IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

IMPAX LABORATORIES, INC.,	:	
	:	
Plaintiff,	:	
	:	Civil Action No. 02-581 JJF
v.	:	
	:	
AVENTIS PHARMACEUTICALS, INC.,	:	
	:	
	:	
Defendant.	:	

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MEMORANDUM OPINION

August 30, 2004

Wilmington, Delaware

Farnan, District Judge.

Impax Laboratories, Inc. ("Impax") filed this action seeking a declaratory judgment that U.S. Patent No. 5,527,814 (the "'814 patent") is invalid, unenforceable, and will not be infringed by Impax's proposed sale of riluzole.

BACKGROUND

I. Procedural

Aventis Pharmaceuticals, Inc. ("Aventis") is a Delaware corporation with its principal place of business in Bridgewater, New Jersey. Aventis was formed in 1999 as part of a merger between Rhone-Poulenc, S.A. and Hoechst, AG. Rhone-Poulenc, S.A., was the parent company of Rhone-Poulenc Rorer, S.A., and Rhone-Poulenc Sante, S.A. (collectively "RPR" or "Aventis").

Aventis owns the '814 patent, which was issued on June 18, 1996, and names Dr. Eric Louvel as the sole inventor. The '814 patent involves the use of the chemical compound riluzole to treat amyotrophic lateral sclerosis ("ALS"), a fatal disease of the central nervous system more commonly known as Lou Gehrig's disease. Aventis sells riluzole under the trade name Rilutek.

Impax is a Delaware corporation with its principal place of business in Hayward, California. On May 16, 2001, Impax filed an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") and sought approval to engage in the manufacture and sale of riluzole for the treatment

of ALS. The FDA approved the ANDA and licensed Impax to make and sell riluzole.

On June 25, 2002, Impax filed the instant lawsuit. Impax alleges that the '814 patent is invalid as anticipated, invalid as obvious, invalid for naming the wrong inventor(s), and unenforceable due to inequitable conduct. Impax also seeks declaratory relief declaring that its proposed sale of riluzole will not induce infringement of certain claims of the '814 patent. Aventis has counter-claimed alleging infringement. Both parties seek costs and attorney's fees if they prevail.

A bench trial in the case was held from October 28, 2003, to October 30, 2003. The parties have filed their post-trial briefs and evidentiary objections. This Memorandum Opinion shall constitute the Court's Findings of Fact and Conclusions of Law pursuant to Federal Rule of Civil Procedure 52.

II. The '814 patent

The claims of the '814 patent describe treating mammals with ALS using an effective amount of riluzole. This is the only known treatment for ALS. Only claims 1 through 5 of the '814 patent are at issue in this case. Impax has stipulated that, if claims 1, 4, and 5 of the '814 patent are valid and enforceable, its proposed sale of riluzole will infringe the claims of the patent and likewise induce infringement of the asserted claims.

The relevant claims of the '814 patent are as follows: "1. A

method for treating a mammal with amyotrophic lateral sclerosis, comprising the step of administering to said mammal in recognized need of said treatment an effective amount of [riluzole]." "2. The method according to claim 1 wherein said amyotrophic lateral sclerosis is with early bulbar involvement." "3. The method according to claim 1 wherein said amyotrophic lateral sclerosis is the bulbar form." "4. The method according to claim 1, wherein said effective amount comprises 25 to 200 mg of said [riluzole]." "5. The method according to claim 4, wherein said effective amount comprises 50 mg."

The '814 patent is a continuation of U.S. Patent Application Serial No. 945,789 ("'789 application"), which claims priority to French Patent Application 92/02696 ("'696 application"). The '696 application was filed on March 6, 1992. (DTX 1; D.I. 148, exhibit 1.)[1]

DISCUSSION

I. Evidentiary Disputes

The parties have raised three evidentiary issues which must be addressed: 1) both parties seek to introduce additional documents into evidence; 2) Impax requests that the Court take judicial notice of the facts adjudicated in a prior case

[1] References to the record evidence are as follows: "DTX" refers to Aventis trial exhibits; "PTX-" refers to Impax trial exhibits; "Tr. of [witness name]" refers to the named witnesses' deposition testimony; Tr. refers to testimony made at trial.

involving Aventis's dealings with the Patent and Trademark Office (the "PTO"); and, 3) Impax seeks to exclude certain evidence it claims is irrelevant hearsay.

A. Admission of Exhibits

There are no objections to the proposed additions to the record. Therefore, the Court will admit PTX-3, PTX-37, PTX-201, PTX-222, DTX 18, and DTX 67 into the record.

B. Judicial Notice

Impax requests that the Court take judicial notice of the facts in Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., et al., No. 95 Civ. 8833 (RPP). Impax contends that the facts adjudicated in Bristol-Myers demonstrate the impermissible patent prosecution practices of Aventis, and are therefore relevant to the patent prosecution practices in the instant case. Impax contends that the facts of Bristol-Myers are offered to demonstrate habit and not character.

Aventis responds that taking judicial notice of the facts of Bristol-Myers is not appropriate and that such evidence would be inadmissible character evidence. Aventis contends that the patents involved in Bristol-Myers involved different inventors and primary patent agents and are generally unrelated to the patent involved in the instant case.

Federal Rule of Evidence 201 ("Rule 201") governs the Court's decision regarding judicial notice. Under Rule 201, a

"judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Use of judicial notice is generally discretionary; however, judicial notice is mandatory if a court is "requested by a party and supplied with the necessary information." Fed. R. Evid. 201.

Admission of the evidence Impax seeks to have judicially noticed could create substantial unfair prejudice in a jury trial. Although certain individuals were involved in both the prosecution at issue in Bristol-Myers and the prosecution of the '814 patent, no individual found guilty of inequitable conduct in Bristol-Myers is central to any of Impax's allegations of unenforceability in the instant case. Further, the facts of Bristol-Myers, inadmissible as evidence of general character, are not strong evidence of habit.

However, the Court notes that, in a bench trial, the danger of undue prejudice is substantially reduced. Thus, the Court will take judicial notice of the adjudicative facts in Bristol-Myers, and weigh these facts in the context of all the evidence in this case.

C. Whether Aventis's Exhibits DTX 119 and 120 Should be Excluded as Irrelevant Hearsay

Aventis submitted two documents, DTX 119 and 120, in an

attempt to clarify the translation of the French word "supprimer," which is used in a letter relevant to Impax's causes of action and by Francoise Maillard in deposition testimony. Certified translations of both the letter and the deposition testimony are in evidence. Aventis's exhibit DTX 119 is an excerpt from a French to English and English to French dictionary. Aventis's exhibit DTX 120 is an excerpt from an "International Terminology for the Windows Interface." (DTX 120.)

