IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WATERS CORPORATION AND WATERS TECHNOLOGIES CORPORATION,	)	
Plaintiffs,	)	
v.	)	C.A. No. 18-1450 (MN)
AGILENT TECHNOLOGIES INC.,	)	
Defendant.	)	

MEMORANDUM OPINION

Karen L. Pascale, Robert M. Vrana, YOUNG CONAWAY STARGATT & TAYLOR LLP, Wilmington, DE; Matthew M. Wolf, David McMullen, Jennifer A. Sklenar, Katie J.L. Scott, ARNOLD & PORTER KAYE SCHOLER LLP – attorneys for Plaintiffs

Chad M. Shandler, Travis S. Hunter, RICHARDS, LAYTON & FINGER, P.A., Wilmington, DE; Anne Elise Herold Li, James K. Stronski, Mark Jansen, Molly Jones, Chiemi Suzuki, CROWELL & MORING LLP – attorneys for Defendants

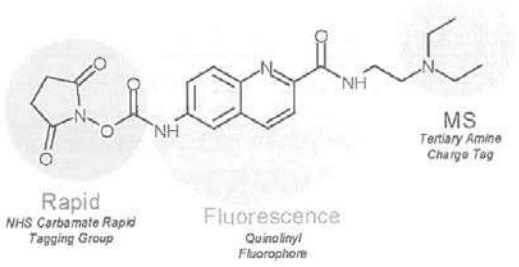
September 20, 2019
Wilmington, Delaware

NOREIKA, U.S. DISTRICT JUDGE:

Presently before the Court is the motion of Plaintiffs Waters Corporation and Waters Technologies Corporation (collectively, "Plaintiffs" or "Waters") for preliminary injunction seeking to enjoin Defendant "Agilent [Technologies Inc. ("Defendant" or "Agilent")] and their officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them" from "any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the InstantPC glycan reagent, and any product that is similar to or only colorably different from that product." (D.I. 7). Defendant opposes the motion. (D.I. 18). The Court has reviewed the briefing, declarations and exhibits (*e.g.*, D.I. 7, 8, 9, 10, 11, 12, 13, 18, 19, 20, 21, 23, 24, 27, 36, 37, 38, 41, 71, 72, 73, 77, 78, 81) and held oral argument on December 21, 2018. For the reasons set forth below, the Court DENIES Plaintiffs' motion. This opinion constitutes the Court's findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a).

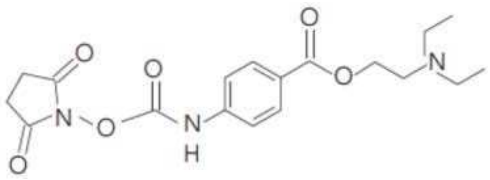
I. BACKGROUND

Plaintiffs develop "analytical solutions . . . to support its customers' scientific discoveries, operations, performance, and regulatory compliance." (D.I. 12 at ¶ 8). In particular, Plaintiffs sell the "GlycoWorks RapiFluor-MS N-Glycan Kit" ("GlycoWorks Kit") which they assert "enables unprecedented fluorescent and mass spectrometric performance for glycan detection while also improving the speed and simplicity of N-glycan sample preparation." (D.I. 8 at 3 (citing D.I. 12 at ¶¶ 10-11)). The chemical structure of the labeling reagent in the GlycoWorks Kit is (D.I. 13 at ¶ 16):



Plaintiffs' GlycoWorks kits make up approximately 75 to 80% of the market for such products. (D.I. 11 at ¶ 8; D.I. 12 at ¶ 14). Plaintiffs also sell mass spectrometry reagents and instruments to be used in conjunction with the GlycoWorks Kit. (D.I. 12 at ¶ 11).

Defendant, through its 2018 acquisition of a company called ProZyme, manufactures products containing InstantPC glycan reagents, which like the GlycoWorks Kit, are used to assist in the detection and labeling of compounds, including for identification of glycosylated proteins during the development of biopharmaceuticals or biologics. (D.I. 18 at 4). The chemical structure of the labeling reagent in InstantPC is (*Id.*; *see also* D.I. 19 at ¶ 10):



ProZyme announced its development of InstantPC in May of 2015,[1] and began selling InstantPC in October of 2015. (D.I.19 at ¶¶ 10, 14). As of December of 2018, ProZyme's InstantPC reagent products had approximately 20 to 25% of the market. (D.I. 11 at ¶ 8; D.I. 12 at ¶ 14). Defendant sells mass spectrometry reagents and instruments, which according to Plaintiffs will be marketed and used in conjunction with InstantPC. (*See* D.I. 12 at ¶¶ 17-18).

[1] The announcement included the structure of the labelling reagent in InstantPC. (D.I. 19 at ¶ 10).

On January 14, 2013, Plaintiffs obtained the exclusive license ("Patent License Agreement") to U.S. Patent No. 9,658,234 ("the '234 Patent")[2] from Ajinomoto Co., Inc. ("Ajinomoto") of Tokyo, Japan. (*Id.* at ¶ 13). The '234 Patent, a continuation of patent applications filed by Ajinomoto, issued on May 23, 2017. (D.I. 8 at 4). On August 7, 2018, Ajinomoto assigned its rights and interests in the '234 Patent to Waters Technologies Corporation. (D.I. 8 at 4). On September 18, 2018, Plaintiffs filed this patent infringement action, alleging infringement of the '234 patent by Agilent "via the manufacture, use, sale, offer to sell, exportation, and/or importation, in whole or in part, of Agilent's InstantPC reagent." (D.I. 1 at ¶ 2).

