United States District Court
District of Massachusetts

Oxford Immunotec Ltd.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. 15-13124-NMG**
	)	
Qiagen, Inc. et al.,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM & ORDER

GORTON, J.

Plaintiff Oxford Immunotec Ltd. ("plaintiff" or "Oxford") alleges defendants Qiagen, Inc., Quest Diagnostics, Inc. and Laboratory Corporation of America Holdings ("defendants" or "Qiagen") infringed its patents relating to a method and kit for diagnosing tuberculosis. Oxford seeks a preliminary injunction to enjoin Qiagen from selling the QFT-Plus one-tube option to new customers currently using a tuberculin skin test or TSPOT.TB.

I. Background

A. Overview of the Patented Technology

Oxford owns six patents describing a method and kit for diagnosing tuberculosis in vitro (outside of the human body). Five of the six patents-in-suit (collectively, "the '646 patent

family") share a common specification. Those five patents, each entitled "Tuberculosis Diagnostic Test," are:

1) U.S. Patent No. 7,632,646 ("the '646 patent"), issued on December 15, 2009,
2) U.S. Patent No. 7,901,898, ("the '898 patent"), issued on March 8, 2011,
3) U.S. Patent No. 8,216,795, ("the '795 patent"), issued on July 10, 2012,
4) U.S. Patent No. 8,507,211, ("the '211 patent"), issued on August 13, 2013 and
5) U.S. Patent No. 9,005,902 ("the '922 patent"), issued on April 14, 2015.

The sixth patent-in-suit, U.S. Patent No. 8,617,821 ("the '821 patent"), entitled "Assay Method for Peptide Specific T-Cells," has a different specification. It was issued on December 31, 2013.

Oxford's amended complaint contains six counts alleging infringement of those six patents, in violation of 35 U.S.C. § 271(a)-(c).

Oxford's motion for preliminary injunction rests on two exemplary patent claims.

Claim 1 of the '211 patent is for:

> A method of in vitro diagnosis of Mycobacterium tuberculosis infection in a host, comprising (a) keeping a population of T cells isolated from said host in contact with a peptide panel comprising one or more epitopes contained within peptide SEQ ID NO: 1, and (b) detecting a recognition response by the T cells to the peptide panel.

Claim 17 of the '898 patent is for:

> A kit for diagnosing infection in a human host by, or exposure of a human host to, a mycobacterium that expresses ESAT-6, comprising a peptide represented by SEQ ID NO: 1.

Plaintiff rests its motion for preliminary injunction on those two claims.

B. The '646 Patent Family

Approximately one-third of the world population is infected by tuberculosis and between 5% and 10% of infected individuals will develop the active disease. Tuberculosis detection is currently performed in one of two ways: through a tuberculin skin test ("TST") or through an in vitro blood test known as an interferon gamma release assay ("IGRA").

Oxford's patents pertain to an IGRA for tuberculosis. When the body encounters a pathogen such as Mycobacterium tuberculosis ("M. tuberculosis"), proteins from that pathogen are broken down into pieces known as peptides comprised of strings of amino acids. T cells, cells that mediate immune responses in the body, become "antigen-experienced" after they encounter a harmful peptide. Then, in a process known as activation, T cells that encounter that peptide a second time

can bind to it. Once activated, the T cells release so-called cytokines, such as IFN-γ, which act as chemical messengers in order to elicit a full immune response.

The '646 patents-in-suit are drawn to a method for diagnosing tuberculosis whereby T cells are placed in contact with peptides from a protein known as ESAT-6. Oxford uses ESAT-6 because it is secreted by M. tuberculosis. After contact, one can measure the level of cytokines released (e.g., IFN-γ) to determine whether there is a tuberculosis infection. Importantly, ESAT-6 is absent from the most common TB vaccine, which means that Oxford's method will trigger fewer false positives than conventional skin tests in people who are vaccinated but not infected with TB.

Oxford's invention also provides a kit for carrying out the claimed method.

