

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WESLEY JESSEN CORPORATION,)
)
Plaintiff,)
)
v.)
) Civil Action No. 01-294-KAJ
BAUSCH & LOMB, INC.,)
)
Defendant.)
)

MEMORANDUM OPINION

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Wilmington, Delaware
April 3, 2003

JORDAN, District Judge

I. INTRODUCTION

Plaintiff Wesley Jessen Corporation (“Wesley Jessen”) moves the Court for an order to show cause why defendant Bausch & Lomb, Inc. (“Bausch & Lomb”) should not be held in civil contempt for violating the terms of a Court imposed injunction (see Docket Item [“D.I.”] 179 at 7-8, D.I. 180 at ¶ 1) prohibiting Bausch & Lomb from further infringing Wesley Jessen’s U.S. Patent No. 4,711,943 (issued Dec. 8, 1987) (the “943 patent”). (D.I. 182.) In conjunction with its motion, Wesley Jessen seeks an order permitting discovery into the allegedly infringing activities of Bausch & Lomb. (D.I. 182 at ¶ 2; D.I. 183 at 1, 8.)

II. BACKGROUND

Wesley Jessen filed this patent infringement suit against Bausch & Lomb on May 3, 2001. (See D.I. 1.) The case came to trial in June, 2002, and, after a five day bench trial, the Court¹ held that Bausch & Lomb infringed Wesley Jessen’s ‘943 patent. (D.I. 146 at 59-74; 147 at ¶ 1.) Wesley Jessen sought no damages, opting instead for a permanent injunction against further infringement of the ‘943 patent by Bausch & Lomb. (D.I. 146 at 103.) On June 26, 2002, the Court entered a permanent injunction enjoining and restraining “Bausch & Lomb . . . [,] its officers, subsidiaries, affiliates, entities controlled by Bausch & Lomb, agents, servants, employees and those persons in active concert or participation with them . . . from making, using, offering for sale, or selling in the United

¹The case was tried before the Honorable Roderick R. McKelvie, prior to his retirement from the Court. It was thereafter assigned to the Honorable Sue L. Robinson for a period and then reassigned to me on January 6, 2003. (D.I. 181.)

States contact lens materials and contact lenses made from the material known as Balafilcom A and the contact lenses marketed under the trade name PureVision.” (D.I. 147 at 2, ¶ 5.) Wesley Jessen now alleges that Bausch & Lomb has violated the terms of the Court’s injunction by shipping from the United States to a Waterford, Ireland production facility both PureVision contact lenses and components of PureVision lenses.² (D.I. 182 at ¶ 1.)

III. STANDARD OF REVIEW

Wesley Jessen must prove three elements by clear and convincing evidence to prevail on a motion for civil contempt: (1) that there was a valid court order, (2) that Bausch & Lomb had knowledge of the order, and (3) that Bausch & Lomb disobeyed the order. *Roe v. Operation Rescue*, 54 F.3d 133, 137 (3d cir. 1995). To obtain discovery based on allegations of civil contempt, Wesley Jessen must make a *prima facie* showing that a court order has been disobeyed. *N.W. Controls, Inc. v. Outboard Marine Corp.*, 349 F. Supp. 1254, 1256 (D. Del. 1972).

²Bausch & Lomb earlier moved the Court to modify the injunction (D.I. 155), contending that it was overly broad since it encompassed activities that are lawful under 35 U.S.C. § 271(e)(1) (2003), which provides that “[i]t 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 patent invention . . . 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.” Bausch & Lomb manufactures and sells extended-wear, soft-lens contact lenses which “are considered regulated medical devices . . . subject to regulation by the Food and Drug Administration (“the FDA”).” (D.I. 179 at 2.) Since the Court’s June 26, 2002 injunction (D.I. 147 at 2, ¶ 5) prevented Bausch & Lomb from conducting activities before the FDA that are permitted by Section 271(e)(1) as to products covered by the ‘943 patent, Bausch & Lomb requested that the Court modify the injunction. (D.I. 179 at 1-3.) The Court granted Bausch & Lomb’s request to modify the injunction in accordance with § 271(e)(1) since both parties agreed (see D.I. 179 at 7 n.1.) on the language and the substance of the modification. (D.I. 179 at 7; D.I. 180 at ¶ 1.)

