IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEXELL THERAPEUTICS, INC., BECTON DICKINSON AND COMPANY, and THE JOHNS HOPKINS UNIVERSITY,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 00-141-RRM
AMCELL CORPORATION, MILTENYI BIOTECH, INC., and MILTENYI BIOTECH GMBH,	)	
Defendants.	)	

MEMORANDUM OPINION

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Wilmington, Delaware
April 19, 2002

McKELVIE, District Judge

This is a patent case. Presently before the court is the motion of plaintiffs Nexell Therapeutics, Inc., Becton Dickinson and Company, and The Johns Hopkins University to amend the court's April 23, 2001 order granting defendant AmCell's motion for summary judgment.

I. BACKGROUND

While the facts and procedural background of this case are more fully set forth in the court's April 23, 2001 opinion,[1] see Nexell Therapeutics, Inc. v. AmCell Corporation, 143 F. Supp. 2d 407 (2001), the court will begin by reviewing the background that is most pertinent to this memorandum.

The plaintiffs are parties with an interest in two patents, U.S. Patent Nos. 4,714,680 (the '680 patent) and 4,965,204 (the '204 patent), that disclose a method to prepare purified suspensions of human stem cells through the use of specific antibodies for therapeutic use in transplantation and other procedures.[2] The patents are collectively referred to as the Civin patents, after their inventor, Dr. Curt Civin. Plaintiff Nexell produces a magnetic cell separation device known as the Isolex system. When used in

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[1] Although the opinion was subsequently revised and reissued on May 16, 2001, the modifications were not substantive. They involved omissions and errors as to the attorneys listed on the cover page.

[2] Johns Hopkins owns the two patents. Johns Hopkins granted an exclusive license to use the patents to Becton Dickinson. Becton thereafter granted an exclusive license to Baxter Healthcare Corporation, which in turn conveyed its rights under the patents to Nexell Therapeutics, Inc.

conjunction with the antibodies identified in the Civin patents, this product can separate stem cells from peripheral blood cells and bone marrow for transplantation and other therapeutic uses.

Defendant Miltenyi Biotec GmbH has developed a magnetic cell separating technology called MACS. Based on MACS, AmCell produces CliniMACS, a device which permits large-scale magnetic cell separation. It is alleged that both Miltenyi Biotec GmbH and Miltenyi Biotec, Inc. promote and market the CliniMACS device, with Miltenyi Inc. acting as the United States "sales office" of its parent, Miltenyi Biotec GmbH. Miltenyi Biotec GmbH holds a license from Becton Dickinson to use the antibodies in the Civin patents for in vitro research. The license agreement, however, excludes the use of the antibodies for in vivo therapeutic research.

On March 1, 2000, Nexell, Becton Dickinson, and Johns Hopkins filed a complaint against AmCell, Miltenyi Biotec GmbH, and Miltenyi Biotec, Inc. alleging that by selling or offering to sell the CliniMACS device for use with certain antibodies, the defendants infringed or actively induced others to infringe the Civin patents, breached the license agreement, and engaged in unfair competition.

A. AmCell's § 271(e)(1) Summary Judgment Motion

On November 8, 2000, AmCell moved for summary judgment of non-infringement, claiming that, pursuant to the statutory exemption set forth in 35 U.S.C. §

271(e)(1),[3] it does not infringe the Civin patents because it is pursuing approval from the Food and Drug Administration ("FDA") for use of the CliniMACS device in conjunction with the antibodies covered by the Civin patents. On December 18, 2000, Nexell, Becton Dickinson, and Johns Hopkins (collectively referred to as "Nexell") cross-moved for a partial summary judgment of infringement, inducement to infringe, and contributory infringement against the defendants, pursuant to 35 U.S.C. §§ 271(a), (b), and (c). On January 31, 2001 the court heard oral argument on the parties' motions.

In its briefing and at oral argument, Nexell contended that the defendants have infringed the claims of the Civin patents by selling or offering to sell the CliniMACS device for use with a reagent known as CD34. In response, AmCell argued that the § 271(e)(1) exemption applies to its allegedly infringing activities because all of its activities were "reasonably related to the development and submission of information" to the Food and Drug Administration FDA for approval of the CliniMACS device for use in conjunction with the CD34 antibodies.

