IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. HOSPIRA, INC. and PFIZER INC., Defendants.	C.A. No. _____ DEMAND FOR JURY TRIAL

COMPLAINT

Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Plaintiffs"), by and through their undersigned attorneys, for their Complaint against Defendants Hospira, Inc. and Pfizer Inc. (collectively, "Defendants") hereby allege as follows:

THE PARTIES

1. Amgen Inc. is a corporation existing under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California, 91320. Amgen Inc. discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry. Founded in 1980, Amgen Inc. is a pioneer in the development of biological human therapeutics. Today, Amgen Inc. is one of the largest biotechnology companies in the world, fueled in part by the success of Neulasta® (pegfilgrastim).

2. Amgen Manufacturing, Limited ("AML") is a corporation existing under the laws of the Territory of Bermuda with its principal place of business at Road 31 km 24.6, Juncos, Puerto Rico 00777. AML manufactures and sells biologic medicines for treating particular diseases in humans. AML is a wholly-owned subsidiary of Amgen Inc.

3. Upon information and belief, Hospira, Inc. ("Hospira") is a corporation existing under the laws of the State of Delaware, with its principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045.

4. Upon information and belief, Pfizer Inc. ("Pfizer") is a corporation existing under the laws of the State of Delaware, with its principal place of business at 235 East 42nd Street, New York, New York 10017.

5. Upon information and belief, Hospira is a wholly-owned subsidiary of Pfizer.

6. Upon information and belief, Defendants collaborate to develop, manufacture, seek regulatory approval for, import, market, distribute, and sell biopharmaceutical products (including products intended to be sold as biosimilar versions of successful biopharmaceutical products developed by others) in this judicial District and throughout the United States.

NATURE OF THE ACTION

7. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, including 35 U.S.C. § 271(e)(2)(C), which was enacted in 2010 as part of the Biologics Price Competition and Innovation Act ("the BPCIA").

8. The asserted patent is United States Patent No. 8,273,707 ("the '707 Patent"), attached hereto as Exhibit 1. Amgen is the owner of all rights, title, and interest in the '707 Patent. The '707 Patent is directed to a process for purifying proteins, including therapeutically important proteins.

9. The BPCIA created an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. 42 U.S.C. § 262(k). The abbreviated pathway (also known as "the subsection (k) pathway") allows a biosimilar applicant (here, Hospira, acting in concert with Pfizer) to rely on the prior licensure and approval status of the innovative biological product (here, Amgen's Neulasta®) that the biosimilar purports to copy. Amgen is the sponsor of the reference

product ("reference product sponsor" or "RPS"), Neulasta®, which is approved by the U.S. Food and Drug Administration ("FDA") to decrease the incidence of infection in patients receiving myelosuppressive anti-cancer drugs. Under the subsection (k) pathway, the biosimilar applicant may rely on its reference product's data rather than demonstrating that the proposed biosimilar product is safe, pure, and potent, as Amgen was required to do to obtain FDA licensure of its reference product under 42 U.S.C. § 262(a).

10. To avoid burdening the courts and parties with unnecessary disputes, the BPCIA also creates an intricate and carefully orchestrated set of procedures for the biosimilar applicant and the RPS to engage in a series of information exchanges and good-faith negotiations between parties prior to the filing of a patent infringement lawsuit. These exchanges are set forth in 42 U.S.C. § 262(*l*)(2)-(*l*)(5) and culminate in an "immediate patent infringement action" pursuant to 42 U.S.C. § 262(*l*)(6).

11. Upon information and belief, Hospira, acting in concert with Pfizer, submitted an abbreviated Biologics License Application ("the Hospira aBLA") for a proposed biosimilar ("the Proposed Hospira Pegfilgrastim Product") to Amgen's Neulasta® product to FDA before the expiration of the '707 Patent.

12. On August 10, 2019, Defendants, through their counsel, sent correspondence to Amgen's counsel asserting that the Hospira aBLA had been "accepted for review by FDA." Upon information and belief, FDA accepted Hospira's aBLA for review prior to that date.

