

United States District Court,
D. New Jersey.

AVENTIS PHARMACEUTICALS, INC., Merrell Pharmaceuticals, Inc., and Carderm Capital L.P,
Plaintiffs.

v.

BARR LABORATORIES, INC,
Defendant.

Aventis Pharmaceuticals, Inc., Merrell Pharmaceuticals, Inc., and Carderm Capital L.P,
Plaintiffs.

v.

Teva Pharmaceuticals USA, Inc,
Defendant.

Aventis Pharmaceuticals, Inc., AMR Technology, Inc,
Plaintiffs.

v.

Barr Laboratories, Inc., Ranbaxy Laboratories Ltd. and Ranbaxy Pharmaceuticals, Inc,
Defendants.

Aventis Pharmaceuticals, Inc., AMR Technology, Inc,
Plaintiffs.

v.

Teva Pharmaceuticals USA, Inc., and Amino Chemicals, Ltd,
Defendants.

No. CIV.A.01-3627(JAG), CIV.A.03-487(JAG), CIV.A.04-1064(JAG), CIV.A.04-1078(JAG)

Jan. 30, 2006.

Background: Patentee and licensees filed application for a preliminary injunction to enjoin generic drug manufacturer and marketers from infringement of patents relating to fexofenadine formulations sold under tradename for antihistamine allergy medication product or inducing patent infringement by marketing, making, using, or selling generic fexofenadine.

Holdings: The District Court, Greenaway, J., held that:

- (1) claim term "substantially pure regioisomer," would be tentatively construed to mean "of greater than 95% purity;"
- (2) plaintiffs failed to establish a substantial likelihood that manufacturer's fexofenadine was made using the patented process;
- (3) defendants raised a substantial question as to invalidity of method patents due to inherent anticipation.

Application denied.

5,750,703. Construed.

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OPINION

GREENAWAY, District Judge.

This matter comes before the Court on the application for a preliminary injunction by Plaintiffs Aventis Pharmaceuticals, Inc., Merrell Pharmaceuticals Inc., Carderm Capital L.P., and AMR Technology, Inc. (collectively "Plaintiffs"), seeking to enjoin Defendants Barr Laboratories, Inc. ("Barr"), Teva Pharmaceuticals USA, Inc. ("Teva"), Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals, Inc.

(collectively "Ranbaxy"), and Amino Chemicals, Ltd. ("Amino") (collectively "Defendants"), from patent infringement, or inducing patent infringement, by marketing, making, using, or selling generic fexofenadine. For the reasons set forth below, the application for a preliminary injunction is denied.

BACKGROUND

This dispute concerns patents owned by, or licensed to, Aventis Pharmaceuticals, Inc., Merrell Pharmaceuticals Inc., Carderm Capital L.P., and AMR Technology, Inc. relating to fexofenadine formulations sold in the United States by Aventis under the tradename ALLEGRA(R). This antihistamine allergy medication product has achieved substantial commercial success in the United States. Between May 2001 and June 2002, Defendants Barr and Teva each filed Abbreviated New Drug Applications ("ANDA") seeking the Federal Drug Administration's ("FDA") approval to market generic drug products containing the same active ingredient, fexofenadine hydrochloride ("fexofenadine"), as ALLEGRA(R). In response, Plaintiffs filed a series of suits for infringement of a larger group of patents than is at issue in this motion for a preliminary injunction; litigation in these suits is ongoing.

On August 31, 2005, the FDA approved Barr's ANDA no. 076191. On September 1, 2005, the FDA approved Teva's ANDA no. 076447. On September 6, 2005, Barr and Teva announced an agreement to market generic fexofenadine jointly. Ranbaxy has manufactured fexofenadine for Barr. Amino has manufactured fexofenadine for Teva.

On September 20, 2005, Plaintiffs asked this Court to order Defendants to show cause why a preliminary injunction against Defendants should not issue. Plaintiffs sought for this Court to enjoin Defendants Teva and Barr from marketing generic fexofenadine, thereby actively inducing infringement of U.S. Patent No. 6,037,353 (filed Mar. 2, 1995) (the " '353 patent"), U.S. Patent No. 6,187,791 (filed Jan. 12, 2000) (the " '791 patent"), and U.S. Patent No. 6,399,632 (filed Sept. 15, 2000) (the " '632 patent") (collectively "the method patents"), and to enjoin Defendants Barr, Teva, Ranbaxy and Amino from making, using, or selling generic fexofenadine, thereby infringing claim 7 of U.S. Patent No. 5,750,703 (filed Feb. 2, 1995) (the " '703 patent" or "process patent"). On September 29, 2005, this Court granted the application and ordered Defendants to show cause why the preliminary injunction should not issue.

Subsequent to the filing of the application for the preliminary injunction, Plaintiffs stated that Barr has not put any fexofenadine manufactured by Ranbaxy on the market, beyond having made a token sale. Plaintiffs have not, however, withdrawn their application for a preliminary injunction against Barr or Ranbaxy.

APPLICABLE LEGAL STANDARDS

I. Preliminary Injunction

As the moving party, a plaintiff "is entitled to a preliminary injunction if it shows: (1) a reasonable likelihood of success on the merits of its claims; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest." *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1370 (Fed.Cir.2005). In order to demonstrate a likelihood of success on the merits on a particular claim of patent infringement, Plaintiffs must show that, in light of the presumptions and burdens that will inhere at a trial on the merits, (1) Defendants likely infringe the patent, and (2) the claims of the patent will likely withstand Defendants' challenges to validity. *Id.* If Defendants "raise[] a substantial question concerning either infringement or validity, *i.e.*, assert[] an infringement or invalidity defense that the patentee cannot prove 'lacks substantial merit,' the preliminary

injunction should not issue." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350-1351 (Fed.Cir.2001). Thus, once the non-movant has raised a substantial question as to infringement or validity, for the preliminary injunction to issue, the movant must prove that this question lacks substantial merit.

[1] [2] "[I]nfraction and validity analyses must be performed on a claim-by-claim basis." *Id.* at 1351. "[I]n cases involving multiple patent claims, to demonstrate a likelihood of success on the merits, the patentee must demonstrate that it will likely prove infringement of one or more claims of the patents-in-suit, and that at least one of those same allegedly infringed claims will also likely withstand the validity challenges presented by the accused infringer." *Id.*

II. Infringement

The test for patent infringement requires a two step analysis: "the claim scope is first determined, and then the properly construed claim is compared with the accused device to determine whether all of the claim limitations are present either literally or by a substantial equivalent." *Id.* "To prove direct infringement, the plaintiff must establish by a preponderance of the evidence that one or more claims of the patent read on the accused device literally or under the doctrine of equivalents. Literal infringement requires that each and every limitation set forth in a claim appear in an accused product." *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1310 (Fed.Cir.2005) (internal citations omitted). Although claim construction is an issue of law, the determination of infringement is a question of fact. *Pause Tech. LLC v. TiVo Inc.*, 419 F.3d 1326, 1329 (Fed.Cir.2005).

III. Validity

In *Amazon*, the Federal Circuit stated the standard for a validity challenge in the context of an application for a preliminary injunction:

Validity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial. The test for invalidity at trial is by evidence that is clear and convincing.... In resisting a preliminary injunction ... one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself.... When moving for the extraordinary relief of a preliminary injunction, a patentee need not establish the validity of a patent beyond question. The patentee must, however, present a clear case supporting the validity of the patent in suit.

Amazon, 239 F.3d at 1358-1359 (citations omitted).

ANALYSIS

I. Plaintiffs have not demonstrated a likelihood of success in establishing that Barr has infringed the process patent.

For purposes of the motion for a preliminary injunction, Plaintiffs assert only claim 7 of the '703 manufacturing process patent. There is no dispute that Ranbaxy has manufactured fexofenadine for Barr. Plaintiffs contend that Ranbaxy has infringed claim 7 of the '703 patent. Under 35 U.S.C. s. 271(g), if Ranbaxy has infringed, Barr is liable as an infringer for importing Ranbaxy's product.

The parties agree that determination of Barr's and Ranbaxy's alleged infringement of claim 7 of the process patent turns on the Court's construction of the phrase "substantially pure regioisomer" in claim 1, the independent claim on which claim 6 and, in turn, claim 7 depend. At issue is the question of the scope of "substantially pure" in regard to the regioisomer p-CPK (i.e., the para regioisomer of cyclopropylketone), an intermediate in the manufacturing process: how pure is "substantially pure?"

A. Tentative claim construction of "substantially pure regioisomer" in the process patent

[3] At the preliminary injunction stage, the district court has the discretion to base its resolution on a tentative claim construction. *Guttman, Inc. v. Kopykake Enters.*, 302 F.3d 1352, 1361 (Fed.Cir.2002). "District courts may engage in a rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves." *Id.*

[4] The Court decides claim construction as a matter of law: "the construction of a patent, including terms of art within its claim, is exclusively within the province of the court." *Markman v. Westview Instruments*, 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). "To ascertain the meaning of claims, we consider three sources: the claims, the specification, and the prosecution history." *Markman v. Westview Instruments*, 52 F.3d 967, 979 (Fed.Cir.1995), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996) (citations omitted).

1. Ascertaining the meaning based on the claims

[5] The Court first looks to the language of the claims themselves to ascertain the meaning and scope of the phrase "substantially pure regioisomer." Claim 1 recites "a process of preparing a piperidine derivative compound" of a formula which includes both fexofenadine and fexofenadone, "said process comprising: providing a substantially pure regioisomer" p-CPK and "converting the substantially pure regioisomer to the piperidine derivative compound" using the compound azacyclonol ("AZA"). '703 Patent col. 23 l. 45-col. 24 l. 34. Claim 6 adds onto this process a step in which the piperidine derivative compound is transformed into an end product in the fexofenadine family. *Id.* col. 25 l. 63-col. 26 l. 16. Claim 7 recites the process of claim 6, with the end product being fexofenadine. *Id.* col. 26 ll. 17-32. Thus, in claim 7, the patented process begins with the "substantially pure regioisomer" p-CPK, often referred to as an intermediate, and finishes with the end product fexofenadine. The parties agree that there is nothing express or implicit in the words of claims 1, 6, or 7 that delimits the purity of the p-CPK intermediate that the process begins with. They agree as well that "substantially pure" has no ordinary or customary meaning to one of ordinary skill in the art. (Def.'s Opp. Br. 44.)

[6] Claim 2 provides information relevant to construction of the phrase at issue. Nonasserted dependent claims may be helpful in construing a term in an independent claim, because the claims must be interpreted consistently. *See Wright Med. Tech., Inc. v. Osteonics Corp.*, 122 F.3d 1440, 1445 (Fed.Cir.1997) ("[W]e must not interpret an independent claim in a way that is inconsistent with a claim which depends from it"); *accord Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1317 (Fed.Cir.2005).

Claim 2 depends from claim 1 and recites steps comprising the "providing a substantially pure regioisomer" of the previous claim. *Id.* col. 24 l. 35-col. 25 l. 22. These steps comprise, in brief, producing a first mixture of regioisomers, which is hydrolyzed to form a second mixture of regioisomers, and then "recovering from the second mixture of regioisomers the substantially pure regioisomer" p-CPK. *Id.* col. 25 ll. 12-13. The parties do not dispute that "mixture" in claim 2 refers to a mixture of meta regioisomers and para

regioisomers. The claim language thus establishes that a "substantially pure regioisomer" is something that is recovered from, and therefore, not the same as, a "mixture of regioisomers." This must mean that a "substantially pure regioisomer" is not a "mixture" of regioisomers. This supports an initial construction of "substantially pure regioisomer" as meaning "the regioisomer substantially different from a mixture." Moreover, if the mixture consists only of para and meta regioisomers, and a non-mixture is recovered, then this non-mixture must logically substantially consist of only the para regioisomer or the meta regioisomer. FN1 Because the parties agree that, as a general rule, the meta regioisomers of fexofenadine are unwanted impurities that should be eliminated, and they do not dispute that one of ordinary skill in the art would have understood this at the time of application, it is reasonable to infer that "substantially pure regioisomer" in claim 2 means "the para regioisomer substantially not mixed with meta regioisomer." Because claims must be interpreted consistently, this analysis provides the initial construction of "substantially pure regioisomer," as used in claim 1.