II. LEGAL STANDARD

Preliminary injunctive relief is an "extraordinary" remedy appropriate only in "limited circumstances." *Kos Pharm., Inc. v. Andrx Corp.*, 369 F.3d 700, 708 (3d Cir. 2004); *see also Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993) ("[A] preliminary injunction is a drastic and extraordinary remedy that is not to be routinely granted."). A preliminary injunction may be granted only if the moving party shows (1) a likelihood of success on the merits, (2) irreparable harm is likely if an injunction is not granted, (3) the balance of equities tips in favor of the moving party, and (4) an injunction is in the public interest. *See Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see also Osorio-Martinez v. Attorney Gen. United States of Am.*, 893 F.3d 153, 178 (3d Cir. 2018); *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1005 (Fed. Cir. 2009). "These factors, taken individually, are not dispositive; rather, the district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested." *Hybritech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 (Fed.

[2] The '234 Patent is attached as Exhibit 1 to the McMullen Declaration (D.I. 9). For purposes of this opinion the Court will refer to that patent itself rather than to its docket number.

Cir. 1988). The Court, however, cannot grant a preliminary injunction unless the moving party establishes ***both*** a likelihood of success on the merits and the existence of irreparable harm without the injunctive relief. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). "[A]ll findings of fact and conclusions of law at the preliminary injunction stage are subject to change upon the ultimate trial on the merits." *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001).

III. DISCUSSION

Plaintiffs assert that "Agilent is infringing several claims of the '234 Patent," but for purposes of its motion, it has focused on "independent claims 1 and 6." (D.I. 8 at 7).[3] The Court begins its analysis by addressing the first preliminary injunction factor – *i.e.*, likelihood of success on the merits – in the context of the asserted claims and defenses.

A. Likelihood of Success

"With regard to the first factor – establishing a likelihood of success on the merits – the patentee seeking a preliminary injunction in a patent infringement suit must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009); *see also Amazon.com,* 239 F.3d at 1350. In evaluating whether Plaintiffs are likely to succeed in proving infringement of the asserted claims, the Court employs the same two-step process used to determine infringement on summary judgment or at trial. *See Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1339 (Fed. Cir. 2003). First, the Court must determine the meaning and scope of

[3] The Court recognizes that there may be additional disputes regarding other claims of the '234 Patent, claim construction issues and defenses going forward. For purposes of the present motion, however, the Court focuses on the claims and defenses presented in conjunction with the motion.

the asserted claims. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). Second, the Court must compare the accused product (InstantPC glycan reagent) to the claims as properly construed. *Id*. Similarly, in assessing whether Plaintiffs are likely to withstand validity challenges involving prior art, the Court compares the asserted claims as construed to the asserted prior art. *See Oakley*, 316 F.3d at 1339. The Court should not grant a preliminary injunction if Defendant "raises a substantial question concerning either infringement or validity." *Amazon.com*, 239 F.3d at 1350; *see also Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1365 (Fed. Cir. 2002) ("substantial question" means assertion of a defense that patentee cannot prove "lacks substantial merit").

1. Infringement

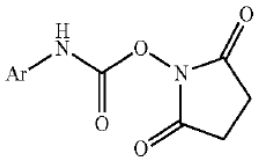
The '234 Patent, titled "Method For Analysis Of Compounds With Amino Group And Analytical Reagent Therefor," is generally directed to carbamate compounds and methods of labeling and analysis with those compounds, which can be used for N-glycan detection. *See* '234 Patent at 1:22-30. According to Plaintiffs' expert:

> the carbamate compounds have a strong fluorescent signal due to an aromatic carbocyclic or heterocyclic group, a strong mass spectrometry signal due to an electronically isolated amino group, and readily react with nitrogen-containing compounds, such as amino acids and proteins. Thus, the claimed carbamate compounds can be used for improved N-glycan labeling, detection, and analysis, including with mass spectrometry.

(D.I. 13 at ¶ 21).

Asserted claims 1 and 6 of the '234 Patent recite, in pertinent part (D.I. 1, Ex. A):

1. A carbamate compound represented by formula (1):



> wherein Ar is an aromatic carbocyclic group or an aromatic heterocyclic group residue, wherein said aromatic carbocyclic group or said aromatic heterocyclic group residue has a substituent; and
>
> wherein, in the bond between Ar and the nitrogen atom of the carbamate group, a carbon atom within the ring of Ar is bound to the nitrogen atom of the carbamate group, a carbon atom within the ring of Ar is bound to the nitrogen atom of the carbamate group, whereby said carbamate compound may be in a form of a salt, and
>
> wherein said substituent contains a sulfonic acid group, a phosphoric acid group, a guanidyl group, a dialkylamino group or a trialkyl ammonium group.
>
> **6**. A method for analyzing a compound with an amino group in a sample, containing at least a compound with an amino group by means of mass spectrometry, said method comprising
>
> labeling said compound with an amino group in said sample by reacting said compound with an amino group with a carbamate compound according to claim **1**, to obtain a mixture comprising a labeled compound, and subjecting said labeled compound to mass spectrometry.

"Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device, i.e., when the properly construed claim reads on the accused device exactly." *Cole v. Kimberly–Clark Corp*., 102 F.3d 524, 532 (Fed. Cir. 1996) (citing *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1580 (Fed. Cir. 1989)). Here, the infringement dispute regarding claims 1 and 6 is whether the accused InstantPC products meet the "substituent contains a sulfonic acid group, a phosphoric acid group, a guanidyl group, a dialkylamino group or a trialkyl ammonium group" limitation of claim 1 (which is incorporated into claim 6).[4] (*See* D.I. 18 at 6; D.I. 23 at 3). Defendant argues that the "substituent" term cannot "include linkers between the aromatic group

[4] For purposes of this motion, there is no dispute that the remaining elements of claim 1 or claim 6 are met by the accused InstantPC products. Nor is there any dispute as to the assertions supporting inducement of claim 6 if the disputed element is met. For purposes of this motion only, the Court accepts that all other claim elements as well as the showing required for inducement have been met.

and the claimed substituent"[5] because "[n]either the patent nor the file history disclose so much as one atom between the aromatic ring and the substituent." (D.I. 18 at 14). Defendant then asserts that because InstantPC includes a linker between the aromatic ring and the functional group, InstantPC cannot literally infringe. (*Id.*).

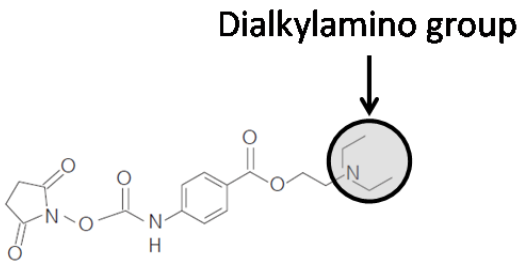
Plaintiffs disagree and argue that the language of the claim – *i.e.*, "contains" – "signifies that the recited 'substituent' may contain additional unrecited elements." (D.I. 23 at 3 (citing *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 499 (Fed. Cir. 1997)). Plaintiffs further argue that "the addition of elements to an otherwise infringing product does not negate infringement." (*Id.* (citing *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1482 (Fed. Cir. 1984)).

Here, on the preliminary record, the Court agrees with Plaintiff. There is "a heavy presumption that claim terms carry their full ordinary and customary meaning, unless it can show the patentee expressly relinquished claim scope." *Epistar Corp. v. Int'l Trade Comm'n*, 566 F.3d 1321, 1334 (Fed. Cir. 2009) (citing *Omega Eng'g v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003)). Moreover, it is well-established that transitional terms such as "comprising," and "containing" are inclusive or open-ended and do not exclude additional, unrecited elements or method steps. *See, e.g.*, *Mars, Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376 (Fed. Cir. 2004) ("[L]ike the term 'comprising,' the terms 'containing' and 'mixture' are open-ended."). And here, the patentee used the word containing consistent with its ordinary meaning as an open-ended term in the specification of the '234 Patent. For example, it referred to "a sample containing at least a compound with an amino group" ('234 Patent, col. 3, lines 50-51, col. 3, lines 57-58) and to a

[5] Defendant asserts that Plaintiffs' construction would allow "any and all combinations of atoms . . . as 'linkers' between the claimed aromatic ring and functional groups." (D.I. 18 at 1).

"substrate containing a stable isotope having a low naturally existing rate" ('234 Patent, col. 15, lines 60-61).

There is no dispute that a substituent is "an atom or radical that replaces another in a molecule as the result of a reaction." (D.I. 13, Ex. 4 at 1052). Applying the plain meaning of the words "substituent contains," the Court construes the disputed term to mean "a substituent that has at least as part of it one of the specified groups claimed." Applying the Court's construction, InstantPC meets the "substituent contains a sulfonic acid group, a phosphoric acid group, a guanidyl group, a dialkylamino group or a trialkyl ammonium group" limitation of claim 1. As depicted below, the substituent in InstantPC contains a dialkylamino group, *i.e.*, two ethyl (-C2H5) groups bound to a nitrogen atom:



(D.I. 8 at 11 (citing D.I. 13 ¶ 45)). This is the only contested limitation of claim 1 or claim 6. Thus, the Court finds the Plaintiffs have demonstrated that they are likely to succeed in proving infringement of claims 1 and 6 of the '234 Patent.

2. Invalidity

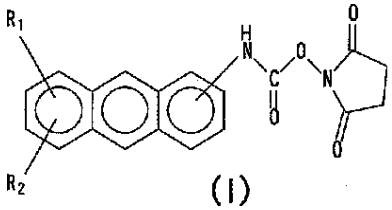
Because the Court finds that Plaintiffs have demonstrated a likelihood of success on infringement of claims 1 and 6 of the '234 Patent, the Court will address whether Plaintiffs are likely to withstand a validity challenge to these claims. Defendant asserts that claims 1 and 6 are invalid for a number of reasons, including patent prosecution laches, double patenting, lack of

written description, and anticipation and obviousness in light of the prior art. (D.I. 18 at 14-18). Defendant also challenges the priority date to which claims 1 and 6 are entitled. (*Id.* at 18-19).