Impax contends that the context in which "supprimer" has been used renders Aventis's submissions irrelevant. Impax further contends that Aventis's submissions are hearsay.

Aventis responds that neither exhibit should be excluded as hearsay because both exhibits are documents generally relied upon by translators and fall within the commercial publication exception of Federal Rule of Evidence 803 ("Rule 803"). Aventis contends that the exhibits are relevant to the translation of "supprimer," and relevant to the instant case.

Under the commercial publication exception of Rule 803, "[m]arket quotations, tabulations, lists, directories, or other published compilations, generally used and relied upon by the public or by persons in particular occupations" are not excluded by the hearsay rule. The Court concludes that PTX 119 and 120 fall within this commercial publication exception and need not be

excluded by the hearsay rule. Further, the Court concludes that PTX 119 and 120 are relevant to the translation of the word supprimer and are therefore admissible evidence.

II. Invalidity

A. Whether the '814 Patent is Invalid as Anticipated

Impax contends that the '814 patent is invalid as anticipated by U.S. Patent No. 5,236,940 (the "'940 patent"), French Patent Application No. 2,640,624 (the "'624 application"), and U.S. Patent No. 4,826,860 (the "'860 patent"). The parties agree that the '940 patent, the '624 application, and the '860 patent qualify as prior art with respect to the '814 patent. (D.I. 148, Ex. 1.)

1. Whether the '940 Patent Anticipates

a. Parties' Contentions

Impax contends that every element of claims 1-5 of the '814 patent is disclosed by the '940 patent. Impax contends that the '940 patent discloses a class of compounds generally required by formula I,[2] and that riluzole is one of these compounds. Impax also contends that the '940 patent teaches how riluzole is useful in treating ALS and how it should be effectively administered.

Aventis responds that the '940 patent specifically excludes

[2] The '940 patent discloses pharmaceutical compounds useful for the treatment of medical conditions associated with the effects of glutamate that it defines as the compounds of formula I. (PX 20 at col. 1.)

riluzole from the compounds in formula I. However, even if it were to assume that the '940 patent does not exclude riluzole, Aventis contends that the '940 patent does not anticipate the '814 patent because it fails to sufficiently describe the invention claimed in the '814 patent. Aventis contends that the '940 patent teaches the use of a broad genus of compounds for treating various diseases and provides no specific instruction for using riluzole to treat ALS. Further, Aventis maintains that the '940 patent actually teaches away from using riluzole.

b. Applicable Legal Standards

A patent, once issued, is presumed valid. See 35 U.S.C. § 282. Thus, the party challenging the patent bears the burden of proving invalidity by clear and convincing evidence. Helifix Ltd. v. Blok-Lok Ltd., 208 F.3d 1339, 1346 (Fed. Cir. 2000). Clear and convincing evidence is evidence that places in the fact finder "an abiding conviction that the truth of [the] factual contentions are 'highly probable.'" Colorado v. New Mexico, 467 U.S. 310, 316 (1984).

Anticipation requires that every element of the claim be found "in a single prior art reference." See In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999). In order for there to be anticipation, there must be no difference between the claimed invention or method and the reference disclosure, as understood by one of ordinary skill in the art. Scripps Clinic & Research

Found. v. Genentech, Inc., 927 F.2d 1565, 1576 (Fed. Cir. 1991); see also Crown Operation Int'l, Ltd. v. Solutia, Inc., 289 F.3d 1367 (Fed. Cir. 2002)(citations omitted). Further, "[a]n anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention." ATD Corp. v. Lydall, Inc., 159 F.3d 534, 545 (Fed. Cir. 1998)(citing In re Spada, 911 F.2d 705, 708 (Fed. Cir. 1990); Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675 (Fed. Cir. 1988)).

c. Findings of Fact and Conclusions of Law

After considering the parties' arguments and the record evidence, the Court concludes that Impax has not demonstrated that the '814 patent is anticipated by the '940 patent. Initially, the Court agrees with Impax that riluzole was not excluded from the compounds included in formula I in the '940 patent. The written description provides, "The compounds of formula (I), with the exception of 6-trifluoromethylthio - and 6-trifluoromethoxy-2-benzothiazolamine [riluzole], are new and, as such, form part of the invention." (PX 20 at col. 1.) Although the '940 patent indicates that the compound riluzole was not novel, the plain language of the quoted portion of the written description provides that riluzole is part of the compounds in formula I by distinguishing it from the other compounds in

formula I.

Even though the Court has concluded that riluzole is within the formula I compounds of the '940 patent, the Court finds that because formula I entails such a large number of compounds (Tr. at 404-05, 362, 364) one of ordinary skill in the art would not have recognized that riluzole was effective in treating ALS without additional detail or guidance that is not found in the disclosure of the '940 patent. Riluzole is not listed as one of the compounds described as "especially advantageous" for the treatment of medical conditions associated with the effects of glutamate (PX 20 at col. 3), nor is it meaningfully discussed in the disclosure of the '940 patent.

Moreover, the Court concludes that the language of the '940 patent evidences that there was substantial uncertainty regarding the effectiveness of treating ALS with glutamate inhibiting compounds. The '940 patent provides:

> The compounds of formula (I) and their salts possess advantageous pharmacological properties . . . useful in the treatment and prevention of convulsive phenomena, schizophrenic disorders, . . . sleep disorders, phenomena linked to cerebral ischaemia . . . and also neurological conditions in which glutamate may be implicated, such as . . . [ALS].

(PX 20 at col. 3.) The Court views the above quoted language as providing only speculation that the compounds in formula I would be useful in treating ALS. Accordingly, the Court concludes that, upon reading the '940 patent, one of ordinary skill in the

art would not have recognized riluzole's effectiveness in treating ALS, and therefore, the Court finds that the '940 patent does not anticipate the '814 patent.

2. Whether the '624 Application Anticipates

The '940 patent claims priority from the '624 application, and therefore, contains disclosures similar to those of the '940 patent regarding possible uses of antiglutamates to treat ALS. (Compare PX 20 with PX 157; Tr. at 299-300.) For this reason, the parties assert virtually identical arguments they made with respect to the '940 patent. (See D.I. 189 at 7, D.I. 182 at 28-33, D.I. 185 at 20-22, D.I. 191 at 11-19.) As with the '940 patent, the parties dispute whether: 1) the '624 application excludes riluzole from formula I; 2) the failure of the '624 application to instruct one of skill in the art to select riluzole out of the large number of compounds included in formula I precludes anticipation; and 3) the '624 application does more than speculate that riluzole will be effective in treating ALS.

