United States District Court,
D. Delaware.

CRITIKON, INC,
Plaintiff.
v.
BECTON DICKINSON VASCULAR ACCESS, INC,
Defendant.

CIV. A. No. 93-108-JJF

July 16, 1993.

Arthur G. Connolly, Jr., of Connolly Bove Lodge & Hutz, Wilmington, Harry J. Roper, George S. Bosy, Raymond N. Nimrod, and Ellen D. Law, of Roper & Quigg, Chicago, IL, Donna M. Malin, of Johnson & Johnson, New Brunswick, NJ, for plaintiff.

Robert K. Payson, and William J. Marsden, Jr., of Potter Anderson & Corroon, Wilmington, Albert E. Fey, Lars I. Kulleseid, Richard M. Barnes, and Philippe Y. Riesen, of Fish & Neave, New York City, Edward F. Mullowney, of Fish & Neave, Palo Alto, California. Leslie Gordon Fagen, and Ellen M. Moskowitz, of Paul Weiss Rifkind Wharton & Garrison, New York City, for defendant.

OPINION

FARNAN**, District Judge.**

I. INTRODUCTION

Plaintiff, Critikon, Inc. ("Critikon") commenced this patent infringement action on March 1, 1993, for alleged infringement of U.S. Patent No. 4,952,207 ("Lemieux patent"). (Docket Item ("D.I.") 1). On April 1, 1993, Critikon amended its Complaint alleging infringement of a second patent, U.S. Patent No. 4,978,344 ("Dombrowski patent"). (D.I. 21). Defendant, Becton Dickinson Vascular Access, Inc.'s ("Becton Dickinson") Answer to the Amended Complaint denies that Becton Dickinson infringed the Lemieux and Dombrowski patents and avers that both patents are invalid and unenforceable. (D.I. 45).

Presently before the Court is Critikon's motion to enjoin Becton Dickinson from making, using, or selling its intravenous ("I.V.") safety catheter which is currently being sold under the designation Insyte(R) Saf-T-Cath(R). Critikon alleges that the Becton Dickinson safety catheter infringes Claim 8 of the Lemieux patent, which is assigned to Critikon. Because Critikon has demonstrated a likelihood of success on the merits, and that it will suffer irreparable harm if Becton Dickinson is not preliminarily enjoined from making and selling its safety catheter, the Court will grant Critikon's motion for a preliminary injunction.

II. TECHNOLOGY BACKGROUND

An I.V. catheter is a hollow tube made of a flexible material that is inserted into the vein or artery of a person to provide them with fluids, drugs or medications. A catheter is placed in the vein through the use of an installing apparatus, which includes a steel hypodermic needle. The needle extends through the hollow passage of the catheter. The needle and the catheter are inserted into the vein together. The needle is then

withdrawn by sliding it back through the catheter. The catheter is left in place with one end of the catheter exposed outside of the person's body. This end of the catheter, called the catheter hub, is then connected to a source of fluids or medications to be administered to the person.

After the needle is withdrawn from the catheter, the health care professional must complete a number of tasks immediately. The health care professional must secure the catheter to the patient. In addition the health care professional must cap the catheter to close access to the person's blood system and to prevent blood loss. Because of the urgency of these procedures, the health care professional will generally set the needle down at a nearby location for later disposal. The problem then is, however, that the exposed needle tip creates the danger of accidental needlesticks, which may transmit bloodborne pathogens, such as AIDS or hepatitis.

The Lemieux patent and the Becton Dickinson safety catheter are both designed to eliminate the risks of such accidental needlesticks. Both involve an improved I.V. catheter-needle apparatus that automatically caps the sharp needle tip as the needle is withdrawn from the patient. This is accomplished through the use of a small mechanical guard, called a needle guard. As the needle is withdrawn from the catheter, the needle guard automatically positions itself over the needle tip and locks into place.