FN1. Other unspecified impurities may be present. As will be discussed further *infra*, the parties dispute whether purity should be understood as regioisomeric purity (purity of the para regioisomer relative to the meta regioisomer) or as chemical purity (purity of the para regioisomer relative to all other substances). Resolution of that dispute is not necessary at this point in the analysis.

[7] Drawings in a patent may be a source of information in claim construction. *Ferguson Beauregard/Logic Controls v. Mega Sys., LLC*, 350 F.3d 1327, 1338 (Fed.Cir.2003); *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed.Cir.2002). In the chemical drawings used in the claims, benzene rings are drawn as hexagons with a circle inside. Each circle is labeled with a letter that corresponds to the substituent of the ring. Defendants observed, and Plaintiffs did not dispute, that the diagrams themselves indicate whether a chemical is or is not a mixture: the drawings of chemicals identified as mixtures in the claims all show a bond line connecting the hexagon to the circle, whereas the drawings of chemicals identified as substantially pure have no such connecting bond line.

This aspect to the drawings appears meaningful in examining claim 2. Thus, in claim 2, a diagram with a connecting line depicts "a first mixture of regioisomers" and "a second mixture of regioisomers." '703 Patent, col. 24 l. 58-col. 25 l. 9. After stating the step of "recovering from the second mixture of regioisomers the substantially pure regioisomer," claim 2 shows a diagram without a connecting line. *Id.* col. 25 ll. 11-22. This provides additional support for the inference that the "substantially pure regioisomer" of claim 2 is not a "mixture."

In addition, the diagram for the piperidine derivative of claim 7, depicting the end product fexofenadine, has no connecting line. *Id.* col. 26 ll. 17-32. This supports the inference that the end product is also not a mixture. While this does not establish that the substantially pure intermediate and the end product have the same purity level, here is a place that the inventor could have expressly differentiated the purity of the substantially pure intermediate from the purity of the end product, but chose not to do so.

Because the inventor may be his own lexicographer, however, one cannot know from the claims alone exactly where to draw the line that distinguishes, in terms of purity level, between the "substantially pure regioisomer" and the "mixture."

2. Ascertaining the meaning based on the specification

[8] The Court next looks to the patent specification as a source of information for claim construction. Federal Circuit law is clear that courts must exercise great care when using the patent specification to limit the scope of claims:

[T]his court recognizes that it must interpret the claims in light of the specification, yet avoid impermissibly importing limitations from the specification. That balance turns on how the specification characterizes the claimed invention. In this respect, this court looks to whether the specification refers to a limitation only as a part of less than all possible embodiments or whether the specification read as a whole suggests that the very character of the invention requires the limitation be a part of every embodiment. For example, it is impermissible to read the one and only disclosed embodiment into a claim without other indicia that the patentee so intended to limit the invention. On the other hand, where the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims.

Alloc, Inc. v. Int'l Trade Comm., 342 F.3d 1361, 1370 (Fed.Cir.2003) (citations omitted). The test for limiting claim scope from the specification is a stringent one: "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) (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed.Cir.2002)).

Of particular interest to the parties are the last two paragraphs in the "Background of the Invention" section:

The above second mixture of regioisomers can be converted to a third mixture of regioisomers of formula: [diagram of fexofenadine] Although the second mixture of regioisomers and the third mixture of regioisomers can be analyzed by HPLC experiments, a practical separation to obtain gram quantities of substantially pure regioisomers has not been achieved.

Each mixture (including the first), would be expected to contain 33% of the para isomer and 67% of the meta isomer. Since these components are inseparable, it has not been possible to obtain either of the regioisomers in each mixture in substantially pure form.

'703 Patent col. 3 l. 66-col. 4 l. 24.

Plaintiffs argue that the only clear disavowal of claim scope in the specification appears in the second paragraph above: because it states that a mixture is not in substantially pure form, and also that a mixture may contain one of the regioisomers at a level of 67%, a "substantially pure regioisomer" must contain one of the regioisomers at a level greater than 67%. This, Plaintiffs argue, draws the line between "substantially pure" and "mixture" that one cannot discern from the claims themselves. Defendants argue that the analysis of the specification need not stop here, and this argument has merit.

The parties do not dispute that this quoted section refers to the prior art Carr process, that the first mixture refers to the intermediate straight-chain PK, the "second mixture of regioisomers" refers to fexofenadone, and the "third mixture of regioisomers" refers to fexofenadine. The second paragraph states that, because the para isomer and meta isomer of fexofenadone or fexofenadine cannot be separated, it has not been possible to obtain these regioisomers in substantially pure form. This establishes that 1) "substantially pure regioisomers" is a term that the inventor applied not only to p-CPK, as in claim 1, but also to fexofenadone and fexofenadine; FN2 and 2) that "regioisomers in substantially pure form" are not mixtures, but are either

the para or the meta isomer only, formed by separating mixtures. This second inference confirms the initial construction derived from the claims discussed *supra*.

FN2. The parties agree that fexofenadine exists in the form of a regioisomer, using conventional chemistry terminology. The cited portion of the specification establishes that the inventor, acting as his own lexicographer, did not exclude fexofenadine from the category of substantially pure regioisomers. Rather, p-CPK, fexofenadone, and fexofenadine may all exist as substantially pure regioisomers.

The parties dispute how the cited paragraphs in the specification should be construed to limit the claims. Defendants argue that they establish that the para and meta regioisomers of fexofenadone and fexofenadine are inseparable. Because mixtures of these products are inseparable, Defendants argue, any separation needed to purify the end product must occur at an early stage, prior to the reaction producing fexofenadone. This issue will be discussed in detail *infra*.

Other parts of the specification provide information relevant to the construction of "substantially pure regioisomer."

i. Both the end product and the p-CPK intermediate are described in the specification as "substantially pure."

Although "substantially pure" describes only intermediates in the claims, it describes the end product at a number of points in the specification: in the abstract ("The present invention relates to a process for preparation of substantially pure piperidine derivative compounds" followed by generic formulae for fexofenadone and fexofenadine), '703 Patent at [57], in the summary of the invention ("The present invention relates to substantially pure piperidine derivative compounds" followed by the same formulae), *Id.* col. 4 ll. 27-28, in the detailed description of the invention (repeating the statement just quoted in the summary), *Id.* col. 6 ll. 19-20, and in two examples of processes for converting the substantially pure regioisomer to the substantially pure piperidine derivative, *Id.* col. 16 ll. 31-col. 19 l. 35. In the background of the invention, in one sentence, the patent groups together intermediates and end products as "substantially pure." *Id.* col. 4 ll. 18-19.

Thus, the inventor describes the invention as involving substantially pure piperidine derivative compounds at three key, prominent points in the specification. While there are two additional points where this phrasing is used in the context of preferred embodiments, the first sentences of the abstract, summary, and detailed description do not refer to particular embodiments but to the invention as a whole. This clearly establishes a limitation of the invention to processes producing substantially pure piperidine derivative compounds. As will be seen *infra*, this conclusion is well-supported by the prosecution history. Moreover, the inventor does not in any way differentiate the meaning of "substantially pure" as it describes the end product from the meaning of "substantially pure" as it describes the intermediate.

ii. Both the end product and the p-CPK intermediate are described in the specification as "regioisomers."

Although only intermediates are described as "regioisomers" in the claims, the specification refers to fexofenadone and fexofenadine regioisomers. In the background of the invention, regarding prior art mixtures of fexofenadine and fexofenadone, the patent states: "a practical separation to obtain gram quantities of substantially pure regioisomers has not been achieved." *Id.* col. 4 ll. 18-19. The patent then

teaches that each mixture contains both meta isomer and para isomer, and that "[s]ince these components are inseparable, it has not been possible to obtain either of the regioisomers in each mixture in substantially pure form." Id. col. 4 ll. 22-24. This expands the scope of "regioisomers" to include not only the intermediate p-CPK, as mentioned in the claims, but also fexofenadone and fexofenadine.

The import of this reading of the specification is that, because both the end product and the p-CPK intermediate are described in the specification as "substantially pure," and both the end product and the p-CPK intermediate are described in the specification as "regioisomers," the specification does not support two definitions of "substantially pure," one for the intermediate and one for the end product, nor can "regioisomer" be read to connote or distinguish purity.

iii. The piperidine derivative compounds have pharmaceutical uses.

[9] "Statements that describe the invention as a whole, rather than statements that describe only preferred embodiments, are more likely to support a limiting definition of a claim term." C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 864 (Fed.Cir.2004).

The specification describes pharmaceutical uses of the substantially pure piperidine derivative compounds. The summary of the invention states: "These compounds are useful in pharmaceutical compositions, particularly as antihistamines, anti-allergy agents, and bronchodilators." '703 Patent col. 5 ll. 6-8. The detailed description of the invention describes pharmaceutical uses of the end products at some length, beginning by stating: "The piperidine derivative compounds of the present invention can be utilized as the biologically active components in pharmaceutical compositions." Id. col. 11 ll. 34-36. The parties do not dispute that only the para regioisomer piperidine derivative compounds are biologically active; the meta regioisomer end product is not. Because only para regioisomer piperidine derivative compounds are biologically active, only these compounds can be utilized for the described use. This could suggest a limitation of the invention to a process producing para regioisomer piperidine derivative compounds. Yet this does not rise to the level of establishing a clear intention to limit claim scope through "words of manifest exclusion or restriction." FN3

FN3. At oral argument, counsel for Plaintiffs stated that the para regioisomer is the end product, and that the meta regioisomer of fexofenadine "is not the end product" of the process patent. (Hr'g Tr. 10, Oct. 27, 2005.) Again, while strongly suggestive, this is not an expression of manifest exclusion either. Plaintiffs also stated that the para regioisomer of CPK leads to the biologically active form of fexofenadine, while the meta regioisomer of CPK does not. (Id. at 34.)

The detailed description teaches how to use the "compounds of the present invention" to "treat" humans. Id. col. 12 l. 27. It discloses treatment methods using the compounds and makes no mention of further purification before such methods as intravenous administration. Id. col. 11 l. 44.

While these statements appear to describe the invention as a whole, rather than preferred embodiments, again, one cannot characterize them as establishing a clear intention to limit claim scope through words of manifest exclusion or restriction. One is not led to the "inescapable conclusion," based only on these specification statements, that the end product of every embodiment must be ready for pharmaceutical use or must be at a particular level of purity. *See* Microsoft Corp. v. Multi-Tech Sys., 357 F.3d 1340, 1348 (Fed.Cir.2004) (employing the "inescapable conclusion" standard in determining whether to find claim limitations in the specification).

