NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ALBANY MOLECULAR RESEARCH, INC. and SANOFI-AVENTIS U.S. LLC, Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	Civil Action No. 09-4638 (GEB-MCA) **MEMORANDUM OPINION** **PUBLIC REDACTED VERSION**

BROWN, Chief Judge

This matter comes before the Court upon the application for emergency relief pursuant to FED. R. CIV. P. 65 and L. CIV. R. 65.1 by Plaintiffs Albany Molecular Research, Inc. and Sanofi-Aventis U.S., LLC. (collectively "plaintiffs" or "AMRI" and "Aventis," respectively), seeking a preliminary injunction against Defendant Dr. Reddy's Laboratories, LTD and Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's" or "DRL"), enjoining Dr. Reddy's from launching commercial sales in the United States of its fexofenadine hydrochloride/pseudophedrine hydrochloride 180 mg/240 mg extended release tablet products under Abbreviated New Drug Application No. 79-043 that allegedly infringe United States Patent No. 7,390,906 (the "'906 patent").

I. BACKGROUND

This patent litigation began on September 9, 2009, when plaintiffs filed a complaint alleging that Dr. Reddy's filed an ANDA pursuant to the Federal Food, Drug and Cosmetic Act seeking approval to engage in the commercial manufacture, use, sale, or importation of their fexofenadine hydrochloride/pseudophedrine hydrochloride 180 mg/240 mg extended release tablet products that are allegedly covered by plaintiff's patent, U.S. Patent No. 7,390,906. (Compl.; Doc. No. 1.) On May 17, 2010, Dr. Reddy's received FDA approval to market their generic fexofenadine product and consented to an injunction until this hearing. Testimony was heard on May 27 and 28, 2010, and the parties stipulated to the entry of a Temporary Restraining Order until a decision on the Preliminary Injunction. Further briefing was received on the claim construction issues and closing arguments were heard on June 7, 2010. For the reasons stated below, the Court will grant plaintiffs' application for a preliminary injunction. This opinion constitutes this Court's findings of fact and conclusions of law pursuant to FED. R. CIV. P. 52(a).

II. DISCUSSION

The '906 patent, entitled "Piperidine Derivatives and Process for Their Production," is a process patent related to the process for preparing fexofenadine that includes the use of a regioisomer intermediate (the "CPK intermediate") of a certain formula. The parties argue over the scope and meaning of the asserted claim 7, and thus it is necessary to interpret the meaning of the claim as a preliminary matter.

A. Claim Interpretation

The first step in a patent infringement analysis is to define the meaning and scope of the claims of the patent. *Markman v. Westview Instruments, Inc.,* 52 F.3d 967, 976 (Fed. Cir. 1995)

(*en banc*), *aff'd*, 517 U.S. 370 (1996). Claim construction, which serves this purpose, is a matter of law exclusively for the court. *Id.* at 979. When construing claims, the court must first consider the intrinsic evidence. Specifically, the focus of the court's analysis must begin and remain on the language of the claims, "for it is that language that the patentee chose to use to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'" *Interactive Gift Express, Inc. v. Compuserve, Inc.,* 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. § 112, ¶ 2).

Generally, there is a presumption that the words of a claim will receive the full breadth of their ordinary meaning. *NTP, Inc. v. Research In Motion, Ltd.*, 392 F.3d 1336, 1346 (Fed. Cir. 2004). The ordinary meaning may be derived from a variety of sources including the claim language, the written description, drawings, the prosecution history, and dictionaries or treatises. *Id.* The presumption may be rebutted if the patentee acted as his or her own lexicographer by clearly setting forth a definition of the claim term unlike its ordinary and customary meaning. *Brookhill-Wilk 1, LLC. v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298-99 (Fed. Cir. 2003). Any intent by the patentee to redefine a term must be expressed in the written description, and must be sufficiently clear. *Merck & Co, Inc. v. Teva Pharms. USA, Inc.,* 395 F.3d 1364, 1370 (Fed. Cir. 2005). When a patent applicant specifically defines a claim term in its description of its invention, that definition controls. *Philips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (*en banc*) ("In such cases, the inventor's lexicography governs.") The Federal Circuit has "repeatedly encouraged claim drafters who choose to act as their own lexicographers to clearly define terms used in the claims in the specification." *Sinorgchem Co. v. ITC*, 511 F.3d 1132, 1136 (Fed. Cir. 2007).