III. *DISCUSSION*

A. Legal Standard-Preliminary Injunction

Injunctive relief in patent cases is authorized by 35 U.S.C. s. 283. The grant or denial of a preliminary injunction is within the sound discretion of the trial court. In determining whether a party is entitled to a preliminary injunction, a court must consider whether: 1) the movant is reasonably likely to succeed on the merits at trial; 2) the movant will suffer irreparable harm if preliminary relief is not granted, 3) the balance of hardships favors granting preliminary relief; 4) the preliminary relief sought is in the public interest. New England Braiding Co. v. A.W. Chesterton Co., 970 F.2d 878, 882 (Fed.Cir.1992); *see also* Eli Lilly and Co. v. Premo Pharmaceutical Labs., Inc., 630 F.2d 120, 136 (3d Cir.), *cert. denied,* 449 U.S. 1014 (1980)

B. Likelihood of Success on the Merits

Critikon has the burden of showing that there is a reasonable likelihood that it will succeed on the merits at trial. Thus, Critikon is entitled to a preliminary injunction only if it clearly shows that its patent is valid, enforceable, and infringed. Hybritech, Inc. v. Abbott Lab., 849 F.2d 1446, 1451 (Fed.Cir.1988); Nutrition 21 v. U.S., 930 F.2d 867, 869 (Fed.Cir.1991) ("[T]he *patentee* carries the burden of showing likelihood of success on the merits with respect to the patent's validity, enforceability, and infringement.").

1. Infringement

Infringement occurs when someone "without authority makes, uses or sells any patented invention within the United States during the term of the patent...." 35 U.S.C. s. 271 (1988). The Court's determination of whether Becton Dickinson's safety catheter infringes Claim 8 of the Lemieux patent involves two steps. First, the Court must determine the scope of Claim 8. Autogiro Co. of America v. U.S., 384 F.2d 391, 401 (Ct.Cl.1967). Then the Court must compare Claim 8, as interpreted, to Becton Dickinson's safety catheter to determine whether it infringes, either literally or under the doctrine of equivalents. *Id.;* Hybritech, 849 F.2d at 1455.

a. Claim Interpretation

In defining the scope of a claim for the purposes of determining whether it has been infringed, the Court begins with the language found in the claim itself.

The claims of the patent provide the concise formal definition of the invention. They are numbered paragraphs which "particularly [point] out and distinctly [claim] the subject matter which the applicant regards as his invention." It is to these wordings that one must look to determine whether there has been infringement. Courts can neither broaden nor narrow the claims to give the patentee something different than what he has set forth.... Although courts are confined to the language of the claims, they are not, however, confined to the language of the claims in interpreting their meaning.

....

In deriving the meaning of a claim, we inspect all useful documents to reach what Justice Holmes called the "felt meaning" of the claim.

Id. at 396-397 (quoting 35 U.S.C. s. 112). The words in a claim may mean either what one skilled in the art would expect the words to mean or what the inventor has defined the word to mean. In interpreting a disputed claim, the Court looks to several factors including: (1) the literal language of the claims, (2) the patent specification, (3) the prosecution history, and (4) expert testimony on how those skilled in the art would interpret the claim. Loctite Corp. v. Ultraseal, Ltd., 781 F.2d 861, 867 (Fed.Cir.1985); McGill, Inc. v. John Zink Co., 736 F.2d 666, 673-75 (Fed.Cir.), *cert. denied,* 469 U.S. 1037 (1984); American Standard, Inc. v. Pfizer Inc., 722 F.Supp. 86, 92 (D.Del.1989). But, "interpreting what is *meant* by a word *in* a claim 'is not to be confused with adding an extraneous limitation appearing in the specification.' " Intervet America, Inc. v. Kee-Vet Labs, Inc., 887 F.2d 1050, 1053 (Fed.Cir.1989) (quoting E.I. duPont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed.Cir.1988)).

Claim 8 of the Lemieux patent is directed to an improved catheter with a small needle guard that encloses the tip of the catheter needle as it is being withdrawn from the catheter once the catheter is in place. Claim 8 of the Lemieux patent reads as follows:

8. An I.V. catheter with a self-locating needle guard comprising:

a catheter assembly including a catheter attached to a catheter hub;

an introducer needle assembly for connection with said catheter assembly, including a hollow needle with a distal tip and a needle hub, said needle being affixed near its proximal end to extend distally exposed from the distal end of said needle hub, and said needle including means located distal said distal end of said needle hub for engaging a needle guard; and

a needle guard, initially located about said needle of the distal end of said needle hub and capable of axial movement relative to said needle, said needle guard including a proximal portion having means for engaging said engaging means of said needle and a distal portion for extending over said needle tip when said proximal portion is engaged with said engaging means of said needle; and

retaining means for retaining said needle guard within said catheter hub prior to engagement of said needle engaging means and said needle guard engaging means.