C. Tuberculosis diagnosis

IGRAs provide more convenience and accuracy than skin tests. There are currently two IGRAs available in the United States market: Oxford's T-SPOT.TB and Qiagen's QuantiFERON-Gold In-Tube ("QFT-Gold") product. Accordingly, both companies seek to convert skin test users, who currently comprise about 80% of the tuberculosis diagnosis market, to IGRA users.

Oxford maintains that the T-SPOT.TB is a superior product to the QFT-Gold because the former uses a single, standardized

tube while the latter requires multiple specialized tubes. The QFT-Plus, Qiagen's next generation product, mimics the QFT-Gold but also contains an additional single test tube option. Qiagen's single tube option has been offered outside the United States. Oxford maintains that the single tube option in the QFT-Plus is meant to emulate their T-SPOT.TB test.

Plaintiff requests that this Court enjoin the sale of the QFT-Plus one-tube option to new customers currently using the skin tests or TSPOT.TB until after trial to prevent defendants' allegedly infringing product from gaining market share at plaintiff's expense.

D. The launch of the QFT-PLUS

On June 8, 2017, Qiagen announced that it had received FDA approval for its next generation "QFT-Plus" product. According to its corporate representative, Qiagen intends to launch the product in the U.S. market in October, 2017. Qiagen maintains that Oxford knew in January, 2017, that Qiagen had applied for FDA approval. In fact, Oxford has been aware of the launch of the QFT-Plus since at least September 2015 and, shortly thereafter, informed Qiagen that it would move for a preliminary injunction when the product launched.

E. Procedural history

Plaintiff filed its complaint in August, 2015. Defendants jointly moved to dismiss that suit in October, 2015, asserting

that Fed. R. Civ. P. 12(b)(6) and 35 U.S.C. § 101 mandated dismissal. The motion was referred to Magistrate Judge Cabell, who issued his report and recommendation ("R&R") regarding the motion on August 31, 2016. He recommended dismissing plaintiff's "kit" claims but denying the defendant's motion to dismiss the plaintiff's "method" claims. Both parties timely objected to the R&R.

On September 30, 2016, this Court adopted, in part, and rejected, in part, the Magistrate Judge's R&R, allowing both the "kit" and the "method" claims to proceed.

Magistrate Judge Cabell found that the "kit" claim was directed towards ineligible subject matter because the peptides used in plaintiff's diagnostic kit exist in nature and have not been changed beyond the act of isolation from the ESAT-6 protein. Accordingly, Magistrate Judge Cabell reasoned, the peptide claims lacked an inventive concept. This Court rejected that finding because, taking the plaintiff's allegations as true, the claimed peptides were

> chemically different than the naturally occurring amino acids in the ESAT-6 protein and that purportedly results in the peptides behaving differently in plaintiff's in vitro tests than would the amino acids in the ESAT-6 protein.

This court thus concluded that the peptides allegedly arise from "human ingenuity" and have a distinctive character and use, thus being drawn to eligible subject matter.

This Court accepted the Magistrate Judge's recommendation that the "method" claims proceed. Defendants claimed that plaintiff's method claims involved "routine and conventional" steps lacking an inventive concept. This Court found, however, that the method claims, when considered in combination, improved on current tuberculosis testing methods and that, accepting the plaintiff's allegations as true, there was no in vitro diagnostic test for tuberculosis in common use before plaintiff developed its test.

In February 2017, the Patent and Trademark Office ("PTO") rejected all five of Qiagen's petitions for inter partes review. Those petitions challenged the patents under 35 U.S.C. § 103.

This Court conducted a Markman hearing on June 8, 2017 and entered an order the following week construing every disputed claim term in plaintiff's favor.

On August 4, 2017, plaintiff filed this motion for a preliminary injunction, seeking to enjoin the U.S. commercialization of the QFT-Plus until after the trial, which is scheduled to begin on January 16, 2018. The scope of the injunction sought has now been narrowed to prohibiting the use of the one-tube option by new customers.

