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Attorneys for Plaintiff
PROZYME, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

PROZYME, INC.,

Plaintiff,

v.

WATERS CORPORATION and WATERS TECHNOLOGIES CORPORATION,

Defendants.

Case No. 3:18-cv-6415

COMPLAINT FOR DECLARATORY JUDGMENT

JURY TRIAL DEMANDED

Plaintiff ProZyme, Inc. ("ProZyme" or "Plaintiff"), by and through its attorneys, brings the following Complaint against Defendants Waters Corporation ("Waters Corp.") and Waters Technologies Corporation ("Waters Tech.") (collectively, "Waters" or "Defendants") for a declaratory judgment of patent non-infringement, invalidity and/or unenforceability as follows:

NATURE OF THE ACTION

1. Pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 and the patent laws of the United States, 35 U.S.C. § 101 *et seq.*, Plaintiff seeks a declaratory judgment of non-infringement, invalidity and/or unenforceability of U.S. Patent No. 9,658,234 ("'234 Patent").

2. ProZyme, the manufacturer and seller of products under the Gly-X and GlykoPrep brand names that contain the InstantPC™ reagent, is a California corporation based in Hayward, California. Waters has brought a case for patent infringement in the United States District Court for the District of Delaware against Agilent Technologies, Inc. – the parent of ProZyme – asserting that ProZyme's products infringe or will infringe the '234 Patent. ProZyme was not named in that lawsuit and is not subject to venue in that district because ProZyme neither resides nor has a regular and established place of business in Delaware. ProZyme brings this action to seek a declaratory judgment that its technology does not infringe a valid and enforceable claim of the '234 Patent.

PARTIES

3. ProZyme is a corporation organized under the laws of California with its principal place of business at 3832 Bay Center Place, Hayward, California 94545.

4. ProZyme was founded in 1990 to establish a high-quality, value-added and customer-driven biochemical reagent company. ProZyme has maintained a commitment to invest in the rapidly-expanding area of glycobiology, and to develop, release and support products that help its customers.

5. At least since 2015, ProZyme's GlykoPrep and subsequent Gly-X branded N-glycan sample preparation technologies have streamlined N-glycan sample preparation. In 2016, ProZyme released its Gly-Q platform, which combines ProZyme's 1-hour N-glycan sample preparation expertise with a rapid (2-minute) CE separation and customized data analysis

software.

6. At its facility in Hayward, California, ProZyme develops and markets its products, and employs forty-four of its total forty-eight employees. None of ProZyme's employees are residents of the state of Delaware.

7. Effective on or about August 1, 2018, all of the shares of ProZyme were acquired by Agilent Technologies, Inc. ("Agilent"), based in Santa Clara, California.

8. On information and belief, Waters Tech. is a corporation organized and existing under the laws of the state of Delaware with a principal place of business at 34 Maple Street, Milford, Massachusetts 01757 and is registered to do business and is doing business in the state of California and in this district. On information and belief, Waters Tech. is the assignee of the '234 Patent.

9. On information and belief, Waters Corp. is a corporation organized and existing under the laws of the state of Delaware with a principal place of business at 34 Maple Street, Milford, Massachusetts 01757. On information and belief, Waters Corp. is a holding company, doing business throughout the world and in this district, through its wholly-owned subsidiary, Waters Tech. On information and belief, Waters Corp. has an exclusive license on the '234 Patent from its wholly-owned subsidiary, Waters Tech.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over these claims pursuant to 28 U.SC. §§ 1331, 1338(a), 2201, and 2202.

11. This Court has personal jurisdiction over Waters, because, on information and belief, Waters has purposely availed itself of the privilege of conducting activities within the state of California and this district. Waters also has, on information and belief, a regular and established place of business within this district at 5720 Stoneridge Drive, Suite 200, Pleasanton, California 94588 from which it develops business, sells, offers to sell, and services its products throughout substantial parts of the state of California, including in this district.

12. In addition to the foregoing, representatives of Waters have purposefully and affirmatively directed their efforts to enforce and/or license the intellectual property at issue in

this case, in particular the '234 Patent at issue in this action, to residents of California. In particular, on information and belief, on or about June 29, 2018, upon receiving public notice that Agilent intended to acquire Prozyme, the Senior IP Counsel of Waters Tech. telephoned Agilent in Santa Clara California, on behalf of both Waters entities, to inform Agilent that Waters was at that point a licensee of the '234 Patent.