Moreover, Plaintiffs argue that, while it would be incorrect to limit the patent to processes producing end products pure enough for pharmaceutical use, such a limitation would not defeat their argument that Ranbaxy has infringed. If this Court construed "substantially pure regioisomer" as to the intermediate to mean "purity sufficient to obtain a pharmaceutical grade piperidine derivative compound," Plaintiffs argue, Ranbaxy would literally infringe, since it necessarily uses p-CPK intermediate at a purity level sufficient to obtain a pharmaceutical grade piperidine derivative compound. Thus, even if this Court found a manifest restriction in the specification to processes producing end product pure enough for pharmaceutical use, this would not shield Ranbaxy from a finding of infringement.

iv. The specification does not support two standards of substantial purity.

The language of the specification does not support two definitions of "substantially pure," one for the intermediate and one for the end product. The inventor applies the phrases "substantially pure" and "substantially pure regioisomers" indiscriminately to intermediate and to end product; there is no evidence that he intended anything other than one common definition. The specification does not, however, establish a clear scope for "substantially pure." Viewed as a whole, the language within the patent strongly suggests that "substantially pure" is a very high level of purity. While it is clear from the patent that a line separates what is "substantially pure" from what is a mixture, neither the claims nor the specification place that line with more clarity or certainty than the 67% line Plaintiffs point to. Because the inventor may act as his own lexicographer, he may define "mixture" and "substantially pure" in idiosyncratic ways. As such, the language of the patent, without more, does not justify limiting "substantially pure" beyond the 67% level Plaintiffs advocate; the language suggesting higher purity does not meet the standard of explicit restriction that the Federal Circuit requires in order to limit claim scope.

Plaintiffs argue that one of ordinary skill in the art would understand that purity standards for intermediates are "often different" from purity standards for end products. (Pls.' Reply Br. 101.) This statement, however, works against them. If one of ordinary skill in the art would understand that such purity standards are often different, one would sometimes understand that they are the same. This supports the conclusion from the specification that this is one of those times, and that "substantially pure" has one uniform meaning in the patent as a whole.

Plaintiffs state that there is nothing in the patent that expressly states that the purity standards are the same. (*Id.* at 101 n. 38.) But, for this to get them to their conclusion, Plaintiffs require a default rule that makes no sense: the reader of the patent should assume that one phrase has different meanings in different contexts unless told otherwise. In reality, the default rule is opposite: the reader assumes that one phrase has a uniform meaning unless told otherwise. As such, in the absence of any express differentiation of the two standards in the patent or prosecution history, Plaintiffs have in effect admitted that one of ordinary skill in the art might understand that the "substantially pure" purity standard for the regioisomer intermediate is the same as that for the "substantially pure" regioisomer end product.

Further support for this interpretation comes from the deposition of the inventor, D'Ambra. Questioned specifically about this issue-whether "substantially pure" means one thing as applied to the end product and another thing as applied to the intermediate-D'Ambra admitted that this distinction does not appear in the patent: "Q: And where do I find that understanding in your patent? A: I don't believe it's clarified in there." (James Decl. Ex. 12 137:10-13.) Of course, Plaintiffs have failed similarly to provide any support for such an understanding either.

3. Ascertaining the meaning based on the '703 prosecution history

The Federal Circuit restated the basic principles guiding the use of the prosecution history in claim construction in *Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1372-73 (Fed.Cir.2005):

[I]n construing the claim, we consider the prosecution history to determine whether the patentee disclaimed or disavowed subject matter, narrowing the scope of the claim terms. In doing so, we examine the entire prosecution history, which includes amendments to claims and all arguments to overcome and distinguish references. Where an applicant argues that a claim possesses a feature that the prior art does not possess in order to overcome a prior art rejection, the argument may serve to narrow the scope of otherwise broad claim language. A disclaimer must be clear and unambiguous.

Id. (citations omitted).

On March 3, 1994, in response to the first office action on the parent application, serial no. 08/083,102, the applicant submitted an amendment to the application in which he asked the examiner to amend claim 1, and argued that the rejection of claims 1-6 and 13-19 under 35 U.S.C. s. 103 should be withdrawn. (James Decl. Ex. 67 at 10.) To support this argument, he distinguished the prior art Carr patents on two bases. One concerned the presence of substituent Z in the piperidine derivative, and the other was based on the purity of the end product. In describing the process in the Carr patents, D'Ambra stated that they:

suggest a recrystallization treatment In attempting to reproduce the synthetic procedures of the Carr patents, applicant has discovered that, even with such recrystallization, the yield of the desired para isomer is about 2%. In addition, the meta isomer is present in an amount of up to 5% in admixture with the desired para product. Accordingly ... although the recrystallization steps in the Carr terfenadine metabolite FN4 patents are effective in removing some of the theoretically-present meta isomer, there remains a quantity of that impurity in the desired para-containing product stream which is inseparable.

FN4. Fexofenadine is sometimes referred to as terfenadine metabolite or terfenadine acid metabolite.

The present invention is directed to a process capable of producing substantially pure piperidine derivative compounds of the formula set forth above in claim 1.

(*Id.* at 9.) As explained by Defendants, and not disputed by Plaintiffs, this states that the Carr process produced a yield of 2%; of that 2%, 5% was an impurity, the meta regioisomer, that could not be removed. It is only this remaining 5% that is inseparable.

The applicant proceeded to distinguish the Carr process:

[T]he Carr terfenadine metabolite patents use a substantially different process than that claimed by the applicant. More particularly, the Carr terfenadine metabolite patents' product is prepared by the above-described prior art process which requires removal of a significant quantity of an impurity by recrystallization and, even after such treatment, it still contains that impurity at a level of up to 5%.

(*Id.* at 11.) The applicant then described the process of the present invention, asserting that it "achieves substantial benefits over the prior art process." (*Id.*) He explained that, by using the substantially pure regioisomer as starting material, the AZA coupling reaction:

yields the piperidine derivative compound of applicant's claimed invention with the desired para configuration. Unlike the prior art process, no separation step is required after that reaction and, even more interestingly, the product of the present process can be prepared in a substantially pure form suitable for pharmaceutical use.

(*Id.* at 11.) The use of the words "substantially pure" in the last sentence clearly expresses the inventor's understanding that the purity level he is defining is to be associated with these words.

The applicant concluded:

Even if a *prima facie* case of obviousness could be established from the combination of Carr, Sheehan, and Morrison (which it cannot), that combination is clearly rebutted by the advantageous results achieved with the process of the present invention. Here, as noted above, the prior art process for making the piperidine derivatives of the present invention produces an impure mixture which can only be partially purified to an impurity level of up to 5%. By contrast, as noted *supra*, the process of the present invention does not yield a product with such an impurity level and, as a result, is able to produce the desired piperidine derivative compounds at a purity level suitable for pharmaceutical use.

(*Id.* at 13.) D'Ambra here expressly used the purity of the end product to distinguish the prior art and overcome an obviousness rejection. This is a clear statement that the process of the invention *does not yield* a product with a 5% impurity level; this sets a minimum purity level for the end product of 95%. Moreover, it explicitly associates that purity level with the words "substantially pure." This operates as an unambiguous surrender of claim scope for claim 1: it does not cover processes which result in piperidine derivative compounds with an impurity level greater than or equal to 5%. It also establishes an unambiguous definition for "substantially pure" as "greater than 95% pure." Here the inventor, acting as his own lexicographer, unambiguously defines that phrase.

These statements clearly disavow processes which result in an impurity level greater than or equal to 5%. Because the language of the patent itself limits it to processes producing a "substantially pure piperidine derivative compound" end product, the prosecution history requires that "substantially pure" in this context be narrowed to the definition "having an impurity level less than 5%." Because, as discussed above, the patent does not support different definitions for "substantially pure," as applied to the intermediate, and "substantially pure," as applied to the end product, the prosecution history narrows the scope of "substantially pure" in claim 1 to "having an impurity level less than 5%."

The case of *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951 (Fed.Cir.2000) is instructive on this point. In that case, the prosecution history contained a statement in which the inventor distinguished the prior art by claiming that the invention had a narrower groove. The Court found this statement to be limiting, concluding: "[f]ollowing from this statement is the inventor's clear disavowal of footwear having a groove width greater than that disclosed in the prior art." *Id.* at 956. The Court explained that it could not disregard this statement, since to do so would:

erase from the prosecution history the inventor's disavowal of a particular aspect of a claim term's meaning. Such an argument is inimical to the public notice function provided by the prosecution history. The prosecution history constitutes a public record of the patentee's representations concerning the scope and meaning of the claims, and competitors are entitled to rely on those representations when ascertaining the

degree of lawful conduct, such as designing around the claimed invention. In the present case, the inventor's statements about groove width are part of the prosecution history and form the totality of the public record upon which competitors rely. Were we to accept HHI's position, we would undercut the public's reliance on a statement that was in the public record and upon which reasonable competitors formed their business strategies.

Id. at 957 (citations omitted).

The instant case presents similar facts. In the prosecution history, the inventor distinguished the prior art as a process producing an end product with an impurity level as high as 5%. Flowing from this is a clear disavowal of processes producing an end product impurity level as high as 5%, as well as a manifest restriction of "substantially pure" end product to piperidine derivative compounds that are greater than 95% pure. These are statements in a public record on which Defendants were entitled to rely in forming their business strategies.

Plaintiffs argue that the "up to 5%" statement is ambiguous; it lacks sufficient clarity to operate as a disavowal. Plaintiffs contend that the statement "the process of the present invention does not yield a product with such an impurity level" is open to differing interpretations, as the antecedent to "such an impurity level" is "an impurity level of up to 5%." Plaintiffs propose, for example, that "an impurity level of up to 5%" literally includes all impurity levels between 0% and 5%, and thus could be read as characterizing the prior art as having a purity level of greater than 95%. This is an illogical reading, because it means 1) that the inventor argued to the patent office that his invention produced results inferior to the prior art; and 2) that the inventor distinguished the prior art by arguing that his process achieved the same result. Because the inventor asserted that the invention "achieves substantial benefits over the prior art process," the only reasonable interpretation is that the invention produces end product purer than the 95% pure end product of the prior art. (James Decl. Ex. 67 at 11.)

The amendment from the '703 prosecution history also supports the conclusion that the end product is limited to substantially pure piperidine derivative compounds. As noted above, D'Ambra stated, "The present invention is directed to a process capable of producing substantially pure piperidine derivative compounds of the formula set forth above in claim 1." *Id.* at 9. This could not be more clear as a statement that the inventor intended "substantially pure" to characterize the end product of the invention as a whole.

4. Ascertaining the meaning based on the '610 prosecution history

Both the '703 patent and patent number 5,578,610 (the " '610 patent") derive from the same parent application, serial no. 08/083,102. The '610 patent issued on November 26, 1996. In September of 1997, an interference was declared; the examiner submitted two rejections, one based on 35 U.S.C. s. 102 and one based on 35 U.S.C. s. 103, requiring the applicant, D'Ambra, to demonstrate that claim 1 of the '610 patent was not unpatentable over the prior art. The parties do not dispute that the interference is within the prosecution history of the '610 patent. (Pl. Reply. Br. 93.)

The examiner's first rejection focused on the definition of "purity" in relation to the piperidine derivative compound in claim 1 of the '610 patent, cited prior art references that produced such compounds at higher levels of purity than that produced by the previously considered Carr '129 patent, and stated: "The term 'substantially pure' broadly reads on the prior art compound...." (James Decl. Ex. 49 at ALB006157.)

[10] "[T]he prosecution history of one patent is relevant to an understanding of the scope of a common term in a second patent stemming from the same parent application." *Microsoft*, 357 F.3d at 1349. *See also* *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed.Cir.1999) ("When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation"). In *Microsoft*, a statement in the prosecution history of an earlier issued patent was applied to the interpretation of a related, subsequently issued patent. *Microsoft*, 357 F.3d at 1350.