II. Analysis

A. Motion for Preliminary Injunction

The purpose of a preliminary injunction is to preserve the relative positions of the parties until a trial on the merits is held. New Hampshire Right to Life Political Action Comm. v. Gardner, 99 F.3d 8, 16 (1st Cir. 1996). To obtain injunctive relief, the plaintiff bears the burden of demonstrating:

> 1) a substantial likelihood of success on the merits, 2) a significant risk of irreparable harm if the injunction is withheld, 3) a favorable balance of hardships and 4) a fit (or lack of friction) between the injunction and the public interest.

Nieves-Márquez v. Puerto Rico, 353 F.3d 108, 120 (1st Cir. 2003) (citation omitted).

No individual factor is dispositive. Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001). Instead, the court "must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested." Printguard, Inc. v. Anti-Marking Sys., Inc., 535 F. Supp. 2d 189, 196 (D. Mass. 2008) (quoting Hybritech, Inc., v. Abbott Labs., 849 F.2d 1446, 1451 (Fed. Cir. 1988)).

1. Likelihood of success on the merits

To establish likelihood of success on the merits, a patentee must demonstrate that it will likely prove that its patent was infringed and is valid. See AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1050 (Fed. Cir. 2010) (citing

Amazon.com, 239 F.3d at 1350-51 (Fed. Cir. 2001)). If an accused infringer raises a "substantial question" regarding enforcement, infringement or validity that the patentee has not shown lacks "substantial merit", a preliminary injunction should not issue. Holmes Products Corp. v. Catalina Lighting, Inc., 67 F. Supp.2d 10, 12 (D. Mass. 1999) (citing New England Braiding Co. v. A.W. Chesterton Co., 970 F.2d 878, 882-83 (Fed. Cir. 1992)).

Defendants contend that plaintiffs have not demonstrated a likelihood of success on the merits because: 1) the asserted claims are unpatentable under Section 101, 2) the asserted claims are invalid as anticipated and/or obvious under Sections 102 and 103, 3) Oxford cannot overcome Qiagen's written description defense, and 4) Qiagen's product does not infringe. The arguments will be considered seriatim.

a. Claims are unpatentable under Section 101

Federal law determines what inventions are patentable. See 35 U.S.C. § 101. Elemental concepts such as "laws of nature, natural phenomena, and abstract ideas" are excluded from Section 101's protection. Diamond v. Diehr, 450 U.S. 175, 185 (1981).

The court applies a two-step process for determining whether the subject matter of an invention is patentable. See

Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012).

First, the court determines whether the patent claims are "directed" to one of the patent-ineligible concepts. Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1047 (Fed. Cir. 2016) (quoting Mayo, 132 S. Ct. at 1296-97). If the claims are directed to an eligible concept, the inquiry is over: the claims are patentable. Thales Visionix Inc. v. United States, 850 F.3d 1343, 1349 (Fed. Cir. 2017).

In step two, the court asks, "[w]hat else is there in the claims before us?" Alice Corp. Pty. v. CLS Bank Int'l, 134 S. Ct. 2347, 2355 (2014) (quoting Mayo, 132 S. Ct. at 1297). The invention is patentable if the claims contain an element or combination of elements that is

> sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.

Id. at 2358 (additional citation omitted).

At the preliminary injunction stage, the trial court "does not resolve the validity question," but rather considers the persuasiveness of the challenger's argument, recognizing that not all evidence is available. See Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1376 (Fed. Cir. 2009).

Defendants assert that the '898 Patent, Claim 17 is unpatentable because it reflects the same natural peptides that had been previously encountered by the T cells. Defendants rely on deposition testimony of the inventor, Dr. Lalvani:

> Q. In your assay, in whatever peptide you are using, does that mean that one of the T cells that is activated has already encountered that peptide before?
> A. Yes.
> Q. That would be a peptide that it has already encountered naturally in the body, correct?
> A. Yes.

