

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

WESLEY JESSEN CORPORATION            )  
  )  
                  Plaintiff,            )  
  )  
          v.                            )     C.A. No. 01-294-###  
  )  
BAUSCH & LOMB INC.,                )  
  )  
                  Defendant.         )

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**MEMORANDUM OPINION**

Dated: December 6, 2002  
Wilmington, Delaware

**ROBINSON, Chief Judge**

**I. INTRODUCTION**

On May 3, 2001, plaintiff Wesley Jessen Corporation filed an action against defendant Bausch & Lomb, Inc., alleging patent infringement. (D.I. 1) After a bench trial, former Judge Roderick McKelvie issued an opinion on June 26, 2002, finding that defendant's accused product infringed plaintiff's patent. (D.I. 146) In conjunction with the opinion, a permanent injunction was entered prohibiting defendant from making, using, or selling the infringing product. (D.I. 147) Presently before the court is defendant's motion to modify the injunction and plaintiff's cross-motion for order to show cause why defendant is not in contempt of the injunction. (D.I. 155, 164) This court has jurisdiction pursuant to 28 U.S.C. § 1331.

**II. BACKGROUND**

Plaintiff is the owner of U.S. Patent No. 4,711,943 entitled "Hydrophilic siloxane monomers and dimers for contact lens materials, and contact lenses fabricated therefrom" ("the '943 patent"). The '943 patent generally relates to extended-wear, soft-lens contact lenses. The '943 patent issued on December 8, 1987 and is set to expire on April 26, 2005.

Prior to this suit, defendant manufactured and sold an extended-wear, soft-lens contact product under the name PureVision. Extended-wear, soft-lens contact lenses are

considered regulated medical devices and are subject to regulation by the Food and Drug Administration ("the FDA"). Prior to commercially marketing its PureVision product, defendant applied for and received FDA approval to market and sell its PureVision product for 1-day wear and 7-day wear. Subsequently, defendant began commercially selling its PureVision product to consumers.

Additionally, defendant applied to the FDA for approval of its PureVision product for 30-day extended wear. For this application, the FDA granted defendant conditional approval. (D.I. 156, Ex. A) The FDA's approval was conditioned on defendant's conducting a post-approval study to collect follow-up data on the adverse effects associated with using the PureVision product for up to 30 days. In response to this imposed condition, defendant and the FDA devised a study to follow at least 6,500 subjects using the PureVision product over the period of one year. In its conditional approval, the FDA stated that defendant's failure to perform the study and submit the data to the FDA would result in the withdrawal of the approval.

Before the study began, plaintiff brought this action against defendant alleging infringement of its '943 patent by defendant's PureVision product. This case went to trial during the pendency of the study, resulting in a finding that defendant's product infringed a number of claims of the '943

patent literally and under the doctrine of equivalents.

Consistent with the finding of infringement, a permanent injunction was entered which provided that:

Bausch & Lomb and its officers, subsidiaries, affiliates, entities controlled by Bausch & Lomb, agents, servants, employees and those persons in active concert or participation with them are hereby ENJOINED and RESTRAINED from making, using, offering for sale, or selling in the United States contact lens materials and contact lenses made from the material known as Balafilcon A and the contact lenses marketed under the trade name PureVision.

(D.I. 147 ¶ 5)

Defendant now contends that this injunction is overly broad and encompasses legal and proper activities under 35 U.S.C. § 271(e)(1). In particular, defendant asserts that its ongoing post-injunction use and sale of its PureVision product in connection with the FDA mandated post-approval study is within the § 271(e)(1) exception and that the injunction should be modified to reflect such.

Plaintiff contends that § 271(e)(1) does not include post-approval studies and defendant is in contempt for violating the injunction by continuing the study after the injunction issued. Plaintiff also argues that defendant's motion to modify the injunction does not fall within the scope of Fed. R. Civ. P. 60(b)(5) or 60(b)(6) and that this court does not have jurisdiction to determine whether or not defendant's post-approval study falls within the § 271(e)(1) exception.