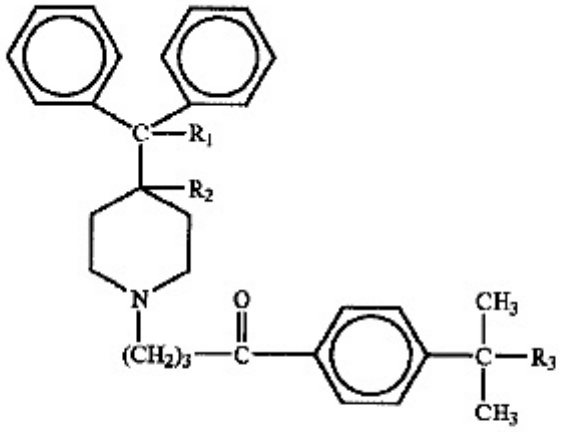
When the patentee has not provided an explicit definition of a claim term, the words of a claim are given their plain and ordinary meaning to a person of ordinary skill in the art. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The person of ordinary skill in the art is deemed to read the claim terms in the context of the entire patent, including the specification. *Phillips*, 415 F.3d at 1313.

A court may also consider extrinsic evidence when an analysis of the intrinsic evidence alone does not resolve the ambiguities of a disputed claim term. *Vitronics*, 90 F.3d at 1582-83. While a court may rely on extrinsic evidence to construe a claim, "what matters is for the court to attach the appropriate weight to be assigned to those sources." *Phillips*, 415 F.3d at 1324. Extrinsic evidence may never be used to contradict intrinsic evidence, however. *Id.* at 1322-23.

2. Analysis

Claim 7 of the '906 patent depends from claim 6 which in turn depends from claim 1. Claim 7, rewritten to include the claims from which it depends, provides as follows:

7 (Composite) A process of preparing a piperidine derivative compound of the formula:



wherein

R_1 is hydrogen or hydroxy;

R_2 is hydrogen;

or R_1 and R_2 taken together form a second bond between the carbon atoms bearing R_1 and R_2;

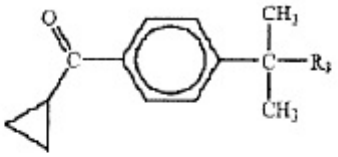
R_3 is –COOH or –$COOR_4$;

R_4 has 1 to 6 carbon atoms;

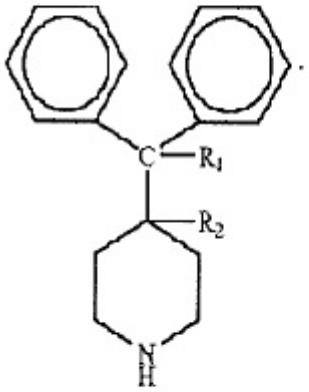
said process comprising:

(a) providing a regioisomer of the following formula:

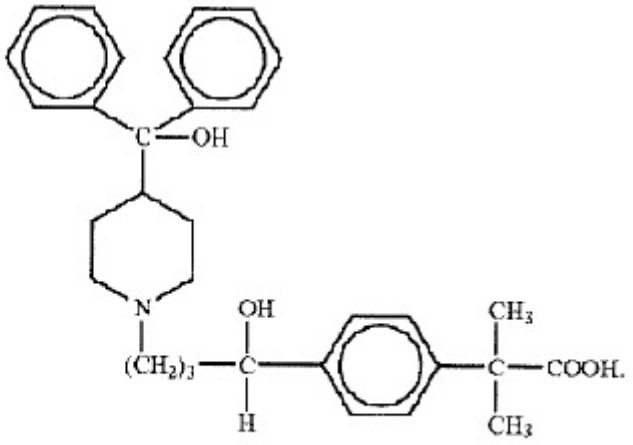
[CPK]



(b) converting the regioisomer to the piperidine derivative compound with a piperidine compound of the formula:



(c) reducing the piperidine derivative under conditions effective to form a hydroxylated piperidine derivative of the formula:



In claim 7, the second compound (labeled CPK above for ease of reference) is the para cyclopropyl ketone ring compound ("CPK") that is the heart of the invention of the '906 patent. It is the para-CPK compound because the left hand portion of the compound is joined to the six-sided central "aromatic" structure at the 4 or para position.

Plaintiffs argue that the claims of the '906 patent are "straightforward and unambiguous." (Pls.' Br. at 13; Doc. No. 40.) Defendants, on the other hand, argue that the purity of the p-CPK is critical to the invention, and that "the common specification[1], the '906 patent's 15-year long prosecution history, and sworn testimony of inventor D'Ambra all clearly and consistently characterize D'Ambra's invention as a process that uses substantially pure p-CPK before the azacyclonol coupling reation." (Defs.' Br. at 26; Doc. No. 80-1) (emphasis added). Defendants also concede that "AMRI deleted all textual reference to 'substantially pure' from the claims of the '906 patent." (*Id.*) Defendants argue that if plaintiffs' construction (or lack thereof) were accepted, then claim 7 of the '906 patent would be invalid for lack of written description and lack of enablement under 35 U.S.C. § 112 ¶ 1.