This exchange, defendants contend, establishes that the plaintiff's claims in its complaint are not true and that the claims are drawn to ineligible subject matter. This Court denied defendants' motion to dismiss plaintiff's "kit" claims, reasoning that the kit peptides, as alleged, are "chemically different than the naturally occurring amino acids in the ESAT-6 protein." Dr. Lalvani's testimony, defendants contend, vindicates the Magistrate Judge's initial finding that the kit peptides are found in nature and have not been changed beyond the act of isolation from the larger ESAT-6.

Plaintiff counters that this exchange is presented out of context, and that elsewhere Dr. Lalvani testified that the relevant peptide is not naturally occurring. Oxford explains that the testimony quoted by defendants referred to whether, in general, a synthesized peptide would react identically to a

naturally occurring peptide of the same length and structure. While plaintiff agrees that is true as a general proposition, it contends the peptides used in Oxford's patent do not occur naturally.

This Court finds plaintiff's explanation persuasive.

Dr. Lalvani identified an epitope that exists naturally in the ESAT-6 protein. He then synthesized a peptide that contains that epitope and used the synthesized peptide in his experiments. Dr. Lalvani created something new with synthesized peptides and simply because a particular peptide contains a naturally occurring epitope that does not change this analysis. See Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2119 (2013) (distinguishing unpatentable naturally occurring DNA strands from patentable synthesized cDNA strands).

Discoveries that possess "markedly different characteristics" from any entity found in nature may be patented. In re Roslin Inst. (Edinburgh), 750 F.3d 1333, 1336 (Fed. Cir. 2014) (quoting Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980)). It is likely that Oxford will be able to demonstrate at trial that 1) Dr. Lalvani's peptides are synthesized and are "markedly different" from naturally occurring peptides and 2) its discovery is the product of "human ingenuity" and not merely "nature's handiwork." See Chakrabarty,

750 F.3d at 309-310. Whether or not Qiagen has raised a "substantial question" as to the validity of Claim 17 of the '898 patent, Oxford's response shows that this objection lacks "substantial merit." Holmes, 67 F. Supp.2d at 12 (additional citation omitted). Accordingly, plaintiff is likely to succeed at trial on the merits of the Section 102 validity issue. See Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1379 (Fed. Cir. 2009) (citing New England Braiding, 970 F.2d at 883).

Defendants further submit that claim 1 of the '211 patent, also known as the "method" claim, is invalid because Oxford did not create an inventive concept. Defendant asserts that the plaintiff's allegations, upon which this Court relied in denying the motion to dismiss, have proven to be false. Those allegations were 1) that plaintiff's method improved on the existing testing procedures for tuberculosis and 2) that there was no in vitro diagnostic test for tuberculosis in common use when plaintiff developed its test. Defendants dispute only the latter claim.

This Court is not convinced by defendants' common use theory. When Oxford applied for its patent the use of IGRAs was not widespread. Less than one hundred IGRA test kits were sold per year in the decade before plaintiff applied for its patent.

Defendants have not raised a "substantial question" with respect to the validity of the '211 patent under Section 101.

On the issue of validity under Section 101, plaintiff appears likely to prevail on the merits.

b. Claims are anticipated and/or obvious

Section 102(b) of the Patent Act provides that an invention is not patentable if it is

> described in a printed publication . . . more than one year prior to the [application] date.

To prove invalidity by anticipation, the movant must show that "every element and limitation of the claim" was described in a single prior art reference, placing a person of ordinary skill in possession of the invention. Sanofi-Synthelabo v. Apotex, Inc., 550 F.3d 1075, 1082 (Fed. Cir. 2008).

Differences between the prior art reference and claimed invention, no matter how small, implicate obviousness, and not anticipation. Net MoneyIN, Inc. v. VeriSign, Inc., 545 F.3d 1359, 1371 (Fed. Cir. 2008).

Pursuant to § 103 of the Patent Act, a patent is invalid for obviousness if

> the differences between the subject matter sought to be patented and the 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. § 103(a). See generally KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007). A patent composed of several elements is not obvious just because all of its elements were known independently in the prior art. KSR Int'l Co., 550 U.S. at 418.