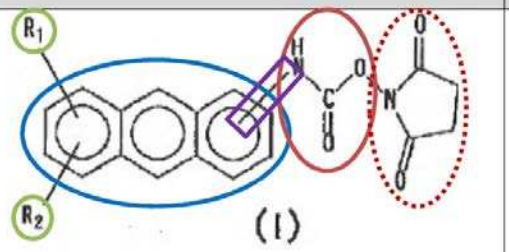
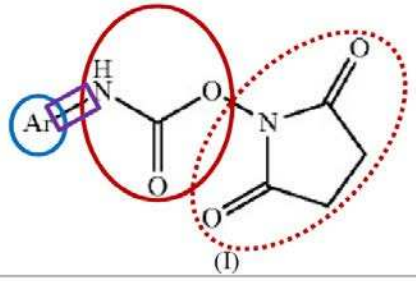
a. Anticipation

Defendant asserts that claim 1 of the '234 Patent is invalid as anticipated by Japanese published patent application JP 10-306075 ("JP '075") (D.I. 73 at Ex. 3) pursuant to 35 U.S.C. §102(b).[6] (D.I. 72 at 7-8). JP '075 is a Japanese patent application filed on May 7, 1997 and published on November 17, 1998. There is no dispute that JP '075 is prior art. Nor does there appear to be any dispute that the abstract of JP '075 was disclosed during the prosecution of the '234 Patent, but the entire patent was not (either in Japanese or translated to English).

Figure 1 of JP '075 depicts the general formula:



In its motion to supplement the record, Defendant provided the following color-coded chart (D.I. 72 at 7), which the Court includes here for ease of reference:

General Formula (I) in JP '075	Formula (1) in Claim 1 of the '234 Patent
	

[6] JP '075 is the subject of a petition for inter partes review ("IPR") that Defendant has filed. Defendant brought JP '075 to the Court's attention through a motion to supplement the record (D.I. 71), which the Court granted. (D.I. 95). Defendant asserts that the anticipation and obviousness arguments involving JP '075 that are raised in the IPR "apply regardless of the construction of [the one disputed] claim term." (D.I 72 at 5).

Formula (I) of JP ’075 meets the carbonate limitation of the preamble of claim 1. As depicted, Formula (I) has the same carbamate moiety (in a solid red circle) and succinimidyl moiety (in a dotted red circle) that is claimed in Formula (1) in the ’234 Patent. Additionally, as shown above, Formula (I) of JP ’075 has an aromatic carbocyclic (blue circle) with a substituent (green circles) as claimed in claim 1 of the ’234 patent.[7] Moreover, as depicted in the purple rectangle, in Formula (I) of JP ’075 and claim 1, the nitrogen on the carbamate is bound to a carbon in the aromatic carbocyclic ring. Finally, in Formula (I) of JP ’075, the substituents (green circles) identified as R1 and R2, “which may be identical or different” are defined as “hydrogen atom, an alkyl group, a sulfo group (-SO3H), or an NR3R4 group (where here R3 and R4 each represent an alkyl group, which may be the same or different).” JP ’075 at ¶15. The NR3R4 group where R3 and R4 are alkyl groups describe a “dialkylamino group” substituent as recited in claim 1.

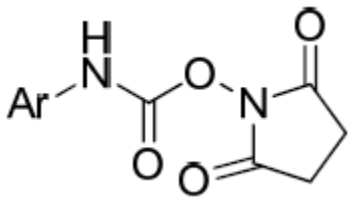
Defendant has made a compelling showing that JP ’075 contains all of the elements of claim 1 of the ’234 Patent, and anticipates that claim. Plaintiffs have not addressed JP ’075 or responded to the anticipation arguments asserted. The Court thus concludes that Defendant has raised a substantial question concerning the validity of claim 1.

b. Obviousness

Claim 6 of the ’234 patent is directed to a method for analyzing a compound with an amino group by labeling the compound with a carbamate compound according to claim 1, and subjecting the labeled compound to mass spectrometry. Defendant asserts that claim 6 would be obvious over U.S. Patent No. 5,296,599 to Cohen (“Cohen”) (D.I. 20, Ex. 8) in combination with an article

[7] The aromatic carbocyclic group of JP ‘075 is an anthryl group. (D.I. 72 at 8 n.5). The ’234 Patent states that aromatic carbocyclic residues include: “phenyl group, naphthyl group . . . and anthryl group (1-, 2- and 5-anthryl groups).” (’234 Patent, col. 7, lines 4-7).

by Roth[8] in combination with an article by Liu.[9] (D.I. 18 at 17-18). Specifically, Defendant argues Cohen discloses a heterocyclic aromatic carbamate compound having the formula:



(*Id.* at 17 (citing D.I. 20 at ¶ 56 (citing Cohen at col. 3, lines 8-21))). It also asserts that Cohen discloses that the ArNH group represents a heterocyclic aromatic amine, which "can be any aromatic ring structure, including polycyclic ring structures, containing from about 1 to about 4 heteroatoms in the ring structure, such as nitrogen (N), oxygen (O), sulfur (S) and combinations thereof." (D.I. 20 at ¶ 56 (citing Cohen, at col. 3, lines 22-29)). According to Defendant's expert, Liu teaches the use of a carbamate compound wherein Ar is a heteroaryl group, specifically a quinolinyl group, to derivatize amino acids, peptides, and proteins for high-sensitivity peptide mapping. (*Id.*). Thus, Defendant argues a "person of ordinary skill would have been motivated, at the time the '234 patent was filed, to modify the Ar of Cohen to be an aryl group or heteroaryl group substituted with a moiety containing an ionized or ionizable group (*e.g.*, sulfonic acid group, a phosphoric acid group, a guanidyl group, a dialkylamino group or a trialkyl ammonium group)." (D.I. 20 at ¶ 57).