Plaintiffs' reply brief notes that adding "substantially pure" to the language of claim 7 would create a requirement that is not in the claim, thus adding a limitation. (Pls.' Reply Br. at 11; Doc. No. 100.) Plaintiffs also note that the specification discusses both "piperidine derivative compounds" and "substantially pure piperidine derivative compounds," and thus supports making such compounds without any specified purity. (*Id.* at 13.); *see also* '906 patent, 5:35-54, 4:27-28.

Defendants also argue that the shorthand diagram of the CPK intermediate used in claim 7

[1] The specification of the '906 patent is exactly the same as the specification of U.S. Pat. No. 5,750,703.

must support a pure para-regioisomer. They argue that when a mixture is intended, the line from the Carbon atom to the benzene ring is drawn *into the center* of the hexagon representing the benzene ring, and not to the apex as shown in claim 1. One of plaintiff's experts, Dr. Barrett, credibly testified that the shorthand form (and the "comprising" transitional language of the claim) only indicates that the para-regioisomer be "present in the reaction mixture and undergoes the conversion." (Barrett Sup. Decl. at ¶ 17.) Defendants further attempt to shoehorn Judge Greenaway's *Markman* ruling in a different case into this one. (Defs.' Claim Constr. Br. at 1; Doc. No. 126.) Judge Greenaway ruled on a different patent with different claims that "substantially pure" means at least 95% purity. If the Court were to add the "substantially pure" limitation to the claims in this case and accept Judge Greenaway's ruling, as defendants argue, then the diagram in Claim 1 of the patent in suit would *still* not suit their definition. Defendants are arguing that the diagram indicates pure (i.e., 100%) para-regioisomer. However, if the Court were to accept Judge Greenaway's claim construction, then a 96-99% purity would not satisfy the purity requirement that the diagram allegedly imposes.

Further, plaintiffs make a claim differentiation argument that holds great weight. In his declarations and on redirect examination, Dr. Barrett testified that Claim 3 of the '906 patent (which is not at issue in this preliminary injunction) *does* refer to an increase in the purity of the compound, while claim 7 does not limit the purity of any compounds. The Court agrees.

Defendants next argue that the "substantially pure" limitation must be read into the claim, or else they fail for lack of enablement and written description under 35 U.S.C. § 112 ¶ 1. The Court rejects this argument. The specification contains discussions of both "piperidine derivative compounds" and "substantially pure piperidine derivative compounds," and necessarily reaches

the making of such compounds with or without any specified purity. '906 patent, 5:35-54, 4:27-28. The fact that the specification teaches *how to purify* a mixture of regioisomers does not mean that only a particular purity of regioisomer is supported. The '906 patent specification supports the claim language by describing a process that involves forming CPK as a regioisomeric mixture and then, if desired, recovering para-CPK from that mixture. *See* Barrett Decl., ¶ 33. The Examples of the '906 patent also describe an actual reduction to practice of "converting" the para-CPK compound without referencing a particular purity.

Defendants also filed a supplemental brief on claim construction, arguing that "substantially pure" must be read into Claim 7 because of, among arguments already made in the original briefing, statements made during the prosecution history of the '906 patent. Defendants argue that AMRI, in prosecuting the '906 patent, distinguished it from Carr based on the use of substantially pure para-CPK of greater than 95% purity. Plaintiffs rebut this by noting that the response cited by defendants was to an Office Action rejecting the application that would later mature into the '906 patent because of double patenting under 35 U.S.C. § 101. Any disavowal of claim scope in the prosecution history must be "both clear and unmistakable." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325-26 (Fed. Cir. 2003). The Response to this Office Action noted one difference between the two sets of claims, noting that some substituents of the recited compound in the '906 patent were limited to hydrogen, whereas there was no such limitation in the Carr patent. After this, the examiner withdrew the double patenting rejection. The Court concludes that the applicant did what was necessary to overcome the double patenting rejection, namely point the examiner to one difference in the claims. Nowhere did AMRI state or imply that Claim 7 requires the use of a substantially pure para-CPK compound. Therefore, there can be no

"clear disavowal" of claim scope regarding the para-CPK compound because there were no arguments during prosecution related to the term.