13. In addition to the contact on or about June 29, 2018, on information and belief, one or more representatives of Waters also directed their patent enforcement to California by additional telephone calls to Agilent, including but not limited to on September 24, 2018 and October 4, 2018, specifically asserting infringement of the '234 Patent by Agilent.

14. Venue is proper in this district under 28 U.S.C. §§ 1391 because Waters has a regular and established place of business in this district located at 5720 Stoneridge Drive, Suite 200, Pleasanton, California 94588.

INTRA-DISTRICT ASSIGNMENT

15. This is an intellectual property action to be assigned on a district-wise basis pursuant to Civil L.R. 3-2(c).

FACTUAL BACKGROUND

PROZYME'S RELEVANT PRODUCTS CONTAINING GLYCAN LABELING REAGENT

16. ProZyme has developed a robust glycobiology portfolio as part of its several reagent offerings. Glycosylation—the binding of glycans (carbohydrates) to human cell proteins—plays an important role in maintaining protein stability and efficacy. Antibodies are proteins that are now used therapeutically. The presence and identity of glycans need to be carefully monitored throughout the antibody drug development process, and high-throughput glycan sample preparation and analysis is a critical tool used by drug developers and others.

17. ProZyme has over 400 products in its glycobiology portfolio. In the past few years, ProZyme's GlykoPrep and subsequent Gly-X brand sample preparation technologies have streamlined N-glycan sample preparation.

18. In or about May 2015, ProZyme announced to the trade at a prominent industry

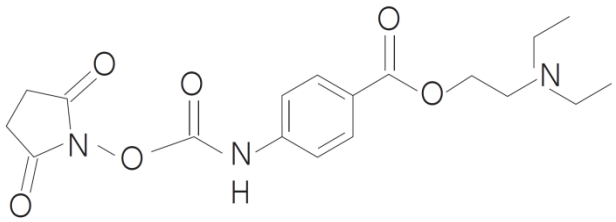
conference in St. Louis, Missouri the development of its InstantPC™ reagent for testing intracellular glycoslyation. The announcement included a poster describing the new reagent and its performance. Representatives of Waters attended the conference, and, on information and belief, observed the disclosure of the InstantPC™ development and its performance.

19. On or about May 31, 2015, ProZyme also announced to the trade that it had developed and planned to begin manufacture and sale of a ProZyme-developed reagent, marketed under the brand names Gly-X or GlykoPrep, used for testing intracellular glycosylation of proteins.

20. In or about July or August, 2015, ProZyme launched sales of the InstantPC™, and Waters, on information and belief, having learned of ProZyme's breakthrough at the conference, also placed an order for InstantPC™.

21. In March 2016, ProZyme released its Gly-Q platform, which combines ProZyme 1-hour N-glycan sample preparation expertise with a rapid (2-minute) CE separation and customized data analysis software.

22. ProZyme's GlykoPrep and Gly-X brand products contain the InstantPC™ reagent, the structure of which is shown below.



23. InstantPC™ is use as a rapidly-reacting glycan label for analysis with fluorescence and mass spectrometry instruments.

24. ProZyme's GlykoPrep and Gly-X brand products compete in the same market as Waters' N-glycan labeling and analysis product that Waters markets as the GlycoWorks RapiFluor-MS N-Glycan Kit ("GlycoWorks Kit"). Waters' GlycoWorks Kit uses the RapiFluor-MS compound as a labeling reagent.

25. On information and belief, Waters at all relevant times has been aware of the

competition from the ProZyme InstantPC™ and the products incorporating it, including as early as May 2015.

26. Waters has alleged that ProZyme's InstantPC™ has obtained a 20-25% share of a market that Waters defines as the "the market for rapid tags for glycan detection with mass spectrometry devices" and that Waters' market share of that market is 75-80%.

THE '234 PATENT

27. The '234 Patent, entitled "Method of Analysis for Compounds with Amino Group and Analytical Reagent Therefor," issued on May 23, 2017 from U.S. Application No. 15/003,235 ("the '235 Application"), which was filed January 21, 2016. The '234 Patent is attached as Exhibit 1.

