

JURISDICTION AND VENUE

5. The patent claims of this action arise under the Patent Laws of the United States, Title 35 of the United States Code.

6. This Court has subject matter jurisdiction over the patent claims asserted herein pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 *et seq.*

7. This Court has personal jurisdiction over Agilent. Upon information and belief, Agilent is a resident of this judicial district, by virtue of its incorporation in the State of Delaware. Upon information and belief, Agilent also has systematic and continuous contacts in this judicial district, regularly transacts business within this district, and regularly avails itself of the benefits of this district. Upon information and belief, Agilent also sells and distributes products in this district and derives substantial revenues from sales in this district.

8. Venue is proper in this district under at least 28 U.S.C. §§ 1391(a) - 1391(c), and 1400(b) as, among other reasons, Agilent resides in this district.

BACKGROUND

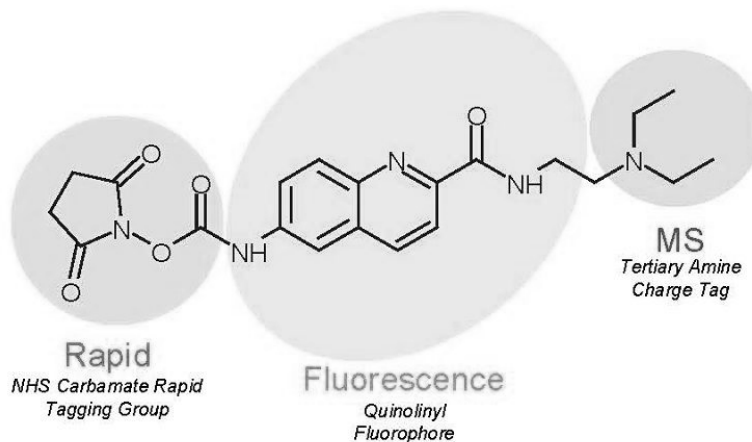
9. Proteins often contain post-translational modifications that affect their function *in vivo*. Glycosylated proteins account for a large proportion of the post-translation modifications. During glycosylation, the reaction by which a carbohydrate is attached to a protein, the carbohydrate is generally attached via a hydroxyl group (-OH) to form an O-linked glycan or via an amine (-NR₂) to form an N-linked glycan.

10. For over 50 years, Waters has developed innovative analytical science solutions to support customer discoveries, operations, performance, and regulatory compliance.

11. In 2015, Waters launched the GlycoWorks RapiFluor-MS N-Glycan Kit. This technology enables unprecedented fluorescent and mass spectrometric performance for glycan detection while also improving the speed and simplicity of N-glycan sample preparation. Low

abundance glycans can thus be easily assigned and characterized by serial fluorescence and mass spectrometric detection. Less sample can be used while still obtaining increased sensitivity.

12. The chemical structure of Waters' GlycoWorks RapiFluor-MS labeling reagent is:



13. Waters has made significant investments into the research, development, and testing its GlycoWorks RapiFluor-MS labeling reagent.

14. Waters has made significant investments into bringing the GlycoWorks RapiFluor-MS product to market.

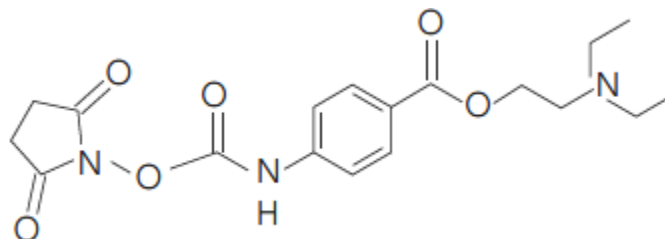
15. To protect its investment, Waters applied for and obtained a number of patents including U.S. Patent No. 9,772,333, and U.S. Patent Application Nos. 14/342,131 and 14/458,760, and 15/005,619.

16. To further protect its investment, Waters acquired rights to intellectual property, including the '234 Patent, from Ajinomoto Co., Inc. ("Ajinomoto"), of Tokyo, Japan.

