

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BRISTOL-MYERS SQUIBB CO., and
BRISTOL-MYERS SQUIBB PHARMA
CO.,

Plaintiffs/
Counterclaim-Defendants,

v.

Civil Action No. 09-651-LPS

MYLAN PHARMACEUTICALS INC.,
MATRIX LABORATORIES LTD., and
MATRIX LABORATORIES INC.,

Defendants/
Counterclaim-Plaintiffs,

v.

MERCK & CO., INC. and
MERCK SHARP & DOHME CORP.,

Counterclaim-Defendants.

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MEMORANDUM OPINION

May 16, 2012
Wilmington, Delaware.



STARK, U.S. District Judge:

I. INTRODUCTION

Bristol-Myers Squibb Co. and Bristol-Myers Squibb Pharma Co. (collectively, “BMS”) filed suit against Mylan Pharmaceuticals Inc., Matrix Laboratories Ltd., and Matrix Laboratories Inc. (collectively, “Mylan” or “Defendants”) in August 2009, alleging infringement of U.S. Patent No. 6,673,372 (“the ’372 patent”). (D.I. 1) Mylan filed counterclaims against Merck & Co., Inc. and Merck Sharp & Dohme Corp. (“Merck,” and collectively with BMS, “Plaintiffs”), seeking a declaratory judgment of invalidity and noninfringement of two additional patents, U.S. Patent No. 6,639,071 (“the ’071 patent”) and U.S. Patent No. 6,939,964 (“the ’964 patent”). (D.I. 36) The Court conducted a *Markman* hearing on October 5, 2011. (D.I. 149) (hereinafter “Tr.”)

II. BACKGROUND

Efavirenz is a drug compound that inhibits reverse transcriptase, and thus is useful in the treatment of the human immunodeficiency virus (HIV). Efavirenz exists in multiple crystalline forms known as polymorphs. The patents-in-suit relate generally to various polymorphs of efavirenz, which are described and claimed using different numerical designations that correspond to characteristic X-ray powder diffraction (“XRPD”) and/or differential scanning calorimetry (“DSC”) values.

The ’372 patent issued on January 6, 2004 and is assigned to BMS. The ’372 patent describes and claims polymorphic forms of efavirenz designated as Forms 1, 2, 3, 4, and 5. (*See* ’372 patent, col. 1, ll. 5-10) The ’071 patent and ’964 patent issued on October 28, 2003 and September 6, 2005, respectively, and are both assigned to Merck. The ’071 and ’964 patents share a common specification, and describe and claim polymorphic forms of efavirenz,

designated as Forms I, II, and III. (See, e.g., '071 patent, col. 2 ll. 1-15)

III. LEGAL STANDARDS

“It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). Construing the claims of a patent presents a question of law. See *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388-90 (1996). “[T]here is no magic formula or catechism for conducting claim construction.” *Phillips*, 415 F.3d at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources “in light of the statutes and policies that inform patent law.” *Id.*

“[T]he words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1312-13 (internal citations and quotation marks omitted). “[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted). The patent specification “is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent” *Id.* (internal citation omitted).

It is likewise true that “[d]ifferences among claims can also be a useful guide For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15 (internal citation omitted). This “presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim.” *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that “the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316. It bears emphasis that “[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff’d*, 481 F.3d 1371 (Fed. Cir. 2007).

In addition to the specification, a court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman*, 52 F.3d at 980. The prosecution history, which is “intrinsic evidence,” “consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent.” *Phillips*, 415 F.3d at 1317. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

A court also may rely on “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. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries “endeavor to collect the accepted meanings of terms used in various fields of science and technology.” *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of ordinary skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Id.* Nonetheless, courts must not lose sight of the fact that “expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Id.* Overall, while extrinsic evidence “may be useful” to the court, it is “less reliable” than intrinsic evidence, and its consideration “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1318-19.

Finally, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude the inventor’s device is rarely the correct interpretation.” *Osram GmbH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007).