In the present case, the '703 patent issued on May 12, 1998, and so Defendants seek to apply a statement from the prosecution history of the earlier issued patent to the interpretation of a related, subsequently issued patent.FN5

FN5. Defendants argue that the similarity between the '703 and '610 patents is supported by the fact that they have the same written description. (Hr'g Tr. 75, Oct. 27, 2005.) Plaintiffs termed the specifications "virtually identical." (Pls.' Reply Br. 94.) Defendants also observe that claim 12 of the '610 patent is a product-by-process claim that is highly similar to claim 1 of the '703 patent. Yet, even if the latter point is correct, claim 12 was not at issue in the '610 interference, and so its possible similarity to claim 1 is not useful here.

Defendants point to several statements made in D'Ambra's October 17, 1997 response (the "D'Ambra response") to the interference submitted to the Board of Patent Appeals and Interferences. (James Decl. Ex. 41.) This response distinguishes at length the '610 patent from the prior art in terms of the purity of the fexofenadine end product. In particular, it states that the patent's "entire thrust as well as that of the subject invention is to produce the desired para product at a higher level of purity than the Carr patents could achieve. As demonstrated by the Wille letter, the purity of the para product prepared according to the Carr patents was no greater than 96.3%." (*Id.* at ALB005582.) The response also states:

When read in light of the specification, one skilled in the art would have understood [] the phrase 'substantially pure' ... to mean that the subject compound has pharmaceutical grade purity and is in a form purer than that attained by the prior art [Carr patents] As demonstrated, *infra*, those skilled in the art recognized that the pharmaceutical grade purity requires an impurity level no greater than 2%, and the Carr Patents were unable to achieve such purity.

(*Id.* at ALB005574.)

Defendants argue that the Board of Patent Appeals and Interferences accepted this definition, as reflected in its final opinion, which states as a finding: "27. A person having ordinary skill in the art would interpret the phrase 'substantially pure' in the context of the D'Ambra ['610] patent to mean no more than 2.0% impurities." (James Decl. Ex. 40 at ALB006988.) Thus, Defendants argue, this Court should construe "substantially pure" in the context of the '703 patent accordingly.

Plaintiffs, however, counter that, in the context of the interference, this construction applied to the purity of the fexofenadine end product, not to the purity of the p-CPK intermediate. This appears to be correct. Dr. D'Ambra's response distinguishes the prior art in terms of the purity of the final product, not the intermediate. The January 16, 1998 Opinion of the Board of Patent Appeals and Interferences examines claim 1 of the '610 patent, which refers only to the "substantially pure piperidine derivative compound" that

is the end product of the '703 patent; there is no express reference to CPK intermediates either in '610 claim 1, the D'Ambra response, or the Opinion. In the last paragraph in the Board's discussion of claim construction, the opinion of the Board applies "substantially pure" only to "pharmaceutical products." (James Decl. Ex. 40 at ALB006991.) There is no basis to infer that the Board intended this construction to apply to intermediates.

Defendants argue that D'Ambra's response implicitly applies the 98% definition to the intermediates, as the response applies the discussion to claims 1-17, and claims 12-17 use "substantially pure" in reference to only the intermediate, not the end product. While this supports Defendants' argument, it does not satisfy the "clear and unambiguous" standard. The prosecution history of the '610 patent shows a clear and unambiguous disclaimer of fexofenadine and fexofenadone end products that are less than 98% pure para isomer. These statements were made to overcome the prior art and thus limit the scope of "substantially pure," as applied to the end product of the '610 patent, and thus, the end product of the '703 patent. They do not, however, show a clear and unambiguous disclaimer of p-CPK intermediates that are less than 98% pure.FN6

FN6. The D'Ambra response does support construing "substantially pure regioisomers" to include end products as well as intermediates. In discussing prior art purification of the end product, D'Ambra stated, "separation to isolate any quantity of the substantially pure regioisomers has never been reported in the prior art" (James Decl. Ex. 41 at ALB005597 n. 2.) This is another example of D'Ambra not distinguishing between "substantially pure regioisomers" as applied to end products and as applied to intermediates.

This Court agrees with Plaintiffs that the cited '610 prosecution history was directed to interpretation of only the "substantially pure piperidine derivative compound" end products of the '610 patent. But this does not render the '610 prosecution history irrelevant to claim construction of "substantially pure regioisomer" in claim 1 of the '703 patent. To the contrary, it supports Defendants' proposed construction: because the '703 patent does not distinguish between "substantially pure" as applied to the intermediate and as applied to the end product, a definition of either applies to both.FN7

FN7. Defendants' expert, Dr. Schuster, observes that, in the claims of the '610 patent, the inventor uses "substantially pure" to describe p-CPK, fexofenadone, and fexofenadine, with no indication that the phrase has different meanings in different contexts. (Schuster Decl. para. 28, 36.) This supports the conclusion that "substantially pure" has one uniform meaning in the context of the '703 patent.

Absent a contrary indication, a descriptive phrase has one uniform meaning in a patent. As established above, the '703 patent does not distinguish between "substantially pure" as applied to end products and as applied to p-CPK. There is nothing within the patent that creates more than one uniform meaning for "substantially pure." FN8 The prosecution history of the '610 patent defines "substantially pure" as "at least 98% pure" in regard to the piperidine derivative end product, and this further supports this Court's construction of "substantially pure regioisomers" in claim 1 of the '703 patent as "of greater than 95% purity." To decide this application for a preliminary injunction, this Court need not reach the question of whether the scope of "substantially pure regioisomer" should be further limited to mean "of purity greater than or equal to 98%." Thus, this Court finds that the cited '610 prosecution history provides additional support for its claim construction and, further, that the question of whether it requires a narrower construction need not be reached.FN9

FN8. D'Ambra admitted this at his deposition. (James Decl. Ex. 12 137:3-13.) At oral argument, Plaintiffs characterized Defendants' quote of this admission as "one of their good points." (Hr'g Tr. 63, Oct. 27, 2005.)

FN9. As an additional point, Plaintiffs argue that the Federal Circuit has endorsed a construction of "substantially" as "largely but not wholly" in other cases such as *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1369 (Fed.Cir.2001). *See also* Hr'g Tr. 53, Oct. 27, 2005. This is misleading both as a characterization of Ecolab and as a statement of patent law. The construction of claim language in one patent is unlikely to be helpful in the construction of claim language in an unrelated patent in a different case. *See, e.g.*, *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1318 (Fed.Cir.2005) ("A particular term used in one patent need not have the same meaning when used in an entirely separate patent, particularly one involving different technology. In fact, there are many situations in which the interpretations will necessarily diverge"). As to Ecolab, the opinion states: "we presume that 'substantially uniform' ... means what it says, 'largely, but not wholly the same in form.'" *Ecolab*, 264 F.3d at 1369. The court did not hold that this determined the completed construction of "substantially uniform," but, instead, remanded the matter to the district court for further determination based on the Federal Circuit's instructions. *Id.* at 1372.

5. Claim construction based on "what the inventor invented"

Defendants argue that Plaintiffs' proposed claim construction attempts to expand the scope of the claim beyond what the inventor actually invented. Defendants rely on the following quote from Phillips: "Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim." Phillips, 415 F.3d at 1316 (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed.Cir.1998)). Defendants argue that the specification, supported by extrinsic evidence, shows that the inventor did not invent a process for producing fexofenadine that used late stage purification, i.e., a process with a purification step occurring after the AZA reaction. This, Defendants contend, operates to limit the construction of "substantially pure regioisomers" to purity levels which will produce an end product of pharmaceutical purity without late stage purification.

This argument asks this Court to depart from Federal Circuit guidance on the role of the specification and extrinsic evidence in claim construction. It does not appear that, in Phillips, the Federal Circuit intended to create a new, additional branch of claim construction analysis based on construing "what the inventors actually invented." Rather, the quote is offered as support for the general principle that claims are construed in the context of the specification. *Id.* In the two sentences following Defendants' quote from Phillips, the Federal Circuit identifies two ways in which the specification may be used in claim construction: it may "reveal a special definition given to a claim term by the patentee," and it may "may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id.* Defendants here appear to contend that the specification reveals an intentional disclaimer of claim scope. Yet, as discussed *supra*, for such an argument to succeed, the Federal Circuit requires that the disclaimer be explicit in the specification. *See Gillette*, 405 F.3d at 1374 ("words or expressions of manifest exclusion or explicit disclaimers in the specification are necessary to disavow claim scope") (citations omitted).

Defendants here attempt again to use the '703 patent's "Background of the Invention" statements about the prior art described *supra*, (e.g., "these components are inseparable"), to limit claim scope; but these

statements are not explicit disclaimers, and their meaning is not clear. It is difficult to understand how to reconcile "a practical separation ... has not been achieved" (suggesting separation is possible but impractical) with "these components are inseparable" one sentence later (suggesting separation is impossible). '703 Patent col. 4 ll. 18-22. Nor does the extrinsic evidence presented clarify what these statements mean. For example, the D'Ambra response describes separation in the prior art to a level of 96.3%, and points to the recrystallization step in example 5 of the Carr patent. (James Decl. Ex. 41 at ALB005581-2.) FN10 The '703 amendment submission also points to the use of late-stage crystallization for purification of the end product. (James Decl. Ex. 67 at 11.) These pieces of extrinsic evidence contradict the statement that separation is impossible. It may be that D'Ambra meant "inseparable" to mean "not 100% separable," but the meaning is ambiguous. Moreover, Defendants agreed that these statements in the specification were directed to describing the prior art, not the present invention. (Hr'g Tr. 157, Oct. 28, 2005.) Thus, in any case, they are not statements about what the inventor actually invented. In sum, Defendants' argument based on "what the inventor invented" does not convincingly point to any clear disclaimer of claim scope.

FN10. At oral argument, the parties frequently referred to crystallization as a late-stage purification process. *See, e.g.*, Hr'g Tr. 440-41, Nov. 3, 2005.

6. Conclusion as to tentative claim construction

For the purposes of determining likelihood of success in showing infringement, it is sufficient for this Court to construe tentatively "substantially pure regioisomer," as used in claim 1 of the '703 patent, to mean "of greater than 95% purity." This construction is derived from the '703 patent's claims, specification, and prosecution history, with confirming support from the '610 prosecution history.

The parties also disputed how purity should be understood. Plaintiffs argued that it means regioisomeric purity, that is, purity relative only to meta regioisomers. Defendants argued that it means chemical purity, that is, purity relative to all other impurities. The parties do not dispute that Plaintiffs' construction of purity results in Ranbaxy's p-CPK measuring higher levels of purity, while Defendants' construction results in lower numbers. Because, as will be discussed *infra*, the highest number for Ranbaxy's p-CPK that Plaintiffs allege, and have evidence to support, does not reach the level needed to literally infringe, the Court need not reach the question of which concept of purity "substantially pure regioisomer" entails.

B. Infringement of the process patent

[11] Having construed the disputed language of claim 1, in the second step of the infringement analysis, the properly construed claim 7 is compared "with the accused device to determine whether all of the claim limitations are present either literally or by a substantial equivalent." *Amazon*, 239 F.3d at 1351.