Defendants next argue that statements made during the prosecution of the parent and related applications assist the Court in reading the "substantially pure" limitation into Claim 7. While the prosecution history of one patent is relevant to an understanding of the scope of a common claim term, *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340 (Fed. Cir. 2004), no such common claim term is present in this case. The prosecution histories at issue do not relate to a common claim term. *Microsoft* also instructs that statements made during prosecution of one application that generally summarize the applicant's "own understanding of the inventions disclosed" in multiple, related patents can be considered when construing the related patents. However, here all of the parent and related applications claim processes involving a "substantially pure regioisomer." The '906 patent does not.

Finally, in the supplemental briefing, defendants raise the argument that if "substantially pure" is not read into Claim 7 of the '906 patent, it reads on the Carr patent due to inherent anticipation. Defendants argue that without a purity requirement, the Carr process creates CPK as a by-product of the azacyclonol coupling reaction which reacts with some of the azacyclonol to make FFA-2, which would be encompassed by an interpretation of Claim 7 of the '906 patent. Defendants claim that "Aventis scientist Dr. Wolf testified that, during [the] azacyclonol coupling reaction disclosed in the Carr '129 patent, some additional part of the CKE mixture is converted to CPK mixture, and a small amount of CPK reacts with azacyclonol to form fexofenadine." Plaintiffs point out that the actual testimony of Dr. Wolf was that the CPK would not react to make fexofenadone under the conditions of example 5B in the '906 patent. He then stated that

"maybe a small amount of it would react." "The mere fact that a certain thing may result from a given set of circumstances is not sufficient" to establish inherency. *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981); *see also Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1297 (Fed. Cir. 2002) ("Inherency does not embrace probabilities or possibilities.") According to Dr. Davies' testimony, the Carr process may be run under certain parameters that would result in CPK reacting to make FFA-2. Because this feature is not always present in the Carr process, and because this feature is not always present in the D'Ambra process, anticipation by inherency cannot be satisfied.

Based on the evidence presented and the oral arguments heard, the Court will not read the "substantially pure" limitation into Claim 7 of the '906 patent. The claim (and the claims that it depends from) are unambiguous and not in need of construction. The Court further concludes that from the disclosure of the '906 patent, a person of ordinary skill in the art would understand that the para-CPK compound could be provided and converted in a regioisomeric mixture – without any requirement that it be in pure or substantially pure form.

B. Injunctive Relief

1. Findings of Fact

The Court finds the following facts to be true, having presided over a hearing in this matter on May 27-28; having viewed all of the exhibits admitted into evidence; and having listened to an examined the testimony of Dr. Barrett, Dr. Singleton, Dr. Westler, Mr. Nagesh, Dr. Sessler, and Mr. Braughton.

a. The Material Supplied to Dr. Reddy's

1. Dr. Reddy's requires its supplier of to provide a supplied material that contains no

more than [redacted]-regioisomer of CKE.[2]

2. That supplier filed a Drug Master File ("DMF") with the FDA, which describes how they make that material. The supplier's DMF describes the prior art process described [redacted].

3. Prior to September 2009, the supplier was reporting to Dr. Reddy's that the [redacted] ratio of regioisomers was [redacted].

4. After a plant visit from Dr. Davies, the [redacted] ratio of regioisomers was discovered to be [redacted], a ratio that is possible using the prior art [redacted] process.

b. Dr. Singleton's Analysis

5. Samples of finished fexofenadine product were then produced to Dr. Daniel Singleton, who performed Kinetic Isotope Analysis (also known as Carbon-13 isotopic analysis). Dr. Singleton analyzed samples obtained from immediate-release fexofenadine tablets that Dr. Reddy's has sold in the United States, but not from Dr. Reddy's sustained-release 24 hour product (because that product is not yet on the market).

6. Dr. Singleton compared the Dr. Reddy's product to a sanofi-aventis commercial fexofenadine product (made with the process of the '906 patent) and a sanofi-aventis development product that was made without going through a CPK intermediate (but made using a method ver silimar to that asserted to be used by Dr. Reddy's, i.e., the Carr process).

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[2] Meta-regioisomer is the undesireable form of CKE, as opposed to the para-regioisomer. The prior art Friedel-Crafts reaction will result in a mixture that is about 50% of each regioisomer.