The Court has reviewed the '624 application and concludes that there are no material differences from the '940 patent that would persuade the Court to reach a finding contrary to the one reached with respect to the '940 patent.[3] Accordingly, for the

[3] One difference noted by Impax between the '940 patent and the '624 application is that the '624 application does not contain language distinguishing riluzole from the other compounds in formula I. However, because the Court did not rely on this limiting language in finding that the '940 patent does not

reasons set forth above – i.e. the lack of detail in guiding one of skill in the art to select riluzole from the large number of compounds in formula I and the speculation that a compound in formula I can be effective in treating ALS – the Court concludes that the '624 application does not anticipate the '814 patent.

3. Whether the '860 Patent Anticipates

a. Parties' Contentions

Impax contends that the '860 patent anticipates the '814 patent because it discloses a method for treating mammals with neuromuscular disorders in which glutamate has been implicated. Impax contends that at the time the '860 patent issued, ALS was the only neuromuscular disease in which glutamate had been implicated.

Aventis responds that the plain language of the '860 patent is inconsistent with Impax's anticipation arguments. Aventis contends that, upon reading the '860 patent, one of ordinary skill in the art would have had no basis to conclude that the only neuromuscular disorder referred to was one in which excitatory amino acids are implicated. Further, Aventis contends that Dr. Ludolph testified that excitatory amino acids have been implicated in at least three neuromuscular disorders other than ALS.

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anticipate the '814 patent, the Court concludes that this difference between the '624 application and the '940 patent is not material.

b. Findings of Fact and Conclusions of Law

The '860 patent was before the examiner during prosecution of the '814 patent, and therefore, Impax's burden of demonstrating invalidity by clear and convincing evidence is heightened. Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360 (Fed. Cir. 1984)(stating that when a party attempts to demonstrate invalidity through use of prior art that was before the examiner, part of the challenging party's burden is to show that the examiner was wrong in his or her decision to grant the patent). Applying this standard to the record evidence, the Court concludes that Impax has not demonstrated that the '814 patent is anticipated by the '860 patent.

First, the Court agrees with Aventis that the plain language of the '860 patent is inconsistent with Impax's claim that the '860 patent teaches the treatment of ALS with riluzole. Impax's expert testified that ALS was the only neuromuscular disease in which glutamate had been implicated at the time of the '860 patent. (Tr. at 301-02.) However, even accepting this testimony, the Court does not view the '860 patent disclosure as teaching the treatment of ALS with riluzole.

The portion of the '860 patent relied on by Impax provides:

> The instant invention concerns a new method for treating cerebrovascular disorders, such disorders are those in which excitatory amino acids, for example, glutamatic [sic] and aspartic acids, are implicated. Such disorders include cerebral ischemia or cerebral infarction resulting from a range of conditions such as thromboembolic or hemorrhagic

> stroke, cerebral vasospasm, hypoglycemia, cardiac arrest, status epilepticus, or cerebral trauma. Other treatments are for schizophrenia, epilepsy, neuromuscular disorders, Alzheimer's Disease, or Huntington's disease.

(PTX 300 at col. 1.) The first sentence states that the invention is a method for treating disorders in which glutamic acids are implicated, and the second sentence provides examples of disorders implicating glutamic acids. In the Court's view, however, a reasonable interpretation of the following sentence (third sentence) does not include a list of disorders in which glutamic acids are implicated; otherwise, the Court expects that the applicants would have continued to use language similar to "such disorders," as used in the second sentence, to define the list of disorders implicating glutamic acids for which the invention of the '860 patent could be used to treat. Moreover, the Court considers the inventors' use of the plural form of neuromuscular disorder to indicate that they were not attempting to teach the use of riluzole for treating, as Impax asserts, the only neuromuscular disease implicating glutamic acid, ALS. For these reasons, the Court concludes that Impax has not met its burden in demonstrating that the '814 patent is anticipated by the '860 patent.

B. Whether the '814 Patent is Invalid as Obvious

1. Parties' Contentions

Impax contends that the '940 patent, the '624 application, the '860 patent, and the articles Neuroprotective Potential of

Merk & Co.'s MK-801 (the "MK-801 article") and Excitatory Amino Acid Neurotransmission and its Disorders, by Edith McGeer (the "McGeer article"), either alone or in combination, render the '814 patent obvious. Impax contends that the aforementioned patents and articles "specifically provide abundant motivation to use riluzole, as a known excitatory amino acid antagonist, in treating ALS in the dosages claimed in the '814 patent." (D.I. 182.)

Aventis responds that the cited evidence does not demonstrate that the '814 patent would have been obvious to one of ordinary skill in the art, particularly in light of the objective evidence of non-obviousness. Aventis argues that, at best, Impax's prior art only rendered using riluzole to treat ALS obvious to try.

2. The Law of Obviousness

Obviousness is a question of law that is predicated upon several factual inquiries. Richardson-Vicks v. Upjohn Co., 122 F.3d 1476, 1479 (Fed. Cir. 1997). In determining whether a patent is invalid as obvious in light of prior art, the trier of fact must consider: 1) the scope and content of the prior art; 2) the level of ordinary skill in the art; 3) the differences between the claimed subject matter and the prior art; and 4) secondary considerations of non-obviousness, such as commercial success, long felt but unsolved need, failure of others, and

acquiescence of others in the industry that the patent is valid. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). When multiple prior art references are being considered in determining obviousness, courts are to consider:

> (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.

In re Vaeck, 947 F.2d 488, 493 (Fed. Cir. 1991). It is not enough that prior art merely pique the interest of one of ordinary skill in the art and make an invention obvious to try. In re Eli Lilly & Co., 902 F.2d 943, 945 (Fed. Cir. 1990).

3. Findings of Fact and Conclusions of Law

Impax has asserted, as evidence of obviousness, the '940 patent, the '624 application, the '860 patent, and the MK-801 and McGeer articles.

The MK-801 article discusses an excitatory amino acid antagonist and states that such antagonists "could [] find a use in chronic neurodegenerative disorders such as... [ALS,]" by "acting to block exogenous or endogenous neurotoxins which are thought to act as excitatory amino acid agonists and contribute to the [etiology] of these conditions." (PTX-61B.)