While the parties dispute the level of purity of Ranbaxy's p-CPK, the highest value that Plaintiffs have alleged is 92%, which would not literally infringe under this Court's construction. Plaintiffs argued different numbers at different points. Initially, at oral argument, Plaintiffs selected 90% as their statement of the purity of Ranbaxy's p-CPK. (Hr'g Tr. 140, Oct. 28, 2005.) At a different point, Plaintiffs asserted that a note on a Ranbaxy document stated a purity level of 92%. (Hr'g Tr. 479, Nov. 3, 2005.) Defendants responded that this was an erroneous calculation, and that the Ranbaxy scientist who made the error testified that it was a mistake. (Hr'g Tr. 489, Nov. 3, 2005.) Even if the 92% figure is accurate, that is not pure enough to literally infringe a claim limitation construed to require greater than 95% purity.

Plaintiffs argued that Ranbaxy's production of p-CPK has a variance of plus or minus 4%, which turns the 92% into 96%, putting Ranbaxy over the 95% line. This argument relies on a distortion of the deposition testimony of Ranbaxy's 30(b)(6) witness, Dr. Khanduri, and actually conflicts with that testimony. On the subject of the regioisomeric purity of the p-CPK Ranbaxy produced, Dr. Khanduri was asked, "So in certain cases, there could be as little as eight percent or as much as 22 percent; would that be correct?" (Pls.' Supp. Letter Ex. D 409:12-15.) Dr. Khanduri answered, "Yeah, you can consider that." (*Id.* at 409:16.) Thus, even setting aside the fact that this interchange concerned rough approximation rather than clear limits, the highest level of regioisomeric purity that Dr. Khanduri agreed to was 92%. The deposition testimony provides no basis for an inference that the purity level has ever reached 96%.

In their Reply Brief, Plaintiffs devoted two paragraphs to arguing infringement under the doctrine of equivalents. (Pls.' Reply Br. 111-12.) At oral argument, given an opportunity to expand on this, Plaintiffs declined to do so and rested on the briefs.FN11 (Hr'g Tr. 125, Oct 27, 2005.) The argument presented is insufficient to show a likelihood of success in proving infringement under the doctrine of equivalents.

FN11. In the Supplementary Letter Brief of November 18, 2005, submitted at the Court's request, Plaintiffs expanded on their argument for infringement under the doctrine of equivalents. This was outside the scope of the Court's request, and the Court has disregarded the additional argument.

Because, under the tentative claim construction described, Defendants have raised a substantial question as to infringement, and Plaintiffs have not shown that this question lacks substantial merit, Plaintiffs have not shown a likelihood of success in proving that Barr and Ranbaxy have infringed the process patent.

II. Plaintiffs have not demonstrated a likelihood of success in establishing that Teva has infringed the process patent.

To show likelihood of success in establishing that Amino and, under 35 U.S.C. s. 271(g), Teva, have infringed the process patent, Plaintiffs seek to invoke the burden-shifting effect of 35 U.S.C. s. 295:

In actions alleging infringement of a process patent based on the importation, sale, offer for sale, or use of a product which is made from a process patented in the United States, if the court finds-

- (1) that a substantial likelihood exists that the product was made by the patented process, and
- (2) that the plaintiff has made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine, the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.

Plaintiffs present an array of arguments directed toward proving that Amino did not manufacture its fexofenadine by the process claimed in its Drug Master File ("DMF"). Plaintiffs also contend that their experts have detected the chemical CPKEE in Amino's fexofenadine samples, and that this is both inconsistent with the DMF process Amino has asserted and consistent with the '703 process. Together, Plaintiffs argue, these establish a substantial likelihood that Amino's product was made by the patented process, meeting the requirement of s. 295(1).

Defendants contend that Plaintiffs' experts' conclusions and analyses regarding the presence of CPKEE are faulty, presenting expert rebuttal to Plaintiffs' experts' analyses. (Matthews Decl. 18.) Defendants offered their own analyses of Amino's fexofenadine, which did not detect CPKEE. (Allegrini Decl. para. 7.)

The conflicting evidence on whether CPKEE is present in the Amino fexofenadine samples creates a factual dispute which is not material at the preliminary injunction stage and need not be resolved. Even if it is true that traces of CPKEE are present in Amino's product, Plaintiffs have not satisfied the requirements of the first prong of s. 295. Moreover, even adjusting the s. 295(1) substantial likelihood standard in accordance with the preliminary injunction reasonable likelihood standard, Plaintiffs still have not shown a likelihood of being able to establish a substantial likelihood at trial.

The parties agree that only one published case addresses the test for "substantial likelihood" under s. 295(1), and both turn to the legislative history of the provision for help in understanding what the statute requires. At oral argument, Plaintiffs quoted the legislative history of the Process Patents Amendments Act of 1987, as contained in Report 100-60 of the House Committee on the Judiciary and Report 100-83 of the Senate Committee on the Judiciary.

Plaintiffs offered this quote from the Senate Report: "To establish a substantial likelihood, for example, a patentee might show that ... physical evidence, such as the exact chemical composition of the product, indicates the use of the patented process." S. REP. No. 100-83, at 45 (1987). Plaintiffs edited this quotation so as to leave out unfavorable language. Where Plaintiffs left marks of ellipsis, the report reads: "a patentee might show that the patented process was the only known method, or the only commercially practical method, for producing the product, or that physical evidence ..." S. REP. No. 100-83, at 45. Viewing the Senate Committee's examples in their entirety, it appears that the Committee contemplated a much more persuasive showing of substantial likelihood than Plaintiffs have offered.

Plaintiffs offered this quote from the House Report: "Adequate circumstantial evidence for example, could include telltale signs of the use of the patented process which could be found in the product itself. When chemical processes are used, unique trace impurities or a characteristic pattern of impurities may be present which fingerprint the process of manufacture." H.R. REP. No. 100-60, at 17 (1987). This quote is incomplete as well. The section continues: "Circumstantial evidence also could include a showing that the patented and process [sic] represent a substantial improvement in effeiciency [sic] over prior processes and that no alternative, economically feasible process exists. This could be demonstrated by showing that the sales price of the product would have to be considerably higher if the product was made by any known process other than the patented one." H.R. REP. No. 100-60, at 17.

The House Report also cautions the Court as to the standard for establishing a substantial likelihood: "This rebuttable presumption, however, cannot be casually established.... [T]he plaintiff is expected to set forth facts ... which form the basis for a reasonable belief that the product was made using the patented process." *Id.* at 16-17.

Even if every allegation made about Amino's manufacturing process were accepted as true, Plaintiffs have not set forth facts sufficient to establish a substantial likelihood that Amino's fexofenadine was made using the patented process, given the insight into that standard provided by the full legislative history.

Plaintiffs' argument rests on the evidence provided by the declarations of two experts, Drs. Atwood and Baldwin, in support of their claim that "[t]he only reasonable conclusion is that Amino is using the '703

process instead of its reported DMF process." (Hr'g Pls.' Slide 8, Nov. 3, 2005.) This greatly overstates the opinions of the experts.

In his declaration, Dr. Baldwin stated:

24. The presence of CPKEE in Amino's fexofenadine samples is consistent with the use of the process of the '703 patent. In my opinion, it is possible that Amino has utilized the D'Ambra process in synthesizing the fexofenadine samples provided to [Plaintiffs] in this lawsuit and therefore that Amino has infringed the process claimed in the '703 patent. Indeed, in light of the evidence I have reviewed above this is the most reasonable conclusion I can draw.

(Baldwin Decl. para. 24.) Dr. Baldwin did not go farther than to say that the presence of CPKEE is consistent with use of the '703 process. He did not state that the *only* reasonable conclusion that one could draw is that Amino used the '703 process; he stated that, given the evidence he was shown, the most reasonable conclusion is that it is *possible* that Amino used the '703 process. This is a far cry from what Plaintiffs have claimed.

[12] Plaintiffs have overstated Dr. Atwood's opinion as well. In his declaration, Dr. Atwood stated:

20. Based on my review of fexofenadine synthetic process set forth in Amino's DMF and other documents, it is my opinion that the presence of CPKEE is inconsistent with the use of this process to synthesize fexofenadine. Therefore, in my opinion, it is likely that Amino has utilized the process of the '703 patent in synthesizing the fexofenadine samples provided to [Plaintiffs] in this lawsuit and therefore that Amino has infringed the '703 patent.

21. Based on my analysis of the defendants' products, it is my conclusion that fexofenadine hydrochloride manufactured by Amino Chemicals contain detectable amounts of CPKEE. I also am of the opinion that the presence of CPKEE is inconsistent with the use of Amino's stated process and therefore, conclude that it is likely that Amino has infringed the '703 patent.

(Atwood Decl. para. 20-21.) Dr. Atwood's statements do not support Plaintiffs' claim that the only reasonable conclusion is that Amino used the '703 process. Nor do they adequately support his own conclusion about infringement. While an expert may offer an opinion on infringement, the Court need not credit unsupported conclusions. *See Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed.Cir.1997) ("Nothing in the rules or in our jurisprudence requires the fact finder to credit the unsupported assertions of an expert witness").

Dr. Atwood's conclusion of infringement makes unwarranted leaps of inference. Based on his opinion that the presence of CPKEE in Amino's samples is inconsistent with the claimed DMF process, he concludes that it is likely that Amino has used the '703 process. Dr. Atwood has not provided a proper foundation for this conclusion: he did not explain the logical connection between his opinion that the sample was not made by the DMF process and the conclusion that this makes it likely that the '703 process was used. Because of this, this Court does not credit Dr. Atwood's conclusion that Amino has utilized the '703 process. This Court finds that the Atwood declaration may support only two inferences: 1) the presence of CPKEE in Amino's samples is inconsistent with use of the DMF process; and 2) the presence of CPKEE is consistent with use of the '703 process.

Thus, the Atwood and Baldwin declarations together at most support the two inferences just stated: 1) the presence of CPKEE in Amino's samples is inconsistent with use of the DMF process; and 2) the presence of CPKEE is consistent with use of the '703 process. At oral argument, Plaintiffs contended that, considering these two inferences together, "[t]he only reasonable conclusion is they're using the patented process." (Hr'g Tr. 503, Nov. 3, 2005.) In addition, they argued that these two points are sufficient to meet the "substantial likelihood" standard. (*Id.*)

Plaintiffs fail to persuade that this conclusion is reasonable, no less that it is the only reasonable conclusion. It is undisputed that non-infringing manufacturing processes may also result in the presence of CPKEE. (Pl. Reply Br. 50.) Thus, CPKEE does not uniquely identify the '703 manufacturing process. Plaintiffs have not presented evidence showing that it is likely that CPKEE indicates use of the '703 process; the most they have shown is that there is evidence *consistent* with use of the '703 process. This Court determines that this is insufficient to establish a reasonable inference of a substantial likelihood of infringement, or of a likelihood of establishing that substantial likelihood at trial.

Plaintiffs have not offered evidence sufficient to show a substantial likelihood, as interpreted by either Congressional committee. The CPKEE evidence, even if true, does not satisfy the House's "fingerprint" test, and even falls short significantly of the Senate's less demanding "exact chemical composition of the product" test. A fingerprint is a unique identifier of a person: one fingerprint identifies one person. The CPKEE marker is not a unique identifier of the '703 process. Plaintiffs admitted that CPKEE is a marker of the Carr process as well. Thus, the presence of CPKEE in the Amino sample does not uniquely identify the '703 process, in the way that a fingerprint uniquely identifies a person.

The Senate Committee appears to have contemplated a less demanding test in which the exact chemical composition of the product only "indicates," as opposed to uniquely identifies, the process of manufacture. Plaintiffs have not satisfied even this test, as the CPKEE it points to is only a marker, one component element among others. It is not the "exact chemical composition of the product," nor have Plaintiffs claimed that it is. Evidence of the exact chemical composition here would include chemical analysis of all the components in Amino's product, and would come closer to the requirement in the House Report of a "characteristic pattern of impurities."