After reviewing Claim 8 together with the other claims and the specification of the Lemieux patent, the relevant prior art, and the deposition testimony and affidavits of Mr. Vaillancourt, Mr. Fischell, and Mr. Luther, the Court interprets Claim 8 to require the following:

(1) First, the needle guard must be self-locating. "Self-locating" as used by Lemieux in Claim 8 means that the needle guard is automatically (without an extra step by the health care professional) positioned over the tip of the needle as the needle is withdrawn from the catheter.

(2) Second, Claim 8 requires a catheter assembly, or a catheter attached to a catheter hub. The catheter is a hollow tube which is inserted into a patient's vein or artery. The catheter hub is the external portion of the catheter which attaches to an infusion tube for administering fluids to the person.

(3) Third, Claim 8 requires an introducer needle assembly that connects to the catheter assembly. The needle assembly is comprised of a needle and a needle hub. The needle hub is that part of the catheter that is handled by the health care professional.

(4) Fourth, Claim 8 requires that the needle assembly be comprised of a hollow needle that is attached at its proximal end to a needle hub and extends distally exposed from the distal end of the needle hub. The word proximal is used to denote that end closest to the health care professional. The word distal is used to denote that end closest to the patient.

(5) Fifth, Claim 8 requires a means, located at the distal end of the needle, for engaging the needle guard as the needle is withdrawn from the catheter. This means, together with the required means on the needle guard, is what allows the needle guard to automatically move into position over the tip of the needle to protect health care professionals and patients from accidental needlesticks.

(6) Sixth, Claim 8 requires a needle guard that is initially positioned around the needle at the distal end of the needle hub and capable of axial movement around the needle.

(7) Seventh, Claim 8 requires that the needle guard contain a means in its proximal portion for engaging the corresponding means found on the needle, and a distal portion of the needle guard that covers the needle tip.

(8) Finally, Claim 8 requires a means for retaining the needle guard in its initial position within the catheter hub until the corresponding mechanisms on the needle and the needle guard engage. The purpose of this disclosure is to ensure that the needle guard remains fixed, next to the catheter hub while the needle is being withdrawn from the catheter and until it is correctly positioned over the tip of the needle. In this regard, the Court rejects Becton Dickinson's interpretation of "within" to require that the needle guard be entirely inside the catheter hub. "Within" as used by Lemieux does not limit Claim 8 to only those safety catheters in which the needle guard is completely inside the catheter hub. It merely requires that whatever portion of the needle guard is within the catheter hub remain there until the needle engages the needle guard through the means described above.

b. ***Literal Infringement***

Once the Court establishes the meaning of the claim, the claim must be read on the accused products or processes to determine whether the accused products or processes infringe on the patent, either literally or under the doctrine of equivalents. Autogiro, 384 F.2d at 401; Palumbo v. Don-Joy Co., 762 F.2d 969, 974 (Fed.Cir.1985). Literal infringement occurs if each element of the claim is found in the accused device. *See* Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed.Cir.1989); American Hoist & Derrick Co. v. Manitowoc Co., 603 F.2d 629, 630 (7th Cir.1979). The Court finds that Critikon has made a clear showing that each of the eight requirements of Claim 8, as interpreted by the Court, is found in Becton Dickinson's safety catheter. Therefore, the Court finds that there is a reasonable likelihood that Critikon will succeed on the issue of infringement.

(1). The needle guard in Becton Dickinson's safety catheter is self-locating as that term is used in Claim 8. The literature that Becton Dickinson distributes to its customers clearly demonstrates that the needle guard moves into position to cover the tip of the needle as the needle is withdrawn from the catheter. Furthermore, it is clear that this is accomplished automatically, or without any extra movements by the health care professional.