13. In August 2019, Amgen and Defendants began exchanging information as required by the BPCIA as detailed infra in paragraphs 40-50.

14. The '707 Patent was included on Amgen's October 14, 2019 disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(A).

15. Under 35 U.S.C. § 271(e)(2)(C), the submission of "an application seeking approval of a biological product" for the purpose of obtaining FDA approval to engage in commercial manufacture, use, or sale, including any amendments or supplementations thereto constitutes one or more acts of infringement: (i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), or (ii) with respect to a patent that could be identified pursuant to 351(l)(3)(A)(i) of such Act if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act. *See Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1672 (2017).

16. The submission of the Hospira aBLA, including on information and belief, any amendments or supplementations thereto, constitutes one or more acts of infringement of one or more claims of the '707 Patent under 35 U.S.C. § 271(e)(2)(C).

17. If FDA approves the Hospira aBLA and Defendants make, offer to sell, sell, use, or import the Proposed Hospira Pegfilgrastim Product within the United States, Defendants will also infringe one or more claims of the '707 Patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

JURISDICTION AND VENUE

18. This action arises under the patent laws of the United States, Title 35 of the United States Code, Title 42 of the United States Code, and under the Declaratory Judgment Act of 1934 (28 U.S.C. §§ 2201-2202), Title 28 of the United States Code.

19. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

20. Venue is proper in this Court pursuant to 28 U.S.C. § 1400(b).

21. This Court has personal jurisdiction over Hospira because, among other things, upon information and belief, Hospira is a Delaware corporation, has conducted business in this

District, has availed itself of the rights and benefits of Delaware law, and has engaged in substantial and continuing contacts with Delaware.

22. This Court has personal jurisdiction over Pfizer because, among other things, upon information and belief, Pfizer is a Delaware corporation, has conducted business in this District, has availed itself of the rights and benefits of Delaware law, and has engaged in substantial and continuing contacts with Delaware.

23. Amgen Inc. is a Delaware corporation and has suffered injury in Delaware as a result of the Defendants' infringement of Amgen Inc.'s patent.

BACKGROUND

A. Amgen Inc.'s Innovative Biological Product, Neulasta® (pegfilgrastim)

24. Amgen is one of the world's leading biopharmaceutical companies and is dedicated to using discoveries in human biology to invent, develop, manufacture, and sell new therapeutic products for the benefit of patients suffering from serious illnesses. Toward that end, Amgen has invested billions of dollars into its research and development efforts.

25. In 2002, Amgen Inc. introduced Neulasta®, an innovative biologic medicine which has benefited millions of cancer patients as a treatment of side effects of certain forms of cancer therapy. Amgen Inc. conducted extensive clinical trials and submitted the results of those trials to FDA in order to prove that Neulasta® is safe, pure, and potent.

26. The active ingredient in Amgen Inc.'s innovative Neulasta® product is a recombinantly expressed, 175-amino acid form of a protein known as human granulocyte-colony stimulating factor ("G-CSF") conjugated to a 20 kD monomethoxypolyethylene glycol (m-PEG) at the N-terminus of G-CSF.

27. Neulasta® is indicated to decrease the incidence of infection in patients receiving myelosuppressive anti-cancer drugs. By binding to specific receptors on the surface of certain

types of cells, Neulasta® stimulates the production of a type of white blood cells known as neutrophils. Neutrophils are the most abundant type of white blood cells and form a vital part of the human immune system. A deficiency in neutrophils is known as neutropenia, a condition which makes the individual highly susceptible to infection. Neutropenia can result from a number of causes; it is a common side effect of chemotherapeutic drugs used to treat certain forms of cancer. Neulasta® counteracts neutropenia.

28. Neulasta® represented a major advance in cancer treatment by protecting chemotherapy patients from the harmful effects of neutropenia and by facilitating more effective chemotherapy regimens.

29. Prior to 2010, any other company wishing to sell its own version of Neulasta® would have had to undertake the same extensive effort to conduct clinical trials to prove to FDA that its proposed version was also safe, pure, and potent.