17. Upon information and belief, ProZyme, Inc. ("ProZyme"), was founded in 1990 in Hayward, California.

18. Upon information and belief, 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 detection by mass spectroscopy.

19. Upon information and belief, the chemical structure of the InstantPC reagent is:



20. Upon information and belief, Agilent completed the acquisition of ProZyme on August 1, 2018.

21. Agilent has indicated that upon completion of the acquisition it would commence sales of ProZyme's products with Instant PC glycan reagents. (See Exs. B-C.)

22. Agilent is a major competitor of Waters in the protein labeling and characterizing market, including for sales of sample preparation, liquid chromatography, and/or mass spectrometry devices which are used by consumers of ProZyme's InstantPC reagent to perform glycan analysis.

THE PATENT

23. The '234 Patent, titled "Method For Analysis Of Compounds With Amino Group And Analytical Reagent Therefor," was duly issued by the United States Patent & Trademark Office on May 23, 2017, and remains unexpired. A true and correct copy of the '234 Patent is attached hereto as Exhibit A. The '234 Patent is a continuation of U.S. patent application Ser. No. 11/514,130, filed on September 1, 2006 (now U.S. Patent No. 9,274,173), which was a continuation of U.S. patent application Ser. No. 10/918,380, filed on August 16, 2004 (now U.S. Patent No. 7,148,069), which was a continuation of International Application No. PCT/JP03/01463, filed on February 13, 2003, which claims priority to Japanese Application No. JP 2002-036446, filed on February 14, 2002.

24. The original assignee of the '234 Patent was Ajinomoto. Ajinomoto granted Plaintiff Waters Technologies Corporation a royalty bearing Exclusive License to the '234 Patent on January 14, 2013. Subsequently, Ajinomoto assigned its entire rights and interest in the '234 Patent to Waters Technologies Corporation on August 7, 2018. An assignment abstract evidencing the recordation of the assignment with the United States Patent and Trademark Office is attached hereto as Exhibit D. Accordingly, Waters Technologies Corporation is now the sole assignee of the '234 Patent with ownership of all substantial rights to exclude others and to enforce, sue, and recover damages for past and future infringements.

25. Agilent has provided and/or will provide products, kits, and devices that are used in the labeling and detection of N-glycans.

26. Agilent has made, used, offered for sale and/or sold and/or will make, use, offer for sale, and/or sell infringing products in the United States.

27. Upon information and belief, Agilent has marketed and/or will market several infringing products containing the InstantPC reagent or products prepared using infringing methods, including product nos. GP96NG-PC, GP24NG-PC, GS96-PC, GS24-PC, GPPNG-PC, GKPC-005, GKPC-103, GKPC-104, GKPC-105, GKPC-106, GKPC-107, GKPC-233, GKPC-234, GKPC-263, GKPC-264, GKPC-301, GKPC-302, GKPC-304, GKPC-305, GKPC-311, GKPC-312, GKPC-313, GKPC-315, GKPC-316, GKPC-317, GKPC-319, GKPC-320, GKPC-321, GKPC-322, GKPC-323, GKPC-325, GKPC-329, GKPC-330, GKPC-401, GKPC-402, GKPC-503, GX24-101, GX24-IPC, GX24-201PC, GX96-101, GX96-201PC, GX96-IPC. Further, Agilent sells the requisite reagents, devices or instruments used with the aforementioned infringing products and/or methods.

28. The infringing products containing the InstantPC reagent have been sold, offered for sale, and marketed by Agilent, and/or will be sold, offered for sale and marketed by Agilent, in this district through advertising in internet, print, and/or television media, and/or by sales staff employed by Agilent.

29. Agilent has infringed and/or will infringe (literally and/or under the doctrine of equivalents), directly, indirectly, and/or through agents or intermediaries, one or more claims of the '234 Patent, including at least claims 1, 6, and 15 of the '234 Patent, by making, using, offering for sale, and/or selling in the United States the products containing or prepared with the InstantPC reagent, or the requisite reagents, devices or instruments used with the aforementioned infringing products.