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[3] Section 271(e)(1) states, in relevant part, that:

> It shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented 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 . . . . 35 U.S.C. § 271(e)(1).

The Supreme Court has held that the term "drugs" covers all products regulated under the Federal Food, Drug and Cosmetic Act. Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990).

Nexell countered that while AmCell may be seeking approval of CliniMACS/CD34, the real purpose that motivated many of its activities was to market and promote its device to physicians; these activities, argued Nexell, exceed the scope of the § 271(e)(1) exemption. According to the plaintiffs, these activities included: (i) sending informational packets and letters to physicians in order to recruit clinicians to participate in FDA studies to evaluate the safety and effectiveness of the CliniMACS/CD34 systems;[4] (ii) maintaining a booth at the American Society of Hematology featuring a display of the CliniMACS device with a sign entitled "CliniMACS – the better alternative . . . Now ready to accept IDE clinical protocols;" (iii) advertising CliniMACS in medical journals; (iv) soliciting clinicians through its website; (v) providing the CliniMACS device to FDA-approved clinical investigators for free and providing the CD34 reagent kits to the investigators on a cost-recovery basis.[5] See Nexell, 143 F. Supp. 2d at 413-18.

Nexell contended that AmCell infringes the claims of the Civin patents because these activities constitute an offer to sell under § 271(a). Further, Nexell contended that AmCell actively induces the clinicians to infringe and contributes to the infringement of

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[4] According to FDA guidelines, for Class III (significant risk) medical devices, such as CliniMACS, if the FDA grants an Investigational Device Exemption (IDE) the manufacturer may ship the device for investigational use in accordance with an FDA-approved protocol. See 21 C.F.R. § 812.1. Manufacturers and clinical investigators can seek and obtain IDEs.

[5] This is mandated by 21 C.F.R. § 812.7.

the Civin patents by providing clinicians the CD34 antibodies with the CliniMACS device.

The plaintiffs also pointed to several instances where the FDA had expressed concerns regarding the scope and effectiveness of AmCell's clinical trials. First, the FDA required AmCell to modify its web site to partition the site into two sections, one for clinicians in the United States and one for clinicians abroad. The FDA then required AmCell to remove language that appeared to constituted an efficacy claim about CliniMACS.[6] Second, on March 30, 2000, the FDA sent a letter to AmCell regarding concerns about the ongoing investigator-sponsored IDEs. Id. The letter stated in relevant part that the FDA

> was concerned that such studies will not provide useful information in support of the clinical development of the device, and are subject to disapproval under 812.30(b)(4) due to deficiencies in study design. In addition, such IDE studies are in violation of 812.7(c), unduly prolonging the investigation of an investigational device . . . We also remind you that 21 C.F.R. 812.7 prohibits promotion and commercialization of an investigational device or representing that an investigational device is safe or effective for the purposes for which it is being investigated.

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[6] The language from AmCell's website, <www.AmCell.com>, stated:

> Regardless of the cause of hematopoietic cells . . . the CliniMACS leads the field in CD34 cell selection with excellent purities and yields in the selected cell population . . . . The device is uncomplicated and easy to use, with a processing time of approximately two and one half hours.

The website provided a small disclaimer that the device was not approved for sale in the United States.

Last, during a June 30, 2000 meeting, representatives from the FDA expressed concern with the design of the clinical trials and stated that "AmCell needs to identify which sponsor-investigator trials they believe can contribute to their clinical development plan." The FDA further cautioned that "[t]here is a point at which further feasibility studies are no longer necessary and ongoing studies need to be completed. These ongoing studies and their endpoints need to be identified in order to establish a uniform protocol for all sponsor-investigator sites."

While the parties dispute the motive behind AmCell's activities, the parties do not dispute the existence of each of the above listed activities. It is also undisputed that the FDA has approved approximately 17 investigator-sponsored CliniMACS IDEs for at least 13 institutions. AmCell maintains that the purpose of all of its activities was to collect data necessary for obtaining FDA approval of CliniMACS/CD34. Nexell, however, questions whether AmCell's promotional activities are reasonably related to the gathering of necessary data. It asserts that the actual purpose of many of these activities was not to obtain FDA approval but to promote and encourage physicians to use AmCell's CliniMACS device over Nexell's Isolex device.