The McGeer article states that riluzole inhibits the release of excitatory amino acids and, more specifically, glutamate.

(PTX 201 at 548-49.) The McGeer article speculates about the "exciting possibility" that excitotoxic damage plays a major role in "a variety of neurodegenerative diseases," and might be treated by inhibiting the release of excitatory amino acids. (Id.) The McGeer article does not specifically mention ALS.

When evaluated individually, the Court finds that the evidence offered by Impax is not sufficiently persuasive to support a finding of obviousness. As discussed above, the asserted patents and patent application are too undefined and uncertain to disclose or render obvious the '814 patent. Furthermore, neither the MK-801 article or the McGeer article contain disclosures about both riluzole and ALS such that the disclosures of the '814 patent are obvious.

Next, the Court will consider whether the alleged prior art, collectively, renders the '814 patent obvious. The crux of Impax's argument, based on this collective evidence, is that riluzole was known to be an antiglutamate and that decreasing glutamate was known to treat ALS. Therefore, Impax contends that it was obvious that using riluzole as an antiglutamate would treat ALS.

The Court views the objective evidence as strongly favoring a finding of non-obviousness. Although Impax has alleged contemporaneous inventorship that would support a finding of obviousness, the evidence offered by Impax is sparse and not

indicative of a solution that was obvious. (E.g. Tr. of V. Meininger at 9-11 (discussing the weak evidence of a relationship between ALS and glutamate excitotoxicity that existed when the contemporaneous proposal to treat ALS with riluzole was made)). In contrast, the Court finds that the evidence offered by Aventis is overwhelming concerning the long, unsuccessful search for a treatment for ALS, the need for such a treatment, and the skepticism of the effectiveness of the '814 patent, all of which support a conclusion of a lack of obviousness. (E.g. Tr. 433, PTX 30.)

Impax has offered testimony that it would have been obvious to Dr. Louvel, given Dr. Louvel's experience and knowledge, to use riluzole to treat ALS. (Tr. of J. Stutzman at 32.) Dr. Rothstein and others have testified that, on entering the experimental trials for riluzole, Aventis must have had a reasonable expectation of success. (See, e.g. Tr. 308.) The Court finds this evidence unpersuasive in establishing that the '814 patent was obvious to one of ordinary skill in the art.

Dr. Rothstein also testified that the glutamate theory was known by those skilled in the art by 1992, and that riluzole was known to be an antiglutamate. (Tr. 273-274, 282-83.) According to Dr. Rothstein, based on the state of knowledge when the '814 patent was filed, it was "obvious [scientists] should be taking antiglutamate drugs and trying them." (Tr. 305-06.)

The Court views Dr. Rothstein's testimony as only establishing that it would have been obvious to consider treating ALS with antiglutamates. Although riluzole was known to be an antiglutamate, the effectiveness of its antiglutamic properties in treating ALS was not established. Accordingly, the Court finds that the theory that an antiglutamate could treat ALS was known but unconfirmed as of the priority date of the '814 patent. (See PTX 303, tab 31, AV 71350; Tr. 338-340.)

For example, Dr. Theodore Munsat, an expert in the relevant art, stated that when the '696 application was filed it was reasonable "to try using anitglutamates in treating ALS," but it was not reasonable to expect "that Riluzole would be successful in treating ALS." (See id. at tab 31, AV 71349-71353.) Dr. Munsat further testified about the uncertainty in treating ALS and the disappointing results of many efforts previous to Dr. Louvel's. (Id.) Additionally, Dr. Rothstein testified that the glutamate theory was only one of the theories explaining the pathogenicity of ALS. (Tr. 345.) Even today, only genetic ALS, which accounts for about five percent of incidences of the disease, has a known etiology. (Tr. 338-40.) The Court concludes that this testimony and the state of the art at the time of the invention of the '814 patent demonstrate the speculative nature of the information regarding the treatment of ALS with an antiglutamate.

As further support for the conclusion of non-obviousness, the Court notes that the '814 patent is not directed simply at treating ALS with antiglutamates; rather, the '814 patent asserts the effectiveness of a specific antiglutamate, riluzole. The record evidence establishes that many antiglutamates have proven unsuccessful in treating ALS and that the exact methodology of riluzole in treating ALS is unknown. (Tr. 274-75; Tr. 349.) Thus, to arrive at the disclosures of the '814 patent one of ordinary skill in the art must have been able to divine that an antiglutamate would treat ALS and that the appropriate antiglutamate was riluzole.

The Court concludes that the evidence does not establish that, at the time of invention, one of ordinary skill in the art would have been able to make these deductions. Although riluzole was known to be an antiglutamate, one of ordinary skill in the art would not have known with reasonable certainty that ALS could be treated with an antiglutamate, much less with the specific antiglutamate riluzole. Accordingly, the Court concludes that Impax has not proven, by clear and convincing evidence, that the prior art alleged renders the '814 patent obvious.

C. Whether the '814 Patent is Invalid for Naming the Incorrect Inventors

Impax contends that the true inventor of the '814 patent was not Dr. Louvel, and that RPR intentionally misled the PTO by not revealing the true inventors of the '814 patent. Impax contends

that a clinical study of riluzole conducted in the 1980's involved a patient afflicted with motor neuron disease and only examined diseases in which glutamate was implicated. Impax contends that this study evidences a conception of the '814 patent that pre-dates Dr. Louvel's employment with RPR.

Aventis responds that Impax's contentions are not supported by the record evidence. Aventis contends that Impax does not name any individual that it contends is the inventor and that Dr. Louvel is the sole inventor of the '814 patent.

Failure to name the true inventors will invalidate a patent. Pannu v. Iolab Corp., 155 F.3d 1344, 1349 (Fed. Cir. 1998). However, "[t]here is a presumption that the inventors named on an issued patent are correct, so misjoinder of inventors must be proven by clear and convincing evidence." Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1472 (Fed. Cir. 1997).

After review of the record evidence and the parties' arguments, the Court concludes that the inventorship allegations made by Impax are unduly speculative and not supported by evidence sufficient to support a finding of invalidity. The clinical study cited by Impax only involved determining the safety of riluzole and was not a study to determine the effectiveness of riluzole in treating diseases. (Doble Tr. at 70-71; PTX 37.) Moreover, Impax has not offered the testimony of any individual that claims to be the inventor of the '814 patent,

let alone corroborating evidence, which is required to satisfy the clear and convincing standard of proof, that could confirm Impax's arguments regarding inventorship. See Price v. Symske, 988 F.2d 1187, 1194 (Fed. Cir. 1993). Therefore, the Court concludes that the '814 patent is not invalid based on any allegations related to inventorship.