30. Agilent's customers (including distributors and retailers) have infringed and/or will infringe (literally and/or under the doctrine of equivalents), directly, indirectly, and/or through agents or intermediaries, one or more claims of the '234 Patent, including at least claims 1, 6, and 15 of the '234 Patent, by using, offering for sale, and/or selling in the United States the infringing products containing the InstantPC reagent, products made with the InstantPC reagent, or products configured for use with the InstantPC reagent. Through sales and marketing activities, including advertising and product labeling, Agilent has and/or will solicit, instruct, encourage, and aid and abet its customers to purchase, use, offer for sale, and/or sell the infringing products containing, made with, or for use with the InstantPC reagent.

31. Agilent's infringement is and/or will be willful. During a June 29, 2018 phone call, prior to the completion of Agilent's acquisition of ProZyme, a representative of Waters informed Agilent in-house patent counsel that Waters was aware of Agilent's plans to acquire ProZyme and that Waters had an exclusive license to the '234 Patent. Nevertheless, Agilent

completed the acquisition of ProZyme and has begun and/or will shortly begin selling such products. Agilent has engaged and/or will engage in the accused activities with knowledge of the '234 Patent and without a license or permission to practice the inventions claimed therein.

32. Any infringement by Agilent has caused, is causing, and/or will continue to cause Waters to suffer irreparable injury for which Waters has no adequate remedy at law, including loss of market share.

33. Waters has been and/or will be damaged by Agilent's infringement, at least in the form of Waters' profits lost due to Agilent's infringement.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 9,658,234

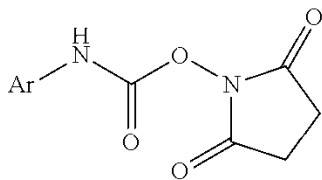
34. Waters realleges paragraphs 1-33 above as if fully set forth herein.

35. The claims of the '234 Patent cover specific carbamate compounds to label primary and secondary amines within another compound. The label assists with the subsequent detection and characterization of the labeled compound. The claims of the '234 Patent also cover methods of labeling and methods of analyzing the labeled compound including by way of mass spectrometry.

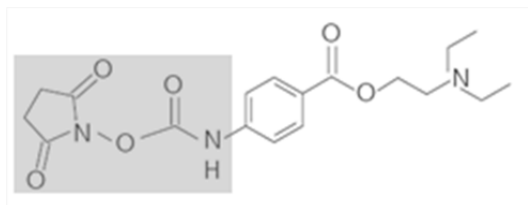
36. Agilent has directly infringed and/or will directly infringe, at least claims 1, 6, and 15 of the '234 Patent in violation of 35 U.S.C. § 271(a) by, for example and without limitation, making, using, offering to sell, selling, and/or importing in and into the United States the InstantPC reagent that meets all the limitations of claims 1, 6, and 15 of the '234 Patent.

37. For example, the compound of claim 1 of the '234 Patent comprises a succinimidyl carbamate of the following structure:

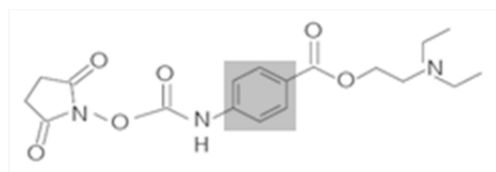
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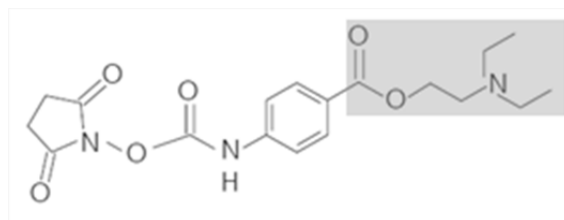
InstantPC is a carbamate compound with an identical structure to the structure depicted in formula (1). *See* highlighted portion of structure below:



According to claim 1 of the '234 patent, "Ar is an aromatic carbocyclic group or an aromatic heterocyclic group residue." In InstantPC, Ar is a six-sided ring with a substituent. The six-sided ring is a carbocyclic compound residue having aromaticity. *See* highlighted portion of structure below:

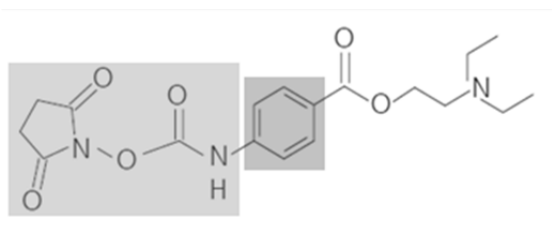


According to claim 1, the "aromatic carbocyclic group or said aromatic heterocyclic group residue has a substituent." In InstantPC, the Ar substituent is highlighted in the structure below:

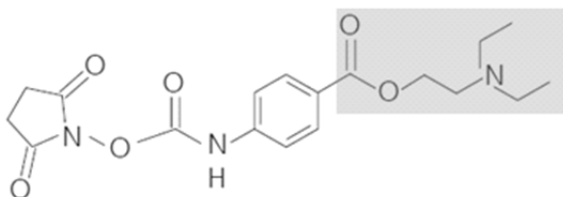


According to claim 1, "in the bond between Ar and the nitrogen atom of the carbamate group, a carbon atom within the ring of Ar is bound to the nitrogen atom of the carbamate group." In InstantPC, the nitrogen atom of the carbamate group (first highlight from the left) is depicted as

being bound to a carbon atom within the six-sided ring (second highlight from the left) in the structure below:



According to claim 1, the “substituent contains a sulfonic acid group, a phosphoric acid group, a guanidyl group, a dialkylamino group or a trialkyl ammonium group.” In InstantPC, the substituent contains a dialkylamino group. *See* highlighted portion of structure below:



38. Claim 6 is a method claim for analyzing a compound with an amino group that requires labeling the amino-containing compound with the carbamate compound of claim 1 and subjecting the labeled amino-containing compound to mass spectrometry. Exhibit E, a ProZyme product guide titled “Gly-X™ N-Glycan Rapid Release and Labeling with InstantPC™ kit” provides that “InstantPC forms a stable urea linkage with glycosylamines released by PNGase F digestion and contains a tertiary amine which generates high MS [mass spectrometry] signals in positive mode.” Exhibit E at 2. As such, a customer using this ProZyme kit would perform all of the steps of at least claim 6 of the ’234 Patent.

39. Claim 15 is a method for labeling a compound with an amino group in a sample containing at least a compound with an amino group, which method is suitable for mass spectrometry, by reacting the compound with an amino group in the sample with a carbamate

compound according to claim 1. Exhibit F, a ProZyme technical note titled “Development of an Instant Glycan Labeling Dye for High Throughput Analysis by Mass Spectrometry” provides that:

Glycoprotein preparation with [the InstantPC reagent] uses an N-Glycanase digestion time of 5 minutes. The short digestion time was enabled by ProZyme’s new proprietary methods, which use denaturants that are both enzyme- and MS-friendly. The denaturant is convenient and rugged, as the solution is stable at room temperature and does not require special handling procedures. To illustrate the cleanup, a mixture of human IgG and bovine fetuin was labeled with IPC. Half of the samples went through the cleanup and the other half did not. Figures 2A and 2B show unbiased and near-complete recovery of this complex mixture of IPC-labeled glycans.

Exhibit F at 2. As such, a customer using this ProZyme kit would perform all of the steps of at least claim 15 of the ’234 Patent. Further, Agilent directly infringes and/or will directly infringe claim 15 by manufacturing InstantPC-labeled glycan standards, including but not limited to products identified in paragraph 27.