B. The Court's April 23, 2001 Opinion and Order

The court considered the parties' cross-motions "as motions for summary judgment on the applicability of the exemption found in § 271(e)(1)." Nexell, 143 F. Supp. 2d at 419. With respect to the § 271(e)(1) exemption to infringement, the crucial

determination for the court was whether AmCell's activities were "solely for uses reasonably related to the development and submission of information." 35 U.S.C. § 271(e)(1). In an opinion and accompanying order, both dated April 23, 2001, the court granted AmCell's motion and denied the cross-motion of Nexell, Becton Dickinson, and Johns Hopkins.

In the discussion section of the opinion, the court reviewed the history of § 271(e)(1) and then noted that in cases such as Telectronics Pacing Sys., Inc. v. Ventritex, Inc., 982 F.2d 1520, 1522-23 (Fed. Cir. 1992) and AbTox, Inc. v. Exitron Corp., 122 F.3d 1019 (Fed. Cir. 1997) "[t]he Federal Circuit has construed the § 271(e)(1) exemption broadly." Nexell, 143 F. Supp. 2d at 421. However, after pausing to consider the role of the FDA in aiding the court to determine whether or not certain activities are "reasonably related" to obtaining FDA approval, the court reasoned that, because the FDA establishes regulations to oversee the development and testing of medical devices, the FDA is in a better position than the courts to determine what activities are "reasonably related" to obtaining regulatory approval and what activities are not "reasonably related" to obtaining regulatory approval. Id. at 422.

Based on the several instances in this case in which the FDA seemed to express concern over certain of AmCell's activities, the court noted that "[i]n this case, it appears that the FDA has found that certain activities are reasonably related to obtaining approval and raised with AmCell whether certain other activities are not reasonably related." Id.

The court explained that "[b]y controlling a manufacturer's commercial messages and disallowing applications for IDEs where the FDA believed that the trial would not yield useful data of where the manufacturer is promoting, test marketing, commercializing, or unduly prolonging the investigation of device, the FDA is telling the courts what activities fall within the scope of the § 271(e)(1) exemption." Id.

The court thus decided that:

> The court will not resolve the issue of whether AmCell's activities are protected by § 271(e)(1). Rather, the court will defer to the FDA. The FDA can resolve the issue and define for AmCell what activities are reasonably related to the development and submission of information necessary to obtaining pre-market approval for its device, and in doing that, it can also identify what activities are not reasonably related to obtaining approval. If AmCell persists in activity that the FDA finds is not reasonably related, Nexell can seek relief from this court, including relief identified in its complaint in this action. Should the FDA decline to identify which of AmCell's activities are not reasonably related to obtaining approval, Nexell can renew its claim for relief.

Id. at 432. The court then granted summary judgment to AmCell "with the understanding that the judgment will not preclude Nexell from revisiting these issues in the future." Id.

C. Plaintiffs' Motion to Amend the April 23, 2001 Order

On May 2, 2001, plaintiffs' counsel sent a letter to Eric M. Blumberg, Esquire, the Deputy Chief Counsel for Litigation at the FDA. The letter enclosed a copy of the court's April 23, 2001 opinion and inquired "whether the FDA will address [the issues identified in the opinion] and, if so, how the parties and FDA can best resolve them." The letter then submitted a series of questions that it asked the FDA to consider,

including: (i) whether the FDA approved CliniMACS/CD34 clinical study is "reasonably related to AmCell's efforts to obtain pre-market approval for CliniMACS/CD34;" (ii) if the FDA would ever approve studies that are not reasonably related to seeking pre-market approval; (iii) if so, whether the FDA would advise them and the court as to which of the defendants' proposed activities are reasonably related to seeking pre-market approval and which are not; and (iv) whether "the defendants' ongoing efforts to promote CliniMACS/CD34, including web sites, medical conferences, medical journals, and direct mail solicitations, [are] reasonably related to seeking approval of CliniMACS/CD34?"