IV. DISCUSSION

1. The Parties' Arguments

There is no dispute between the parties regarding the validity of the Court imposed injunction in this case. (See *generally* D.I. 183; D.I. 184; D.I. 185; D.I. 190; D.I. 192.) The parties also do not dispute that Bausch & Lomb knew of the injunction. (*Id.*) The parties' dispute centers on whether Bausch & Lomb's export of PureVision contact lenses and components of PureVision contact lenses contravenes the prohibition in the Court's injunction against making, using, offering for sale, or selling the '943 patented invention in the United States. (D.I. 183 at 2-7; D.I. 184 at 5-16; D.I. 185 at 1-10; D.I. 192 at 1-2.) The parties also dispute whether Wesley Jessen's contempt allegations warrant discovery into these matters, and whether 35 U.S.C. § 271(f)(1) or (f)(2)³ should be read into the Court's injunction. (*Id.*)

³Section 271(f)(1) and (f)(2) provides as follows:

(f)(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(f)(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

Citing *Johns Hopkins University v. Cellpro, Inc.*, 152 F.3d 1342 (Fed. Cir. 1998), Bausch & Lomb argues that exporting patented inventions is not patent infringement because it is not a “use” of the invention. (D.I. 184 at 9 (citing *Cellpro* at 1366).) Bausch & Lomb further argues that its activities cannot constitute a prohibited “offer to sell” because case law provides that an “offer to sell” is not an act of infringement unless “[t]he sale itself, the shipment of the product, the delivery of the product” would be in the United States. (D.I. 190 at 17-18 (discussing *Cybiotronics, LTD v. Golden Source Electronics, LTD*, 130 F. Supp. 2d 1152 (C.D. Cal. 2001); *Quality Tubing, Inc. v. Precision Tube Holdings Corp.*, 75 F. Supp. 2d 613 (S.D. Tex 1999).) This is so, reasons Bausch & Lomb, “because the U.S. patent statutes don’t control overseas activity. They can’t reach overseas activity.” (*Id.* at 18.) Therefore, maintains Bausch & Lomb, its activities do not contravene the Court’s injunction because it did not “offer to sell” or “sell” the ‘943 patented invention in the United States. (*Id.*; see also D.I. 184 at 14-16.) Bausch & Lomb further asserts that Wesley Jessen has failed to make a *prima facie* showing that Bausch & Lomb has engaged in any prohibited activity and therefore it would be inappropriate to allow Wesley Jessen to conduct any discovery. (*Id.*)

As to 35 U.S.C. § 271(f)(1) and (f)(2), Bausch & Lomb, noting that the express language of the Court’s injunction does not enjoin activity under § 271(f)(1) or §271(f)(2), argues that under Supreme Court, Third Circuit, and Federal Circuit authority, the Court cannot read into the injunction “activities not specifically prohibited.” (*Id.* at 11-12 (citing *Terminal R.R. Ass’n of St. Louis v. United States*, 266 U.S. 17 (1924); *Ford v. Kammerer*,

450 F.2d 279 (3d Cir. 1971); *KSM Fastening Sys., Inc. v. H.A. Jones Co., Inc.*, 776 F.2d 1522 (Fed. Cir. 1985)).) (D.I. 184 at 11-14.)

For its part, Wesley Jessen argues that Bausch & Lomb's exporting activities amount to an infringing "use," "offer to sell," or "sale" of the '943 patented invention. (D.I. 183 at 2-4; D.I. 185 at 1-7; D.I. 192 at 1-3.) Wesley Jessen argues that *Cellpro* does not control the present situation because, unlike *Cellpro*, the infringing products in this case were made after the patent issued and were exported after the Court imposed its injunction. (D.I. 183 at 3-4; D.I. 185 at 1-3.) Moreover, asserts Wesley Jessen, even if *Cellpro* were controlling, the shipments at issue here, in and of themselves, amount to patent infringement in contempt of the Court's injunction because the shipping amounts to a "use" of the patented invention within the United States. (D.I. 183 at 3-4; D.I. 185 at 4-7.)