III. Unenforceability

A. Parties' Contentions

Impax contends that Aventis intentionally withheld several prior art references from the PTO. Specifically, Impax contends that several publications, the knowledge of others skilled in the art, a questioning letter from the FDA, the survival advantages of riluzole, unsupportive test data, and the level of acceptance for the glutamate theory were intentionally withheld from or misrepresented to the PTO.

Aventis responds that all of the information not provided to the PTO was immaterial, superfluous, or less pertinent than the disclosed information. Aventis also contends that Impax has overstated the acceptance of the glutamate theory at the time of the patent application and that there is no credible evidence of an intent to deceive or mislead the PTO.

B. Standard of Law of Unenforceability

As a general matter, patent applicants and their attorneys have a duty of candor, good faith and honesty in their dealings

with the PTO. 37 C.F.R. § 1.56(a). The duty of candor, good faith and honesty includes the duty to submit truthful information and the duty to disclose to the PTO information known to the patent applicants or their attorneys that is material to the examination of the patent application. Elk Corp. of Dallas v. GAF Bldg. Materials Corp., 168 F.3d 28, 30 (Fed. Cir. 1999). Breach of the duty of candor, good faith, and honesty may constitute inequitable conduct. Id. If it is established that inequitable conduct occurred with respect to one or more claims of an application before the PTO, the entire patent is rendered unenforceable. Kingsdown Med. Consultants v. Hollister Inc., 863 F.2d 867, 877 (Fed. Cir. 1988). A party can commit inequitable conduct by misrepresenting a material fact, failing to disclose material information, or submitting false material information with an intent to deceive. Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1362-63 (Fed. Cir. 2003). Inequitable conduct must be proven by clear and convincing evidence. Kingsdown, 863 F.2d at 872.

To establish inequitable conduct due to the failure to disclose material information or the submission of false information, the party raising the issue must prove by clear and convincing evidence that: 1) the information is material; 2) the knowledge of the information and its materiality is chargeable to the patent applicant; and 3) the applicant's submission of false

information or its failure to disclose information resulted from an intent to mislead the PTO. Id. at 877.

The parties dispute the standard of materiality that should be used in examining the '814 patent. The basis of this dispute is a 1992 amendment to 37 C.F.R. § 1.56 which rephrased the PTO's standard for materiality. The Federal Circuit has not decided whether the standard for materiality in inequitable conduct cases is governed by equitable principles or by PTO rules and has not ruled on whether the standard should be changed to reflect the PTO's amendment. Dayco, 329 F.3d at 1364. In this case, the Court finds that, under either standard, Impax has not proven inequitable conduct.

C. Findings of Fact and Conclusions of Law

1. Whether Aventis Withheld Two Articles on the Glutamate Theory and Riluzole

Impax contends that Aventis withheld two material prior art references related to treating ALS with riluzole: 1) the MK-801 article; and 2) "Excitatory Amino Acid Receptors in the Vertebrate Central Nervous System" by Graham L. Collingridge and Robin A.J. Lester (the "Collingridge article").[4] Impax contends that Aventis intended to deceive the PTO by withholding these

[4] Aventis also responds to an allegation by Impax that the McGeer article was withheld. Impax does not cite the McGeer article in its post-trial briefing on unenforceability; however, even if Impax maintained its contention regarding the McGeer article, the Court finds that Impax has not demonstrated materiality or intent with respect to it.

articles and, in doing so, engaged in inequitable conduct.

Aventis responds that the information it did disclose rendered the MK-801 and Collingridge articles superfluous. Specifically, Aventis contends that "Riluzole Antagonises Excitatory Amino Acid-Evoked Firing in Rat Facial Motorneurons In Vivo," by Girdlestone, et al. (the "Girdlestone article") (PTX 303, tab 11), and "Excitotoxins and Amyotrophic Lateral Sclerosis," by Dr. Munsat (the "Munsat article") (PTX 202, tab 19), disclose the glutamate theory and the glutamate inhibiting properties of riluzole. (D.I. 185 at 37.)

The MK-801 article discusses an excitatory amino acid antagonist and states that such antagonists "could [] find a use in chronic neurodegenerative disorders such as... [ALS,]" by "acting to block exogenous or endogenous neurotoxins which are thought to act as excitatory amino acid agonists and contribute to the [etiology] of these conditions." (PTX-61B.)

The Collingridge article is a review of hundreds of research articles. The Collingridge article states that it places a "particular emphasis" on the "types and pharmacology of excitatory amino acid receptors and their roles in neurotransmission in the vertebrate nervous system," but also discusses excitotoxicity, and the possibility that excitotoxins may be responsible for ALS and other neurodegenerative disorders. (PTX 60 at 194-95.) The Collingridge article states that these

excitotoxins may be exogenous or endogenous, and theorizes on how ALS could be caused by endogenous excitotoxins, explaining that "abnormalities in glutamate metabolism or transport could lead to excitotoxic effects of the natural transmitter in ALS." (Id.) In support of this theory, the Collingridge article cites an article by A. Plaitakis and J.T. Caroscio (the "Plaitakis article"), which was disclosed during the prosecution of the '814 patent. (Id.)

The MK-801 and Collingridge articles are the subject of an October 1990 memorandum by Ms. Morvan. (PTX 59.) In her memorandum, Ms. Morvan states that the antiglutamate-ALS correlation was described in the Collingridge and MK-801 articles, and therefore, patenting riluzole to treat ALS would be difficult. (Id.) However, in her deposition, Ms. Morvan testified that she had been mistaken in her memorandum on the MK-801 and Collingridge articles. (Morvan Dep. Tr. at 119-21.) Ms. Morvan testified that, as she received additional information, she changed her mind. (Id.)

The Court finds that Ms. Morvan's memorandum is of limited value. Ms. Morvan's knowledge in the state of the art was limited and her memorandum does not read as a definitive analysis regarding the matter. However, even were the Court to accept that Ms. Morvan's memorandum establishes the materiality of the information in the MK-801 and Collingridge articles, Impax would

still need to show that the information in the MK-801 and Collingridge articles was not otherwise disclosed.