7. Dr. Singleton's analysis concluded that the Dr. Reddy's product has a carbon-13 isotopic profile "very similar to the sanofi-aventis commercial fexofenadine product and significantly different" from the sample development product not made using the patented process.

c. Dr. Davies' Plant Visit

8. Dr. Davies, an expert in cyclopropyl ketones, visited both Dr. Reddy's and its supplier's production facilities in India in the Summer of 2009. He noticed that both DRL and its supplier were not using a [redacted] in their testing of the raw supplied material, which led to the original erroneous reporting of high-purity starting material. After this [redacted] was corrected, his testing confirmed that the [redacted] ratio of the supplied material was [redacted].

9. The process that Dr. Davies' witnessed at the DRL and the supplier's facilities was the manufacture of fexofenadine using the prior art [redacted] process, slightly modified to require only [redacted].

d. [redacted]

10. Dr. Davies' analysis during his plant visit was limited to a product known to DRL and its supplier as "[redacted]."

11. The supplier was making another product, labeled "[redacted]," for export to non-U.S. markets. [redacted] was made by the supplier and shipped to Dr. Reddy's until production was stopped in [redacted], the [redacted] supplied product had approximately [redacted] regioisomer, a purity that mandates the use of a CPK intermediate.

e. [redacted]

12. Plaintiffs will lose market share, suffer price erosion, lose research opportunities, and lose brand recognition if the generic D-24 product is allowed on the market and later found to be infringing.

13. The loss of brand recognition and associated goodwill that will result from a premature launch by DRL would have a devastating, yet incalculable, negative effect on the [redacted].

2. Conclusions of Law

A preliminary injunction is "a drastic and extraordinary remedy that is not to be routinely granted." *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993). In order to obtain the extraordinary relief of a preliminary injunction, plaintiffs must establish: (1) that they are likely to succeed on the merits, (2) that they are likely to suffer irreparable harm in the absence of preliminary relief; (3) that the balance of equities tips in their favor, and (4) that an injunction is in the public interest. *See, Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1375-76 (Fed. Cir. 2009).

a. Likelihood of Success on the Merits

"[T]he patentee seeking a preliminary injunction in a patent infringement suit must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent." *Id.* at 1376. To defeat plaintiffs' motion, Dr. Reddy's need not prove non-infringement or invalidity; it merely needs to "raise[] a substantial question concerning either

infringement or invalidity, i.e., assert[] an infringement or invalidity defense that [Plaintiffs] cannot prove 'lacks substantial merit . . . .'" *Amazon.com, Inc. v. BarnesandNoble.com, Inc.*, 239 F.3d 1343, 1350-51 (Fed. Cir. 2001); *see also New England Braiding v. A.W. Chesterton Co.*, 970 F.2d 878, 882-83 (Fed. Cir. 1992) ("The district court cannot be held to have erred . . . where the evidence presented in support of invalidity raises a substantial question, although the defense may not be entirely fleshed out.")

Plaintiffs argue that they are entitled to burden shifting under 35 U.S.C. § 295. That provision applies to actions "alleging infringement of a process patent based on the importation, sale, offer for sale, or use of product which is made from a process patented in the United States." Under § 295, if the plaintiff proves: (1) that a substantial likelihood exists that the defendants' generic was made using the patented process, and (2) that plaintiffs have made a reasonable but unsuccessful effort to determine the process actually used to make the generic, then the defendants shall be presumed to have been made by the patented process. Defendants' will then have the burden of establishing that their generic was not made using the patented process. *Nutrinova Nutrition Specialties and Food Ingredients GmbH v. Int'l Trade Comm'n*, 224 F.3d 1356 (Fed. Cir. 2000).

Defendants argue that plaintiffs fail to meet either requirement for burden shifting under § 295. (Defs.' Opp'n Br. at 40.) They argue that the first prong has not been met because plaintiffs have not established a substantial likelihood that Dr. Reddys' fexofenadine is made by a process that infringes the '906 patent, for the same reasons they argue noninfringement. Regarding the second prong, defendants argue that plaintiffs have not made a reasonable effort to determine the process actually used. Defendants argue that plaintiffs have had access to "literally thousands of

pages of the supplier's and [Dr. Reddy's] documents from which Aventis is able to determine the manufacturing process used by [Dr. Reddy's] to make fexofenadine." (Defs.' Br. at 42.) Defendants argue that the plaintiffs' choice not to believe the produced documents should belie any burden shifting. The Court concludes that a determination on this burden-shifting analysis is unnecessary at this time.

Aside from the § 112 written description and enablement requirements already dealt with in the claim construction section, defendants do not challenge the validity of the '906 patent. Instead, they argue that their process for making fexofenadine is not infringing. Plaintiffs argue that defendants are infringing the '906 patent because Dr. Reddy's discloses in their [redacted] each step recited in claim 7, except the use of the CPK intermediate. (Pls.' Br. at 14-16.)