Defendants contend that plaintiff's claims are invalid because they are anticipated under Section 102 and obvious under Section 103. Specifically, they allege that two studies (Melendez-Herrada 1997 and Pathan 1997) anticipate both asserted claims.

Qiagen notes that several groups of researchers investigated T-cell response to ESAT-6 peptides prior to plaintiff's priority date. Although defendants have demonstrated that some researchers were actively investigating the development, they have not shown that the claimed invention as a whole would have been obvious. Even if those skilled in the art were considering using ESAT-6, as defendants assert, it does not follow that the development was obvious.

"Mere identification in the prior art of each element is insufficient" to establish obviousness. Abbott Labs. v. Andrx Pharms., Inc., 452 F.3d 1331, 1336 (Fed. Cir. 2006) (citing In re Kahn, 441 F.3d 977, 986 (Fed. Cir. 2006)). Instead, Qiagen must articulate the reasons why one of ordinary skill in the art

would have been motivated to select and combine the references. See id. It has failed to do so. "Obvious to try" does not constitute "obviousness" and this Court is reminded that when determining obviousness it "must avoid hindsight bias and must be cautious of arguments reliant upon ex post reasoning". Arendi S.A.R.L. v. Apple Inc., 832 F.3d 1355, 1361 (Fed. Cir. 2016) (citing KSR, 550 U.S. at 421) (internal quotation omitted).

Finally, this Court notes that Qiagen presented similar, if not identical, arguments with respect to anticipation and obviousness to the PTO during inter partes review. The PTO did not find those arguments meritorious.

Plaintiff is likely to prove that its patent claims were not anticipated or obvious.

c. Qiagen's written description defense

To satisfy the written description requirement, the patent's description must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (quoting Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1562-63 (Fed. Cir. 1991)) (internal quotations omitted). That is,

> the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.

Id. (citing Vas-Cath, 935 F.2d at 1563).

Defendants maintain that Oxford's claim, construed as peptides "comprising SEQ ID. NO. 1" encompasses a genus of all peptides comprising SEQ ID. NO. 1. According to defendants, one skilled in the art would not know whether a particular peptide would be effective but that argument is unpersuasive.

First, the SEQ ID. NO. 1 designation constitutes a "common structural feature" that satisfies the written description requirement. Second, the Court notes that the PTO reviewed Oxford's patents for adequate written description as part of the application process and found the description satisfactorily clear.

Plaintiff is likely to be successful in proving that its patents are not invalid for a lack of written description.

d. Qiagen's product does not infringe

Defendants contend that the QFT-Plus does not infringe Oxford's patents. First, they assert that the QFT-Plus does not "diagnose" tuberculosis infection. Second, they suggest that the Markman order limits the phrase "peptide SEQ ID NO: 1" to a specific 15 amino acid sequence, which the QFT-Plus does not employ. Finally, defendants request that this Court re-construe the '898 patent. Their arguments fall short.

On the first issue, Qiagen's claim that the QFT-Plus does not actually "diagnose" is belied by the first page of its QFT-Plus package insert which states that the product is "[f]or in vitro diagnostic use." Second, the Markman order does not limit Oxford's patent to a single 15 amino acid sequence. The relevant construction includes analogues. Finally, Qiagen proffers no new evidence to justify altering the '898 construction.

Qiagen is not likely to be successful in avoiding Oxford's claims of infringement.

2. Irreparable Harm

Plaintiffs seeking injunctive relief must make a "clear showing" that substantial and immediate irreparable harm is "likely" in the absence of an injunction. Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 22 (2008). A mere showing that the moving party "might lose some insubstantial market share as a result of [the] infringement is not enough." Apple, Inc. v. Samsung Elecs. Co., 678 F.3d 1314, 1325 (Fed. Cir. 2012) ("Apple I"). Here, plaintiff has not made the required "clear showing" of irreparable harm.

Plaintiff's quintessential contention, both in briefing and at oral argument, is that Oxford will suffer an irreparable injury of lost customers if an injunction is not entered.