### III. STANDARD OF REVIEW

Motions under Rule 60(b) "may not generally substitute for an appeal." Marshall v. Board of Ed. of Bergenfield, NJ, 575 F.2d 417, 424 (3d Cir. 1978). Rather, relief under Rule 60(b) is available only under such circumstances that the "overriding interest in the finality and repose of judgments may properly be overcome." Martinez-McBean v. Government of the Virgin Islands, 562 F.2d 908, 913 (3d Cir. 1977). However, during the pendency of an appeal, a district court is not divested of jurisdiction to modify injunctions. Venen v. Sweet, 758 F.2d 117, 121 n.2 (3d Cir. 1985).

Under Rule 60(b)(5) a court may relieve a party from a final judgment or order when "it is no longer equitable that the judgment should have prospective application." Fed. R. Civ. P. 60(b)(5). A party can show that a judgment should no longer have prospective application if it can demonstrate "a significant change in either factual conditions or the law." Rufo v. Inmates of Suffolk County Jail, 502 U.S. 367, 384 (1992). Ordinarily, modification should not be granted where a party relies upon events that actually were anticipated at the time it entered into a decree. Id. at 385.

Rule 60(b)(6) is a catchall provision which allows a court to relieve a party from the effects of an order for "any other reason justifying relief from the operation of the judgment."

Fed. R. Civ. P. 60(b)(6). It is within the sound discretion of the trial court to grant or deny relief under this section. Lasky v. Continental Products Corp., 804 F.2d 250, 256 (3d Cir. 1986). However, relief from judgment pursuant to Rule 60(b)(6) provides for extraordinary relief and may only be invoked upon a showing of exceptional circumstances. Coltec Indus. v. Hobgood, 280 F.3d 262, 273 (3d Cir. 2002); In re Fine Paper Antitrust Litig., 840 F.2d 188 (3d Cir. 1988).

#### **IV. DISCUSSION**

##### **A. The Court's Jurisdiction to Hear Defendant's Motion**

Plaintiff initially contended that this court did not have jurisdiction to hear defendant's motion to modify the injunction. Plaintiff asserted that since defendant was essentially seeking a declaratory judgment that its post-approval activities were non-infringing activities under § 271(e)(1), this court was not in a position to address defendant's motion. (D.I. 165 at 2) However, in order to properly put the issue before the court, plaintiff cross-moved for an order to show cause why defendant should not be held in contempt for violating the injunction. Therefore, the court may now reach the merits of defendant's arguments.

##### **B. Defendant's Motion to Modify the Injunction**

Defendant argues that the language of the permanent injunction is overly broad in light of 35 U.S.C. § 271(e)(1) and

must be amended to permit legal activities under this section.

(D.I. 156 at 1) Defendant further argues that this amendment may be made by this court pursuant to Rule 60(b)(5) or 60(b)(6) which state in relevant part:

On motion and upon such terms as are just, the court may relieve a party or a party's legal representative from a final judgment, order, or proceeding for the following reasons:

(5) the judgment has been satisfied, released, or discharged, or a prior judgment upon which it is based has been reversed or otherwise vacated, or it is no longer equitable that the judgment should have prospective application; or

(6) any other reason justifying relief from the operation of judgment.

Fed. R. Civ. P. 60(b)(5), 60(b)(6).

Plaintiff argues that defendant's intended modification does not fall within the scope of Rule 60(b)(5). (D.I. 165 at 3) It argues that there has been no significant change in the facts or law since the injunction was entered and that defendant could have anticipated the injunction. Furthermore, defendant knew its ongoing FDA study would be affected by the injunction and it should have moved to amend under Rule 59(e) within 10 days of entry of judgment. The court agrees with plaintiff. Defendant was on notice of the court's injunction when judgment was entered and should have foreseen that the injunction as worded would affect its FDA study. The appropriate remedy would have been a Rule 59(e) motion. Additionally, there has been no change in the circumstances or law related to this case. Therefore,

modification of the injunction under Rule 60(b)(5) would be improper.