(2), (3). A visual inspection of Becton Dickinson's safety catheter convinces the Court that it contains a hollow catheter tube attached to a catheter hub, and a needle assembly for connection with the catheter assembly. Becton Dickinson contends that its needle assembly is not "connected" to the catheter assembly in the manner contemplated by Claim 8. Becton Dickinson argues that the needle assembly and the catheter assembly in its safety catheter are not "connected" because they are separated by the needle guard. The Court is not persuaded by this argument. If one picks up the Becton Dickinson device, the needle assembly and the catheter assembly are connected, and must be so connected for the catheter to be operable.

(4). A visual inspection of the Becton Dickinson needle assembly also reveals that a hollow needle attached at its proximal end to the needle hub extends distally exposed from the distal end of the needle hub. Becton Dickinson insists that its needle is not "distally exposed from the distal end of the needle hub"; but rather is enclosed by the catheter except at the very distal end. The Court finds no merit to this contention. A review of the specifications and the drawings convinces the Court that "distally exposed" does not literally mean uncovered when the device is assembled and ready to be used. The limitation "distally exposed" is found in the part of Claim 8 where the inventor was focused solely on the needle assembly, not the entire catheter assembly.

(5). The Becton Dickinson safety catheter has a means, located on the distal tip of the needle, of engaging the needle guard. This limitation found in Claim 8 is written as a "means plus function" limitation. A claim written with "means plus function" language is literally infringed if the accused product performs the identical claimed function using the same or an equivalent or interchangeable structure. Valmont Indus., Inc. v. Reinke Mfg. Co., 983 F.2d 1039, 1041-42 (Fed.Cir.1993); Palumbo v. Don-Joy Co., 762 F.2d 969, 974-75 (Fed.Cir.1985).

The engaging means found on the needle in the Becton Dickinson safety catheter performs the identical function as that described in Claim 8, i.e. to engage the needle guard. Moreover, the Becton Dickinson needle engages the needle guard using an equivalent structure as that described in the Lemieux patent. At the distal end of the needle of the Becton Dickinson safety catheter is a bump or ridge where the outside diameter of the needle increases. As the needle is pulled through the needle guard, the diameter of the ridge on the needle is too large to pass through the proximal end of the needle guard. Thus, the ridge on the needle engages with the needle guard causing the needle guard to move into position over the tip of the needle. The ridge on the tip of the needle in the Becton Dickinson device is the equivalent of the notch described in the Lemieux patent.

(6). The needle guard is initially positioned around the needle at the distal end of the needle hub and capable of axial movement around the needle.

(7). The needle guard on the Becton Dickinson's device has a means for engaging the corresponding means on the needle. Once again, this limitation is written as a "means plus function" limitation. As discussed above, the function in both devices is identical and Becton Dickinson's locking mechanism is equivalent to the notch structure described in the Lemieux patent.

(8). Finally, the Becton Dickinson safety catheter has a means to ensure that the needle guard remains fixed at the based of the catheter hub while the needle is being withdrawn from the catheter, and until the needle engages the needle guard. The retaining means limitation is also written using "means plus function" language. Therefore, the Court must determine whether the structure described in the Lemieux patent is identical to or the equivalent of the structure used by Becton Dickinson.

In the Lemieux patent, the needle guard is retained within the catheter hub by a frictional force-the needle guard presses against the inside of the catheter hub until the needle engages with the needle guard. Mr. Vaillancourt testified that the needle guard in the Becton Dickinson device is likewise held in place by a frictional or mechanical force until the needle engages with the needle guard. Therefore, the Court finds that

the Becton Dickinson structure is interchangeable with that described in the Lemieux specification.

c. Doctrine of Equivalents

The Court also finds that Critikon has a reasonable likelihood of succeeding on its burden of proving that Becton Dickinson's safety catheter infringes the Lemieux patent under the doctrine of equivalents. Infringement under the doctrine of equivalents occurs when the alleged infringer's product or process performs substantially the same function, in the same manner, to obtain substantially the same result as the claimed invention. Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950). Thus, Becton Dickinson's safety catheter infringes the Lemieux patent under the doctrine of equivalents if it performs the same function, in the same manner, to obtain substantially the same result as the catheter disclosed in Claim 8 of the Lemieux patent. Id. at 608.