After review of the Girdlestone and Munsat articles, the Court finds that these articles contain disclosures similar to the MK-801 and Collingridge articles. The Girdlestone article discloses that riluzole was a glutamate antagonist. (D.I. 303, tab 11, AV 71787.) The Munsat article discloses that "[recent data suggest[s] that [ALS] could be the result of motoneuron damage induced by endogenous or exogenous excitotoxins and especially by excitatory amino acids." (D.I. 122, exhibit 13.)

Based on the Girdlestone and Munsat articles, the PTO initially accepted the proposition Impax contends is established by the MK-801 and Collingridge articles and denied the '814 patent, finding that one of ordinary skill would have been motivated "to employ riluzole in the treatment of any form of the motor neuron disease, ALS, because riluzole was known in the art as an antiglutamate agent, and antiglutamate agents were known in the art for the treatment of ALS." (D.I. 303, tab 19, AV 71855.) However, Aventis then produced a declaration from Dr. Munsat discussing the unexpectedness of treating ALS with riluzole and convinced the PTO to grant the '814 patent.

The Court is not persuaded by Impax that the Collingridge article disclosed relevant information that is absent from the Munsat article. The Collingridge article discusses the undefined

possibility that ALS might be treated by an antiglutamate. This disclosure is not different or contrary to the disclosure of the Munsat article. Additionally, the Plaitakis article, on which the Collingridge article's statements on ALS and endogenous glutamate relied, was disclosed during the prosecution of the '814 patent.

Further, the MK-801 article is not different or contrary to the disclosure of the Girdlestone article. Thus, the Court finds that the PTO was informed about and knew of riluzole's antiglutamic properties during the prosecution of the '814 patent. (See e.g. D.I. 303, tab 11, AV 71787.) And, applying the principle that "a patentee has no obligation to disclose an otherwise material reference if the reference is cumulative or less material than those already before the examiner, Halliburton Co. v. Schlumberger Technology Corp., 925 F.2d 1435, 1440 (Fed. Cir. 1991), the Court finds that the disclosures of the MK-801 and Collingridge articles were, in essence, contained in the prior art submitted to the PTO. In the Court's view, the PTO was informed about the glutamate theory and the antiglutamate properties of riluzole, and therefore, the failure by Aventis to disclose the MK-801 and Collingridge articles does not support a finding of inequitable conduct.

2. Whether Aventis Withheld Unsupportive Test Data

In 1993 and 1994, Aventis conducted comparative tests on

riluzole and seven other compounds, Pharm 1001 through 1007 (the "comparative tests"). In the comparative tests, Aventis compared the effects of riluzole on dissociated rat spinal cord cells. (PTX 303, tab 12, AV 071236.) The effects of the compounds on three attributes of the cells were analyzed: number of neurons, number of neurites per neuron, and neuronal diameter. (Id. at AV 071237-38.) In the comparative tests, a compound's effect on number of neurons was used to screen for extraneous effects of the compound. An increase in the number of neurites per neuron was thought to indicate effectiveness in treating ALS, and an increase in neuronal diameter was thought to indicate neuronal health and to be pertinent to treating ALS. (Doble dep. (April 29, 2003), pp. 225-26, 32.)

Of the compounds, only riluzole significantly increased the number of neurites per neuron and the neuronal diameter. (PTX 47; PTX 48.) However, some of the other compounds also showed positive results. (Id.) Pharm 1002 showed an increase in neuron diameter and in neurites per neuron, Pharm 1003 showed an increase in neuron diameter, and Pharm 1005 showed an increase in neuron diameter. (Id.)

During the prosecution of the '814 patent, Aventis submitted the comparative test results for riluzole, Pharm 1006, and Pharm 1007 to the patent examiner, but did not submit the test results for the other Pharm compounds. (PTX 303, tab 12, AV 071235, et.

seq.) In submitting the comparative test results to the examiner, Aventis represented that the results comparing riluzole with two compounds described in the '940 patent, Pharm 1006 and Pharm 1007, demonstrated that the effects of riluzole were not obvious. (Id. at 71231.)

Impax contends that Aventis's decision to withhold data on some of the comparative tests was improper. Impax contends that the test results for Pharm 1002, Pharm 1003, and Pharm 1005 contradicted Aventis's representations to the PTO on the testing and were material information that should have been disclosed.

After considering the parties' arguments and reviewing and considering the record evidence, the Court finds that Aventis's partial disclosure of the comparative test results was not inappropriate. Only Pharm 1006 and Pharm 1007 are compounds from the '940 patent. (PTX 20.) Therefore, the Court finds that Aventis's withholding of the results for Pharms 1002, 1003, and 1005, was not inconsistent with its representation to the patent examiner that its invention was not obvious as demonstrated by comparing the test results of riluzole and Pharm 1006 and 1007, both of which are found in the '940 patent.

Despite the limited purpose for which Aventis submitted the comparative test results, Impax contends that the withheld comparative test results, particularly those of Pharm 1002, 1003, and 1005, were material because these comparative tests attempted

to demonstrate the effectiveness of various compounds (many of which were analogues of riluzole) at treating ALS. (Doble dep. (April 29, 2003), pp. 225-26, 32.) The Court disagrees.

Dr. Luis Barbeito and Dr. Alvaro G. Estevez, the doctors who conducted the comparative tests, testified that none of the Pharm compounds tested showed the same pattern of effects as riluzole. (PTX 47 at AV 150443; PTX 48 at AV 150662.) Although some of the Pharm compounds produced significant positive results in one of the two relevant parameters – an increase in neurites per neuron or an increase in neuron diameter – none of the Pharm compounds from the withheld tests produced results significant in both parameters. For example, Pharm 1002 produced increases in neuron diameter and neurites per neuron, but only produced significant increases in neuron diameter. (PTX 47 at AV 150442.) Thus, the withheld comparative testing did not produce results that indicated effectiveness in treating ALS. (Doble dep. (April 29, 2003), pp. 225-26, 32.)

In addition, noticeably absent from Impax's materiality argument is evidence indicating that positive results in one parameter were significant enough to merit inclusion. Dr. Doble stated what each parameter attempted to measure and how each parameter was thought to measure effectiveness in treating ALS, but did not establish the reliability of each hypothesis. (Doble Dep. Tr. (April 29, 2003).) When asked whether the hypothesis on

neurites per neuron has proven correct, Dr. Doble testified that the hypothesis had not been proven. (Doble dep. (April 29, 2003) at pp. 228-29.) Without evidence establishing the reliability and relevance of the tests, the Court cannot find that the threshold for relevance used by Aventis was low or that it excluded material information.