30. Developing a new therapeutic product from scratch is extremely expensive: studies estimate the cost of obtaining FDA approval of a new biologic product at more than $2.5 billion. *See* DiMasi J.A. *et al*., Innovation in the pharmaceutical industry: New estimates of R&D costs, 47 J. Health Econ. 20, 25-26 (2016), attached hereto as Exhibit 2.

31. Amgen Inc. is the sponsor of the Biologics License Application ("BLA") for Neulasta®.

32. AML manufactures Neulasta®.

33. Amgen USA Inc. is a wholly-owned subsidiary of Amgen Inc. Amgen USA Inc. purchases Neulasta® from AML, and is the distributor of Neulasta® in the United States.

34. Plaintiffs profit from each sale of Neulasta® in the United States.

B. Defendants Seek Approval to Market a Proposed Biosimilar Version of Neulasta® by Taking Advantage of the Abbreviated Subsection (k) Pathway of the BPCIA

35. Upon information and belief, Hospira, acting in concert with Pfizer, submitted the Hospira aBLA with FDA pursuant to Section 351(k) of the Public Health Service Act to obtain approval to commercially manufacture, use, offer to sell, sell, and import into the United States the Proposed Hospira Pegfilgrastim Product, a proposed biosimilar version of Plaintiffs' Neulasta® product.

36. Upon information and belief, Defendants sought FDA approval for the Proposed Hospira Pegfilgrastim Product by submitting the Hospira aBLA under the abbreviated licensing pathway of 42 U.S.C. § 262(k), which allows Defendants to reference and rely on the approval and licensure of Plaintiffs' Neulasta® product in support of their request for FDA approval.

37. Upon information and belief, the Proposed Hospira Pegfilgrastim Product is designed to copy and compete with Plaintiffs' Neulasta®.

38. Upon information and belief, Defendants did not seek to independently demonstrate to FDA that their biological product is "safe, pure, and potent" pursuant to 42 U.S.C. § 262(a), as Amgen did in its BLA for its innovative biological product Neulasta®. Rather, upon information and belief, Defendants submitted their aBLA requesting that FDA evaluate the suitability of their proposed biosimilar product for licensure, expressly electing and seeking reliance on Amgen's FDA license for Neulasta®. Accordingly, the Hospira aBLA is based upon publicly available information regarding FDA's previous licensure determination that Neulasta® is "safe, pure, and potent." 42 U.S.C. § 262(k)(2)(A)(iii)(I).

39. The Hospira aBLA is predicated on Plaintiffs' trailblazing efforts. Defendants have publicly announced that they submitted the Hospira aBLA under the subsection (k) pathway to obtain approval to commercially manufacture, use, offer to sell, sell, and/or import into the United

States the Proposed Hospira Pegfilgrastim Product that they assert is a biosimilar version of Plaintiffs' Neulasta®. *See* Exhibit 3, Pfizer Form 10-Q for the Quarterly Period Ended September 29, 2019, at 82.

C. The Information Exchange Under 42 U.S.C. § 262(*l*)

40. On August 10, 2019, Defendants, through their counsel, sent correspondence to Amgen's counsel asserting that the Hospira aBLA had been "accepted for review by FDA" and "[i]n accordance with 42 U.S.C. § 262(l)(2), Pfizer will produce to Amgen a copy of its aBLA and related information." Upon information and belief, FDA accepted Hospira's aBLA for review prior to that date.

41. Under 42 U.S.C. § 262(*l*)(2)(A), Hospira was required to provide to Amgen "a copy of the application submitted to [FDA] under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." On August 15, 2019, pursuant to § 262(*l*)(2)(A), Defendants provided Amgen Inc.'s counsel with black-and-white tiff images of the Hospira aBLA submission without usable hyperlinks.

42. Upon information and belief, the tiff images of the Hospira aBLA that Defendants provided to Amgen Inc. comprised a format different than and less complete than the format provided to FDA.