Defendant further argues that based on Roth, which teaches that mass spectrometry is effective for analyzing compounds with amine groups, such as peptides, a person of ordinary skill

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8 K. D. Roth et. al., *Charge Derivatization of Peptides for Analysis by Mass Spectrometry*, Mass Spectrom. Rev. 1998; 17:255 ("Roth") (D.I. 20, Ex. 11).

9 H. Liu et al., *Femtomole Peptide Mapping by Derivatization, High-Performance Liquid Chromatography, and Fluorescence Detection*, Anal. Biochem. 2001, 294, 7-15 ("Liu") (D.I. 20, Ex. 10).

in the art would have been motivated to optimize the compounds of Cohen for mass spectrometry. (*Id.* at ¶¶ 57-58). According to Defendant, the person of ordinary skill in the art would have recognized that, "for enhanced mass spectrometry detection of amine containing groups, a heteroaromatic group substituted with a charged group would have worked as well as an aromatic group substituted with a charged group." (*Id.* at ¶ 58; *see also id.* at ¶ 60 (table)).

Plaintiffs disagree with Defendant's analysis. The gist of the arguments raised by Plaintiffs against obviousness focus on the fact that neither Cohen nor Roth nor Liu *disclose the compound claimed in claim 1* or offer reasons to make the specific molecular modifications needed to obtain that compound, rather than the use of that compound in mass spectrometry. (D.I. 23 at 8-9). The Court's analysis of the issues, however, is complicated by the fact that it has already found that Defendant has raised a substantial question concerning the disclosures of compounds in JP '075 that anticipate claim 1, an issue that Plaintiffs did not address. The Court further notes that Plaintiffs' expert opined (D.I. 13 at ¶ 21) that "the carbamate compounds [of the '234 Patent] have . . . a strong mass spectrometry signal due to an electronically isolated amino group, and readily react with nitrogen-containing compounds, such as amino acids and proteins," suggesting that it is the characteristics of the compound that a person of ordinary skill would recognize make it useful as a label in mass spectrometry as required by claim 6.

The Court has reviewed the arguments presented from both sides.[10] In view of the obviousness challenge presented by Defendant and the response of Plaintiffs, the Court finds that there are difficult questions relating to obviousness of claim 6 of the '234 Patent on both sides.

[10] The Court is mindful that, even at the preliminary injunction stage, objective indicia of nonobviousness should be considered alongside the evidence of obviousness before reaching a conclusion about whether there is a substantial question as to validity. *See Titan Tire Corp.*, 566 F.3d at1379. Here, however, there was no discussion of objective indicia of nonobviousness in the parties' briefs or at oral argument.

That each side makes compelling arguments renders this Court unable to find that Defendant's obviousness challenge lacks substantial merit, thus weighing against issuance of a preliminary injunction. *See, e.g.*, *Baxalta Inc. v. Genentech, Inc.*, No. 17-509-TBD, 2018 WL 3742610, at *8 (D. Del. Aug. 7, 2018) (Dyk, J., sitting by designation) ("With respect to both of the merits issues, the parties have presented challenging questions of law and sharply conflicting expert testimony. Both issues are best decided on the basis of a more developed record. But Genentech has at the very least established that there are difficult questions with respect to infringement and invalidity. These difficult merits questions weigh in favor of denying injunctive relief at this stage.").[11]

B. Irreparable Harm

"A party seeking a preliminary injunction must establish that it is likely to suffer irreparable harm if the preliminary injunction is not granted and there is a causal nexus between the alleged infringement and the alleged harm." *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1368 (Fed. Cir. 2017); *see also Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1375 (Fed. Cir. 2012) (causal nexus requires some connection between the alleged infringement and harm such "that the infringing feature drives consumer demand for the accused product"). The moving party must demonstrate that immediate irreparable harm is likely in the absence of injunctive relief – not merely that irreparable harm may possibly occur at some point in the future. *See Winter*, 555 U.S. at 22 (2008) ("Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with our characterization of injunctive relief as an extraordinary remedy . . . ."). Further, the moving party must make a "clear showing" of the risk of irreparable harm to obtain the injunctive relief. *See Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012).

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[11] Having found that Plaintiffs have not established a likelihood of success as to validity, *i.e.*, anticipation of claim 1 and obviousness of claim 6, the Court does not address the other validity challenges raised by Defendant.