IV. DISCUSSION

A. “Form 1,” “Form 2,” and “Form 4” (’372 patent)

1. Plaintiffs’ Proposed Construction: “a polymorphic crystal form of [efavirenz] that can be distinguished from other forms”
2. Defendants’ Proposed Construction: “a crystalline form of efavirenz characterized by the powder x-ray diffractogram and differential calorimetry thermogram depicted [for each Form in the Figures]”
3. Court’s Construction: “a polymorphic crystal form of [efavirenz] that can be distinguished from other forms”

B. “Form I,” “Form II,” and “Form III” (’071 and ’964 patents)

1. Plaintiffs’ Proposed Construction: “a polymorphic crystal form of [efavirenz] that can be distinguished from other forms by its x-ray powder diffraction pattern”
2. Defendants’ Proposed Construction: “a crystalline form of efavirenz characterized by at least the key diffraction peaks identified [for each Form in the specification and Figures]”
3. Court’s Construction: “a polymorphic crystal form of [efavirenz] that can be distinguished from other forms by its x-ray powder diffraction pattern”

While there are several “Form” terms in dispute – Forms 1, 2, and 4 from the ’372 patent, and Forms I, II, and III from the ’071 and ’964 patents – the parties agree that they present the same basic dispute, which the Court need only resolve once. (Tr. at 4-5; 35-36)

As already noted, the patents-in-suit are directed to various polymorphic forms of efavirenz, with each polymorph described and claimed using a different numerical designation corresponding to various XRPD and/or DSC values. For example, Figures 1-4 of the ’372 patent depict the full XRPD diffractograms for Forms 1-4 of efavirenz, respectively. Figures 5-8 likewise depict the full DSC thermograms for Forms 1-4 of efavirenz, respectively. Similarly, Figures 3-5 of the ’071 and ’964 patents depict the full XRPD diffractograms for Forms I-III of

efavirenz, respectively, while Figure 6 depicts the full DSC thermogram for Form III.

The parties agree that the various “Form” terms have no standard meaning in the art standing alone. Instead, these terms can only be understood in the context of XRPD and/or DSC data that serve to distinguish the various polymorphs of efavirenz from one another. (D.I. 133, Ex. R, Atwood Decl. ¶ 12; D.I. 124, Ex. B, Hollingsworth Decl. ¶¶ 17-18)

The parties’ claim construction dispute concerns whether the “Form” terms incorporate by reference the entirety of the XRPD and DSC patterns set forth in the Figures (as Defendants propose) or whether, instead, the various “Form” terms should simply be viewed as shorthand references whose defining characteristics are supplied by the particular XRPD and/or DSC values expressly recited in the claims (as Plaintiffs propose). The Court concludes that Plaintiffs’ construction is better supported by the intrinsic record and, therefore, adopts that construction, for the following reasons.

Plaintiffs’ construction is supported by the claims. It is undisputed that some claims recite the “Form” terms by expressly referencing particular Figure(s) from the specification. (*See, e.g.*, ’372 patent, claims 1, 6, 14, 24; ’071 patent, claims 1-4) Plaintiffs concede, and the Court agrees, that those claims – but only those claims – should be limited, accordingly, by the recited Figures.¹ By contrast, the Court finds no basis for importing the Figures into those claims that do not expressly reference any Figures. *See generally IGT v. Bally Gaming Int’l, Inc.*, 659 F.3d 1109, 1117 (Fed. Cir. 2011) (“[C]laim language must be construed in the context of the claim in which it appears. Extracting a single word from a claim divorced from the surrounding limitations can lead construction astray.”). Defendants’ construction ignores the

¹During the hearing, counsel for Plaintiffs acknowledged that “without question, for claims that call out a particular figure, those claims are limited to that figure.” (Tr. at 5-6)

context of the surrounding claim language and improperly imports limitations from the Figures into the claims. *See MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333 (Fed. Cir. 2007) (“[P]atent coverage is not necessarily limited to inventions that look like the ones in the figures. . . . To hold otherwise would be to import limitations onto the claim from the specification, which is fraught with ‘danger.’”).