Impax's lack of evidence stands in contrast to the evidence submitted by Aventis that minimizes the value of the testing. The patent examiner explicitly excluded the submitted testing from her decision, and stated that "the applicant has not demonstrated that the testing procedure discussed in the declaration would be accepted by one of ordinary skill in the art as showing the activity of compounds in the claimed method of treatment." (PTX 303, tab 19, AV 71856.) Further, Aventis has asserted, and Dr. Brooks has testified, that the comparative test results were not as valuable as the results of human clinical trials which were submitted to the PTO. (Tr. 410.)

Moreover, the Court notes that even if it were to find a minimal level of materiality with respect to the withheld comparative test results, the complete absence of evidence establishing an intent to deceive would prevent a finding of inequitable conduct. Impax has not offered evidence demonstrating that Aventis's decision to withhold some of the comparative test results was made for some sinister reason.

Thus, although demonstrating a high level of materiality may compensate for a lesser showing of intent, Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1234 (Fed. Cir. 2003), where, as here, there is minimal evidence of materiality and intent, clear and convincing evidence of inequitable conduct does not exist.

3. Whether Letters and an Editorial Critical of the Results of Aventis's Test of Riluzole Were Intentionally Withheld

In March 1994, the New England Journal of Medicine ("NEJM") published "A Controlled Trial of Riluzole in Amyotrophic Lateral Sclerosis," by G. Bensimone (the "Bensimone article"). The Bensimone article published the results of trials conducted to examine treating ALS with riluzole. The same issue of the NEJM contained an editorial, "Riluzole for the Treatment of Amyotrophic Lateral Sclerosis - Too Soon to Tell?," by Lewis Rowland (the "Rowland editorial"), which commented on the tests referenced in the Bensimone article. In July 1994, NEJM published several letters ("NEJM letters") which also discussed the Bensimone article and the tests of riluzole.

Impax contends that the Rowland editorial and NEJM letters are material information that Aventis intentionally withheld from the PTO. Impax contends that the Rowland editorial and the NEJM letters undermine and contradict the Bensimone article and Aventis's assertions about riluzole and its effectiveness in

treating ALS.

The Court finds that the Rowland editorial and the NEJM letters do not directly contradict the Bensimone article. The Rowland editorial does not dispute any of the findings or disclosures of the Bensimone article, but gives an analysis of these findings and disclosures and comments on the meaning of the results. The Rowland editorial discusses the state of ALS research, urges caution in examining a proposed treatment, and points out the minor benefit seen from the use of riluzole in the tests described in the Bensimone article. Similarly, the NEJM letters criticize the trial's methodology and express skepticism at the result of the trials.

Further, the Court finds that the Rowland editorial and the NEJM letters are not comprehensive in their analysis of the Bensimone article and do not contain particularly unique or persuasive comments on treating ALS with riluzole. The Roland editorial and NEJM letters give cursory impressions and opinions, but do not contain substantive information. Several of the concerns and opinions in the Rowland editorial and the NEJM letters are also expressed in the Bensimone article itself. Thus, the Court does not find the Rowland editorial or NEJM letters to be material information.

Additionally, the trial discussed in the Bensimone article was the first of two trials conducted on treating ALS with

riluzole. The patent examiner was informed of the results of both trials and the second trial confirmed the results of the first, lessening the validity and merit of the skepticism and criticism focused solely on the first trial. (PTX 303, tab 29, Av 71341-43.)

Similar to the consideration of the comparative testing, the Court finds that even if the NEJM letters and the Bensimone article were material, the evidence of materiality alone is insufficient to establish an intent by Aventis to deceive the PTO. Therefore, the Court concludes that Impax has not proven, by clear and convincing evidence, that the '814 patent is unenforceable based on Aventis's decision not to submit the Rowland editorial or the NEJM letters to the PTO.

4. Whether a Letter from the FDA was Intentionally Withheld

On February 28, 1996, the FDA sent Aventis a letter discussing Aventis's proposed marketing of riluzole, pointing out various misleading or unsupported statements, and offering suggestions on how to make appropriate changes. (PTX-56; PTX-61A.) Although the FDA's comments were directed at Aventis's proposed marketing, Impax contends that they were also material to the prosecution of the '814 patent.

Impax contends that, during the prosecution of the '814 patent, Aventis and its agents made several representations that were contradicted by the FDA letter. Specifically, Impax

contends that the FDA's statements that "'claims regarding survival benefit must be qualified with an indication of the magnitude of the effect and that claims of the statistical significance for certain points were not substantiated,'" contradicted Aventis's representations on the effect of riluzole on ALS survival. (D.I. 182 at 85 (quoting PTX-61A).) Impax also contends that Dr. Doble knew of the FDA letter, was involved in prosecuting the '814 patent, and can be presumed to have withheld the letter with an intent to mislead the PTO.

Aventis responds that the FDA letter does not contradict any position Aventis took during the prosecution of the '814 patent. Aventis contends that the FDA letter does not contest riluzole's effectiveness and, in fact, approves labeling for the product which states that riluzole extends survival.

The Court finds that Impax has not demonstrated a contradiction between the FDA letter and Aventis's representations to the PTO. The FDA letter criticizes certain marketing representations made by Aventis, but does not question any representation Aventis made in prosecuting the '814 patent. Further, Impax has offered no evidence demonstrating an intent to conceal the letter. Accordingly, the Court concludes that Impax has not, by clear and convincing evidence, demonstrated that the letter is material information or that the letter was withheld from the PTO with an intent to deceive.

5. Whether Aventis Committed Inequitable Conduct with Respect to the Acceptance of the Glutamate Theory

Impax contends that, in prosecuting the '814 patent, Aventis consistently withheld information and attempted to mislead the PTO into believing that the glutamate theory was not accepted. Impax contends that the record evidence demonstrates a pattern of deception concerning the glutamate theory and active suppression and concealment of evidence by Aventis that might have endangered the '814 patent.

Impax contends that the following evidence establishes a pattern of deception by Aventis: 1) Ms. Morvan's previously discussed memorandum that addresses the disclosures of the MK-801 and Collingridge articles; 2) the undisclosed information on the glutamate theory; 3) the letter from Dr. Louvel that acknowledges the scholarship on the link between ALS and excitatory amino acids; 4) letters from Aventis's Patent Department advocating a dynamic policy to get a patent on riluzole and objecting to the publication of articles that might jeopardize the '814 patent; 5) the requested deletion/suppression of a statement about the role of glutamate in ALS in an article on ALS and glutamate; 6) a letter to the FDA stating that "even though the etiology of [ALS] remains to be elucidated, the role of glutamate in the pathophysiology of ALS is generally accepted"; and 7) the practices of Aventis's patent department in prosecuting a different patent.