Next, on May 7, 2001, plaintiffs Nexell, Becton Dickinson, and Johns Hopkins moved to amend the court's April 23, 2001 order. By their motion, plaintiffs urged the court to adopt the following amendments in order to clarify its ruling: (i) a clarification that AmCell's motion was for *partial* summary judgment because it did not address or resolve certain allegedly infringing activities raised in plaintiffs' complaint that fell outside the scope of the § 271(e)(1) exemption (i.e., the decision did not address the merits of AmCell's asserted defense under the Becton Dickinson license); (ii) a statement that AmCell's motion was granted in part and denied in part, because the court stated that it would defer to the FDA on the § 271(e)(1) issue; (iii) a statement requiring AmCell to disclose, on an ongoing basis, documents that reflect the FDA's decision making with respect to activities relating to the CliniMACS/CD34, in order to monitor which of

AmCell's activities are reasonably related to AmCell's obtaining approval of CliniMACS/CD34 and which are not; (iv) a statement providing that the plaintiffs may apply to the court for further relief if the FDA does not resolve these issues; and (v) an injunction enjoining the defendants from engaging in infringing activities outside the scope of 35 U.S.C. § 271(e)(1) or the Becton Dickinson license.

Defendants oppose the plaintiffs' motion. They argue that no amendment is necessary, because the court deferred to the FDA's judgment that AmCell's activities were reasonably related to obtaining approval. Defendants maintain that because AmCell has not conducted any disapproved clinical trials and has not persisted in any activity that the FDA opposed, their activities must fall in the safe harbor of § 271(e)(1). Moreover, the defendants complain that plaintiffs' counsel's letter to the FDA was an unwarranted and inappropriate attempt to intervene between AmCell and the FDA. Defendants assert that the court's April 23, 2001 opinion "does not give Nexell or anyone else the right to intervene with the FDA, or to gain access to confidential communications between the FDA and AmCell."

In July 11, 2001, the FDA responded to plaintiffs' counsel's letter and declined to answer the questions raised by the plaintiffs. The FDA stated that, based on its reading of the court's April 23, 2001 opinion,

> It is not clear to the FDA what, if anything, the court expects the agency to do in this litigation. On the one hand, the court could be suggesting that the FDA . . . has made and will continue to make certain determinations regarding AmCell's activities that will be relevant to the court's

> consideration of whether these activities are protected by section 271(e)(1) . . . On the other hand, the court could be suggesting, as you indicate in your letter, that [the] FDA independently determine whether various CliniMACS activities fall with the section 271 exemption.

Blumberg Letter to Ware, July 11, 2001. To the extent the court was suggesting the former, the FDA merely noted that the ultimate construction and application of § 271(e)(1) lies with the court and that a such the court could determine to what extent, if any, the actions and statements of the FDA are relevant indicators of which activities are reasonably related to the approval process and which are not.

However, the letter stated that if the court intended the FDA to determine whether AmCell's activities falls within the § 271(e)(1) exemption, the FDA declined to make this determination. In so doing, the FDA noted that the FDA is not called upon in the normal course of its duties to construe the patent laws in private litigation. Moreover, the FDA remarked that the standards used to evaluate AmCell's conduct are not the same as the standard contained in § 271(e)(1). For example, the FDA may reject an IDE application based solely on safety concerns that are wholly unrelated to whether the IDE is being used for promotional or commercial purposes. Therefore, according to the FDA, "there is no reason to assume any direct correlation between [the] FDA's evaluation of AmCell's submissions and the appropriate construction of section 271."

II. DISCUSSION

The court's April 23, 2001 order states that AmCell's "motion for summary judgment is granted" and that "plaintiffs' cross-motion for partial summary judgment is

denied." Plaintiffs submit that the court should amend the order to clarify that AmCell's motion was for *partial* summary judgment and to state that both parties' motions are granted in part and denied in part. They also request additional amendments requiring AmCell to provide communications between the FDA and AmCell to the plaintiffs and seek an injunction enjoining AmCell from engaging in any activities that exceed the scope of § 271(e)(1).