28. On information and belief, the '234 Patent is currently scheduled to expire on February 13, 2023.

29. On information and belief, according to the U.S. Patent and Trademark Office ("USPTO") assignment database, as of August 7, 2018, Waters Tech. is the named assignee of the '234 Patent.

30. On information and belief, upon Waters learning as early as May 2015 of ProZyme's breakthrough with the InstantPC™ reagent, and upon Waters learning of the intended launch of the Gly-X and/or GlykoPrep products incorporating this reagent, Waters caused their licensor, Ajinomoto Co., Inc., to petition the USPTO on an expedited basis for a continuation patent with claims that they hoped to obtain and assert against ProZyme's breakthrough Gly-X and/or GlykoPrep products containing the InstantPC™ reagent. This resulted in the '235 Application which was filed on January 21, 2016, with 45 claims, approximately eight months after Waters, on information and belief, learned of the InstantPC™ breakthrough at the May 2015 conference, and about four months after Waters had been shipped InstantPC™ reagent in or about September 2015.

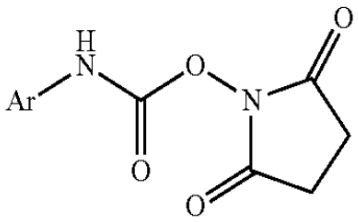
31. On or about April 19, 2016, the applicants of the '235 Application filed a preliminary amendment, cancelling originally filed claims 1-45 and replacing them with new proposed claims 46-60. In making this filing, the applicants of the '235 Application represented

to the USPTO that support for new proposed claims 46-60 "can be found in Claims 1-45 as originally filed," and that, "[i]n particular . . . , support for the substituent containing a dialkylamino group or trialkyl ammonium group can be found on page 12, lines 15 to 17" of the original January 21, 2016 application.

32. Page 12, lines 15-17 of the original '235 Application states: "Examples of suitable polar substituents include: sulfonic acid group, phosphoric acid group, guanidyl group, dialkylamino group and trialkyl ammonium group."

33. The '234 Patent issued on May 23, 2017 with 15 claims, of which claim 1 is the only independent claim, and claims 2-15 depend directly or indirectly from claim 1.

34. Claim 1 of the '234 Patent recites:

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

35. Each of claims 1-15 of the '234 Patent requires "said aromatic carbocyclic group or said aromatic heterocyclic group residue has a substituent" and "said substituent contains a sulfonic acid group, a phosphoric acid group, and guanidyl group, a dialkylamino group or a trialkyl ammonium group."

THE CONTROVERSY BETWEEN THE PARTIES

36. As alleged above in paragraph 12, on or about June 29, 2018, when Waters

became aware of Agilent's plan to acquire the stock of ProZyme, the Senior IP Counsel of Waters Corp. telephoned Agilent in Santa Clara, California, and on behalf of Waters, informed Agilent that Waters was a licensee of the '234 Patent.

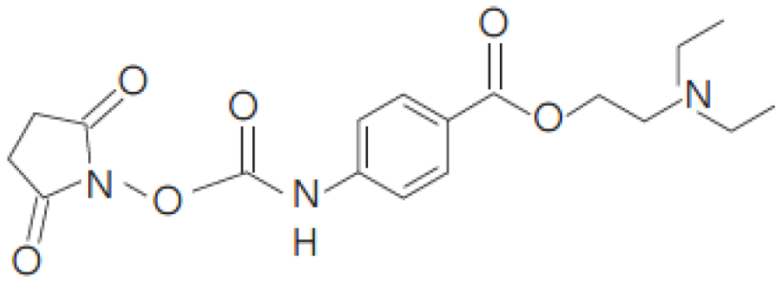
37. Agilent acquired the stock of ProZyme on August 1, 2018 and holds ProZyme as a wholly-owned subsidiary, and, on information and belief, Waters acquired and became the assignee of the '234 Patent on or about August 7, 2018.