Wesley Jessen also contends that the shipments abroad were preceded by an "offer to sell" the patented invention in the United States, and, therefore, under *Rotec Indus., Inc. v. Mitsubishi Corp.*, 215 F.3d 1246 (Fed. Cir. 2000), Bausch & Lomb has infringed the '943 patent and violated the injunction. (D.I. 183 at 3-4; D.I. 185 at 2-4; D.I. 192 at 1-3.) Similarly, Wesley Jessen argues that a "sale" of the infringing products may have occurred in the United States before the products were exported, constituting another violation of the Court's injunction. (*Id.*)

As to components of PureVision lenses, Wesley Jessen argues that the shipping of those components constitutes infringement under 35 U.S.C. § 271(f)(1) or (f)(2) and thus is in contravention of the Court's injunction because "the injunction should be read to cover *all* acts of infringement." (D.I. 183 at 4-7, D.I. 185 at 8-10; D.I. 190 at 8-10.) Finally,

regarding discovery, Wesley Jessen contends that, at a minimum, Bausch & Lomb's activities warrant an order permitting discovery into Bausch & Lomb's allegedly infringing and contemptuous activities. (D.I. 182 at ¶ 2; D.I. 183 at 1, 8.)

2. Analysis

a. "use"

The Court is unpersuaded by Wesley Jessen's argument that exporting or shipping patented inventions to foreign destinations constitutes an infringing "use" under § 271(a). It stretches the fair meaning of the word "use" beyond recognition to say that shipping a product is a use of the product. More to the point, however, the Federal Circuit has already held that "neither export from the United States nor use in a foreign country of a product covered by a United States patent constitutes infringement."⁴ *Cellpro*, 152 F.3d at 1366. It follows that the export of a patented invention, even if motivated by commercial interests, cannot, in and of itself, be an infringing "use" of the patented invention. Bausch & Lomb, therefore, did not "use" Wesley Jessen's patented invention by shipping PureVision contact lenses and components of PureVision contact lenses to Waterford, Ireland.

b. "offer to sell" and "sale"

In 1994, Congress amended 35 U.S.C. § 271(a) to add to the list of activities that constitute patent infringement the unauthorized "offer to sell" a patented invention. Uruguay Round Agreements Act, Pub. L. No. 103-465, § 533(a), 108 Stat. 4809, 4988 (1994). On January 1, 1996, that amendment took effect. See *id.* § 534, 108 Stat. at 4990.

⁴See also *Quantum Group, Inc. v. Am. Sensor, Inc.*, No. 96 C 0761, 1998 WL 171837, *6 (N.D. Ill. April 10, 1998) ("[R]eceiving, storing or shipping the products" is not a "use."); *Amgen, Inc. v. Elanex Pharms., Inc.*, No. C93-1483D, 1996 WI 84590, *4 (W.D. Wash. Feb. 6, 1996) ("[S]hipping the product overseas does not infringe the ... patent.").

The Federal Circuit first addressed that new form of infringement in *3D Sys., Inc. v. Aarotech Labs., Inc.*, 160 F.3d 1373, 1378 (Fed. Cir. 1998).