Aventis responds that its disclosures concerning the glutamate theory were appropriate and not misleading. Aventis contends that it did not attempt to deceptively discredit the glutamate theory or misrepresent its level of acceptance.

After considering the parties' arguments and the record evidence, the Court concludes that Aventis did not make a material misrepresentation to the PTO regarding a lack of acceptance of the glutamate theory. First, as discussed previously, the theory that an antiglutamate could treat ALS was known but unconfirmed at the time of prosecution of the '814 patent. See supra section II(B)(2). Additionally, Aventis submitted articles to the patent examiner that dealt with the glutamate theory, and there is insufficient evidence that Aventis misled or intended to mislead the PTO about the theory and its level of acceptance. Although Aventis advised the FDA that the role of glutamate in the pathophysiology of ALS was generally accepted, Aventis also stated that the etiology of ALS was unknown. In making these statements, Aventis did not establish that the glutamate theory was the accepted explanation of the etiology of ALS or that an antiglutamate would be effective in treating ALS.

In sum, the Court finds that Aventis disclosed the glutamate theory to the PTO and did not mislead the PTO in its disclosure. Accordingly, the Court concludes that Impax has failed to

demonstrate a misrepresentation necessary to support its allegations of concealment.

In addition, the Court concludes that Impax's evidence falls short of establishing a general policy, by Aventis, of concealing information on the glutamate theory. The Court finds the decisions in Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., et al., No. 95 Civ. 8833 (RPP), relied on by Impax, to be of limited relevance here. Further, the "suppressive" memoranda and letters adduced demonstrate a high level of concern about producing scholarship that discloses the '814 patent. However, the Court concludes that it is not enough that, in producing documents and scholarship for public viewing, Aventis was concerned about the effects these documents might have on its patent prosecution; an intent to mislead the PTO and a material misrepresentation or a withholding of information must have occurred, none of which Impax has established in this case.

IV. Exceptional Case

Both parties contend that this is an exceptional case and that attorneys fees and costs should be awarded pursuant to 35 U.S.C. § 285. Aventis contends that the Court should deny Impax's request because Impax bases its arguments on the presumption that Aventis committed inequitable conduct in obtaining the '814 patent. In addition, Aventis contends that it should be awarded fees because Impax had no reasonable basis to

initiate the instant lawsuit when it had little to no evidence in support of its arguments.

Impax responds that an award of fees in this case are justified because Aventis engaged in inequitable conduct in procuring the '814 patent. With respect to Aventis's request for attorney fees, Impax contends that this request is inappropriate because it has not sold any riluzole, and there is no claim for damages or willful infringement.

Attorney's fees may be awarded to the prevailing party in a patent case if a court finds the case to be exceptional. 35 U.S.C. § 285. Among the types of conduct that may render a case "exceptional" are "inequitable conduct before the P.T.O., misconduct during litigation, vexatious or unjustified litigation, and frivolous suit." Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 455 (Fed. Cir. 1985)(citing Beckman Instruments, Inc. v. LKB Produkter AB, 892 F.2d 1547, 1551 (Fed. Cir. 1989)). Once a court determines that a case is exceptional, a court may exercise its discretion to award reasonable attorneys fees to the prevailing party. Mach. Corp. of Am. v. Gullfiber AB, 774 F.2d 467, 470 (Fed. Cir. 1985).

After reviewing the parties' pre- and post-trial submissions, the Court concludes that neither party should be granted attorney's fees. With respect to Impax's request, the Court notes that Impax's has not prevailed on its arguments

concerning inequitable conduct or adduced evidence of bad faith on the part of Aventis in procuring the '814 patent.

With regard to the request of Aventis, the Court cannot find that, after presiding over the trial in this case, Impax's filing of this action was done without investigation or that the arguments presented in its submissions were without any basis in law or fact. The Court is without evidence that would persuade it to find an abuse of the judicial process by Impax, and therefore, the Court will deny the request of Aventis for attorney's fees.

CONCLUSION[5]

For the reasons discussed, the Court concludes that the '814 patent is valid and enforceable. The Court also concludes that claims 1, 4, and 5 of the '814 patent have been infringed based on Impax's proposed manufacture and sale of riluzole. No later than September 6, 2004, Aventis shall submit a Proposed Judgment Order with notice to Impax.

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[5] The parties also contest whether Impax's proposed manufacture and sale of riluzole will induce infringement of claims 2 and 3 of the '814 patent. The Court has found that claims 1, 4, and 5 of the '814 patent are valid and enforceable and, therefore, it is undisputed that Impax's manufacture and sale of riluzole will infringe these claims. (See D.I. 148 at Ex. 1.) Under these circumstances, Impax may not engage in the manufacture or sale of riluzole regardless of whether its proposed actions would induce infringement of claims 2 and 3 of the '814 patent. Therefore, the Court finds it unnecessary to render a decision regarding the parties' arguments on indirect infringement.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

IMPAX LABORATORIES, INC.,	:	
	:	
Plaintiff,	:	
	:	Civil Action No. 02-581 JJF
v.	:	
	:	
AVENTIS PHARMACEUTICALS, INC.,	:	
	:	
	:	
Defendant.	:	

O R D E R

At Wilmington, this 30th day of August, 2004, for the reasons discussed in the Memorandum Opinion issued this date;

IT IS HEREBY ORDERED that:

1) Impax Laboratories, Inc.'s ("Impax") Motion To Admit Documents Into Evidence (D.I. 184) and Aventis Pharmaceuticals, Inc.'s ("Aventis") Cross-Motion To Admit Documents (D.I. 187) are **GRANTED**;

2) Impax's Motion In Limine Pursuant To Fed. R. Evid. 201(d) That The Court Take Judicial Notice Of Adjudicated Facts Of Public Record In Bristol-Myers Case (D.I. 175) is **GRANTED**;

3) Aventis's Cross-Motion In Limine To Exclude From Evidence The Facts Of The Bristol-Myers Case (D.I. 181) is **DENIED**;

4) U.S. Patent No. 5,527,814 (the "'814 patent") is valid

and enforceable;

5) Impax's proposed manufacture and sale of riluzole infringes claims 1, 4, and 5 of the '814 patent;

6) Aventis shall submit a Proposed Judgment Order to the Court no later than September 6, 2004.

JOSEPH J. FARNAN, JR.
UNITED STATES DISTRICT JUDGE