Based on the reports from both the Senate and House committees considering the legislation enacting s. 295, Congress intended that a plaintiff present more persuasive evidence of likelihood of use of the infringing process than Plaintiffs have offered.

The declaration of Defendants' chemistry expert, Dr. Matthews, supports this legal conclusion. Dr. Matthews explained that there is a standard analytical chemistry technique which generates a "total impurity profile." (Matthews Decl. at 17.) According to Dr. Matthews, a total impurity profile can serve as a "fingerprint" for a sample. (*Id.*) Dr. Matthews stated that this analysis was not presented in the declarations of Plaintiffs' experts, Drs. Atwood and Gross. (*Id.*) Thus, a standard analysis could have obtained a chemical fingerprint from the Amino samples, and been capable of providing evidence sufficient to meet the "fingerprint" and "exact chemical composition" standards discussed in the legislative history.

Moreover, Dr. Matthews stated that, from a chemist's perspective, as a general rule, "presence of a single impurity does not provide the specificity required to suggest that a sample was synthesized using a certain process." (*Id.* at 18.) In addition, Dr. Matthews observed that the presence of CPKEE is consistent with use of the Carr process. (*Id.*) Dr. Matthews' expert opinion that the Plaintiffs' experts' tests are insufficient, as a

matter of science, to support their claim that Amino has used the '703 process, supports this Court's legal conclusion.

Furthermore, the legislative history indicates that Congress likely did not intend for a plaintiff under these facts to qualify for the benefits of s. 295. The House Report states the intent to limit s. 295 to "those cases, where the manufacturer is not subject to discovery under the Federal Rules of Civil Procedure." H.R. REP. No. 100-60, at 16. Plaintiffs do not claim that Amino has not been subject to discovery under the Federal Rules. The House Report states as well that "the plaintiff will not have had the benefits of the discovery process." (*Id.*) Given its extensive arguments based on materials obtained in discovery, Plaintiffs cannot claim that they have not had benefits of the discovery process.

Plaintiffs argue that an analogous case is *Pfizer Inc. v. F & S Alloys & Minerals Corp.*, 856 F.Supp. 808 (S.D.N.Y.1994). Specifically, Plaintiffs claim that the court there based a finding of s. 295(1) substantial likelihood on similar evidence to that adduced here. The comparison, however, does not help Plaintiffs because the Pfizer court had the benefit of evidence that is absent here: a Pfizer employee had visited the foreign factory and had handwritten notes of a conversation with the factory's chief engineer, in which the engineer admitted facts which indicated use of an infringing process. *Id.* at 814. The court relied on this evidence in finding a substantial likelihood. *Id.* at 815. Plaintiffs have not presented any evidence here that Amino employees have admitted facts indicating use of an infringing process.

In presenting its case for Amino's infringement, Plaintiffs made a number of other allegations. In brief, Plaintiffs contend:

- a. Amino misrepresented to Teva the source of its April 2001 reference sample MD-400, which was made neither by Amino nor by its DMF process.
- b. The Amino DMF process uses a process described in both a European patent application and an internal Dipharma document as having disadvantages "which prevent its industrial application." (Pl. Br. Supp. 49)
- c. Amino has misrepresented the source of a number of samples to the FDA and to customers.
- d. The Amino Laboratory Notebook shows that the one lab test of Amino's DMF process was a failure.
- e. Amino's batch records indicate that Amino's industrial-scale manufacturing went perfectly from the start, which is not credible and shows that the batch records are fabrications.
- f. Inconsistencies in Amino's batch records indicate that the records are false.
- g. Amino's claimed process would produce hazardous contamination. Amino's indifference to this shows it is not using the DMF process.
- h. Dipharma's continued investigations on the manufacturing process show that the DMF process was not commercially viable and support that Amino is not using that process.

The parties hotly dispute these allegations, but the Court need not address these factual disputes. Even if all of these allegations are true, they show at most that Amino did not use its claimed DMF process to manufacture fexofenadine. They are not otherwise probative of the issue of whether the process Amino uses

infringes the '703 patent. Had Plaintiffs offered evidence that only two processes for producing fexofenadine existed, evidence ruling out one might be significantly probative of use of the other process. In the absence of evidence about how many possible fexofenadine production processes exist, Plaintiffs cannot establish a substantial likelihood that the '703 process was used by showing that one other process was not used.

Because Plaintiffs have failed to satisfy the substantial likelihood prong of 35 U.S.C. s. 295, this Court need not reach the issues related to the second prong, which looks to the "reasonable effort to determine the process actually used."

III. Defendants have not raised a substantial question as to the validity of the process patent.

Defendants make two arguments to challenge the validity of the '703 patent, both predicated on the Court not agreeing with their proposed claim construction of "substantially pure regioisomer:" 1) any other construction of "substantially pure" renders the patent invalid for indefiniteness; and 2) any other construction of "substantially pure" renders the patent anticipated by Carr. Neither argument presents a substantial question as to the validity of the '703 patent.

[13] As to the first argument, Defendants contend that any construction of "substantially pure regioisomer" other than "98% or greater purity" makes the patent indefinite. Defendants argue that patents must be sufficiently definite that a person of ordinary skill may determine whether or not a particular practice infringes: "[a] claim is indefinite if, when read in light of the specification, it does not reasonably apprise those skilled in the art of the scope of the invention." *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1342 (Fed.Cir.2003). Yet Amgen sets a fairly high bar for invalidating a claim for indefiniteness: "[t]he standard of indefiniteness is somewhat high; a claim is not indefinite merely because its scope is not ascertainable from the face of the claims. Rather, a claim is indefinite under s. 112 P 2 if it is insolubly ambiguous, and no narrowing construction can properly be adopted." *Id.* (citation omitted). Defendants have not argued, no less shown, that the insolubly ambiguous standard is met.

Moreover, the Federal Circuit has not had great difficulty construing "substantially." *See, e.g., Ecolab*, 264 F.3d at 1367 ("[T]he term 'substantially' is a descriptive term commonly used in patent claims to avoid a strict numerical boundary to the specified parameter.") Defendants have not raised a substantial question of invalidity due to indefiniteness.

[14] In the alternative, Defendants argue that, if the Court does not accept their claim construction, then the Carr patent inherently anticipates. At trial, Defendants have "the burden of showing invalidity by clear and convincing evidence. This burden is especially difficult when, as is the present case, the infringer attempts to rely on prior art that was before the patent examiner during prosecution." *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1348 (Fed.Cir.2004) (citations omitted).

The parties do not dispute that the Carr patent does not expressly mention the use of CPK, nor that the Carr patent teaches that CBP is reacted with AZA to produce fexofenadone. Defendants argue that 1) the CBP-AZA reaction inherently produces some CPK as a by-product; and 2) the '703 patent teaches that CPK in the presence of AZA will react to form fexofenadone, and then fexofenadine, thus including every element of claim 7 of the '703 patent. Defendants point to the declaration of their expert asserting that CPK is inevitably formed during the Carr process. (Schuster Decl. para. 48-50.) Plaintiffs counter that Defendants have not established that such CPK is a "substantially pure regioisomer." Moreover, under the tentative claim construction established herein, such CPK must be more than 95% pure to anticipate.

Defendants have presented no evidence that such CPK would be of any particular level of purity. Without such evidence, they have failed to present evidence that every element of claim 7 is disclosed or inherent in the Carr patent. Defendants have not raised a substantial question as to the validity of the '703 patent.

IV. Plaintiffs have shown a likelihood of success in proving infringement of the method patents by inducement.

Plaintiff asserts three treatment method patents in seeking a preliminary injunction: the '353 patent, the '791 patent, and the '632 patent. Each of the three is directed to a method of using fexofenadine to treat hepatically impaired patients, resulting in reduced cardiac side effects. FN12 During this preliminary injunction phase, the parties uniformly have treated these patents as indistinguishable for purposes of argument on infringement and validity. This Court will follow suit and address all three together.

FN12. More specifically, the patents are directed to using fexofenadine to treat: 1) patients with impaired liver function (caused by interaction with the drug ketoconazole, among other causes) while avoiding cardiac events associated with terfenadine ('353); 2) patients susceptible to the cardiac side effects of QT prolongation and/or ventricular tachycardia when using terfenadine ('791); and 3) patients who do not metabolize terfenadine at the normal rate while avoiding cardiac arrhythmias associated with terfenadine ('632).

Because Barr and Teva are not themselves physicians treating patients, Plaintiffs do not allege that they directly infringe the method patents. Rather, Plaintiffs assert that they induce infringement of the method patents by selling generic fexofenadine with a product label which has information about the cardiac effects of fexofenadine and such effects in hepatically impaired patients. Under 35 U.S.C. s. 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer."

[15] The Federal Circuit has stated the legal standard for inducement of patent infringement under 35 U.S.C. s. 271(b) as follows: "[i]n order to succeed on a claim of inducement, the patentee must show, first that there has been direct infringement, and second, that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *Cross Med.*, 424 F.3d at 1312 (citations omitted). Where, as in the instant case, there is no dispute that the alleged inducer had knowledge of the patents at issue, it is sufficient to show intent to induce the specific acts constituting infringement. *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1378 (Fed.Cir.2005). A frequently-cited case, *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed.Cir.1990), states that to succeed on this theory, a plaintiff must prove that the defendants' actions "induced infringing acts *and* that [they] knew or should have known [their] actions would induce actual infringements." Intent may be inferred from the totality of the circumstances. *Insituform Techs., Inc. v. CAT Contr., Inc.*, 385 F.3d 1360, 1377 (Fed.Cir.2004).

Although *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, --- U.S. ----, 125 S.Ct. 2764, 162 L.Ed.2d 781 (2005), was not a patent case, the Supreme Court noted the similarities between inducement of infringement in copyright and patent law, and the Federal Circuit has cited it approvingly for its guidance on inducing infringement: "[e]vidence of active steps taken to encourage direct infringement, such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe." *MEMC*, 420 F.3d at 1379 (quoting *Grokster*, 125 S.Ct. at 2779 (citations omitted)).

[16] The parties do not dispute that Defendants' sales of generic fexofenadine will result in treatment of allergies of hepatically impaired patients. Plaintiffs will likely succeed in showing that direct infringement has occurred, and that Barr and Teva sold the generic fexofenadine that was prescribed. At issue is whether Defendants have actively induced infringement, and whether the requisite intent to induce may be inferred.

Plaintiffs argue that Barr and Teva actively induce infringement with their product labels, which "spell out explicitly that their products may safely be administered to the specific patient populations" identified in the patents. (Pls.' Br. 14.) Plaintiffs point to these sections of the label:

1. "Special populations" cites research on pharmacokinetics with subjects with hepatic impairment. (Katcoff Decl. Ex. 19 at BAR FH 019952.)
2. "Hepatic impairment: The pharmacokinetics of fexofenadine hydrochloride in patients with hepatic disease did not differ substantially from that observed in healthy patients." (*Id.* at BAR FH 019953.)
3. Under "Drug interactions with Erythromycin and Ketoconazole:" "No differences in adverse events or QTc interval were observed when patients were administered fexofenadine alone or in combination with erythromycin or ketoconazole." (*Id.* at BAR FH 019955.)
4. Under "Pharmacodynamics:" "Effects on QTc ... no statistically significant increase in mean QTc interval." (*Id.* at BAR FH 019953.)