38. On September 18, 2018, Waters alleged that the manufacturing, sale, and marketing of products containing ProZyme's InstantPC™ reagent infringed or would infringe the '234 Patent in a patent infringement suit Waters filed against Agilent in the U.S. District Court for the District of Delaware, captioned *Waters Corporation and Waters Technologies Corporation v. Agilent Technologies Inc.*, No. 18-cv-01450 (D. Del.) ("*Waters v. Agilent*"). A true and correct copy of the complaint in *Waters v. Agilent* is attached as Exhibit 2 (with Exhibits A-F thereto).

39. Waters brought the *Waters v. Agilent* case against Agilent, not against ProZyme, but concerning ProZyme's allegedly infringing activities.

40. Waters has taken the position in the *Waters v. Agilent* complaint, and in a preliminary injunction motion it filed and served in *Waters v. Agilent* effective October 9, 2018, that ProZyme has been and currently is, infringing the '234 Patent. On information and belief, Waters did not name or add ProZyme as a defendant in *Waters v. Agilent* because ProZyme is a California corporation and does not have offices or facilities located in Delaware subjecting it to suit in Delaware under 28 U.S.C. § 1400(b).

41. Waters' allegations in *Waters v. Agilent* include that "in 2015, ProZyme launched products under the Gly-X or GlykoPrep brand names containing its InstantPC™ glycan reagent for labeling and subsequent detection of N-glycans, including by mass spectrometry." Ex. 2 ¶ 18. Waters also alleges in *Waters v. Agilent* the chemical structure of ProZyme's InstantPC™ reagent as follows:



Id. at ¶ 19.

42. Waters furthers alleges in detail that the chemical structure of ProZyme's InstantPC™ reagent, represented above, infringes the '234 Patent. *E.g.*, *id.* at ¶¶ 37-38.

43. Waters additionally alleges that ProZyme's product guide, "Gly-X™ N-Glycan Rapid Release and Labeling with InstantPC™ kit" (attached by Waters as Exhibit E to the *Waters v. Agilent* complaint), and a ProZyme-published "technical note," "Development of an Instant Glycan Labeling Dye for High Throughput Analysis by Mass Spectrometry" (attached by Waters as Exhibit F to the *Waters v. Agilent* complaint), induce customers using ProZyme's InstantPC™-containing products to infringe method claims 6 and 15 of the '234 Patent. *Id.* at ¶¶ 38-39.

44. In *Waters v. Agilent*, Waters bases their allegations that Agilent is infringing or will infringe the '234 Patent on Agilent's acquisition of ProZyme on August 1, 2018, *id.* at ¶ 20, and therefore, Waters alleges, Agilent is or should be liable for ProZyme's allegedly-infringing activities since Agilent is now the sole shareholder of ProZyme. Waters also seeks a preliminary and permanent injunction that would enjoin ProZyme's business as it relates to any InstantPC™ reagent, product or related kit.

45. In view of the foregoing, an actual case and controversy exists between ProZyme and Waters with respect to the '234 Patent that is within the scope of this Court's jurisdiction pursuant to 28 U.S.C. § 2201.

46. Namely, a real, immediate, and justiciable case or controversy exists between ProZyme and Waters as to the lawfulness of ProZyme's activities in making, using, selling, and marketing products containing the InstantPC™ reagent, namely, whether the '234 Patent that Waters obtained to prevent competition from ProZyme in the market defined by Waters, *i.e*, the

market for rapid tags for glycan detection with mass spectrometry devices, is valid, enforceable, and/or infringed by ProZyme.

COUNT I

(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '234 PATENT)

47. Plaintiff incorporates by reference and re-alleges Paragraphs 1-46 as if set forth herein.

48. An actual and justiciable controversy exists between ProZyme and Waters concerning non-infringement of the '234 Patent.

49. ProZyme has not infringed and does not infringe any valid and enforceable claim of the '234 Patent directly or indirectly, either literally, or under the doctrine of equivalents.

50. Waters has alleged in *Waters v. Agilent* the making, using, offering to sell, selling, and/or importing into the United States of the InstantPC™ reagent has infringed and/or will infringe at least claims 1, 6, and 15 of the '234 Patent.

51. Waters has also alleged in *Waters v. Agilent* that ProZyme's "Gly-X™ N-Glycan Rapid Release and Labeling with InstantPC™ kit" product guide induces a customer to practice the method of claim 6.