It cannot be seriously disputed that the Becton Dickinson safety catheter performs the same function to achieve the same result as Claim 8 of the Lemieux patent. They both provide for a catheter with a needle guard that moves into position passively-without intervention by the health care professional-for the purpose of protecting health care professionals and others from accidental needlesticks.

Furthermore, the Becton Dickinson device accomplishes this in substantially the same manner as that taught by Claim 8. The needle guard remains stationary until a means on the distal tip of the needle engages with a means on the needle guard. At this point, the needle guard becomes affixed to the tip of the needle.

2. Validity

In addition to contending that its safety catheter does not infringe Claim 8 of the Lemieux patent, Becton Dickinson also contends that the Lemieux patent is invalid. Becton Dickinson asserts invalidity on three grounds: (1) invalid as obvious under 35 U.S.C. s. 103 in light of U.S. Patent No. 4,834,718 ("the McDonald patent") and U.S. Patent No. 4,832,696 ("the Luther patent"); (2) invalid as anticipated under 35 U.S.C. s. 102 by the McDonald patent; and (3) invalid under 35 U.S.C. s. 112 as inoperable. The question for the Court in resolving this motion for a preliminary injunction is whether Critikon has demonstrated a reasonable likelihood that Becton Dickinson will fail to meet their burden at trial of proving by clear and convincing evidence that the Lemieux patent Claim 8 is invalid. Although Critikon retains the burden of showing that Becton Dickinson's attack on the Lemieux patent's validity will likely fail, this determination must be made "in the context of the presumptions and burdens that would inhere at trial on the merits." H.H. Robertson Co. v. United Steel Deck, Inc., 820 F.2d 384, 388 (Fed.Cir.1987). Thus, while Critikon must demonstrate that it is entitled to the preliminary injunction, the Court must make that determination in the context of the presumption of validity that the Lemieux patent would enjoy at trial and Becton Dickinson's heavy burden of establishing invalidity by clear and convincing proof.

a. Obviousness, 35 U.S.C. s. 103

In his affidavit, Becton Dickinson's expert, Mr. Fischell, states his opinion that Claim 8 is obvious from the Luther patent. Appendix to Defendant Becton Dickinson's Memorandum in Opposition to Critikon's Motion for P.I. ("Def. Appendix"), Exhibit J, at para.para. 16-17. Section 103 states:

a patent may not be obtained ... if the differences between the subject matter sought to be patented and prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. s. 103 (1988). The Court's determination of obviousness requires resolution of three issues: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the pertinent prior art. Graham v. John Deere Co., 383 U.S. 1, 17 (1966). The Court must also weigh any relevant secondary considerations such as the commercial success of the

challenged patent, long felt but unsolved needs in the art, and the failure of others to solve the problem. Id. at 17-18. A review of these considerations convinces the Court that Critikon is reasonably likely to succeed on the issue of Claim 8's obviousness.

(1) Prior Art

The McDonald Patent. The McDonald patent discloses a catheter with a protective housing designed to cover the needle tip for the purpose of preventing accidental needlesticks. The housing is comprised of a long barrel and a guard hub. After the needle is withdrawn from the emplaced catheter, the proximal end of the housing engages with a groove on the handle, which the Court finds to be similar to the needle hub in the Lemieux patent.

The Luther Patent. The Luther patent also discloses a needle with an assembly for protecting the needle tip. The assembly includes an elongated housing, a needle secured to the housing, and a needle guard positioned around the needle which slides along the inside of the housing. Following insertion of the catheter and needle into the patient, the housing, and thus the needle, is retracted. The health care professional withdraws the needle by pressing forward against a tab on the needle guard while retracting the housing and attached needle. The housing and needle thus move rearward relative to the needle guard as the needle guard slides along the inside of the housing. The needle guard remains stationary until notches on the needle guard engage with the housing. At this point the needle guard becomes fixed covering the entire needle.