Plaintiffs’ construction is also supported by the specification. The specification of the ’372 patent repeatedly describes different Form embodiments using less than the full set of XRPD and/or DSC data shown in the Figures. (D.I. 122 at 7-8; *see* ’372 patent, cols. 3-8) Plaintiffs correctly note that the inventors’ description of these embodiments with varying levels of detail demonstrates a “clear intent to claim crystal forms of efavirenz that required less than the full [XRPD] diffractograms and [DSC] thermograms as depicted in the Figures.” (*Id.* at 8) Similarly, the common specification of the ’071 and ’964 patents also describes embodiments without fully incorporating the data from the Figures. (*See, e.g.*, ’071 and ’964 patents, col. 5, ll. 5-65) The Court finds no clear words or expressions of “manifest exclusion or restriction” in the patents-in-suit that would justify strictly limiting the various “Form” terms to the complete XRPD and/or DSC patterns illustrated in the Figures. *See Liebel-Flarsheim*, 358 F.3d at 906.

The prosecution history further supports Plaintiffs’ construction. During prosecution of the ’372 patent, claims reciting the “Form” terms, standing alone, were initially rejected by the Examiner for lack of enablement, and were allowed only after the applicants amended and added various claims to recite specific XRPD and/or DSC data from the Figures. (D.I. 124 at 9; Florence Decl., Ex. 5-6) The Court agrees with Plaintiffs that such changes would have been unnecessary if the meaning of the various “Form” terms were properly understood already to incorporate the Figures. (D.I. 133 at 7)

Accordingly, the Court will adopt Plaintiffs' originally-proposed construction for the various "Form" terms.²

C. "Characterized by" ('372 patent)

Court's Construction: "Having the physical characteristics recited in the subject claims, which may or may not distinguish it from other forms of efavirenz."

Following the claim construction hearing, the parties reached an agreement on the construction for the term "characterized by," which appears in claims 16-23 and 34-40 of the '372 patent. (D.I. 141) The Court will adopt the parties' agreed-to construction.

D. "Comprising 4 (or 6) or more 2θ values selected from the group consisting of" ('372 patent)

1. Plaintiffs' Proposed Construction: "the pattern includes at least 4 (or 6) of the 2θ values selected from the group, but is not necessarily limited to 4 (or 6) 2θ values, whether selected from the group or not"
2. Defendants' Proposed Construction: "the x-ray powder diffraction pattern must include at least 4 (or 6) of the 2θ values selected from 10.2 ± 0.2, 11.4 ± 0.2, 11.6 ± 0.2, 19.1 ± 0.2, 20.6 ± 0.2, 21.3 ± 0.2, 22.8 ± 0.2, 24.8 ± 0.2, 27.4 ± 0.2, 28.2 ± 0.2, and 31.6 ± 0.2"

²Following the claim construction hearing, the parties submitted a joint letter updating the Court regarding the status of various disputed terms argued at the hearing. (D.I. 141) In the joint letter, Plaintiffs sought to modify their originally proposed construction to conform with the Court's previous constructions of similar "Form" terms in a separate case involving different patents, *Pfizer Inc. v. Dr. Reddy's Labs. Ltd.*, No. 09-943-LPS, 2011 U.S. Dist. LEXIS 19180 (D. Del. Feb. 28, 2011). (*Id.* at 2) Defendants objected to Plaintiffs' proposed modifications on the grounds that they had not had a fair opportunity to address those constructions during the claim construction proceedings. (*Id.* at 5) In view of Defendants' objections, as well as Plaintiffs' representations that their proposal "does not change the claim scope" (*id.*), the Court will not consider Plaintiffs' modified proposal.