52. Waters has additionally alleged in *Waters v. Agilent* that ProZyme's "Development of an Instant Glycan Labeling Dye for High Throughput Analysis by Mass Spectrometry" technical note induces a customer to practice the method of claim 15 of the '234 Patent.

53. Independent claim 1 of the '234 Patent requires "said aromatic carbocyclic group or said heterocyclic group residue has a substituent," and "said substituent contain a sulfonic acid group, a phosphoric acid group, a guanidyl group, a dialkylamino group or a trialkyl ammonium group."

54. The claim term "said substituent contain a sulfonic acid group, a phosphoric acid group, a guanidyl group, a dialkylamino group or a trialkyl ammonium group" must be construed to require that such recited groups be directly bound to the aromatic based on, among other things, the intrinsic evidence, including the specification and statements made in prosecution, as

well as admissions made by Waters Tech. in the prosecution of later patent claims allowed in 2018.

55. ProZyme's accused products that contain the InstantPC™ reagent do not infringe the claims of the '234 Patent because InstantPC™ lacks "a sulfonic acid group, a phosphoric acid group, a guanidyl group, a dialkylamino group or a trialkyl ammonium group" bound as a substituent to the aromatic as the claim, properly construed, requires. Instead, InstantPC™ has a linker, which is not included in the claim scope under a proper construction of claim 1 and it lacks one of the recited groups bound as a substituent to the aromatic.

56. ProZyme's accused products also do not infringe claims 2-15 of the '234 Patent, which depend directly or indirectly from claim 1 and because each incorporates the same substituent limitation that is absent in the InstantPC™ reagent.

57. ProZyme does not make, use, offer to sell, sell, and/or import into the United States a carbamate compound that meets claims 1-15 of the '234 Patent for at least the above-stated reasons.

58. ProZyme does not actively induce others to infringe claims 1-15 of the '234 Patent by causing, instructing, urging, encouraging, and/or aiding others to directly infringe claims 1-15 of the '234 Patent by making, using, offering to sell, selling, and/or importing into the United States InstantPC™ reagent because, among other reasons, there is no direct infringement for the above-stated reasons.

59. ProZyme does not contribute to its customers' direct infringement of claims 1-15 the '234 Patent by providing products that are used in the infringing methods that are not suitable for any non-infringing use at least because, among other reasons, ProZyme's InstantPC™ reagent does not meet the compound substituent limitations of the patent claims for the above-stated reasons.

60. ProZyme does not infringe any valid and enforceable claim of the '234 Patent.

61. An actual and justiciable controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, exists between Plaintiff and Defendants concerning non-infringement of the '234 Patent.

62. Consequently, a declaratory judgment should be entered declaring that ProZyme does not infringe any valid and enforceable claim of the '234 Patent, directly or indirectly, either literally or under the doctrine of equivalents.

COUNT II

(DECLARATORY JUDGMENT OF INVALIDITY OF THE '234 PATENT)

63. Plaintiff incorporates by reference and re-alleges Paragraphs 1-62 as if set forth herein.

64. An actual and justiciable controversy exists between ProZyme and Waters concerning invalidity of the '234 Patent.

65. The claims of the '234 Patent are invalid because they do not comply with one or more of the requirements for patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112; and/or for obviousness-type double patenting; and/or for statutory double patenting.

66. One non-limiting example of how one or more claims of the '234 Patent are invalid is that the claims are invalid under 35 U.S.C. § 112, for at least a lack of written description. Claim 1 requires "said aromatic carbocyclic group or said heterocyclic group residue has a substituent," and "said substituent contain a sulfonic acid group, a phosphoric acid group, a guanidyl group, a dialkylamino group or a trialkyl ammonium group." To the extent the claim is construed to allow other atoms or groups between the recited aromatic group and the recited sulfonic acid group, phosphoric acid group, guanidyl group, dialkylamino group, or trialkyl ammonium group, then claim 1 would cover carbamate compounds that are not described in the specification. A person of ordinary skill in the art reading the original patent application for the '234 Patent would not have recognized that the specification describes the full scope of carbamate compounds where the substituent can be any number, identity or structure of atoms or groups so long as it contains in some part of the substituent structure the recited sulfonic acid group, phosphoric acid group, guanidyl group, dialkylamino group, or trialkyl ammonium group. And a person of ordinary skill in the art would not have recognized that the '234 Patent inventors actually possessed the full scope of such carbamate compounds based on such a construction of the substituent limitation by the filing date of the original application for the '234 Patent.