At issue in *3D Systems* was whether promotional letters, order solicitations, and price quotations directed at residents of plaintiff's forum state by an out-of-state defendant created minimum contacts with the forum state to establish personal jurisdiction over the defendant. *Id.* at 1378-79. The Federal Circuit applied the test for personal jurisdiction set forth in *Akro Corp. v. Luker*, 45 F.3d 1541, 1545-46 (Fed. Cir. 1995), and held that the defendant's contact with the forum state was sufficient to establish personal jurisdiction. *3D Systems.*, 160 F.3d at 1378-80. In addressing the second prong⁵ of the *Akro* three-prong test, *i.e.*, whether the claim arises out of or relates to purposeful activities directed by defendant to the forum, the Court confronted the meaning of "offer to sell" under § 271(a). *Id.* The Federal Circuit reasoned that "[t]he statutory character of the 'offer to sell' requires us to 'look back to federal law on the conceptualization' of the 'offer to sell' itself." *Id.* at 1379. The Court first considered applying principles used in analyzing the "on sale" bar of 35 U.S.C. § 102(b) but, reasoning that the policy reasons underlying the two provisions differed, "decline[d] to import the authority construing the 'on sale' bar ... into the 'offer to sell' provision of § 271(a)." *Id.* n.4. The Court then held that "[a]s a matter of federal statutory construction, the price quotation letters can be regarded as 'offer[s] to sell'

⁵In *Akro* the Federal Circuit:

outlined a three-prong minimum contacts test for determining if specific jurisdiction existed: (1) whether the defendant purposefully directed its activities at residents of the forum, (2) whether the claim arises out of or relates to those activities, and (3) whether assertion of personal jurisdiction is reasonable and fair.

3D Sys., 160 F.3d at 1378 (citing *Akro*, 45 F.3d at 1545-46.).

under § 271 based on the substance conveyed in the letters, *i.e.*, a description of the allegedly infringing merchandise and the price at which it can be purchased.”⁶ *Id.* at 1379. In reaching its holding, the Court reasoned that “the prohibition added to § 271(a) would be hollow indeed[]”, *id.*, if potential infringers were permitted to engage in the “activity ... [defendant] has engaged in, *i.e.*, generating interest in a potential infringing product to the commercial detriment of the rightful patentee.” *Id.*

The Federal Circuit again examined “offer to sell” liability under § 271(a) in *Hollyanne Corp. v. TFT, Inc.*, 199 F.3d 1304 (Fed. Cir. 1999), to address “whether an offer to donate is the equivalent of an offer to sell” *Id.* at 1308. The Court concluded that “to be an offer to sell for purposes of section 271(a) the alleged offer must include more than a mere invitation to accept a gift.” *Id.* at 1309-10. “[T]he offer [must] include ... the hallmarks of a potential commercial transaction” *Id.*

Finally, in *Rotec, supra*, the Court dealt with the “offer to sell” language in a case more analogous to the one at bar. The plaintiff in *Rotec* sued for patent infringement, pointing to a number of commercial activities it alleged the defendants undertook in the United States and arguing that the defendants had made here an “offer to sell” plaintiff’s patented invention. 215 F.3d at 1248-50. “Defendants moved to dismiss for failure to state a claim, arguing that Rotec could not prove that Defendants committed the alleged act of infringement -- the offer to sell -- within the United States[]”, *id.* at 1250, because the “offer was made in China, not the United States, thereby absolving them of any § 271(a) liability.” *Id.* at 1251.

⁶The Court also stated that its definition of “offers to sell” in § 271(a) “harmonizes with the broad definition of “offer to sell” provided in § 271(i).” *Id.*

The Federal Circuit approached the issue by first noting that “extraterritorial activities ... are irrelevant to the case ..., because ‘[t]he right conferred by a patent under our law is confined to the United States and its territories, and infringement of this right cannot be predicated on acts wholly done in a foreign country.’” *Id.* at 1251 (citing *Dowagiac Mfg. Co. v. Minnesota Moline Plow Co.*, 235 U.S. 641, 650 (1915)). The question thus became “whether Defendants’ activities in the United States ... [were] sufficient to establish an ‘offer for sale,’ as that phrase is used in § 271(a).” *Id.* The Court traced the historical and legislative history surrounding the addition of this language in § 271(a), noting that “other than stating that an ‘offer to sell’ includes only those offers ‘in which the sale will occur before the expiration of the term of the patent,’ 35 U.S.C. 271(i) (Supp. 1997), Congress offered no other guidance as to the meaning of the phrase.” *Id.* at 1252. The Court stated, however, that “Congress sought to strengthen the protections” provided for by § 271(a) when it added the “offer to sell” prohibition. *Id.* (citations omitted).