43. Upon information and belief, the Hospira aBLA was provided to FDA in Electronic Common Technical Document (eCTD) format with fully working hyperlinks.

44. Defendants' failure to provide "a copy of the application submitted to the Secretary under subsection (k)" as required by 42 U.S.C. § 262(*l*)(2)(A) materially prejudiced and impeded Amgen Inc.'s ability to review the Hospira aBLA.

45. On October 14, 2019, Amgen provided Defendants, pursuant to 42 U.S.C. § 262(*l*)(3)(A), with a list of patents for which Amgen believes a claim of patent infringement could reasonably be asserted with respect to the making, using, offering to sell, or importing into the United States of the Proposed Hospira Pegfilgrastim Product. This list included the '707 Patent.

46. On October 30, 2019, Defendants, through their counsel, sent a letter to Amgen's counsel stating that "pursuant to 42 U.S.C. § 262(l)(8)(A), Pfizer hereby provides notice that it will commence commercial marketing of [the Proposed Hospira Pegfilgrastim Product], as described in [the Hospira aBLA], no earlier than 180 days from the date of this letter."

47. On October 30, 2019, Defendants provided Amgen with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) (the "(3)(B) Statement"). Amgen understands that Defendants elected not to provide Amgen with a list of patents as provided in 42 U.S.C. § 262(*l*)(3)(B)(i). Rather, Defendants elected to fulfill their obligation under 42 U.S.C. § 262(*l*)(3)(B)(ii) pursuant to subparagraph (B)(ii)(I) by providing "a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of [Defendants] that [each listed patent] is invalid, unenforceable, or will not be infringed by the commercial marketing of [the Proposed Hospira Pegfilgrastim Product]."

48. On December 27, 2019, Amgen provided Defendants with its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C) describing "on a claim by claim basis, the factual and legal basis" of Amgen's opinion that certain claims of the '707 Patent will be infringed by the commercial marketing of the biological product that is the subject of the Hospira aBLA, and Amgen's "response to the statement concerning validity and enforceability" as to the '707 Patent in Defendants' October 30, 2019 statement under 42 U.S.C. § 262(*l*)(3)(B).

49. On January 13, 2020, Amgen and Defendants engaged in a negotiation under 42 U.S.C. § 262(*l*)(4)(A), which requires the parties to engage in "good faith negotiations" in an effort to "agree on which, if any, patents . . . shall be the subject of an action for patent infringement under [42 U.S.C. § 262(*l*)(6)]." Amgen and Defendants agreed that the '707 Patent would be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6). Amgen and Defendants reached this agreement within 15 days of beginning their negotiations under 42 U.S.C. § 262(*l*)(4)(A).

50. Amgen filed this Complaint within the time required under 42 U.S.C. § 262(*l*)(6) because Amgen filed this Complaint within 30 days after Amgen and Defendants reached agreement that the '707 Patent would be the subject of an action for patent infringement under § 262(*l*)(6).

THE PATENT-IN-SUIT

51. Amgen Inc. is the owner of all rights, title, and interest in the '707 Patent.

52. AML has an exclusive license under the '707 Patent. Under the exclusive license, AML possesses exclusionary rights in the '707 Patent.

53. The '707 Patent is titled "Process For Purifying Proteins." The '707 Patent was duly and legally issued on September 25, 2012 by the United States Patent and Trademark Office. The inventors of the '707 Patent are Anna Senczuk and Ralph Klinke.

54. The '707 Patent is directed to a process for purifying proteins.

CAUSES OF ACTION

FIRST COUNT
(PATENT INFRINGEMENT OF THE '707 PATENT)

55. The allegations of paragraphs 1-54 are repeated and incorporated herein by reference.

56. Upon information and belief, by their aBLA submissions to FDA, Defendants seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to engage in the commercial manufacture and/or sale of the Proposed Hospira Pegfilgrastim Product, a proposed biosimilar version of Amgen's Neulasta®.

57. Upon information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Proposed Hospira Pegfilgrastim Product prior to the expiration of the '707 Patent.