67. Claims 2 and 3 of the ’234 Patent each depend from claim 1 and recite “wherein said substituent contains a dialkylamino group or a trialkyl ammonium group.” For the same reasons described above for claim 1, claims 2 and 3 are invalid under 35 U.S.C. § 112, for at least a lack of written description because to the extent the claims are construed to allow other atoms or groups between the recited aromatic group and the recited dialkylamino group or trialkyl ammonium group, then claims 2 and 3 would cover carbamate compounds that are not described in the specification. A person of ordinary skill in the art reading the original patent application for the ’234 Patent would not have recognized that the specification describes the full scope of carbamate compounds where the substituent can be any number, identity or structure of atoms or groups so long as it contains in some part of the substituent structure the recited dialkylamino group or trialkyl ammonium group. And a person of ordinary skill in the art would not have recognized that the ’234 Patent inventors actually possessed the full scope of such carbamate compounds based on such a construction of the substituent limitation by the filing date of the original application for the ’234 Patent.

68. Claims 4-15 depend either directly or indirectly from claim 1 and do not add limitations that limit the substituent recited in claim 1. For the same reasons described above for claim 1, claims 2-14 are invalid under 35 U.S.C. § 112, ¶ 1, for lack of written description.

69. A second non-limiting example of how one or more claims of the ’234 Patent are invalid is that the claims are obvious 35 U.S.C. § 103 in view of prior art disclosing carbamate compounds used to label amine-functional compounds. For example, the claims of the ’234 Patent are invalid as obvious in view of one or more references, alone or in combination with another, including U.S. Patent No. 5,295,599; Roth *et al.*, Mass Spectrometry Reviews, 17:255-274 (1998); Brophy *et al.*, Organic Mass Spectrometry, Vol. 14, No. 7, 379-86 (1979); Rudd & Dwek, Current Opinion in Biotechnology, 8: 488-97 (1997); and Biemann &Scoble, Science, 237: 992-98 (1987).

70. Claims 1-15 of the ’234 Patent are in addition invalid and unenforceable on the grounds of obviousness-type double patenting over U.S. Patent No. 9,274,123 (“the ’123 Patent”) and U.S. Patent No. 7,148,069 (“the ’069 Patent”). The ’234, ’123 and ’069 Patents have

common alleged inventors. Claims 1-15 of the '234 Patent, owned by Waters, are not patentably distinct from claims 1-20 of the '123 patent and claims 1-35 of the '069 Patent, both of which patents are owned by a separate entity, Ajinomoto Co, Inc. of Japan.

71. Claims 1-15 of the '234 Patent are invalid and unenforceable on the grounds of statutory double patenting over the '069 Patent. Claims 1-15 of the of the '234 Patent encompass subject matter that is recited in at least claims 3, 5-8, 14-16, 28, and 34.

72. An actual and justiciable controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, exists between Plaintiff and Defendants concerning invalidity of the '234 Patent.

73. Consequently, a declaratory judgment should be entered declaring that the '234 Patent is invalid.

COUNT III

(DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '234 PATENT DUE TO DOCTRINE OF UNCLEAN HANDS)

74. Plaintiff incorporates by reference and re-alleges Paragraphs 1-73 as if set forth herein.

75. An actual and justiciable controversy exists between ProZyme and Waters concerning the application of the doctrine of unclean hands to render the '234 Patent unenforceable for one or more reasons, including at least the following:

76. On information and belief, after learning of ProZyme's breakthrough InstantPC™ reagent as early as May 2015, Waters became involved in the filing of a continuation application through its exclusive licensor, Ajinomoto, in an effort to seek new claims that it could be argued would cover InstantPC™. That continuation application is the previously referenced '235 Application and was filed on January 21, 2016.