3. Court's Construction.³ “the x-ray powder diffraction pattern must include at least 4 (or 6) of the 2θ values selected from 10.2 ± 0.2 , 11.4 ± 0.2 , 11.6 ± 0.2 , 12.6 ± 0.2 , 19.1 ± 0.2 , 20.6 ± 0.2 , 21.3 ± 0.2 , 22.8 ± 0.2 , 24.8 ± 0.2 , 27.4 ± 0.2 , 28.2 ± 0.2 , and 31.6 ± 0.2 ”

The parties' dispute concerns whether and to what extent the scope of this term, as it appears in claims 16-23 of the '372 patent,⁴ is limited to the specific 2θ values appearing in the Markush group (as Defendants propose), and whether the open-ended transitional phrase “comprising” permits the inclusion of additional 2θ values not expressly recited in the Markush group (as Plaintiffs propose). On balance, the Court agrees with Defendants that the Markush language “selected from the group consisting of” is fully closed and, thus, defines the limited range of possible 2θ values within the scope of this term, notwithstanding the presence of the open-ended transitional phrase “comprising.” See *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1372 (Fed. Cir. 2005) (“A Markush group by its nature is closed.”); *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007) (noting that “comprising” is “not a weasel word with which to abrogate claim limitations” and “does not reach into each of the [claim limitations] to render every word and phrase therein open-ended”) (internal quotation marks omitted).⁵ Plaintiffs' proposed construction would effectively read the Markush language out of

³The Court's construction includes an additional 2θ value, 12.6 ± 0.2 , which is recited in Claim 16 but appears to have been inadvertently omitted from Defendants' proposed construction.

⁴Claim 16 of the '372 patent recites the following: “Form 5 of crystalline Efavirenz which is characterized by an x-ray powder diffraction pattern comprising four or more 2θ values selected from the group consisting of: 10.2 ± 0.2 , 11.4 ± 0.2 , 11.6 ± 0.2 , 12.6 ± 0.2 , 19.1 ± 0.2 , 20.6 ± 0.2 , 21.3 ± 0.2 , 22.8 ± 0.2 , 24.8 ± 0.2 , 27.4 ± 0.2 , 28.2 ± 0.2 , and 31.6 ± 0.2 .”

⁵See also *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1281 (Fed. Cir. 2003) (noting that although “an indefinite article ‘a’ or ‘an’ in patent parlance [typically] carries the meaning of ‘one or more’ in open-ended claims containing the transitional phrase ‘comprising,’” the same “indefinite article [when] used in conjunction with a Markush grouping does not receive such latitude because a proper Markush group is limited by the closed language term

the claims, contrary to the maxim that all claim terms should be given meaning whenever possible. *See Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) (“A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.”).⁶

E. “Characterized by a differential scanning calorimetry thermogram having a peak at about 108°C to about 110°C” (‘372 patent)

1. Plaintiffs’ Proposed Construction: “Having, but not limited to, a differential scanning calorimetry peak between about 108°C to about 110°C”
2. Defendants’ Proposed Construction: “Having at least one differential scanning calorimetry peak between about 108°C to about 110°C, but no additional peak at or near 138°C”
3. Court’s Construction: “Having, but not limited to, a differential scanning calorimetry peak between about 108°C to about 110°C”

The parties dispute whether the applicants disclaimed the presence of a DSC peak at or near 138°C. During prosecution, the Applicants deleted Figure 10 – which contained a peak at or near 138°C – because it had been incorrectly included as part of the patent application. (D.I. 124 at 14-15) The applicants explained to the Examiner that Figure 10 did not in fact correspond to Form 5, and further represented that the “XRPD and DSC peak listings for Form 5 are correctly described within the specification and the Form 5 is properly characterized by these peaks.” (*Id.*; Florence Decl., Ex. 7) According to Defendants, the combined acts of deleting Figure 10 while maintaining that the specification adequately described Form 5 “unequivocally

‘consisting of’”) (internal quotation marks omitted).

⁶By contrast, the Court’s construction does not read the term “comprising” out of the claims; with the exception of the 2θ values which are specifically limited by the Markush language, the overall claim otherwise remains open to the presence of additional elements.

disavowed Form 5 having a peak in its thermogram at or near 138°C.” (D.I. 124 at 15)

The Court agrees with Plaintiffs that Defendants have failed to meet the high standard for establishing a prosecution disclaimer. *See Omega Eng'g, Inc., v. Raytek Corp.*, 334 F.3d 1314, 1325-26 (Fed. Cir. 2003) (stating that disclaimer “requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable”).