Defendants submit the declarations of Drs. Markley and Westler, attacking the data acquisition and data analysis used by Dr. Singleton in conducting the Kinetic Isotope Analysis. Drs. Markley and Westler argue that Dr. Singleton's testing and analysis were flawed on several levels. First, they argue that the signal-to-noise ratio ("SNR") in Dr. Singleton's data was far too low, and that their methods for improving signal strength made their data more reliable. Next, they argue that Dr. Singleton erred in not performing a linear baseline correction to his data before the Fourier Transform was performed.

Dr. Singleton responded by stating that the Signal to Noise Ratio is only relevant up to a certain point, and any signal strength above this threshold is irrelevant. He credibly testified that the mathematical methods that Markley and Westler used to increase the signal to noise ratio in their data were unnecessary as his data had an acceptable signal strength. Dr. Singleton credibly

testified that line-broadening, as performed by Drs. Markley and Westler, has two negative effects on the data: it increases problems with overlapping lines and it increases error from noise due to the increase in width of integration ranges. Dr. Singleton also noted that baseline correction, as done by Drs. Markley and Westler, was not done in his testing and analysis because it "allow[s] the subjective operator manipulation of the data." (Supp. Singleton Decl. at ¶ 7.) He further argued that he did not use line-fitting as done by Drs. Markley and Westler because the model line drawn by the computer does not exactly correspond to the real shape of the peak, and can lead to error. The Court also notes that Dr. Singleton's analysis is based on 220 NMR Spectra, while Drs. Markley and Westler only ran three NMR Spectra.

The Court finds that Dr. Singleton competently and credibly testified that the generic D-24 samples he tested were prepared using the process of the '906 D'Ambra patent. Drs. Markley and Westler's attempts to discredit his data collection and analysis methods fall short of the mark. Dr. Singleton, an expert in Carbon-13 NMR analysis, concluded with greater than 95% statistical confidence that the DRL samples he tested were made using a CPK intermediate. He also competently and credibly noted the errors in Drs. Markley and Westler's analyses, which can lead to large amounts of error, subjective bias, and overall poor results.

Defendants introduced the testimony of Dr. Davies, an expert in cyclopropyl ketones, who visited both Dr. Reddy's and its supplier's production facilities in India in the Summer of 2009. He noticed that both DRL and the supplier were not using a [redacted] in their testing of the raw supplied material, which led to the original reporting of high-purity supplied material. After this [redacted] was corrected, his testing confirmed that the [redacted] ratio of the supplied material was [redacted]. Dr. Davies' declaration is voluminous but his conclusion is simple: what he

witnessed at the DRL and the supplier's facilities was the manufacture of fexofenadine using the prior art [redacted] process, slightly modified to require only [redacted]. On cross examination, Dr. Davies admitted that his observations did not take place during a normal manufacturing day at either facility, but that both facilities had prepared for his arrival and slowed the manufacturing process to allow him to take samples at certain points. He also notes that CPK is produced as a byproduct of the prior art Carr process, and intimates that this CPK that is made during the Carr process is what Dr. Singleton's testing uncovered: a conclusion which is also supported by Dr. Sessler's expert report (marked as Defendant's 17). However, neither Dr. Davies or Dr. Sessler testified that the para-CPK produced by the Carr process is anywhere near the concentration necessary to affect Dr. Singleton's tests.

The Court does not doubt Dr. Davies' methods or conclusions that the process he witnessed was the prior art [redacted] process as described in [redacted]. However, this does not obviate Dr. Singleton's conclusions that defendants' D-24 samples were made using a CPK intermediate as covered by the '906 patent. All Dr. Davies' testing proves is that he witnessed, on his one visit, the process as described in the [redacted]. The Court also notes that Dr. Davies' requested production files for 10 prior production batches in 2009 and three random batches for each year going back to 2006, all of which show that the enrichment of the [redacted] ratio occurred [redacted] at the end of the [redacted] stage – consistent with the [redacted]. He claims that if the supplier or DRL were lying to him regarding their processes for making fexofenadine, they would have also had to fabricate these random records.