Next, in its reply brief, defendant contends that modification of the injunction pursuant to Rule 60(b)(6) would be proper. (D.I. 170 at 8) Defendant fails to cite to any cases in support of its argument, nor does it cite any facts alleging that there are "exceptional circumstances" requiring a modification, the standard in this jurisdiction. See Coltec Indus. v. Hobgood, 280 F.3d 262, 273 (3d Cir. 2002). However, given the fact that the parties do not disagree on the language or the substance of the proposed modification,<sup>1</sup> and for the reasons that follow, the court will grant defendant's motion and modify the injunction to read as follows:

Bausch & Lomb and its officers, subsidiaries, affiliates, entities controlled by Bausch & Lomb, agents, servants, employees and those persons in active concert or participation with them are hereby ENJOINED and RESTRAINED from making, using, offering for sale, or selling in the United States contact lens materials and contact lenses made from the material known as Balafilcon A and the contact lenses marketed under the trade name PureVision, but are not prevented from undertaking those activities which are permitted by 35 U.S.C. § 271(e)(1).

**C. Plaintiff's Motion for Contempt**

Plaintiff argues that notwithstanding the modified language

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<sup>1</sup>Both parties agree that activities permitted under 35 U.S.C. § 271(e)(1) are not acts of infringement and, therefore, are outside the scope of the injunction. Consistent with the parties' position, the court will modify the injunction to explicitly state this proposition.

of the injunction, defendant's activities are in violation of the injunction and defendant should be held in civil contempt. (D.I. 165 at 7) In order to prevail on a motion for civil contempt, a plaintiff must prove three elements by clear and convincing evidence: (1) that a valid order of the court existed; (2) that the defendants had knowledge of the order; and (3) that the defendants disobeyed the order. Roe v. Operation Rescue, 54 F.3d 133, 137 (3d Cir. 1995).

The parties do not dispute the first two elements. They both agree that a valid court order exists and defendant has knowledge of the order. The parties do dispute the third element, whether or not defendant disobeyed the order. At the center of the dispute is whether or not defendant's post-approval activities fall within the scope of 35 U.S.C. § 271(e)(1).

The parties contend that whether post-approval activities are within the scope of § 271(e)(1) is an issue of first impression. Neither party cites, nor has the court found, any cases that squarely address this issue. Therefore, the court must make its determination in light of the language of the statute and guiding principles from the Federal Circuit. Section 271(e) states in relevant part:

(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)

which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

\* \* \*

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

35 U.S.C. § 271(e).

In its interpretation of the statute, defendant argues that the Federal Circuit has construed the § 271(e)(1) exception broadly, as recognized by this court. See Abtox, Inc. v. Exitron Corp., 122 F.3d 1019, 1030 (Fed. Cir. 1997); Nexell Therapeutics, Inc. v. Amcell Corp., 143 F. Supp. 2d 407, 421-22 (D. Del. 2001). Furthermore, courts have deferred to the FDA in determining what activities are reasonably related to the development and submission of information. In light of these principles, defendant asserts that since the FDA conditioned its approval of defendant's 30-day extended use application of its PureVision product on this post-approval study, the activities pursued in carrying out the study are reasonably related to the development and submission of information to the FDA and, therefore, are within the scope of the § 271(e)(1) exception. Defendant contends that its post-approval study is limited in scope and

duration and notes that the FDA stated that if defendant fails to conduct the study and submit data to the FDA, its conditional approval will be revoked.

Plaintiff contends that § 271(e)(1) does not apply to defendant's post-approval study and, therefore, defendant's activities are in violation of the court's injunction regardless of its language. In support of its argument, plaintiff asserts that it is only defendant's 30-day extended use application that is conditional, not use for either daily or 7-day use. Furthermore, plaintiff argues that defendant has not introduced any evidence that the FDA would revoke its conditional approval if defendant did not complete the study. Finally, plaintiff argues that the language and legislative history of § 271(e)(1) supports the conclusion that the statute does not include post-approval activities.

For the following reasons, the court concludes that defendant's post-approval activities are within the scope of § 271(e)(1). Plaintiff's first argument - that defendant already has approval for daily and 7-day use of its PureVision product and will not be precluded from marketing its product for these uses after the expiration of the patent - is irrelevant. Although defendant does have unconditional approval for its PureVision product for daily and 7-day use, its approval for 30-day extended use is conditioned by the FDA on completion of the

study. The fact that defendant does have other approved uses for its product does not preclude defendant from seeking approval for the full range of uses for its product within the bounds of § 271(e) (1).