Here, the prosecution history does not clearly and unambiguously demonstrate that the applicants intended to surrender or exclude a peak at or near 138°C from the scope of their claimed invention. To the contrary, the deletion of Figure 10 was a clerical correction which neither discussed nor characterized the scope of the claimed invention; accordingly, the deletion did not surrender any subject matter. *See Aspex Eyewear, Inc. v. Miracle Optics, Inc.*, 170 Fed. Appx. 710, 714 (Fed. Cir. Mar. 2, 2006) (“[W]e cannot say that the canceling of Figure 8 was a clear and deliberate disclaimer of the claim coverage suggested by Figure 8 . . . [as the applicant] took the position that Figure 8 was no longer necessary.”); *Straussler v. U.S.*, 290 F.2d 827, 832 (Ct. Cl. 1961) (“[W]e do not believe that cancelling a part of the specification . . . has the effect of a disclaimer or a limitation of the claims . . . [where] nothing was amended, cancelled, or withdrawn to avoid an art rejection.”).

F. “Form 5” (’372 patent)

1. Plaintiffs’ Proposed Construction: “A polymorphic crystal form of [efavirenz] that can be distinguished from other forms”
2. Defendants’ Proposed Construction: Indefinite
3. Court’s Construction: “A polymorphic crystal form of [efavirenz] that can be distinguished from other forms”

According to Defendants, “Form 5” of the ’372 patent is indefinite because the XRPD and DSC peak values recited in connection with Form 5 substantially overlap with those for

other “Form” terms. Thus, in Defendants’ view, Form 5 is indistinguishable from other Forms. (D.I. 124 at 11-12; Hollingsworth Decl. ¶¶ 50-55)

Plaintiffs respond that Defendants’ indefiniteness arguments are misplaced, because they fail to recognize that other dependent claims recite additional limitations that do, in fact, distinguish Form 5 from other polymorphs of efavirenz. (D.I. 133 at 10) Thus, Plaintiffs argue, Defendants’ arguments do not establish the indefiniteness of the term “Form 5” *per se*, but are instead directed to the alleged invalidity of certain individual claims that happen to recite “Form 5,” which is an issue not presently before the Court. Plaintiffs also contend that Defendants’ indefiniteness theory relies on a misguided selection of peak values that improperly incorporates background noise. (D.I. 133 at 11; Atwood Decl. ¶ 21)

The Court agrees with Plaintiffs that “Form 5” can and should be defined in the same manner as Forms 1, 2, and 4. Thus, the Court will construe “Form 5” to mean “a polymorphic crystal form of [efavirenz] that can be distinguished from other forms.”

The Court will reserve its ultimate determination on the issue of indefiniteness for trial. Defendants correctly note that “[e]ven if a claim term’s definition can be reduced to words, the claim is still indefinite if a person of ordinary skill in the art cannot translate the definition into meaningfully precise claim scope.” *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244,

1251 (Fed. Cir. 2008). Whether a skilled artisan could translate the Court's construction of "Form 5" into a meaningfully precise claim scope appears to involve factual determinations,⁷ such as whether Defendants have improperly relied on background noise as the basis for their indefiniteness theory.⁸ These factual disputes should be resolved at trial rather than as part of claim construction.⁹

G. "No detectable peaks" ('071 and '964 patents)

1. Plaintiffs' Proposed Construction: "no 2 θ peaks present in the x-ray powder diffraction pattern that are found in [the other Forms], but are not found in [the claimed Form] of [efavirenz]"
2. Defendants' Proposed Construction: Indefinite
3. Court's Construction: "no 2 θ peaks present in the x-ray powder diffraction pattern that are found in [the other Forms], but are not found in [the claimed Form] of [efavirenz]"

Defendants contend that the limitation "no detectable peaks" is indefinite because a skilled artisan would understand this language to require completely distinct XRPD patterns as