(2) Differences Between Prior Art and Claim 8

As Mr. Vaillancourt points out, the McDonald and Luther patents are distinct from Lemieux Claim 8 in two significant respects. First, the Luther patent does not teach or suggest a *self-locating* needle guard. It does not teach an apparatus where the needle guard automatically latches onto the tip of the needle as the needle is being withdrawn from the catheter. With regard to the Luther catheter, the health care professional must actively push forward on the needle guard tab to hold the needle guard stationary, enabling it to engage with the housing.

Second, neither the McDonald nor the Luther patent teaches or suggests that the engaging means be on the needle itself. The protective mechanism in the Luther patent engages with a means on the needle hub. These differences are significant. The uniqueness of the Lemieux patent is the engaging means on the needle which enables the needle guard to lock into position over the tip of the needle without any distinct motion on the part of the health care professional.

There is nothing in the prior art to suggest that this engaging means on the needle and the passive positioning of the needle guard would have been obvious to one of ordinary skill in the art. This conclusion is supported by the evidence regarding the commercial success enjoyed by the Becton Dickinson safety catheter which incorporates these unique characteristics. For example, the chart submitted to the Court during oral argument shows that Critikon sold approximately 1.8 million safety catheters in its first year of production. It also projects sales of 2 million catheters in 1993. Moreover, Becton Dickinson notes that since its entry in the market, eighty hospitals have committed to using the safety catheter, while another four-hundred are in the process of evaluating it for possible use. This type of rapid growth convinces the Court that the disclosures contained in the Lemieux patent and incorporated in Becton Dickinson's device were not made obvious by the Luther and McDonald patents.

b. Anticipation, 35 U.S.C. s. 102

Becton Dickinson also alleges that Claim 8 of the Lemieux patent is invalid under 35 U.S.C. s. 102 as anticipated by the McDonald patent. To establish anticipation at trial Becton Dickinson would have to prove that the McDonald patent discloses each and every element of Claim 8. Mannesmann Demag Corp. v. Engineered Metal Prods. Co., 605 F.Supp. 1362, 1367-68 (D.Del.1985), *aff'd,* 793 F.2d 1279 (Fed.Cir.1986);

see also Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 677 (Fed.Cir.1988).

As discussed above, the McDonald patent does not teach an apparatus where the engaging means is located on the needle itself. Therefore, the Court concludes that Critikon is reasonably likely to succeed at trial on the issue of anticipation.

c. Non-enablement, 35 U.S.C. s. 112

Finally, Becton Dickinson alleges that the device as described in the patent specification is inoperable. Section 112, of Title 25 of the United States Code requires that the patent specification contain a description of the invention sufficient to enable one skilled in the art to make and use the claimed invention. FN1 In Mr. Fischell's opinion, the Lemieux safety catheter would not work because the needle guard would not release from the catheter as the needle is withdrawn from the patent. Mr. Fischell's conclusion is primarily based on the drawings found in the patent. However, patents themselves and drawings in a patent specification are not intended as production specifications. That some design work is necessary does not render a patent non-enabling as long as the amount of experimentation is not unduly extensive. U.S. v. Telectronics, Inc., 857 F.2d 778, 785 (Fed.Cir.) (citing Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1576 (Fed.Cir.1984)), *cert. denied,* 490 U.S. 1046 (1988).

Mr. Vaillancourt testified that the needle guard would release from the catheter hub as one of ordinary skill in the art would construct the Lemieux safety catheter after some experimentation. Mr. Luther agrees with Mr. Vaillancourt. It is Mr. Luther's opinion that the Lemieux patent could be made. Significantly, Mr. Fischell never stated that the Lemieux patent could not be made by one of ordinary skill in the art; he merely stated that the invention according to the drawings would be inoperable. Thus, on this record, the Court finds that Critikon is reasonably likely to succeed on the issue of non-enablement.

d. Enforceability

Finally, Becton Dickinson contends that Critikon committed inequitable conduct during the prosecution of the Lemieux patent by withholding relevant and invalidating prior art from the Patent Examiner. Specifically, Becton Dickinson alleges that Critikon should have and failed to cite the Luther and McDonald patents as prior art. Critikon argues that the Luther and McDonald patents are cumulative of other prior art provided to the Patent Office.