Plaintiffs base these requests on their contention that the court's opinion did not rule in AmCell's favor on their asserted § 271(e)(1) defense, but instead merely deferred to the FDA on the issue. According to the plaintiffs, therefore, whether § 271(e)(1) exempts AmCell's allegedly infringing activities from infringement liability remains an open issue. Moreover, AmCell argues, because the court treated the motion as reaching only "the applicability of the exemption found in § 271(e)(1)," the decision did not determine that AmCell is entitled to summary judgment on its license defense. Therefore, should the court find that summary judgment is appropriate on the § 271(e)(1) issue, should it rule in favor of AmCell, the court should only grant AmCell partial summary judgment, because that finding does not reach the license defense.

On the issue of its § 271(e)(1) defense, however, AmCell, has a different reading of the court's opinion. According to AmCell, the court already deferred to the FDA and ruled that the complained of activities of AmCell were reasonably related to obtaining FDA approval and therefore fall within the scope of the § 271(e)(1) exemption. Based on

these findings, AmCell contends, the court properly granted AmCell's summary judgment motion.

A. Allegedly Infringing Activities Relating to FDA Trials: the § 271(e)(1) Defense

From their positions it is apparent that the parties have two vastly different readings of the court's opinion. The ostensible ambiguity in the opinion is also apparent from the response of the FDA to the letter sent by plaintiff's counsel. See Blumberg letter to Ware, July 11, 2001. ("It is not clear to the FDA what, if anything, the court expects the agency to do in this litigation."). The court did not intend, by its decision, for the parties to solicit an advisory ruling from the FDA as to which of AmCell's activities were reasonably related to obtaining the FDA's approval and which were not, nor did it expect the FDA to provide one. Rather, the court merely attempted to underscore that the FDA, by actively enforcing its regulatory guidelines and approving or disapproving of clinical trials, generally ensures that the activities that parties seeking approval, such as AmCell, are engaged in are reasonably related to the clinical trials. That is, unless the court is confronted with the extreme case in which either it is clear that certain otherwise infringing activities are outside the FDA approval process or the FDA itself affirmatively indicates that a party's activities are not reasonably related to obtaining its approval, the court will not find that accused activities that a defendant objectively believes could generate information that is likely to be relevant to the FDA approval process are not "reasonably related" to obtaining FDA approval. See Intermedics v. Ventritex, 775 F.

Supp. 1269, 1280-81 (N.D. Cal. 1991), aff'd without op., 991 F.2d 808 (Fed. Cir. 1993) (Table).

Based on the facts before the court, the court determined that AmCell's activities were "reasonably related" to obtaining FDA approval and therefore could not constitute acts of infringement. However, the court also stated in its April 23, 2001 opinion that if the additional evidence regarding the FDA's regulation of AmCell demonstrated to the court that its otherwise infringing activities were not "reasonably related" to obtaining FDA approval, the court would revisit its earlier ruling. No such evidence has been submitted.[7] The court therefore stands by its determination that AmCell's activities were "reasonably related" to obtaining FDA approval within the meaning of § 271(e)(1) exemption.

By this memorandum, the court seeks to clarify its earlier ruling with respect to the parties' cross-motions. Because the court has determined that it correctly granted AmCell's motion for summary judgment on its § 271(e)(1) defense and correctly denied

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[7] Moreover, as pointed out by the FDA in its letter, even in situations where the facts indicate that the FDA has expressed disapproval with certain aspects of the clinical trials, this disapproval does not necessarily have bearing on the question of whether the activities are "reasonably related" to gathering information for the FDA. FDA concerns could be unrelated to excessive commercialization and can range from safety concerns to practical concerns about the design and effectiveness of the trial.

Additionally, when determining whether an activity is "reasonably related" to the FDA approval process, the court must evaluate this objectively from the perspective of the defendant. Thus, if the defendant reasonably believes that certain otherwise infringing activities would yield necessary information for FDA approval, but the FDA subsequently disagrees, the FDA's opinion does not convert those activities from exempt under § 271(e)(1) to infringing activities.

the plaintiffs' motion for summary judgment on that issue, the court will deny the portion of the plaintiffs motion to amend its order that relates to the § 271(e)(1) issue. The court's reasoning is set forth below.