⁷The Court acknowledges it is not entirely clear whether indefiniteness is purely an issue of law, or whether it involves underlying factual determinations. Because the parties in this case appear to agree that indefiniteness can involve underlying factual components, the Court will resolve the indefiniteness issue after allowing the parties to present their evidence at trial. (Tr. at 59, 80)

⁸To the extent that Defendants are arguing that the overlapping peaks between Form 5 and other Forms render it impossible to distinguish among polymorphs, those arguments might implicate enablement rather than indefiniteness. See *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1359 (Fed. Cir. 1999) ("A claim is inoperable when it contains a limitation that is impossible to meet."); *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1334 (Fed. Cir. 2010) ("[I]f this particular embodiment is inoperable . . . then the basis for invalidity would be a lack of enablement, not indefiniteness."); *Miles Labs., Inc. v. Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993) ("The invention's operability may say nothing about a skilled artisan's understanding of the bounds of the claim.").

⁹Plaintiffs appear to agree. (See Tr. at 80 ("On all of this indefiniteness argument, . . . [t]here is an absolute battle of the experts. The stage has been set for trial on this issue . . . and we look forward to having that day in Court."))

between Forms I, II, and III – with no overlapping peaks whatsoever – whereas the XRPD values actually described in the '071 and '964 patents exhibit some overlapping peaks. (D.I. 124 at 18) (citing '071 patent, col. 5 ll. 15-39) Plaintiffs respond that a skilled artisan would expect polymorphs of the same compound to share at least one or more peaks in common, and that the proper analysis involves a comparison of the “characteristic peaks” for each Form. (D.I. 133 at 16; Ex. R, Hollingsworth Decl. ¶ 26)

In the Court’s view, the parties’ respective positions again reveal underlying factual disputes that should be resolved at trial rather than as part of claim construction. For example, whether a skilled artisan would truly expect different polymorphs to share one or more peaks in common, and whether or how a skilled artisan would objectively distinguish characteristic peaks of a particular polymorph from the common peaks shared by different polymorphs, are matters on which the Court will need to receive testimony. Therefore, the Court will reserve judgment on these questions and the ultimate indefiniteness determination for trial.¹⁰

V. CONCLUSION

For the foregoing reasons, the Court will construe the terms of the patents-in-suit consistent with this Memorandum Opinion. An appropriate Order follows.

¹⁰Again, it is not entirely clear to the Court that Defendants’ arguments raise an indefiniteness issue under 35 U.S.C. § 112 ¶ 2, as opposed to an issue of written description or enablement under 35 U.S.C. § 112 ¶ 1.

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MERCK & CO., INC. and
MERCK SHARP & DOHME CORP.,

Counterclaim-Defendants.

ORDER

At Wilmington, this **16th** day of **May 2012**,

For the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that the claim language of U.S. Patent Nos. 6,673,372 (“the ’372 patent”); 6,639,071 (“the ’071 patent”); and 6,939,964 (“the ’964 patent”), shall be construed as follows:

1. **“Form 1”** is construed to mean “a polymorphic crystal form of [efavirenz] that can be distinguished from other forms.”
2. **“Form 2”** is construed to mean “a polymorphic crystal form of [efavirenz] that can be distinguished from other forms.”