Here, Plaintiffs argue that they will be irreparably harmed if the Court does not enjoin Defendant because Agilent and Waters are direct competitors and Plaintiffs will suffer a reduction in market share and eroded prices that monetary damages will not be adequate to compensate. (D.I. 8 at 14-16). As discussed below, the Court disagrees. As discussed below, Plaintiffs have failed to demonstrate that immediate irreparable harm is likely given 1) Plaintiffs delay in seeking enforcement of their patent rights for InstantPC, and 2) that the expressed harm with respect to lost downstream sales, market share, and price erosion is too speculative. Moreover, the Court finds that any harm Plaintiffs may suffer between now and the culmination of trial is compensable with money damages.

1. Delay

Injunctive relief has been found to be inappropriate where a Plaintiff has had no apparent urgency in requesting it. *See Apple,* 678 F.3d at 1325 ("The district court correctly noted that delay in bringing an infringement action and seeking a preliminary injunction are factors that could suggest that the patentee is not irreparably harmed by the infringement."); *High Tech. Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995). Here, as discussed *supra*, Waters gained "an exclusive and non-transferable license" Patent License Agreement from Ajinomoto on January 14, 2013 for the rights to the family of patents to which the '234 Patent was added when it issued on May 23, 2017. (D.I. 38, Ex. 1). Assuming Waters immediately gained the exclusive license to the '234 Patent under the Patent License Agreement, it also gained certain litigation rights on May 23, 2017. Indeed, the Patent License Agreement states that "[Waters] shall promptly send a report to [Ajinomoto] if [Waters] becomes aware of any infringement or threatened infringement by a third party of the Patents in the Field in the Patent

Territory" and "shall discuss the response to such infringement or threatened infringement in good faith." (*Id.* at Art. 9.1).

Waters argues that there was no delay because it only became the holder of all rights and title to the '234 Patent on August 7, 2018 and the two-month delay between that acquisition and the filing of this suit was reasonable. (D.I. 23 at 1-2). It is well-established, however, that "[w]here an exclusive license agreement transfers less than 'all substantial rights' in the patents, 'either the licensee or the licensor may sue, but both of them generally must be joined as parties to the litigation.'" *EMC Corp. v. Pure Storage, Inc.*, 165 F. Supp. 3d 170, 174 (D. Del. 2016) (citing *Alfred E. Mann Found. For Scientific Research v. Cochlear Corp.*, 604 F.3d 1354, 1360 (Fed. Cir. 2010)). ProZyme began selling InstantPC in October of 2015. Under *EMC*, Plaintiffs could have sued ProZyme[12] for infringement upon the issuance of the '234 Patent by joining Ajinomoto as a plaintiff, but they chose not to do so. Similarly, when Plaintiffs learned of the impending sale of ProZyme to Agilent in June of 2018, they could have brought suit against ProZyme for infringement by joining Ajinomoto as a plaintiff, but again Plaintiffs chose not to. Instead, after acquiring all rights and title on August 7, 2018, Waters waited another six weeks to file this action against Agilent and then another sixteen days to file this motion. The Court understands Plaintiffs' contention that acquisition of Prozyme by Agilent may be a fundamental change to the market[13] and they did not have full rights to sue individually until August 7, 2018, but even so, Plaintiffs were made aware of the impending change as early as June of 2018. If imminent and irreparable

[12] Though ProZyme is not before the Court, and venue would not be proper regardless, the Court considers Plaintiffs' actions with respect to this non-party because Plaintiffs have sought a preliminary injunction against Agilent, that also enjoins that actions its subsidiaries and other affiliates, of which ProZyme is one.

[13] Prior to the acquisition, ProZyme had up to 25% of the market. While majority, ProZyme's share represented a substantial share.

harm was expected, Plaintiffs certainly could have and should have moved with greater dispatch. The delay in asserting the '234 Patent cuts against a notion that the availability and sale of InstantPC is creating an irreparable harm to Waters.

2. Other Asserted Harm

The Federal Circuit has found that "lost sales standing alone are insufficient to prove irreparable harm; if they were, irreparable harm would be found in every case involving a 'manufacturer/patentee, regardless of circumstances.'" *Automated Merchandising Sys., Inc. v. Crane Co.*, 357 Fed. App'x 297, 300-01 (Fed. Cir. 2009) (citing *Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006)). Here, Waters argues not only that it will lose sales of its GlycoWorks Kit, but also that it will lose downstream, or convoyed, sales if Agilent is allowed to sell InstantPC. (D.I. 8 at 17). Waters argues "both Waters and Agilent routinely sell the requisite reagents, devices or instruments used in conjunction with, or downstream of, the infringing products and methods." (*Id.*). Plaintiffs, however, have not shown, on the record before the Court, that Defendant is making, or will imminently make, downstream sales of its own machines or other products due to its ability to sell or market the InstantPC product.[14] Thus, the harm of downstream sales is too speculative to support a finding of irreparable harm.

Plaintiffs' alleged loss of market share is also too speculative. The Federal Circuit has found "lost market share must be proven (or at least substantiated with some evidence) in order for it to support entry of a preliminary injunction, because granting preliminary injunctions on the basis of speculative loss of market share would result in granting preliminary injunctions 'in every patent case where the patentee practices the invention.'" *Automated Merchandising Sys.*, 357 Fed.

[14] InstantPC is just one of a number of products manufactured and sold by ProZyme, and now Agilent. This further reduces the likelihood that customers are making downstream sales *because of* Agilent offering InstantPC.