Rule 56(a) of Title 37, Chapter 1 of the Code of Federal Regulations provides that applicants and their attorneys must "disclose to the [PTO] information they are aware of which is material to the examination of the application." 37 C.F.R. 1.56(a) (1989). This expresses the general duty of candor, good faith, and honesty that applicants for patents and attorneys representing applicants owe the U.S. PTO. FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 n. 8 (Fed.Cir.1987); Hycor Corp. v. Schlueter Co., 740 F.2d 1529, 1538 (Fed.Cir.1984); American Standard Inc. v. Pfizer Inc., 722 F.Supp. 86, 141 (D.Del.1989) (citing Precision Inst. Mfg. Co. v. Automotive M.M. Co., 324 U.S. 806, 818 (1945)). Any knowledge or action taken by the attorney is chargeable to the applicant. FMC Corp., 835 F.2d at 1415 n. 8.

At trial Becton Dickinson would have the burden of proving by clear and convincing evidence (1) the existence of material prior art, (2) that Critikon knew of the material prior art and its materiality, and (3) Critikon failed to disclose the material prior art to the PTO with the intent to mislead the PTO. FMC Corp., 835 F.2d at 1415; Under Sea Industries, Inc. v. Dacor Corp., 833 F.2d 1551, 1559 (Fed.Cir.1987).

Information is considered material if "there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." 37 C.F.R. s. 1.56(a); Specialty Composites v. Cabot Corp., 845 F.2d 981, 992 (Fed.Cir.1988). However, an applicant need not disclose all prior art. J.P. Stevens & Co. v. Lex Tex Ltd., 747 F.2d 1553, 1559 (Fed.Cir.1984), *cert. denied,*

474 U.S. 822 (1985). The applicant need not disclose prior art which is no more pertinent or merely cumulative to that considered by the examiner. Rolls-Royce, Ltd. v. GTE Valeron Corp., 800 F.2d 1101, 1107 (Fed.Cir.1986).

The Court must also find an intent to mislead or deceive the PTO prior to finding inequitable conduct. Hewlett-Packard Co. v. Bausch & Lomb, Inc., 882 F.2d 1556, 1562 (Fed.Cir.1989), *cert. denied,* 493 U.S. 1076 (1990). The Court must view the conduct in light of the totality of the circumstances, "including the nature and level of culpability of the conduct and the absence or presence of affirmative evidence of good faith." *Id.* (citing Kingsdown Medical Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876 (Fed.Cir.1988)); *see also* Consolidated Aluminum Corp. v. Foseco Int'l, Ltd., 910 F.2d 804, 809 (Fed.Cir.1990); RCA Corp. v. Data General Corp., 887 F.2d 1056, 1065 (Fed.Cir.1989).

The Court finds that Critikon is reasonably likely to succeed in demonstrating that the Luther and McDonald patents are cumulative of other prior art presented to the PTO during the prosecution of the Lemieux patent. Moreover, Becton Dickinson has pointed to no evidence, circumstantial or otherwise, FN2 to show that Critikon acted with an intent to deceive the PTO in not disclosing the McDonald and Luther patents.FN3 Therefore, the Court concludes Critikon is likely to prevail on the issue of the enforceability in addition to validity and infringement of the Lemieux patent.

C. Irreparable Harm

Critikon contends that it will be irreparably harmed by Becton Dickinson's continued alleged infringement in four ways. First, Critikon asserts that because it and Becton Dickinson are the only two competitors in the safety catheter market, it stands to lose its currently dominant market share. Second, Critikon asserts that it stands to lose prospective business opportunities as Becton Dickinson attracts prior Critikon customers. Third, Critikon asserts that its reputation and good will as an innovator in the catheter market will suffer irreparably. Finally, Critikon asserts that there is a significant risk that other potential infringers will enter the market absent a preliminary injunction.