Dr. Davies' analysis, however, was only for one product, which the supplier refers to as "[redacted]." A representative from the supplier testified that the supplier was making another product, labeled "[redacted]," for export to non-U.S. markets. [redacted] was made by the supplier and shipped to Dr. Reddy's until production was stopped in [redacted], and plaintiff introduces three exhibits (labeled P-2 through P-4) indicating that the [redacted] supplied product had approximately [redacted] regioisomer, a purity that mandates the use of a CPK intermediate. Though Mr. [redacted] insists that the [redacted] product was no longer produced after [redacted] (and the '906 patent did not issue until 2008), the Court concludes that the fact that the supplier was making an the other supplied material with a para-regioisomer purity level similar to product made using the process '906 patent, coupled with Dr. Singleton's persuasive analysis that defendants' generic D-24 products are being made using the process of the '906 patent, lead to the inescapable conclusion that DRL or its supplier is using a supplied material prepared with a CPK intermediate as covered by the '906 patent.

The Court concludes that plaintiffs have shown a high likelihood of success on the merits even absent the burden-shifting provision of § 295, and therefore does not need to reach that issue, and that defendants have not raised the "substantial question" to defeat this prong of the plaintiffs' preliminary injunction application. However, as current samples of defendants' D-24 product as prepared to be sold in the United States were not made available, Dr. Singleton only tested other fexofenadine samples and one sample of a different Dr. Reddy's fexofenadine product. If the defendants produce credible tests of current samples of their generic D-24 product that they propose to sell in the United States absent this injunction, and this analysis shows that a [redacted] method was used for its production, then they may seek modification or dissolution of this injunction.

b. Irreparable Harm

Plaintiffs must provide a "clear showing" that they will suffer irreparable harm in the absence of injunctive relief. *Nutrition 21 v. United States*, 930 F.2d 867, 870-71 (Fed. Cir. 1991). The Supreme Court has emphasized that irreparable harm must be established as a separate element, independent of any showing of likelihood of success; irreparable harm can no longer be presumed. *Winter v. Natural Resources Defense Counsel, Inc.*, 129 S. Ct. 365, 375-76 (2008); *eBay Inc. v. MercExchange L.L.C.*, 547 U.S. 388 (2006). Plaintiffs argue that money damages would not make them whole because a launch of a generic fexofenadine product would bring a sharp downward pressure on the price of the drug and cause them to lose market share.

In cases where a presumption of irreparable harm is not available, it has been held that loss of market share and price erosion do not by themselves amount to irreparable harm. *Nutrition 21*, 930 F.2d at 871 (Fed. Cir. 1991); *Eli Lilly v. American Cynamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996) ("Such a rule would convert the 'extraordinary' relief of a preliminary injunction into a standard remedy available whenever the plaintiff has shown a likelihood of success on the merits."); *See also Altana Pharma AG v. Teva Pharmaceuticals USA, Inc.*, 532 F. Supp. 2d 666, 682 (D.N.J. 2007) (finding plaintiffs have not established irreparable harm despite contending "loss of revenue, price erosion, decrease in market share, loss of research opportunities, [and] reduction in workforce"), *aff'd* 566 F.3d 999 (Fed. Cir. 2009); *Novartis v. Teva*, 2007 WL 1695689, at *26-28 (D.N.J. June 11, 2007) (finding that plaintiff failed to establish irreparable harm because damages were calculable, Teva had the ability to pay any damages award, and the possibility of loss of market share, price erosion and lost research opportunities do not constitute irreparable harm); *In re Gabapentin Patent Litigation*, Nos. 00-2931, 01-1537 (D.N.J. Aug. 20,

2004) (JCL), Transcript at pp. 12-14 ("Loss of market share, or price erosion, lost sales, and even lost market opportunities in my view can be reduced to dollars, not easily but feasibly." (quoted in *Altana*, 532 F. Supp. 2d at 683-84.)

However, it has also been held that the types of harm argued in this case rise to the level of "irreparable." *Abbott Labs. v. Sandoz*, *Inc.*, 544 F.3d 1341, 1361-62 (Fed. Cir. 2008) (finding that the district court's conclusion that price erosion constituted irreparable harm was not an abuse of discretion); *see also Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1368 (Fed. Cir. 2001) (likelihood of price erosion and loss of market position are evidence of irreparable harm); *Bio-Technology Gen. Corp. v. Genentech, Inc*., 80 F.3d 1553, 1566 (Fed. Cir. 1996) (loss of revenue, goodwill, and research and development support constitute irreparable harm); *Polymer Technologies, Inc. v. Bridwell*, 103 F.3d 970, 975-76 (Fed. Cir. 1996) (loss of market opportunities cannot be quantified or adequately compensated, and is evidence of irreparable harm).