Customers in the medical sector, Oxford explains, are "sticky". Oxford maintains that Qiagen will make a herculean effort to entice customers to use its new product in the short time remaining before trial. Because the IFRA market has only two suppliers, Oxford contends, every customer that Qiagen gains will be at Oxford's expense and that relationship is likely to persist for years. The alleged harm is not quantifiable and therefore cannot be remedied by money damages.

Two major considerations stand is plaintiff's way.

First, plaintiff's motion has come at a conspicuously late date in this litigation. Oxford knew in January, 2017, that Qiagen was about to apply for FDA approval of the QFT-Plus and planned to launch the product in the second half of 2017. It waited until August 30, 2017, to file its motion for a preliminary injunction and its explanation for the delay is underwhelming.

Plaintiff contends that it waited this long because defendant asked it to. Such a contention is dubious. In response to plaintiff's discovery inquiry, counsel for defendant stated that

> Qiagen does not know when or whether the QFT-Plus product will be approved for sale in the United States. But it is fair to say that the approval is not imminent.

Plaintiff characterizes that statement as Qiagen "urg[ing] Oxford to wait until FDA approval" before filing its motion for preliminary injunction. Such a reading is a stretch.

Oxford had reason to know in January, 2017, that the QFT-Plus would be "rolled-out" in the second half of this year. Its delay until late August, 2017, counsels against its claim of urgency.

Second and perhaps more important to the question of irreparable harm, plaintiff has not established that money damages would be insufficient. "Evidence of potential lost sales alone does not demonstrate irreparable harm." Metalcraft of Mayville, Inc. v. The Toro Co., 848 F.3d 1358, 1368 (Fed. Cir. 2017)(citing Abbott Labs., 452 F.3d at 1348 (Fed. Cir. 2006)). Plaintiff must do more than demonstrate that it might lose market share as a result of defendant's infringement. Apple I, 678 F.3d at 1325. It must make a "clear showing that it is at risk of irreparable harm." Apple Inc. v. Samsung Elecs. Co., 695 F.3d 1370, 1374 (Fed. Cir. 2012) ("Apple II") (quoting Apple I, 678 F.3d at 1325) (emphasis added) (additional citations omitted). As the Supreme Court has explained,

> Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with our characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.

Winter, 555 U.S. at 22 (citing Mazurek v. Armstrong, 520 U.S. 968, 972 (1997) (per curiam)).

If plaintiff prevails at trial, it is likely that the infringing aspects of the QFT-Plus will be permanently enjoined. Oxford does not proffer evidence of how, between now and the trial, irreparable harm may occur. In fact, its own financial projections, such as its 2016 U.S. Commercial Strategy Revenue Projection, forecast the anticipated monetary harm that an infringing QFT-Plus product would cause. To Oxford, it was quantifiable.

Oxford may well lose some customers to Qiagen due to the QFT-Plus and defendant's assurances to the contrary are cold comfort. Qiagen's "service/kit" contrast is a distinction without a difference because both target the same TST customers and Qiagen's forecast that no customers would be gained for six to twelve months fails to account for the inroads made before then. Nevertheless, Oxford has the burden of proving irreparable harm with respect to its motion and it has failed to make the "clear showing" that it is entitled to injunctive relief. See Apple II, 695 F.3d at 1374.

As a final matter, this Court rejects Qiagen's causal nexus arguments. Defendants aver that the single-tube option is not provided for in Oxford's claims and therefore no "causal nexus" between alleged infringement and harm exists. See Apple Inc. v.

Samsung Elecs. Co., 735 F.3d 1352, 1360 (Fed. Cir. 2013) ("Apple III") (citation omitted) (holding that to show irreparable harm the patentee must demonstrate a "causal nexus between [the defendant's] infringement and the alleged harm" to the patentee). The Court finds that it is likely that Oxford will be able to establish such a nexus.