The Court is convinced that Critikon will suffer irreparable harm absent a preliminary injunction. First, where, as here, there has been a strong showing of validity and infringement, irreparable harm can be presumed from the continued infringement of a valid patent. Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1581 (Fed.Cir.), *cert. denied,* 464 U.S. 996 (1983); E.I. duPont de Nemours v. Polaroid Graphics, 706 F.Supp. 1135, 1144 (D.Del.1989). This presumption has its origin in the nature of patent rights. Because patent rights are of finite duration, the mere passage of time creates irremediable harm. H.H. Robertson Co., 820 F.2d at 390. In addition, the very nature of the patent right is the ability to exclude others. Once a determination is made that a patent is likely valid and infringed, the patent holder should be entitled to the full enjoyment of his patent rights. Smith Int'l, Inc., 718 F.2d at 1581. Finally, the "opportunity to practice an invention during the notoriously lengthy course of patent litigation may itself tempt infringers." H.H. Robertson Co., 820 F.2d at 390 (citing Teledyne Indus., Inc. v. Windmere Products, Inc., 433 F.Supp. 710 (S.D.Fla.1977)). If courts refuse to grant preliminary injunctions where the infringement is as clear as it is in this case, the rights of patent holders will become diluted, and potential infringers will be encouraged to play the odds.

D. Public Interest

Granting the preliminary injunction will also serve the public interest. Becton Dickinson has argued to the Court that a preliminary injunction would run against the public interest because hospitals have already begun to use their safety catheter. They argue that the disruption that would result from forcing the hospitals to find a new safety catheter or resort to the old catheter would place many health care professionals and patients at risk.

The Court agrees that it is in the public interest to minimize the disruption in hospitals in terms of their selection of safety catheters. However, because of the strong showing on the issue of infringement, the Court believes that such disruption will be minimized by granting the preliminary injunction. If not preliminarily enjoined, Becton Dickinson will embark on a campaign to persuade hospitals to buy and use its safety catheter. If successful, as Becton Dickinson anticipates it would be, many hospitals will begin use Becton Dickinson's device. Then, if as the Court has presently found, Critikon succeeds at trial and obtains an ultimate determination of infringement, disruption will result in not only the hospitals presently using device, but in addition, all of the hospitals which may be persuaded to begin using it between now and trial. For this reason, the Court believes that it is in the public interest to enjoin Becton Dickinson's efforts at this time.

E. Balance of the Hardships

The Court finds the balance of hardships also tips in favor of granting a preliminary injunction. Becton Dickinson is still in the early stages of marketing its safety catheter, whereas Critikon's product has been on the market for over a year. The hardship facing Becton Dickinson in delaying its entry into the market three to six months is not as severe as that faced by Critikon by not being able to enforce its apparently valid patent, and the potential harm that will result to its reputation and goodwill as an innovator in the safety catheter market.

IV. CONCLUSION

In sum, a review of the four factors that the Court must consider in determining the appropriateness of a preliminary injunction convinces the Court that Critikon is entitled to a preliminary injunction. The Court finds Critikon has clearly demonstrated that Lemieux patent Claim 8 is valid and enforceable. In addition, Critikon has made a clear showing that Becton Dickinson's safety catheter infringes Claim 8 literally and under the doctrine of equivalents. Further, the clear showing that Claim 8 is valid and infringed leads the Court to conclude that Critikon will suffer irreparable harm if Becton Dickinson is not preliminarily enjoined from making and selling its safety catheter. Moreover, the Court finds the balance of hardships and the public interest favor granting the preliminary injunction. Accordingly, the Court will grant Critikon's motion for a preliminary injunction.

An appropriate Order will be entered.

FN1. Section 112 states in relevant part:
[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same....
FN2. Because direct evidence of an intent to deceive rarely exists, the Court may rely on circumstantial evidence leading to an inference of intent to mislead as the basis for a finding of inequitable conduct. Hewlett-Packard Co., 882 F.2d at 1562.

FN3. On June 25, 1993, Becton Dickinson submitted a letter describing newly discovered evidence which they allege shows Critikon's awareness of the "highly relevant" McDonald patent. Even if the evidence does demonstrate knowledge of the existence of the McDonald patent, it does not demonstrate that Critikon knew of its materiality with respect to the Lemieux patent nor intent to deceive the PTO.

D.Del.,1993.
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