Equally unavailing is plaintiff's next argument that defendant has produced no evidence that the FDA would actually revoke defendant's conditional acceptance if it did not complete the study. In support of this contention, plaintiff submits a declaration that the FDA might be willing to accept other alternatives to its approved study. The explicit terms of the FDA's conditional approval letter, however, state that "[f]ailure to comply with the conditions of approval invalidates this approval order." (D.I. 156, Ex. A) No further evidence is necessary and plaintiff's assertion that defendant should be expected to stop its study and hope the FDA does not enforce the terms of its own conditional approval is not persuasive.

Finally, plaintiff argues that the language and legislative history of § 271(e) (1) support the conclusion that post-approval activities are not within the scope of the statute. The court disagrees. Nowhere in the express language of § 271(e) (1) does Congress make a distinction between pre-approval and post-approval activities. In fact, the only standard Congress placed in the text of § 271(e) (1) is that the activity must be "solely for uses reasonably related to the development and submission of

information under a Federal law.”

In this case, defendant’s post-approval study is narrowly tailored and directly related to the development and submission of information to the FDA. The text of the FDA’s conditional approval letter states:

Your postapproval study will collect 1 year follow-up data to evaluate the serious adverse events associated with the use of PureVision lenses when used for approximately 30 day continuous wear for 5000 subject years. The postapproval study will assess the rate of microbial keratitis that occurred during the 1 year follow-up period. The ongoing results of this study must be submitted annually to the FDA in the PMA annual report. Additionally, you must submit a final report and revised labeling in a PMA supplement when the postapproval study is completed.

(D.I. 156, Ex. A at 2) Thus, on its face, defendant’s study protocol is reasonably related to the development and submission of information as determined by the FDA. Since Congress has not distinguished between pre-approval and post-approval activities in the text of § 271(e)(1), nor have any courts proposed such a distinction, this court will not engage in rewriting the text of § 271(e)(1) to include such a limitation.

Plaintiff cites to the following legislative history of § 271(e)(1) in support of its contentions:

The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement.

H.R. No. 98-857, at 45 (1984), reprinted in 1984 U.S.C.C.A.N.

2647, 2678. Nowhere in this language, however, does Congress show an intent to limit the § 271(e)(1) exception solely to pre-approval activities. Rather, the clear language states that the purpose of the § 271 exception is to allow for a drug maker to prepare for commercial activity after a patent expires. In this case, that is exactly what defendant is doing. It is performing its study to garner unconditional approval for 30-day extended use of its PureVision product. After plaintiff's patent expires in 2005, defendant will be able to commercially market its FDA approved product. Plaintiff has submitted no evidence that defendant's study is not a bona fide effort to obtain FDA approval or that the study is merely a marketing plan. Given that defendant's protocol was approved and required by the FDA, the court concludes that it is solely for uses reasonably related to the development and submission of information as required by § 271(e)(1).

Consistent with this conclusion and the language of § 271(e)(3) which states "no injunctive or other relief may be granted which would prohibit [lawful activities under § 271(e)(1)," the court will modify the injunction and deny plaintiff's motion for contempt.

#### **IV. CONCLUSION**

For the reasons stated, defendant's motion to modify the injunction (D.I. 155) is granted and plaintiff's cross-motion for contempt (D.I. 164) is denied. An appropriate order shall issue.

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

WESLEY JESSEN CORPORATION            )  
  )  
                  Plaintiff,                )  
  )  
          v.                                )     C.A. No. 01-294-###  
  )  
BAUSCH & LOMB INC.,                 )  
  )  
                  Defendant.             )

**O R D E R**

At Wilmington, this 6th day of December, 2002,  
consistent with the memorandum opinion issued this same day;

IT IS ORDERED that:

1. Defendants' motion to modify the injunction (D.I. 155) is granted.
2. Plaintiff's cross-motion for order to show cause why defendant is not in contempt of the injunction (D.I. 164) is denied.

Sue L. Robinson  
United States District Judge