Deciding what constitutes an “offer to sell” is to be undertaken by giving that phrase its “ordinary meaning in contract law, as revealed by traditional sources of authority[,]” and by looking to “the norms of traditional contractual analysis.” *Id.* at 1254. In the case before it, the Court determined that the defendants did not “offer to sell” plaintiff’s patented invention in the United States because the evidence:

[D]oes not show that any Defendant communicated a “manifestation of willingness to enter into a bargain, so made as to justify another person in understanding that his assent to that bargain is invited and will conclude it.”

Id. at 1257 (quoting *Restatement (Second) of Contracts* § 24 (1979)).

What emerges from Federal Circuit cases dealing with “offer to sell” liability under § 271(a) is the conclusion that an unauthorized “offer to sell” a patented invention within the United States creates a separate cause of action for patent infringement. See *3D Sys.*, 160 F.3d at 1378-79 (stating that the “offers to sell” language in § 271(a) is “hollow” if potential infringers could escape liability for the type of contact defendant engaged in, *i.e.*, sending promotional letters, order solicitations, and price quotations to potential purchasers of a patented invention). The geographic location and physical destination of the subject matter of the “offer” appear to be immaterial to the analysis, so long as the “offer” was made in the United States. See *Rotec*, 215 F.3d at 1251 (determining whether defendants’ activities in the United States amount to an “offer to sell” for purposes of § 271(a) when the evidence showed that the actual sales agreement was signed in China and no part of the alleged infringing product was ever manufactured or present in the United States). By the same token, the “sale” contemplated by the “offer to sell” need not take place in the United States or be intended to take place in the United States for there to be infringement because of the “offer to sell.” *Id.*; *cf. Rotec*, 215 F.3d at 1258 (Newman, J., concurring) (“[T]he majority opinion necessarily accepts the critical premise that an ‘offer to sell’ made in the United States can constitute patent infringement even when the contemplated sale could not infringe the patent.”).

In light of the foregoing, the Court rejects Bausch & Lomb’s argument that an “offer to sell” can only take place if there is also an unlawful sale within the United States. Congress obviously intended the addition of the “offer to sell” language to mean something more than what the statute already meant. Requiring that there be an actual or

contemplated infringing “sale” of the invention for there to also be an unlawful “offer to sell” makes the “offer to sell” language in § 271(a) superfluous. Such a conflation of the liability for an “offer to sell” and a “sale” is very unlikely to have been Congress’s intention, especially since one purpose for adding the “offer to sell” language to § 271(a) was to bring the United States’ patent protection into conformity with foreign patent protection. See *Rotec*, 215 F.3d at 1253 (“Accordingly, we must recognize one of the agreements’ [the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) agreements] declared purposes: harmonizing worldwide patent law.”); see also *id.* (“Ultimately, however, the United States agreed to the broader protections provided by others, suggesting that the amendment to § 271(a) reflects the approaches of the other signatory nations.”).

As noted by Bausch & Lomb, some district courts have taken a different approach to this problem, holding that an “offer to sell” under § 271(a) is not patent infringement unless it is tied to an actual or contemplated infringing “sale” in the territorial jurisdiction of the United States. See *Cybiotronics*, 130 F. Supp. 2d at 1170 (holding that “liability under Section 271(a) does not extend to ‘offers to sell’ which do not contemplate actual ‘sales’ of goods to be consummated within the United States); *Quality Tubing*, 75 F. Supp. 2d at 625 (holding that “contracting, in the United States, to manufacture, sell, and deliver a [patented] product in Scotland and Norway, for use in Norway[]” is not patent infringement). Judge Newman, dissenting in *Rotec*, also advocated a similar position. 215 F.3d at 1259 (Newman, J., concurring) (“[b]y requiring that the actual sale of the thing offered will occur before the patent expires, the statute [§ 271(i)] makes clear that the sale must be one that will infringe the patent.”) That contradictory authority is not ultimately persuasive, however,