While reasonable minds can differ as to the subjective intentions of AmCell, each of the activities raised by the plaintiffs was nonetheless conducted pursuant to soliciting clinicians to enter into FDA-approved clinical trials. In this case, therefore, the court found that each of the accused activities is "reasonably related" to obtaining FDA approval and thus covered by the exemption of § 271(e)(1). See Abtox, 122 F.3d at 1029 (finding that as long as the activity is reasonably related to obtaining FDA approval, the underlying purposes or attendant consequences of the activity is not relevant to the exemption); Intermedics, 26 U.S.P.Q. 2d at 1526 ("the inquiry is not generally whether the allegedly infringing party has engaged in conduct that shows it has purposes beyond generating and presenting data to the FDA"); see also Elan Transdermal Ltd. v. Cygnus Therapeutics Sys., 24 U.S.P.Q. 2d 1926, 1932-33 (N.D. Cal. 1992) (explaining that in § 271(e), "solely" is correctly read as modifying "uses" and not "reasonably related" and that therefore courts focus on the infringing uses alleged by the patentee rather than on the subjective intention of the alleged infringer). Accordingly, the court granted summary judgment in favor of AmCell.

The events that followed the issuance of the court's April 23, 2001 opinion and order, including the exchange between plaintiffs' counsel and the FDA, have further

convinced the court that its decision with respect to these matters was correct. As a policy matter, inquiring into the motivation behind activities that are conducted under the auspices of FDA-approved clinical trials would be contrary to Congress's intent in enacting § 271(e)(1), because it would chill parties from engaging in the very pre-approval testing that Congress sought to encourage. This is not to say that no pre-approval activity could rise to the level of commercialization and exceed the scope of the § 271(e)(1) exemption. However, a large degree of deference to activities conducted in furtherance of FDA-approved clinical trials is appropriate.

Therefore, courts have determined that activities should only be found to exceed the scope of the § 271(e)(1) exemption when they have no objectively reasonable application towards obtaining FDA approval. Such a finding might be appropriate where either the defendants' actions or communications from the FDA to the defendant clearly indicate that the defendant could not reasonably believe that its activities are related to obtaining FDA approval. In making this determination, considerable leeway must be given to the defendant, because "it will not always be clear to parties setting out to seek FDA approval for their new product exactly what kinds of information, and in what quantities, it will take to win that agency's approval." Intermedics, 775 F. Supp. at 1280.

Such deference to activities conducted in the course of FDA clinical trials is supported by the limited case law that exists on this topic. The Court of Appeals for the Federal Circuit has concluded that activities that are at least as "commercially extensive"

as AmCell's activities in this case nonetheless fall under the § 271(e)(1) exemption when they are conducted pursuant to an FDA clinical trial. See Teletronics, 982 F.2d at 1522-25 (Fed. Cir. 1995) (demonstration at conference in order to solicit clinical investigators for IDE falls under § 271(e)(1) exemption); Chartex International PLC v. M.D. Personal Product Corp., 1993 WL 306169, at *2-3 (Fed. Cir. Aug. 12, 1993) (displaying product at trade shows and conducting studies of consumer response to gather information for clinical testing fall under § 271(e)(1) exemption); see generally Brian D. Coggio and Francis D. Cerrito, The Application of The Patent Laws to the Drug Approval Process, 4 No. 1 Andrews Intell. Prop. Litig. Rep. 3 (Aug. 6, 1997) (reviewing the many otherwise infringing activities that have been found to be exempted under § 271(e)(1)).

The rationale behind this broad construction of the § 271(e)(1) exemption was explained quite nicely in Intermedics, 775 F. Supp. at 1280. There, the court stated that:

> We infer that the phrase "reasonably related" (to development of information for the FDA) as used in § 271(e)(1) reflects Congress' acknowledgment that it will not always be clear to parties setting out to seek FDA approval for their new product exactly what kinds of information, and in what quantities, it will take to win that agency's approval. Thus Congress used this phrase to communicate its intention that the court's give parties some latitude in making judgments about the nature and extent of the otherwise infringing activities they would engage in as they sought to develop information to satisfy the FDA.