3. **“Form 4”** is construed to mean “a polymorphic crystal form of [efavirenz] that can be distinguished from other forms.”
4. **“Form 5”** is construed to mean “a polymorphic crystal form of [efavirenz] that can be distinguished from other forms.”
5. **“Form I”** is construed to mean “a polymorphic crystal form of [efavirenz] that can be distinguished from other forms by its x-ray powder diffraction pattern.”
6. **“Form II”** is construed to mean “a polymorphic crystal form of [efavirenz] that can be distinguished from other forms by its x-ray powder diffraction pattern.”
7. **“Form III”** is construed to mean “a polymorphic crystal form of [efavirenz] that can be distinguished from other forms by its x-ray powder diffraction pattern.”
8. **“Characterized by”** is construed to mean “having the physical characteristics recited in the subject claims, which may or may not distinguish it from other forms of efavirenz.”
9. **“Comprising 4 (or 6) or more 2θ values selected from the group consisting of”** is construed to mean “the x-ray powder diffraction pattern must include at least 4 (or 6) of the 2θ values selected from 10.2 ± 0.2 , 11.4 ± 0.2 , 11.6 ± 0.2 , 12.6 ± 0.2 , 19.1 ± 0.2 , 20.6 ± 0.2 , 21.3 ± 0.2 , 22.8 ± 0.2 , 24.8 ± 0.2 , 27.4 ± 0.2 , 28.2 ± 0.2 , and 31.6 ± 0.2 .”
10. **“Characterized by a differential scanning calorimetry thermogram having a peak at about 108°C to about 110°C”** is construed to mean “having, but not limited to, a differential scanning calorimetry peak between about 108°C to about 110°C.”

11. **“No detectable peaks for Form II or Form III”** is construed to mean “No 2θ peaks present in the x-ray powder diffraction pattern that are found in either Form II or Form III, but are not found in Form I of [efavirenz].”
12. **“No detectable peaks for Form I or Form III”** is construed to mean “No 2θ peaks present in the x-ray powder diffraction pattern that are found in either Form I or Form III, but are not found in Form II of [efavirenz].”
13. **“No detectable peaks for Form I or Form II”** is construed to mean “No 2θ peaks present in the x-ray powder diffraction pattern that are found in either Form I or Form II, but are not found in Form III of [efavirenz].”
14. **“As exhibited in Fig. 3”** is construed to mean “Correspondence within the standard deviation of the major peaks of the x-ray powder diffraction pattern of Fig. 3, as listed in the Table in col. 5, within the calibrated precision of a diffractometer for a diffraction angle, wherein the corresponding 2θ values are reproducible to +/- 0.10 or 0.20 degrees.”
15. **“Characterized by crystallographic D-spacings of 14.5, 8.5, 8.0, 7.2, 6.7, 6.2, 5.2, 4.6, 4.4, 4.2, and 3.6 Angstroms”** is construed to mean “an x-ray powder diffraction pattern that contains at least the D-spacings of 14.5, 8.5, 8.0, 7.2, 6.7, 6.2, 5.2, 4.6, 4.4, 4.2, and 3.6 Angstroms within the calibrated precision of a diffractometer for a diffraction angle, wherein the corresponding 2θ values are reproducible to +/- 0.10 or 0.20 degrees.”
16. **“Characterized by crystallographic D-spacings of 14.5, 8.5, and 7.2 Angstroms”** is construed to mean “an x-ray powder diffraction pattern that contains at least the D-spacings of 14.5, 8.5, and 7.2 Angstroms within the

calibrated precision of a diffractometer for a diffraction angle, wherein the corresponding 2θ values are reproducible to +/- 0.10 or 0.20 degrees.”

17. **“Characterized by crystallographic D-spacings of 14.5, 8.5, 7.2, 6.2, 4.4, and 4.2 Angstroms”** is construed to mean “an x-ray powder diffraction pattern that contains at least the D-spacings of 14.5, 8.5, 7.2, 6.2, 4.4, and 4.2 Angstroms within the calibrated precision of a diffractometer for a diffraction angle, wherein the corresponding 2θ values are reproducible to +/- 0.10 or 0.20 degrees.”
18. **“Characterized by crystallographic D-spacings of 14.5, 8.5, 8.0, 7.2, 6.7, 6.2, 4.4, and 4.2 Angstroms”** is construed to mean “an x-ray powder diffraction pattern that contains at least the D-spacings of 14.5, 8.5, 8.0, 7.2, 6.7, 6.2, 4.4, and 4.2 Angstroms within the calibrated precision of a diffractometer for a diffraction angle, wherein the corresponding 2θ values are reproducible to +/- 0.10 or 0.20 degrees.”
19. **“Substantially pure form”** is construed to mean “a compound having a purity of at least 90%.”


UNITED STATES DISTRICT JUDGE