given the Federal Circuit's decisions in *3D Systems, Hollyanne Corp.*, and *Rotec*. In addition, at least one other district court had the opportunity to address this issue and adopted a similar view before the Federal Circuit in *Rotec* further clarified the meaning of the "offer to sell." See *Halmar Robicon Group, Inc. v. Toshiba International Corp.*, C.A. No. 98-501, 1999 U.S. Dist. LEXIS 19869, *8-*13 (W.D. Penn. 1999) (denying summary judgment in a motion to dismiss a claim for patent infringement for "offering to sell" a patented invention since the evidence indicated that the "offer to sell" included indicia of a commercial sale).

Bausch & Lomb's policy arguments for a more restrictive reading of the "offer to sell" language in § 271(a) are unpersuasive. One such argument is that American business opportunities should not be hampered by a patentee having the exclusive right to "offer to sell" a patented invention if the sale is to take place overseas. Cf. *Quality Tubing*, 75 F. Supp. 2d at 625 ("This construction does not expand the territorial jurisdiction of the United States patent laws and does not inhibit the ability of American companies to compete abroad.") That argument does not account for the fact that it is for Congress, not the Court, to make such policy determinations. Beyond that, the argument begs the question of why a patentee should not have an exclusive right to make offers to sell within the United States. "[T]he policy underlying the 'offer to sell' liability under § 271(a) includes preventing a competitor from generating interests in a potentially infringing product to the commercial detriment of the rightful patentee." *Rotec*, 215 F.3d at 1254 n.3 (internal quotes omitted). Allowing competing offers to sell would be to the detriment of a patentee's opportunity to offer sales, whether foreign or domestic. Cf. *Jefferson Parish Hospital District No. 2 v.*

Hyde, 466 U.S. 2, 16 (1984) (“[I]f the government has granted the seller a patent or similar monopoly over a product, it is fair to presume that the inability to buy the product elsewhere gives the seller market power.”)

The Court concludes that an unauthorized offer to sell a patented product, which offer is made in the United States, is a violation of 35 U.S.C. § 271(a). If such an offer were made in this case, it would also be a violation of the previously entered injunction.

c. 35 U.S.C. § 271(f)(1) or (f)(2)

The Court will not make explicit or implicit modifications of its injunction to incorporate the provisions of 35 U.S.C. § 271(f)(1) or (f)(2), as urged by Wesley Jessen. The Court’s injunction states that the defendant cannot make, use, offer for sale, or sell, in the United States “contact lens materials and contact lenses made from the material known as Balafilcom A and the contact lenses marketed under the trade name PureVision.” (D.I. 179 at 7-8; D.I. 180 at ¶ 1.) To the extent that Bausch & Lomb has violated or will violate the terms of the Court’s injunction by making, using, selling, or offering to sell additional or existing articles patented in the ‘943 patent, Wesley Jessen is fully protected by the Court’s injunction. To go beyond the broad wording of the injunction at this stage is unwarranted.

d. Discovery

Although the Court cannot now find, as Wesley Jessen requests, that Bausch & Lomb is in contempt of the Court’s injunction, the Court also cannot hold, as Bausch & Lomb asserts, that the law conclusively absolves or protects Bausch & Lomb’s allegedly infringing activities. Wesley Jessen has made a *prima facie* showing that commercial

transactions between Bausch & Lomb and a related entity in Ireland may involve offers to sell or sales within the United States. The Court, therefore, will grant Wesley Jessen's request to take discovery directed to uncovering whether Bausch & Lomb has engaged in offering for sale, or selling, in the United States "contact lens materials and contact lenses made from the material known as Balafilcom A and the contact lenses marketed under the trade name PureVision[]", as prohibited by the Court's injunction (see D.I. 179 at 7-8; D.I. 180 at ¶ 1). The Court will reserve decision on the question of contempt until that discovery is concluded. The parties are directed to confer and submit for the Court's approval a discovery plan, in accordance with this Opinion and the Order to follow.