The Intermedics court, therefore, developed the following test, which has since been widely accepted, to determining whether an activity is "reasonably related" under § 271(e)(1):

> we should ask: would it have been reasonable, objectively, for a party in defendant's situation to believe that there was a decent prospect that the "use" in question would contribute (relatively directly) to the generation of kinds of information that was likely to be relevant to the process by which the FDA would decide whether to approve the product.

Id. Applying this test to the facts in this case, the court remains convinced that AmCell's allegedly infringing activities do not exceed the scope of the § 271(e)(1) exemption. The court will thus deny plaintiffs' motion to the extent it seeks to alter the court's decision that AmCell's FDA-trial related activities are shielded from infringement by § 271(e)(1). Accordingly, the court will not modify its order granting summary judgment to AmCell on its § 271(e)(1) defense.[8]

B. Allegedly Infringing Activities Not Relating to FDA Trials: the Becton Dickinson License Defense

As counsel for the plaintiffs underscored during oral argument, there is another issue aside from the § 271(e)(1) defense that the court must consider in relation to its motion to amend. Putting aside AmCell's ongoing activities in FDA trials, Nexell contends that AmCell is involved in other infringing activities that are unrelated to FDA trials. Specifically, Nexell asserts that AmCell continues to provide free CliniMACS devices with the CD34 reagent to clinical sites that have not been approved by the FDA. More specifically, Nexell contends that once AmCell agrees to support a clinician, the

[8] Given the court's finding that AmCell's FDA related activities are protected by § 271(e)(1), the court does not feel that plaintiffs' suggested modifications relating to either (i) allowing the monitoring, by plaintiffs, of future communications between AmCell and the FDA; or (ii) enjoining the defendants from engaging in infringing activities outside the scope of 35 U.S.C. § 271(e)(1) are wise or necessary.

device is installed at the clinical site, but notes that even after these particular cites are disapproved for FDA trials, Nexell fails to remove the device. Thus, according to the plaintiffs, AmCell is infringing the Civin patents by installing its allegedly infringing device and reagent for clinicians, outside of the FDA trial process, who are potential customers of the plaintiffs.

AmCell's position, and its affirmative defense to plaintiffs' arguments, is that these activities are covered by a license agreement between its affiliate Miltenyi Biotec GmbH and Becton Dickinson. That license agreement expressly excludes "research dedicated to a therapeutic in vivo use." It is clear that the license insulates AmCell from infringement liability for in vitro research uses of the device, but excludes from its scope therapeutic uses such the treating of patients. Beyond this, however, the parties dispute the scope of the exclusion. AmCell asserts that any in vitro research use is covered by the license, while Nexell asserts that certain research that is directed at obtaining approval for clinical use, even if it is currently in vitro research, is "research dedicated to a therapeutic in vivo use" that is excluded from the license.

Defendants do not claim that their provision of CliniMACS to clinicians in the United States would be authorized by the Becton Dickinson license if such uses were for clinical – not research – use. AmCell asserts, however, that its uses fall within the scope of the license because it is only and can only be used for research purposes– i.e., they are only in vitro experimental uses. At oral argument, AmCell emphasized that because

its products were labeled "for research," a presumption arises under the license that they are being used for only that limited purpose, since no clinician can legally use such products on patients (i.e. therapeutically) without FDA approval. See 21 U.S.C. § 515. AmCell further argued that if a clinician who has applied to use the CliniMACS CD34 system does not obtain FDA approval, that clinician does not get the software necessary to use the CliniMACS device on patients; he may only use it for research, which is a protected use under the Becton Dickinson license. AmCell thus concludes that in light of those facts and since the plaintiffs have not yet come forward with evidence on infringement (which rebuts this presumption), the court properly granted complete summary judgment on noninfringement in favor of AmCell.