App'x at 301 (citing *Nutrition 21 v. United States*, 930 F.2d 867, 871 (Fed. Cir. 1991)). Here, Plaintiffs argue that "[n]ow that ProZyme has been acquired by much larger Agilent, Agilent has the ability to compete with Waters" and "will leverage its extensive global customer base . . . to promote use of [InstantPC]." (D.I. 8 at 15). Plaintiffs themselves, however, note that "customers who purchase reagents . . . tend to be long term customers" and that they currently occupy 75-80% of the market. (*Id.* at 17). From this, it appears less likely that the loss of market share will occur as suggested. Under these facts, Plaintiffs' potential loss of market is too speculative for a finding of irreparable harm.

Finally, Plaintiffs' argument as to price erosion is also too speculative. This District has previously found that "[p]rice erosion can justify a finding of irreparable harm." *Symbol Techs., Inc. v. Janam Techs., LLC*, 729 F. Supp. 2d 646, 664 (D. Del. 2010) (citing *Sanofi–Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382–83 (Fed. Cir. 2006)). In *Symbol*, the court was presented with "concrete pricing evidence" showing that the plaintiff had to reduce the price of its product by nearly half to compete with defendant's alleged infringing product. *Id.* The Court found "some degree of price erosion as a result of [the defendant's] conduct" but noted "without more, the Court is not persuaded that this evidence supports a finding that [the plaintiff's] price erosion damages are incapable of being quantified, or that [the plaintiff] could not be fully compensated by a monetary award." *Id.* at 664-65. Here, Plaintiffs have not offered concrete pricing evidence relating to the sale of its GlycoWorks Kit versus InstantPC, which has been on the market for more than three years. Nor have Plaintiffs offered evidence that there has been any change in pricing since the Agilent's acquisition of ProZyme four months ago. The crux of Plaintiffs' price erosion argument asks the Court to accept the assertion that "customers will request price discounts on future purchases in light of Agilent's attempts to target those same customers with product that is

similar to Waters' GlycoWorks Kit" and "*if* Waters has to provide a discount or lower price to compete with Agilent, it will be difficult, if not impossible, for Waters to ever raise prices to their original level." (D.I. 8 at 16 (emphasis added)). Not only is this entirely speculative, the argument is undercut by Plaintiffs' assertions that "the most significant customers . . . are pharmaceutical companies . . . , and once they have validated these methods, it is very difficult to get them to change." (*Id.*). Considering Waters' dominant market position and the assertion of low-turnover, Plaintiffs' price erosion argument cannot support a finding of irreparable harm.

Finally, even if, *arguendo*, the Court were to find that any of the above assertions of harm were concrete or immediate, the Plaintiffs' have still failed to show that such harms could not be properly remedied through monetary damages. "The burden is . . . on the patentee to demonstrate that its potential losses cannot be compensated by monetary damages." *Automated Merchandising Sys.*, 357 Fed. App'x. at 301. Plaintiffs argue "it will be nearly impossible" to calculate the loss of downstream sales and price erosion. (D.I. 8 at 16). However, "calculating damages in patent cases is often a complex task, yet that alone does not allow a plaintiff to establish irreparable harm." *Chestnut Hill Sound Inc. v. Apple Inc.*, C.A. No. 15-261-RGA, 2015 WL 6870037, at *5 (D. Del. Nov. 6, 2015). Given the weakness of Plaintiffs' downstream sales and price erosion arguments and its inability to provide any evidence beyond bold assertions that damages would be "impossible" to calculate, the Court finds that Waters has not met its burden of demonstrating that its potential losses cannot be compensated by monetary damages.

Considering the above, the Court find Plaintiffs have failed to meet their burden in showing irreparable injury is likely in the absence of an injunction.

C. Remaining Factors

Because Plaintiff has failed to establish that it would suffer irreparable harm without injunctive relief, the court need not reach the remaining factors in the four-part analysis. *See, e.g.*, *Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1356 (Fed. Cir. 2002) ("[A] trial court may . . . deny a motion based on a patentee's failure to show any one of the four factors – especially either of the first two – without analyzing the others."); *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 973-74 (Fed. Cir. 1996) ("[A] trial court need not make findings concerning the third and fourth factors if the moving party fails to establish either of the first two factors."). The absence of irreparable harm is alone a sufficient basis to deny Plaintiffs' request for a temporary restraining order and preliminary injunction. *See, e.g.*, *Integra Lifesciences Corp. v. Hyperbranch Med. Tech., Inc.*, No. 15-819-LPS-CJB, 2016 WL 4770244, at *7 (D. Del. Aug. 12, 2016) ("In light of the Court's conclusion below that Plaintiffs have not sufficiently demonstrated [irreparable harm], no injunction could issue. And so, an assessment of Plaintiffs' likelihood of success on the merits is not required for purposes of resolving the Motion."); *Chestnut Hill Sound Inc.*, 2015 WL 6870037, at *2 ("Because I find, however, that CHS has not shown that it will suffer irreparable harm if a preliminary injunction is not granted, an assessment of CHS's likelihood of success on the merits is not necessary to the adjudication of CHS's motion."). Nevertheless, in an abundance of caution, the Court will briefly address the remaining factors.

