated with the performance of the x-ray diffraction test itself." (Laird Decl. para. 39.)

Considering the text of the specification and the views of both experts, the Court concludes that "about" encompasses only measurement errors inherently associated with PXRD testing.

D. Claims 2-5

Finally, the parties also dispute the proper interpretation of Claims 2-5. Lupin urges the Court to construe them as process claims, which would cover only the process steps themselves, not the resulting product. Alternatively, if construed as product-by-process claims, Lupin urges the Court to limit the patented product to Crystal A. Abbott and Astellas contend that Claims 2-5 are product-by-process claims but that the covered product need not be limited to Crystal A.

[17] [18] A product-by-process claim is one in which the claimed product "is defined at least in part in terms of the method or process by which it is made." Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 158, 109 S.Ct. 971, 103 L.Ed.2d 118 (1988). A product-by-process claim is typically indicated by "the wording of the claim" itself. Biacore v. Thermo Bioanalysis Corp., 79 F.Supp.2d 422, 456 (D.Del.1999). Courts have found certain language to be indicative of product-by-process claims. For example, product-by-process claims have been found where the claims used language such as "prepared in accordance with," "by the process of," "product of the process," "resulting from the process of," and "being produced by the process comprising." Id. (citations omitted). Here, the words "obtainable by," used in Claims 2 and 5 (Claims 3 and 4 are dependant on Claim 2), similarly indicate product-by-process claims.

[19] First, the natural reading of Claims 1-5 indicates that the process limitations are not the only important features of Claims 2-5. No party disputes, for example, that Claim 1 claims a product which is then defined according to certain peaks described in Claim 1. The structure of Claim 1 is clear: first the claimed product is named, then it is described according to certain features. The structure of Claim 2 is naturally read in the same way: first the claimed product is named ("crystalline [cefdinir]"), then it is described according to certain process limitations. Claims 3 and 4, which are dependent on Claim 2, are structured similarly, and Claim 5 is structured in precisely the same way as Claims 1 and 2. Thus, the natural reading of Claims 1-5 leads to the conclusion that the claimed product is first named in each claim, and then, second, defined in a particular way.

Second, that interpretation of the claims is supported by the '507 patent's prosecution history. When Astellas originally submitted its '507 patent application, the application contained nine claims. Claims 6-9 were deleted during the application process. Claims 1-5 were drafted as they appear in the ' 507 patent. Claims 6-9 were worded as follows:

6. A process for preparing crystalline [cefdinir] which comprises acidifying a solution containing [cefdinir] at room temperature and under warming.

7. A process of claim 6, wherein a solution containing [cefdinir] is an aqueous solution of an alkali metal salt of said compound.

8. A process of claim 7, wherein the acidifying of the solution is carried out at the temperature from room temperature to 40 (deg.)C at the pH from 1 to 4.

9. A process for preparing crystalline [cefdinir] which comprises dissolving [cefdinir] in an alcohol, continuing to stir the solution slowly under warming, then cooling the solution to room temperature and allowing the solution to stand.

United States Patent Application No. 07/229,489 at Claims col.2 l.27-col.3 l.20. Claims 6-9 are structured similarly to Claims 1-5, but have a notable difference in wording. Claims 6-9 each begin with the words "a process." Thus, given the manner in which Claims 1-5 are structured (claiming the patented product at the outset before subsequently defining it), one would naturally read Claims 6-9 to claim "a process" which was subsequently defined by certain steps.

Lupin argues, however, that the '507 patent's prosecution history compels the conclusion that Claims 2-5 are process claims. (Lupin Br. at 21.) Lupin bases its argument on the fact that Claims 6-9 were described by

the patent examiner as "substantial duplicates of Claims 2-5." '507 Patent File History, 11/20/89 Supplemental Amendment (Paper No. 7) at 1. Lupin reads the patent examiner's language to indicate that Claims 6-9 were duplicative because Claims 2-5 already claimed processes. The meaning of "substantial duplicates" is not that clear, however. One might just as easily conclude that Claims 6-9 provided Astellas a "duplicative" layer of protection because anyone using the process steps described in those claims would inevitably produce a cefdinir product that would, by definition, infringe Claims 2-5. Because the significance of the patent examiner's language is not apparent, it cannot control the Court's construction of Claims 2-5.

Other evidence from the prosecution history is instructive, however. As Abbott and Astellas point out, Astellas explicitly told the patent examiner that "[t]he crystalline form of the compound represents the inventive concept" of the patent application, not "the *method of preparation*." '507 Patent File History, 10/27/89 Response (Paper No. 6) at 6 (emphasis in original). Based on that clarification, it is not surprising that Abbott and Astellas would choose to eliminate duplicative process claims rather than claims that pertained to the product. *See* '507 Patent File History, 11/20/89 Supplemental Amendment (Paper No. 7) at 1.

Accordingly, based on the wording of Claims 2-5 and the patent's prosecution history, the Court concludes that Claims 2-5 are product-by-process claims. The significance of that finding under Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834 (Fed.Cir.1992) and Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565 (Fed.Cir.1991), need not be decided here.

CONCLUSION

For the reasons set forth above, Claims 2-5 of the '507 patent are construed as product-by-process claims. The '507 patent's disputed claim terms have the following definitions:

(1) "Crystalline" means "Crystal A;"

(2) "shows" requires the display of a powder X-ray diffraction pattern which demonstrates the existence of the relevant peaks to a scientifically acceptable degree of certainty either visually or by other appropriate means of data display;

(3) "peaks" is the plural of "peak;" a "peak" exists at a powder X-ray diffraction angle that corresponds to an intensity measurement greater than measurements attributable to "noise" if that angle is immediately preceded by and immediately followed by powder X-ray diffraction angle with a lower intensity measurement; "noise" refers to those portions of a PXRD pattern produced by intrinsic measurement error, and which cannot be associated with a scientifically significant quantity of the material which is the subject of the PXRD test;

(4) "about" encompasses measurement errors inherently associated with powder X-ray diffraction testing.

The Clerk of the Court is directed to send a copy of this Memorandum Opinion to all counsel of record.

It is so ORDERED.

E.D.Va.,2007.

Lupin Ltd. v. Abbott Laboratories

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