40. Agilent has actively induced and/or will actively induce others to infringe at least claims 1, 6, and 15 of the ’234 Patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging, and/or aiding others to directly infringe at least claims 1, 6, and 15 of the ’234 Patent by making, using, offering to sell, selling, and/or importing in and into the United States the infringing InstantPC reagent, as detailed above. Agilent’s active inducement has included and/or will include, for example and without limitation, marketing, selling, and offering to sell the InstantPC reagent, providing instructions on how to use the InstantPC reagent, selling instrumentation or devices for use with the InstantPC reagent, and promoting the use of the InstantPC reagent. For example, Agilent has encouraged and/or will encourage customers including scientists, researchers, and healthcare professional to use the InstantPC reagent by means of marketing materials and videos. Agilent also has instructed and/or will instruct customers on how to use the InstantPC reagent by means of product manuals. Selected product

guides and manuals describing the structure and use of the InstantPC reagent are attached as Exhibits E-F and show that Agilent has encouraged and/or will encourage its customers to infringe the '234 Patent.

41. Agilent also has contributed and/or will contribute to its customers' direct infringement of the '234 Patent in violation of 35 U.S.C. § 271(c) by providing products that are used in the infringing methods and that are not suitable for any substantial non-infringing use.

42. Agilent had actual knowledge of the '234 Patent prior to the filing of this Complaint. Agilent nevertheless has commenced and/or will commence infringement of at least claims 1, 6, and 15 of the '234 Patent following its acquisition of ProZyme and has induced and contributed and/or will induce and contribute to infringement of, at least claims 1, 6, and 15 of the '234 Patent. Agilent's infringement is objectively reckless, knowing deliberate, and willful.

43. Upon information and belief, Agilent knows or is willfully blind to the fact that Agilent's actions have infringed and/or will infringe and have induced and contributed and/or will induce and contribute to infringement of the '234 Patent with the knowledge and intent that one or more claims of the '234 Patent be infringed.

44. Agilent's infringement has caused, is causing, and/or will cause Waters to suffer irreparable injury for which Waters has no adequate remedy at law, including loss of market share and customer goodwill. Waters is therefore entitled to a preliminary and permanent injunction against Agilent's further infringement of the '234 Patent.

45. Waters has been and/or will be damaged at least in the form of its profits lost due to Agilent's infringement of the patented compounds and methods as well as non-patented products and instrumentation sold in conjunction with the patented compounds. Waters is entitled to recover all damages from Agilent and the total profits lost due to Agilent's

infringement in an amount proven at trial, but no less than a reasonable royalty as provided by 35 U.S.C. § 284, before any enhancement for the willfulness of Agilent's infringement.

PRAYER FOR RELIEF

WHEREFORE, Waters respectfully requests the following relief:

A. The entry of a judgment in favor of Waters, and against Agilent, that Agilent has directly infringed and induced and contributed to infringement of one or more claims of the '234 Patent and declaring that Agilent's importing, making, using, offering to sell, and/or selling the InstantPC reagents in the United States are and would be acts of infringement of one or more claims of the '234 Patent;

B. The entry of a judgment in favor of Waters, and against Agilent, that Agilent has willfully infringed one or more claims of the '234 Patent;

C. The entry of a judgment in favor of Waters, and against Agilent, that Agilent and its officers, employees, agents, attorneys, affiliates, successors, assigns and others acting in privity or concert with it be preliminarily and permanently enjoined from making, using, offering to sell, and selling or inducing or contributing to others to make, use, offer to sell, or sell any product that infringes the '234 Patent, including the InstantPC reagent, and from importing the same into the United States;

D. The entry of a judgment awarding Waters all damages resulting from Agilent's infringement, including Water's lost profits and no less than a reasonable royalty, and that such amount be trebled based on Agilent's willful infringement;

E. The entry of a judgment declaring that this is an exceptional case and awarding Waters its attorneys' fees in this matter pursuant to 35 U.S.C. § 285;

J. The entry of a judgment in favor of Waters, and against Agilent, that interest, costs, and expenses be awarded in favor of Waters; and

K. That this Court order such other relief as the Court may deem just and proper.

JURY DEMAND

Waters hereby demands trial by jury in this action on all issues so triable.

Dated: September 18, 2018

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