A patentee need not demonstrate that a "patented feature is the one and only reason for consumer demand." Id. at 1364. Rather, the patentee must show that an infringing feature "drives consumer demand." Apple II, 695 F.3d at 1375. Oxford's use of specific peptides, present in Oxford's claims, satisfies the causal nexus.

Plaintiff's shortcomings with respect to proof of irreparable harm do not include its failure to demonstrate a causal nexus.

Nevertheless, Oxford has not made a "clear showing" that the launch of Qiagen's QFT-Plus product with the single tube option will cause immediate and long-term harm that cannot be quantified and remedied by monetary damages. Its delay in bringing this motion impugns its claim of exigency. More importantly, its own internal analysis indicates that the harm can be quantified and remedied by money damages.

This factor weighs in favor of defendant.

3. Balance of Hardships

To assess the balance of hardships, the court weighs the magnitude of the threatened injury to the patent holder, considered in light of the strength of the success on the merits showing, against the harm that a preliminary injunction may inflict on the accused infringer. Holmes, 67 F. Supp. 2d at 14 (D. Mass. 1999) (citing H.H. Robertson, Co. v. United Steel Deck, Inc., 820 F.2d 384, 390 (Fed. Cir. 1987)) (internal quotations omitted).

Plaintiff alleges that the potential harm to it as a relatively small, single product company is grave. The harm to the defendant, plaintiff avers, is a non-critical monetary loss. Defendant counters that it has invested substantial resources in the QFT-Plus. In addition, it claims, little harm can befall Oxford during the four months in question.

Oxford Immunotec is essentially a one-product company, with that one product being the T-SPOT.TB test. That product accounted for more than 90% of Oxford's total revenue of $86 million in 2016. Qiagen, in contrast, sells over 500 core products. Approximately 10% of Qiagen's one billion plus revenue for 2016 resulted from sales of QuintiFERON products.

Defendants note that they are prioritizing the transition of existing companies from their QFT-Gold product to their QFT-

Plus. This process will take six to twelve months, they explain, during which time Oxford need not worry about Qiagen pursuing the skin test market. Although that may be Qiagen's priority, it does not follow that Qiagen will sit idly by as Oxford pursues the skin test market.

If an injunction is imposed, Qiagen risks a four-month delay in transitioning existing customers whereas, in the absence of injunctive relief, Oxford risks the loss of a substantial portion of the market for its single core product. Although the balance of harms, in this case, seems to favor Oxford slightly, the scales are not so unbalanced as to overcome the ultimate transitory nature of the potential harm to Oxford.

4. Public Interest

Finally, the Court considers the impact of granting or denying an injunction on the public interest. In considering this impact, the court "should focus on whether a critical public interest would be injured by the grant of injunctive relief." Metalcraft, 848 F.3d at 1369.

Defendants stress that an injunction would remove a useful tool from healthcare providers, harming the public health. Plaintiff relies on the public interest in patent rights. There are surely off-setting public interests at play

in this case and thus it is not a controlling factor. See Hearst Stations Inc. v. Aereo, Inc., 977 F. Supp. 2d 32, 41 (D. Mass. 2013) (explaining that "[w]here the public interest factors cut both ways" this factor does not weigh heavily in the Court's analysis).

III. Conclusion

The several factors to be considered with respect to granting a preliminary injunction do not weigh heavily in either party's favor in this case. Therefore, because preliminary injunctive relief is a "drastic and extraordinary remedy that is not to be routinely granted," Inverness Med. Switzerland GmbH v. Acon Labs., Inc., 323 F. Supp. 2d 227, 234 (D. Mass. 2004) (quoting Intel Corp. v. ULSI Sys. Tech., Inc., 995 F.2d 1566, 1568 (Fed. Cir. 1993)) (internal quotation omitted), it will not be awarded here. Plaintiff has not made the "clear showing" necessary to entitle it to this extraordinary remedy. See Winter, 555 U.S. at 22.

ORDER

In accordance with the foregoing, plaintiff's motion for preliminary injunction (Docket No. 195) is DENIED.

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated September 26, 2017