Here, plaintiffs argue that they will lose market share, suffer price erosion, lose research opportunities, and lose brand recognition if the generic D-24 product is allowed on the market and later found to be infringing. Defendants rebut this by arguing that the damages "boil down to money" and do not rise to the level of "irreparable" as long as Dr. Reddy's is capable of paying any damages that may be awarded if plaintiffs prevail at trial. Defendants further argue that Aventis' delay of almost two years before asserting the '906 patent against DRL's D-24 product defeats the claim of irreparable harm. In reply, plaintiffs argue that the loss of brand recognition and associated goodwill that will result from a premature launch by DRL would have a devastating, yet incalculable, negative effect on the [redacted]

[redacted]. (Braughton Supp. Decl. at ¶¶ 2-4.) Plaintiffs further argue that DRL may not be able to pay the damages at trial [redacted], which DRL does not rebut. Further, Aventis argues that they did not delay in bringing suit and sought injunctive relief when it became apparent that DRL was preparing an at-risk launch that then would cause irreparable harm. They further argue that DRL has not alleged that it has suffered material prejudice attributable to the alleged delay.

The Court concludes that plaintiffs have made the requisite showing of irreparable harm in this case. Though many of the damages alleged will "boil down to money," the calculation of these damages will be very difficult. Also, the loss of goodwill associated with the brand is the type of injury that is the definition of "irreparable." *eBay*, 547 U.S. at 391 (irreparable injury is an injury "that remedies available at law, such as monetary damages, are inadequate to compensate for that injury.") Though not controlling in this case, the Lanham Act specifically defines the loss of goodwill as an irreparable harm in the injunction context. 15 U.S.C. § 1125(c)(1); *see also Pappan Enters., Inc. v. Hardee's Food Sys., Inc.*, 143 F.3d 800, 805 (3d Cir. 1998) ("Grounds for irreparable injury include loss of control of reputation, loss of trade, and loss of goodwill. Irreparable injury can also be based upon the possibility of confusion.") For all the reasons stated above, the Court concludes that a showing of irreparable harm has been made.

c. Balancing the Equities

Plaintiffs argue that the injury that they will suffer absent the entry of an injunction will be "substantial." (Pl.'s Br. at 36.) They argue that they will lose market share due to the generic launch and "will be forced to compete in a market where it has a right to exclude." (*Id.* at 37.)

They argue that if a generic launch is not enjoined, and the generic is later found to be infringing at trial, they will have a "difficult time restoring [their] pre-generic launch market position." (*Id.*) Defendants argue that the balance of equities tips in their favor because "[Dr. Reddy's] has raised a substantial issue as to noninfringement" and because plaintiffs delayed for 2 years after the issuance of the '906 patent before asserting it against Dr. Reddy's product. (Defs.' Br. at 39.) Defendants argue that they will be harmed if an injunction is entered, arguing that they have raised a "substantial question of noninfringement" and again pointing to plaintiffs' "unexplained delay of almost two years following the issuance of the '906 patent." (Def.'s Br. at 39; Doc. No. 80-1.) The Court concludes that the balance of the equities favors the plaintiffs. Any sales that Dr. Reddy's would lose if this injunction is improvidently granted would be time-shifted, and lost sales will not be destroyed. Plaintiffs, on the other hand, would suffer devastating and irreversible losses if an injunction is not issued and the '906 patent is later found to be infringed.

c. The Public Interest

The two competing public interests here are the public interest in patent rights (argued by plaintiffs) and the public interest in low priced generic drugs (argued by defendants). "The public has an interest in upholding and preserving patent rights." *Solarex Corp. v. Advanced Photovoltaic Sys., Inc.*, 34 U.S.P.Q.2d 1234, 1241 (D. Del. 1995). Although the public has an interest in lower prices, that interest is "strongly outweighed by the public policy of enforcing new patent rights and encouraging inventors to develop new products." *A.K. Stamping Co. v. Instrument Specialties Co.*, 106 F. Supp. 2d 627, 656 (D.N.J. 2000). "[W]hile the statutory framework under which [Defendant] filed its ANDA does seek to make low cost generic drugs available to the public, it does not do so by entirely eliminating the exclusionary rights conveyed

by pharmaceutical patents." *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005). The Court concludes that the public interest in protecting patent rights outweighs the public interest in low cost generic drugs, and thus this factor favors plaintiffs.

III. CONCLUSION

For the reasons stated herein, the Court will grant plaintiffs' motion for preliminary injunction. An appropriate form of order is filed herewith.

Dated: June 14, 2010

s/ Garrett E. Brown, Jr.
GARRETT E. BROWN, JR., U.S.D.J.