77. In *Waters v. Agilent*, Waters alleges that Ajinomoto "granted Plaintiff Waters Technologies Corporation a royalty bearing Exclusive License to the '234 Patent on January 14, 2013" notwithstanding the '234 Patent did not issue until May 23, 2017 from the '235 Application filed on January 21, 2016. In this allegation, Waters admits that it had the exclusive license to the family of patents and pending applications as early as January 2013 and, on

information and belief, participated in and directed the prosecution of the '235 Application in early 2016 to obtain the claims of the '234 Patent.

78. The original claims allowed in the '234 Patent family in the earlier applications were directed to the carbamate compounds that required one of five specific substituents – which included a dialkylamino group – be bound to the aromatic ring. Waters knew in 2015 that the InstantPC™ reagent did not meet this limitation because it had additional functional groups instead bound as the substituent to the ring and acting as a linker between the aromatic ring and the dialkylamino group in the InstantPC™ reagent.

79. With this knowledge and motivation, the '235 Application was amended on April 19, 2016, on information and belief, with the knowledge of Waters, to delete all the claims from the original application. In their place, applicant added new claims that omitted the claim language requiring that the substituent be bound to the ring and further adding the word "contains" that was not previously in the claims or the specification to describe the composition of the substituent.

80. In prosecution of the '235 Application, applicant told the examiner that "[s]upport for the new Claims 45 to 60 can be found in Claims 1-45, as originally filed." Applicant further told the examiner "support for the substituent containing a dialkylamino group or a trialkyl ammonium group can be found on page 12, lines 15 to 17 [of the original application]." Neither the original claims nor the referenced page 12 teach or support the scope of the substituent limitation so broad as to include any group so long as it contains one of five recited functional groups as required for the infringement allegation in *Waters v. Agilent*.

81. Based on this amendment and applicant's representation, new claims 45-60 of the '235 Application with the "contains" language were allowed and issued as the '234 Patent on May 23, 2017. Because the '234 Patent purports to claim priority to the original application in its family, it expires in 2023.

82. In *Waters v. Agilent*, Waters has alleged infringement and sought a preliminary injunction based on a claim construction of the substituent limitation in these new claims that would allow any substituent of any size, identity or collection of atoms or groups so long as in

some part of the substituent one of the specified functional groups from the original claims – including for example the dialykylamino group – is contained someplace in the structure of the substituent.

83. Before a different examiner, Waters also has prosecuted its own, separate patent family, specifically Application No. 14/342,131 ("'131 Application"). The '131 Application published on August 28, 2014 with claims that the '234 Patent would anticipate to the extent the "contains" substituent limitation is construed as it is now by Waters in *Waters v. Agilent*. Waters as the exclusive licensee and now the assignee and owner of the '234 Patent has nonetheless failed to disclose this reference which is prior art and would be anticipatory to the '131 Application if the "contains" language is construed there how Waters has construed it in *Waters v. Agilent*.

84. Waters has disclosed the earlier two patents in the '234 Patent family, none of which have claims with the "contains" language and all of which require in claims directed to the carbamates that the recited substituent be bound to the aromatic ring.

85. Waters filed its most recent IDS, or disclosure of prior art, in the '131 Application as recently as June 28, 2018, and, once again, the '234 Patent was omitted. Nonetheless, and only one day later, on June 29, 2018, as referenced above, counsel for Waters contacted Agilent in connection with Agilent's potential acquisition of ProZyme, to allege that the '234 Patent – inconsistent with Waters decision to withhold it in the '131 Application – would be relevant to the InstantPC reagent presumably on the ground that it covers any compound in claim 1 with the recited functional group even if there is a linker between the aromatic and the functional group such that the functional group is not bound as a substituent to the aromatic ring.

86. On September 13, 2018, the USPTO issued a notice of allowance in the '131 Application, which will mature into a patent upon payment of the relevant fees. Based on its claimed priority date, the patent that issues from the '131 Application will expire no earlier than 2032, while the '234 Patent now owned by Waters expires in 2023.

87. Waters has leveraged the '234 Patent in *Waters v. Agilent* and earlier based on the contention that "contains" as it relates to the substituent limitation of those claims encompasses

the InstantPC™ reagent. Yet contemporaneously, Waters has failed to disclose the '234 Patent and its "contains" language which is prior art, and, if construed as in *Waters v. Agilent*, would anticipate the claims in the '131 Application.