The plaintiffs disagree. Nexell alleges that AmCell's accused activities are the very uses that are expressly excluded from the scope of the license. It argues that even if the uses of the CD34 at these facilities are not actual in vivo therapeutic uses, as AmCell maintains, that activity may nonetheless be "dedicated to a therapeutic use" and thus expressly excluded from the license (and infringing) if they are being used for research and the goal of that research is to treat patients. Moreover, Nexell states, the defendants have been unwilling to provide them with any discovery as to the exact nature of the use of the allegedly infringing product at these facilities. Thus, because factual and legal disputes exist on this issue, Nexell reasons that summary judgment on this issue cannot be appropriate. Plaintiffs further argue that since the court stated in its earlier opinion

that it was treating the parties' cross-motions "as motions for summary judgment on the applicability of the exemption found in § 271(e)(1)," the accompanying order should have only granted partial summary judgment on that issue. Last, plaintiffs correctly point out that since the license defense is an affirmative defense, see Fed. R. Civ. P. 8(c), AmCell bears the burden or proof on this issue. See McCoy v. Mitsuboshi Cutlery, Inc., 67 F.3d 917, 920 (Fed. Cir. 1995) ("A licensee, of course, has an affirmative defense to a claim of patent infringement.").

The court agrees with plaintiffs that it did not, by its order, intend to grant summary judgment in favor of AmCell on its license defense. Although AmCell styled its motion as a motion for summary judgment and not a motion for partial summary judgment, the court did not consider the license issue in its opinion. Nor was the license issue fully briefed by the parties.[9] Moreover, as to whether AmCell can successfully carry its burden on its license defense, both fact issues – concerning the nature of the use of the CD34 reagent at these non-FDA facilities– and legal issues – relating to whether such use falls within or outside of the scope of the Becton Dickinson license – remain unresolved.

[9] While the parties alluded to the non-FDA-approved research uses and the license issue in their recitation of the facts, the legal argument in both sets of briefs was directed at § 271(e)(1). In addition, plaintiffs, in a footnote in one of their briefs, explained that they had not moved for summary judgment on the license issue because they had not yet obtained adequate discovery on the issue.

It may well be true that when the facts regarding the nature of this use are developed, it will be clear that the uses fall under the license. However, at this point, because plaintiffs represent that defendants have not provided them with discovery as to the specific uses of CD34 at these facilities and the defendants bear the burden of establishing their license defense, the court is not comfortable that a sufficient factual record exists to support a grant of summary judgment in favor of AmCell on this issue. Therefore the court will grant in part plaintiffs' motion to amend and modify the order to grant *partial* summary judgment, which is limited to the § 271(e)(1) issue.

In the future, should the parties develop the underlying facts concerning these non-FDA approved clinician research activities and should those fact issues be undisputed, leaving only the legal question of contract interpretation as to the scope of the license, the court will entertain motions for summary judgment on this issue.

III. CONCLUSION

AmCell's infringement claims relate to two types of activities: those purportedly carried out in relation to ongoing FDA trials and those that are not being carried out under the auspices of FDA trials.

AmCell's defense to the former activities is that its FDA-related activities are shielded by § 271(e)(1) exemption. While the court is not unsympathetic to plaintiffs' claims, when Congress set forth the § 271(e)(1) exemption, it intended to insulate otherwise infringing activities from patent infringement liability when those activities

are conducted pursuant to the FDA approval process. In interpreting § 271(e)(1), courts have universally adopted a broad construction of the exemption. Based on this construction and the evidence before the court, the court finds that AmCell's activities in this case do not rise to a level that exceeds the scope of § 271(e)(1). Therefore, those activities are protected by that statute. Based upon this finding, the court does not believe that any of the plaintiffs' requested modifications to the court's earlier order that relate to § 271(e)(1), are warranted and will deny plaintiffs' motion those respects.

AmCell's defense to the latter activities is that these non-FDA-related activities are shielded by the Becton Dickinson license. As the court did not consider this defense and fact issues remain as to whether the defense has merit, the court will grant plaintiff's motion to amend in part to clarify that it did not grant summary judgment to AmCell on its license defense.

The case will thus proceed only on the issues of whether AmCell's non-FDA-related activities of providing CliniMACS and the CD34 reagent to non-FDA-approved clinicians are acts of infringement, and whether, if they are found to be infringing, AmCell can prove that they are nonetheless covered by the Becton Dickinson-Miltenyi Biotec GmbH license.

The court will issue an order consistent with this memorandum opinion.