Plaintiffs point to a November 15, 2002 letter in which Barr asked the FDA if it could take items 2 through 4 above off the label. (Katcoff Decl. Ex. 21 at BAR FH 015015.) In this letter, Barr sought to omit "aspects of [the label] concerning the subject matter of the '632, '353 and '791 patents." (*Id.*) In support of this request, Barr argued to the FDA, "allowing Barr to omit these aspects of the labeling will ensure that the vast majority of patients who take this product will not be deprived access to a lower cost generic medicine simply because the innovator has patented the use of the product by patients with impaired hepatic functions." (*Id.* at BAR FH 015016.) The FDA refused, stating that "the deleted sections include important safety information to help the practitioner choose the most appropriate product among available drugs.... Without this information, a practitioner might choose an alternative drug with a less desirable safety profile..." (Katcoff Decl. Ex. 22 at BAR FH 019846.)

Despite the FDA's denial of Barr's requested changes to the label, Barr eventually proceeded to sell generic fexofenadine with the unchanged label. The correspondence with the FDA, together with the subsequent sale and the other undisputed facts already described, is sufficient to show a likelihood of success in proving at trial that Barr has induced infringement of the method patents. At the preliminary injunction stage, the correspondence is sufficient to show a likelihood that Barr knew that the label would induce infringement. At oral argument, Barr contended that the proper inference from the letter is only that Barr was concerned that Plaintiffs would take the unjustifiable action they are now taking to enjoin the sale on the basis of patent infringement. (Hr'g Tr. 389, Nov. 3, 2005.)

Even adopting Barr's questionable reading of the letter, the FDA's response can reasonably be read as telling Barr that, in the FDA's view, the label would play an important role in inducing acts that, as Barr's letter shows, Barr knew would be infringing. The FDA response states the FDA's expectation that physicians will use the cited safety information on the label-information on cardiac side effects in hepatically impaired

patients-in choosing what medication to prescribe. It is only a small step to infer that once physicians have used the cited safety information on the label to choose to treat hepatically impaired patients with generic fexofenadine, they will do so, thus infringing the method patents. Despite knowing the FDA's expectation, Barr proceeded to sell generic fexofenadine. As Plaintiffs pointed out, and Defendants did not dispute, Barr did not follow any of the routes available FN13 to challenge the FDA's decision, but chose instead to sell fexofenadine with the present label. (*Id.* at 419.) This is sufficient circumstantial evidence to show a likelihood of success for Plaintiffs in proving Barr's specific intent to induce the acts which constitute infringement. For Barr to succeed at trial, it would likely need to show that the FDA was wrong. At this stage, it has not shown a likelihood of success in this regard.

FN13. *See, e.g.*, 21 C.F.R. s. 314.103 (outlining procedures for applicants to resolve disputes with the FDA).

At oral argument, Defendants admitted that every inference that may be made about Barr from the FDA correspondence may be made about Teva as well, as Teva would have written the same letter to the FDA had they not viewed it as a futile formality. (Hr'g Tr. 365-66, Nov. 2, 2005.) This Court concludes that Plaintiffs have demonstrated a likelihood of success in proving at trial that Barr and Teva induced infringement of the method patents.

Defendants dispute both that the labels induce infringement, and that they have the necessary intent to induce infringement. Defendants argue that the labels do not induce infringement because they do not instruct, direct, or encourage infringement. *See, e.g.*, Hr'g Tr. 380-81, Nov. 3, 2005. Even if Defendants successfully persuaded the finder of fact that the labels did not instruct, direct, or encourage infringement-which they have not yet done-this would not be legally sufficient to establish that the labels do not induce infringement.

The Federal Circuit has held that a broad range of actions may induce infringement: instructing, directing and encouraging are elements of a larger set. *See* 5-17 DONALD S. CHISUM, CHISUM ON PATENTS (2005) s. 17.04 ("The Section 271(b) prohibition on active inducement of infringement covers a wide variety of acts"). In *Grokster*, the Supreme Court took a broad view of what acts may induce infringement. *Grokster*, 125 S.Ct. at 2770. The Court used broad language in stating that the "inducement rule" requires "affirmative steps taken to foster infringement." *Id.* Thus, Defendants' argument that the label does not instruct, direct or encourage infringement, even if accepted as true, does not suffice when the law creates liability for the broad range of affirmative steps that may be taken to foster infringement. The letter from the FDA shows that the FDA expected that the label information would play an important role in physicians' choice to practice a treatment method that Barr knew would be infringing. That Defendants proceeded to sell the drug regardless demonstrates the required affirmative steps.

Defendants point to the Supreme Court's statement in *Grokster* that "[t]he inducement rule ... premises liability on purposeful, culpable expression and conduct." *Id.* at 2780. The evidence that, after the FDA told Barr that physicians would use the label information to select their product for a use that Barr knew to be infringing, Barr chose to sell the product with this label, is sufficient to establish a likelihood of success for Plaintiffs in proving purposeful and culpable conduct.

Defendants attempt to refute this by interpreting "intent" as subjective rather than objective. In effect, they ask this Court to apply a subjective test in which "intent" means "desire." Defendants argue that, since they

never desired that anyone infringe the patents, they cannot have the necessary intent to induce infringement. But Defendants have provided no legal justification for applying a subjective standard. Plaintiffs point to 21 C.F.R. s. 201.128, which, in conjunction with 21 C.F.R. s. 201.5, requires adequate labeling for all intended uses of a drug, and expressly states:

The words 'intended uses' ... refer to the objective intent of the persons legally responsible for the labeling of drugs.... This objective intent may, for example, be shown by labeling claims [I]f a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.

21 C.F.R. s. 201.128. Although this regulation does not, of course, set intent standards for patent law, because the intent requirement has been established by judicial interpretation of 35 U.S.C. s. 271(b), the regulation supports the application of an objective standard in cases involving drug labeling. The formulation of the inducement rule in *Grokster* indicates an objective standard as well: the Supreme Court held that the inducement rule relies on an objective assessment of both "affirmative steps taken" and "purposeful, culpable expression and conduct." The Court determines what is affirmative or purposeful from an objective viewpoint, not by undertaking an analysis of whether the accused inducer subjectively experienced a purpose or an intent that the steps affirm. Put more simply, if one could escape liability for inducing infringement just by saying, "I never wanted anyone to infringe," this would eviscerate the statutory protection.

V. Defendants have raised a substantial question of invalidity of the method patents, and Plaintiffs have not shown this has no merit.

A. Defendants have raised the substantial question of whether the method patents are invalid as inherently anticipated by the Carr patent.

"Anticipation is a question of fact, including whether or not an element is inherent in the prior art." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1346 (Fed.Cir.1999). "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *Id.* "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." *Id.* at 1347.

"A reference includes an inherent characteristic if that characteristic is the 'natural result' flowing from the reference's explicitly explicated limitations." *Eli Lilly & Co. v. Barr Labs.*, 251 F.3d 955, 970 (Fed.Cir.2001). The Federal Circuit also recognizes a "necessarily present" test: "a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed.Cir.2005) (citing *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed.Cir.1991)). "[I]nherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure." *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed.Cir.2003).

[17] At trial, Defendants would have "the burden of showing invalidity by clear and convincing evidence. This burden is especially difficult when, as is the present case, the infringer attempts to rely on prior art that was before the patent examiner during prosecution." *Glaxo*, 376 F.3d at 1348 (citations omitted). Moreover,

the prosecution history of the '353 patent shows that on October 6, 1995, the patent examiner rejected claims 8-11, but not claims 1-7, as inherently anticipated by Carr. (James Decl. Ex. 7.) This suggests that the examiner considered whether the claims at issue were inherently anticipated by Carr, and decided against it. This places a heavy burden at trial on Defendants to show that the examiner was wrong. At the preliminary injunction stage, however, they need only raise a substantial question as to validity.

As discussed briefly *supra*, the three method patents are variants on a theme. For example, claim 1 of U.S. Patent No. 6,037,353 recites this treatment method:

A method of treating a histamine-mediated condition in a patient having impaired liver function due to disease or due to administration of a concomitant drug which inhibits normal liver metabolic function while avoiding cardiac events associated with the administration of terfenadine, said method comprising administering to said patient an effective antihistaminic amount of a compound of the formula [fexofenadine].

'353 Patent, col. 5 ll. 25-37. Reduced to its essence, this claims a method of administering an effective antihistaminic amount of fexofenadine to a particular kind of patient (that is, patients having impaired liver function) while avoiding certain cardiac events. The parties did not argue that the other method patents differ materially for purposes of the present analysis.

Defendants point to the Carr patent, U.S. Patent No. 4,254,129 (filed Apr. 10, 1979) (the " '129 patent"), which discloses a method of treating patients with fexofenadine as an antihistamine; this patent expired four years ago. Claim 11 of the Carr patent states: "A method of treating allergic reactions in a patient in need thereof which comprises administering to said patient an effective amount of a compound of claim 1." '129 Patent, col. 18 ll. 65-67.

Defendants argue that the treatment methods in the method patents are inherent in the Carr patent, and that the inventions in the patents at issue entail only a recognition of properties already inherent in the Carr method. If true, Carr inherently anticipates the method patents and renders them invalid.

The inherent anticipation analysis begins by identifying the characteristic of the invention that is not explicit in, and thus is missing from, the prior art reference. The parties identify the characteristic differently at this starting point, affecting the rest of their analyses. Defendants argue that this is the characteristic of fexofenadine of having minimal cardiac side effects in hepatically impaired patients; more broadly, the characteristic is the cardiac safety of fexofenadine. The next question is whether this characteristic is a natural result flowing from the reference's explicit limitations. Defendants argue that, whether the characteristic is cardiac safety or having minimal cardiac side effects in hepatically impaired patients, this characteristic is a natural result flowing from the Carr method of treatment with fexofenadine. Defendants contend that practice of the Carr method has always resulted in the characteristic of minimal side effects in hepatically impaired patients. Thus, the characteristic is inherent in the prior art.

[18] Plaintiffs argue in rebuttal that the characteristic missing from the prior art reference should be defined as being a member of a subpopulation. Plaintiffs suggest that each method patent defines the subpopulation somewhat differently, but that, broadly speaking, the characteristic is "being a member of the subpopulation of hepatically impaired patients." Although Plaintiffs build this into an argument about the genus/species relationship, discussed *infra*, how they identify the characteristic missing from the prior art has profound effects on their ensuing analysis. While Defendants have identified the missing characteristic as a

characteristic of the method of treatment with fexofenadine, Plaintiffs have identified the missing characteristic as membership in a subpopulation that is the object of the treatment method. This raises the threshold question of whether it is valid to differentiate methods based on a characteristic of the patient treated. As will be seen in the ensuing discussion, this Court finds that, for purposes of the inherent anticipation inquiry, it is not valid to do so. Thus, Plaintiffs have begun with an invalid premise that bedevils the rest of their inherent anticipation analysis.

A corollary to this premise is important as well: the method must be distinguished from the object acted upon by the method, the patient. In comparing the patents, then, there are two distinct areas of analysis: the methods used, and the object of the method. Plaintiffs have overlooked this crucial distinction and confused the two. This failure to distinguish method from object seemingly generates much confusion in their argument.