88. Waters' apparent role in directing the prosecution of the '234 Patent and its ownership of the '234 Patent, as well as its role in directing prosecution of the '131 Application, required and involved misleading the USPTO to obtain and maintain these two patents. Waters' litigation conduct in threatening suit on the '234 Patent and then suing on it and seeking a preliminary injunction without disclosing the contrary positions Waters has taken before the USPTO to obtain the allowance of claims in the '131 Patent that will not expire until at least 2032 also represents litigation misconduct.

89. Waters has unclean hands before the USPTO, which, along with the related litigation misconduct in *Waters v. Agilent*, is grounds for a finding of unclean hands that should bar enforcement of the '234 Patent.

COUNT IV

(DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '234 PATENT DUE TO PROSECUTION HISTORY LACHES)

90. Plaintiff incorporates by reference and re-alleges Paragraphs 1-89 as if set forth herein.

91. An actual and justiciable controversy exists between ProZyme and Waters concerning the application of prosecution history laches to render the '234 Patent unenforceable.

92. Application No. 11/514,130 ("the '130 application"), which issued as the '123 Patent (the parent patent to the '234 Patent), was filed on September 1, 2006. The '130 Application issued as the '123 Patent on March 1, 2016, almost ten years after the '130 Application was filed. Between September 1, 2006 and March 1, 2016, there were developments in the field of labeling and mass spectrometry detection, including development of ProZyme's InstantPC™. Upon information and belief, Waters and/or Ajinomoto were aware of these developments throughout the prosecution of the '130 Application.

93. Ajinomoto delayed prosecution of the application that issued as the '123 Patent for

ten years by filing Office Action Replies and by filing Requests for Continued Examination ("RCEs") that did not substantially advance prosecution of that application. With each Reply and RCE, Anjiomoto also filed a petition for an extension of time.

94. During Anjiomoto's delay, ProZyme invested in developing its InstantPC™, which ProZyme announced in or about May 31, 2015.

95. In the intervening time, ProZyme also filed and obtained patent protection on its InstantPC™, such as U.S. Patent Nos. 8,124,792 and 8,445,292.

96. After ProZyme developed and announced to the industry that its InstantPC™ was ready, Ajinomoto waited an additional eight months before filing the application that issued as the '234 Patent.

97. The unreasonable delay during prosecution of the '130 Application and the unreasonable delay in the filing of the '234 Patent resulted in material prejudice, intervening rights and injury to ProZyme. For example, ProZyme continued to invest time and money in obtaining patent prosecution, testing, in research and development, and marketing of InstantPC™.

98. Therefore, there exists an actual and justiciable controversy between Waters and ProZyme with respect to the unenforceability of the '234 Patent due to prosecution history laches.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for the following relief:

a. That a judgment be entered declaring that the claims of the '234 Patent are invalid;

b. That a judgment be entered declaring that the manufacture, use, offer for sale, sale, or importation of products containing the InstantPC™ reagent or any kit or product containing such reagent does not infringe any valid claim of the '234 Patent;

c. That Defendants and their agents, representatives, attorneys and those persons in active concert or participation with them who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Plaintiff or any of their customers, dealers or suppliers, or any prospective or present sellers, dealers, distributors or customers or Plaintiff, or charging any of them either orally or in writing with infringement of the '234 Patent;

d. That a declaratory judgment be entered that the claims of the '234 Patent are unenforceable due to the equitable doctrine of unclean hands;

e. That a declaratory judgment be entered that the claims of the '234 Patent are unenforceable due to the equitable doctrine of prosecution latches;

f. That this case be found to be exceptional due to Defendants' unclean hands;

g. That Plaintiff be awarded costs, attorneys' fees and other relief, both legal and equitable to which they may be justly entitled; and

h. That Plaintiff be awarded such other and further relief as the Court deems just and proper.

DATED: October 19, 2018

CROWELL & MORING LLP

By: */s/ Mark T. Jansen*

Mark T. Jansen
Chiemi D. Suzuki
Ethan W. Simonowitz
Attorneys for Plaintiff
PROZYME, INC.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, ProZyme hereby demands and requests trial by jury.

DATED: October 19, 2018

CROWELL & MORING LLP

By: */s/ Mark T. Jansen*

Mark T. Jansen
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PROZYME, INC.