1. Balance of Equities

In the third factor of the preliminary injunction inquiry, the Court looks at "the potential injury to the plaintiff if an injunction does not issue versus the potential injury to the defendant if the injunction is issued." *Novartis Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578, 596 (3d Cir. 2002). This factor "assesses the relative effect of granting or

denying an injunction on the parties." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 862 (Fed. Cir. 2010), *aff'd*, 564 U.S. 91 (2011). Here, this factor slightly favors Defendant.

As discussed above, Plaintiffs have not shown that they are likely to be irreparably harmed by Defendant's sale of InstantPC. As to potential harm to Defendant, Plaintiffs argue that an injunction will ensure that "the status quo [can] be maintained pending trial" because "Agilent's sale of the infringing product will change the market in irreparable ways." (D.I. 8 at 18). Plaintiffs' argument that an injunction will maintain the status quo, however, is flawed. The "status quo" includes a 75-80% market share for Waters and 20-25% market share for InstantPC. Plaintiffs request for relief broadly includes "any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the InstantPC glycan reagent." (D.I. 7). Plaintiffs essentially ask the Court to alter the status quo – essentially decreasing the InstantPC share to zero pending trial, even though Plaintiffs' conduct suggests that even up to 20-25% market share did not induce them to sue ProZyme prior to the acquisition.

2. Public Interest

Finally, the Court must ask whether granting "an injunction is in the public interest." *Winter*, 555 U.S. at 20; *see also Celgard, LLC v. LG Chem, Ltd.*, 624 Fed. App'x 748, 752 (Fed. Cir. 2015). "There is no question that the public has an interest in the enforcement of patent rights . . . ." *Baxalta*, 2018 WL 3742610, at *12. It is also clear, however, that "the public interest factor requires consideration of other aspects of the public interest." *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1341 (Fed. Cir. 2012); *see also Hybritech*, 849 F.2d at 1458 ("[T]he focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief.").

Here, the product at issue is "used in the critical pathway for biologic drug development and FDA submission." (D.I. 18 at 19). "[F]or good reason, courts have refused to permanently enjoin activities that would injure the public health." *Cordis Corp. v. Bos. Sci. Corp.*, 99 F. App'x 928, 935 (Fed. Cir. 2004). For example, courts have refused to grant an injunction when doing so would eliminate "an important alternative for patients." *Conceptus, Inc. v. Hologic, Inc.*, No. 09-02280 (WHA), 2012 WL 44064, at *3-4 (N.D. Cal. Jan. 9, 2012); *see also Hybritech*, 849 F.2d at 1458 (affirming district court's exclusion of certain cancer test kits and hepatitis test kits from the scope of an injunction because "the public interest is served best by the availability of these kits").

Here, there is a strong countervailing public interest in allowing Defendant's InstantPC products to remain available for drug development and regulatory approval. Defendant has asserted that an injunction would create a shortfall in the availability of the reagent "harm[ing] the ability of researchers to continue efforts to develop new biopharmaceuticals," where they would be forced to revalidate and resubmit their workflows to regulators prior to using Plaintiffs' product. (D.I. 18 at 19-20). And evidence has been offered by Waters itself that the most economically significant customers for these products are pharmaceutical companies who must validate their methods. (D.I. 12 at ¶ 20). It is undisputed that for those customers who are currently using the InstantPC product, this validation process would have to be repeated if they were forced to switch to the GlycoWorks Kit. Thus, these customers may well lose months of time waiting for the production of more GlycoWorks Kits and the revalidation of their processes before they can resume their work.

The Court is, thus, convinced that that the entrance of a preliminary injunction will affect certain research and testing as time and money are spent revalidating and calibrating processes in accordance with the dictates of such an order. In *Hybritech*, the Federal Circuit upheld a lower

court's finding that public interest favored the continued presence of cancer and hepatitis screening kits on the market. 849 F.2d at 1458. The lower court specifically stated "[w]hatever else the court does, it will not cut off the supply of monoclonal test kits for cancer patients who are now using the Abbott product." *Hybritech Inc. v. Abbott Laboratories*, C.A. No. 86-7461/AK(PX), 1987 WL 123997, at *21 & n.17 (C.D. Cal. July 14, 1987) (noting "Abbott offered evidence that monitoring of cancer patients . . . involved generation of a 'baseline'. . . that would have to be repeated if the patient were switched to another CEA product."). Here, the public benefits from having the continued presence of a product already validated for use in biologic drug development and FDA submission is a significant countervailing factor weighing against the public interest inherent in protecting patent rights.

IV. CONCLUSION

Although Plaintiffs have shown a likelihood of success as to infringement of the asserted claims of the '234 Patent, Plaintiffs have failed to show that the prior art challenges raised by Defendant lack substantial merit. Moreover, Plaintiffs have not shown that they are likely to suffer irreparable harm in the absence of an injunction, that the balance of equities weighs in their favor or that the public interest favors enjoining the sale of the InstantPC glycan reagent (and "any product that is similar to or only colorably different from that product"). In weighing the relevant factors, the Court thus concludes that preliminary injunctive relief is not appropriate here. Accordingly, Plaintiffs' motion for a preliminary injunction (D.I. 7) is DENIED. An appropriate order will follow.