The distinction between characteristics of the method and characteristics of the patient is crucial to the inherent anticipation analysis of method claims. The failure to observe this distinction is apparent in the genus/species analysis that Plaintiffs advocate. Plaintiffs contend that the Carr patent disclosed a genus of treatment methods and that methods such as that disclosed in the '353 patent are species of that genus. This approach fails because it confuses characteristics of the method with characteristics of the patient. FN14 As will be discussed further-and this is the simple bottom line here-the treatment method of the Carr patent does not differ from the treatment method of the '353 patent. The methods themselves do not have a genus/species relationship. Rather, they are identical. Both teach that one can treat patients with allergies with fexofenadine. Had Plaintiffs contended that the method patents actually taught a new method of using fexofenadine to treat hepatically impaired patients, the methods themselves might differ. The claims clearly differ, but the difference is essentially a characteristic of the patient, not of the method.FN15 In terms of patient characteristic, there is a genus/species relationship: the Carr method is addressed to all patients, while the '353 patent is addressed to a subpopulation of patients within all patients.

FN14. Plaintiffs' reference to *Eli Lilly & Co. v. Barr Labs.*, 251 F.3d 955, 971 (Fed.Cir.2001), does not help them on this issue. Plaintiffs cite Lilly as an example of a case in which two treatment method claims, one for fluoxetine treatment of animals and the other for fluoxetine treatment of humans, were found to be in a genus/species relationship. This is a distorted truncation of that court's analysis. The Lilly court differentiated between the characteristics of the method and the characteristics of the patient. There, as here, the method characteristics showed no difference; the patient groups, as here, were in a genus/species relation. The Lilly court did not decide the case on the comparison of the patient group characteristics alone. Had they done so, the case would support Plaintiffs' approach here. In Lilly, because comparison of the method characteristics showed that the methods were not patentably distinct, and because comparison of the patient characteristics showed a prior art genus and a later species, the court held that the claims were not patentably distinct. *Id.* at 972. The lesson from Lilly is, thus, quite contrary to what Plaintiffs suggest: one must separate the analysis of the method characteristics from the analysis of the patient characteristics. Plaintiffs assert that analysis of patient characteristics is sufficient. As Lilly shows, it is not.

FN15. More precisely, the method patent claims specify a method, used with a certain kind of patient, while avoiding certain side effects of terfenadine. *See, e.g.*, claim 1 of the '353 patent. The claim component of avoiding certain side effects of terfenadine is necessarily present in every method that does not use terfenadine. It is therefore not a focus of the inherency analysis.

Plaintiffs say that the methods have a genus/species relationship, but it is only the patient populations that have such a relationship. This error leads to untenable conclusions about what was invented. Plaintiffs argue that the method patents are selection inventions which are "ubiquitous" in patent law. (Hr'g Tr. 229, Oct. 28, 2005.) But, as the phrase suggests, selection inventions must be *inventions*: the genus and species must be inventions. Carr did not invent or discover allergic patients and Plaintiffs did not invent or discover hepatically impaired allergic patients. In the context of the Carr patent, the method patents are not selection inventions.

Plaintiffs' failure to recognize the method/patient distinction generates more confusion as their argument progresses. Plaintiffs point to the language of Carr claim 11, which claims a method of treatment of "a patient." They then argue that "a patient" means "any patient among the population of all," which they contend means, essentially, "each and every particular instance of treating every particular patient." (Hr'g Tr. 335, Nov. 2, 2005.) Thus, Carr teaches a universe of treatment instances. Plaintiffs then argue that, to inherently anticipate a treatment method for the hepatically impaired subpopulation, every treatment instance in the universe of treatment instances must involve a hepatically impaired patient. Because every treatment instance in the universe of treatment instances does not involve a hepatically impaired patient, the characteristic is not found necessarily in the prior art. The logic is convoluted and troublesome here.

Stripped of the confusing detail, Plaintiffs appear to be arguing here that when two things have a genus/species relationship, species characteristics must be present whenever there is any embodiment of the genus. Viewed as an abstract proposition, it is clear that this cannot be true, since it obliterates the distinction between genus and species if every embodiment of a genus must show the characteristics of every species.

Moreover, Plaintiffs have confused the prior art reference with instances of use of its teachings: the characteristic must be both missing from, and inherent in, the reference itself, not in its use. "[A] prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed.Cir.2003). The characteristic must be necessarily present in the disclosure of the reference, not necessarily present in every instance of practice of its teachings. The characteristic of treating hepatically impaired patients is necessarily present in the teaching of the Carr reference, which discloses a method for treating all patients; it need not be present in every instance of use or practice of the Carr method.

Plaintiffs' argument fails not only as a matter of logic, but as a matter of patent law. As a threshold matter, even if the Carr method and the methods of the method patents did stand in a true genus/species relationship, a genus may anticipate a species. The fact that patents on a species *may* be patentable over a prior art genus does not mean that they *must* be. Sometimes, they are not. *See, e.g.*, *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 246 F.3d 1368, 1380 (Fed.Cir.2001) (hereinafter " BMS ").

[19] But, more importantly, Plaintiffs have failed that to show that the law of inherent anticipation in method patents does not dictate the outcome in this matter. As the foregoing discussion indicates, Plaintiffs' genus/species approach fails to put the focus where it belongs, on the methods in these method patents. When seeking to determine whether one method anticipates another, the issue at the core of the inquiry is, under 35 U.S.C. s. 102, the question of novelty: what is patentably new? As Plaintiffs argue, a species is often, but not always, patentably new over a prior art genus. But use of the same method, for the same

purpose, on a subgroup of an old group will not be patentably new. For Plaintiffs to show that Defendants' position does not have merit, they must show, at a minimum, that it is possible that an old method, for an old use, on a subgroup of an old group could be patentably new. They have not done so.

In *BMS*, the Federal Circuit stated succinctly a basic principle of inherent anticipation in method or process patents: "Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent." *BMS*, 246 F.3d at 1376. The present case falls squarely within this principle. The method of treating allergies with fexofenadine was a known process as of the date of the Carr patent. Woodward et al. later discovered a result of that process: it did not cause cardiac side effects in hepatically impaired patients. The treatment process of the method patents is directed to the same purpose as the Carr treatment process; Plaintiffs do not claim that the purpose of "treating allergic reactions" in Carr claim 11 differs from the purpose of "treating a histamine-mediated condition" in '353 claim 1.FN16 As such, under *BMS*, the newly discovered results are unpatentable because they are inherently anticipated.

FN16. Plaintiffs overlook this principle in citing *Rapoport v. Dement*, 254 F.3d 1053, 1063 (Fed.Cir.2001). *Rapoport* concerned a new purpose, or new use, of an old process; the old use of the old process did not inherently anticipate the new use. The instant case is not analogous.

The Federal Circuit most recently addressed the issue of new versus old uses in *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368 (Fed.Cir.2005), holding that a patent that disclosed use of a particular composition and particular method, but not to treat skin sunburn, did not inherently anticipate a patent on the use of the same composition and method to treat that problem. The use of an old method for treatment of a new problem (skin sunburn) is patentably new. *Id.* at 1378-79. In the present case, Plaintiffs have not argued that the method patents are directed to the treatment of a new problem; rather, the method patents claim a new benefit which, as the Federal Circuit reiterated, "does not render the old invention patentable." *Id.* at 1377. In *BMS*, the court construed a claim's preamble, "[a] method for treating a cancer patient to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity." *Id.* at 1375-6. The court saw this as "a statement of purpose and intended result" and, comparing the actual steps of the method in the patent with the method in the prior art reference, held that it "does not result in a manipulative difference in the steps of the claim." *Id.* at 1376. Thus, in comparing the process of the invention with that in the prior art, the *BMS* court looked for an identity of physical steps. Applying this approach to the present case, the new method and the old method have an identity of physical steps.FN17 As in *BMS*, the fact that the '353 process is associated with a new intended result does not render it patentably new.

FN17. The '353 patent's "Detailed Description of the Invention" states: "[c]ompounds of [formulae for fexofenadine] ... are prepared and used as described in Carr et al. [U.S. Pat. No. 4,254,129, issued Mar. 3, 1981]." '353 Patent, col. 2 ll. 31-35. The identity of steps used is expressly stated in the patent.

The discoveries of Woodward et al. are fairly described as previously unappreciated properties of the Carr treatment method and as scientific explanations for the prior art's functioning, and are thus not patentably new. FN18 *See Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed.Cir.1999) ("[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer").

FN18. Defendants argued that the property of fexofenadine that minimizes cardiac side effects in hepatically impaired patients stems from the physiology of its interaction with heart tissue. Specifically, according to

researcher Dr. Eller, fexofenadine, unlike terfenadine, does not block potassium channels in cardiac tissue. (James Decl. Ex. 13 at 68-69.) Because fexofenadine has the intrinsic property of not blocking potassium channels in the heart tissue of every patient treated, this property is necessarily present whenever fexofenadine is used.

It is clearly true that the set of all patients and the set of hepatically impaired patients has a genus/species relationship. As discussed above, however, Plaintiffs have a confused argument about how this fact relates to instances of use, and how instances of use enters into the anticipation inquiry. Atlas Powder is instructive on the question of how instances of use should figure into the inherent anticipation analysis. In Atlas Powder, the patent at issue, the Clay patent, claimed a blasting composition which consisted of, *inter alia*, a certain emulsion that was 10-40% of the composition by weight. *Id.* at 1344. The Egly prior art reference disclosed all the claimed characteristics, except for entrapped aeration, for compositions which were 20-67% emulsion by weight. *Id.* at 1345. The court held that the entrapped aeration characteristic must be inherent only in the subset of compositions that overlapped: "[w]hile Egly compositions containing amounts approaching 67% by weight of water-in-oil emulsions may have little or no entrapped air, the evidence established that at emulsion levels below 40%, Egly compositions 'inevitably and inherently' trap sufficient amounts of air to enhance sensitivity." *Id.* at 1349. Thus, it did not matter that entrapped aeration was not present in some instances of use of the Egly teachings—instances in which the set of Egly uses did not overlap with the set of Clay uses. The crucial question was whether the entrapped aeration was necessarily present when the sets of uses overlapped.

Applying the Atlas Powder analysis to the instant case, the first tasks are to identify the characteristic in question (cardiac safety in the hepatically impaired) and the overlapping set of instances of use (treatment of hepatically impaired patients). The crucial question, then, is whether cardiac safety in the hepatically impaired is necessarily and inevitably present when the Carr treatment method is used with hepatically impaired patients. Because this is an undisputed truth here, following Atlas Powder, Carr inherently anticipates the method patents. Following the Atlas Powder analysis, it does not matter if the Carr method did not inevitably and inherently result in the characteristic at issue for patients outside the hepatically impaired subset.

Because this Court finds that Defendants have raised a substantial question as to invalidity of the method patents due to inherent anticipation, it need not address their arguments of invalidity due to obviousness. (Def.'s Opp. Br. 93.)

CONCLUSION

To show an overall likelihood of success on the merits, Plaintiffs needed to show a likelihood of success in defending at least one claim of one patent from Defendants' challenges to infringement and validity. Although Defendants did not raise a substantial question as to the validity of the process patent, Plaintiffs did not demonstrate a likelihood of success in prevailing on infringement of this patent. As to Barr and Ranbaxy, tentative claim construction, together with the evidence submitted, raised a substantial question as to infringement of the process patent, which Plaintiffs did not show lacked substantial merit; as to Teva and Amino, Plaintiffs did not demonstrate a likelihood of success in proving infringement of the process patent. While Plaintiffs demonstrated a likelihood of success in prevailing on inducement of infringement of the method patents, Defendants raised a substantial question as to the validity of the method patents which Plaintiffs did not show lacked substantial merit. Because Plaintiffs have not shown an overall likelihood of

success on the merits, this Court need not address the other factors in the preliminary injunction analysis. For the reasons stated above, Plaintiffs' application for a preliminary injunction is denied.

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