58. Defendants committed an act or acts of infringement with respect to the '707 Patent under 35 U.S.C. § 271(e)(2)(C) when Hospira submitted the Hospira aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Proposed Hospira Pegfilgrastim Product.

59. Defendants' participation in, contribution to, inducement of, aiding or abetting the submission of the Hospira aBLA and any amendment(s) or supplementation(s) thereto constitutes direct, contributory, or induced infringement of one or more claims of the '707 Patent under 35 U.S.C. § 271(e)(2)(C).

60. Upon information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Proposed Hospira Pegfilgrastim Product will infringe, literally or under the doctrine of equivalents, one or more claims of the '707 Patent.

61. Representative claim 1 of the '707 Patent recites:

> A process for purifying a protein on a hydrophobic interaction chromatography column such that the dynamic capacity of the column is increased for the protein comprising
>
> > mixing a preparation containing the protein with a combination of a first salt and a second salt,
> >
> > loading the mixture onto a hydrophobic interaction chromatography column, and

eluting the protein,

wherein the first and second salts are selected from the group consisting of citrate and sulfate, citrate and acetate, and sulfate and acetate, respectively, and wherein the concentration of each of the first salt and the second salt in the mixture is between about 0.1 M and about 1.0.

62. Upon information and belief, the process by which Defendants manufacture and/or seek to manufacture the Proposed Hospira Pegfilgrastim Product satisfies each limitation of the claims of the '707 Patent, literally or under the doctrine of equivalents. Defendants practice a process for purifying a protein on a hydrophobic interaction chromatography column as defined in the '707 Patent. Defendants mix a preparation containing the protein with a combination of a first salt and a second salt selected from the group consisting of citrate and sulfate, citrate and acetate, and sulfate and acetate, respectively. The concentrations of the first salt and second salt in Defendants' process fall within the claimed range and/or are equivalent to a concentration within the claimed range. Defendants load the mixture of the preparation containing the protein with a combination of a first salt and a second salt onto the hydrophobic interaction chromatography column, and then elute the protein. Further, contrary to Defendants' arguments, Amgen is not barred from asserting infringement under the doctrine of equivalents based on prosecution history estoppel, preclusion, or any other doctrine.

63. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Amgen has provided Hospira with a detailed statement describing with respect to the '707 Patent, on a claim by claim basis, the factual and legal bases of Amgen's opinion that such patent will be infringed by the commercial marketing of the biological product that is the subject of the Hospira aBLA. Amgen's detailed statement includes, refers to, and relies on confidential information that Hospira provided to Amgen pursuant to 42 U.S.C. § 262(*l*)(2). Amgen does not repeat its detailed statement here because under 42

U.S.C. § 262(*l*)(1), Amgen is not permitted to include confidential information provided by Hospira "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

64. Amgen will be irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '707 Patent. Amgen is entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants from any further infringement. Amgen does not have an adequate remedy at law.

65. To the extent Defendants commercialize their product prior to the expiration of the '707 Patent, Amgen will also be entitled to damages under 35 U.S.C. § 284.

66. The submission of the Hospira aBLA to FDA, the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Proposed Hospira Pegfilgrastim Product before the expiration of the '707 Patent will cause and/or has caused injury to Amgen, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

SECOND COUNT
(DECLARATORY JUDGMENT OF INFRINGEMENTOF THE '707 PATENT)

67. The allegations of paragraphs 1-66 are incorporated herein by reference.

68. Upon information and belief, Defendants seek FDA approval under Section 351(k) of the Public Health Service Act (42 U.S.C § 262(k)) to manufacture and sell the Proposed Hospira Pegfilgrastim Product, a proposed biosimilar version of Amgen's Neulasta®.

69. Upon information and belief, Defendants intend to, and will, manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Hospira Pegfilgrastim Product immediately upon FDA licensure of the Hospira aBLA, which upon information and belief FDA has accepted for review prior to August 10, 2019.

70. If Defendants manufacture, use, offer to sell, or sell within the United States, or import into the United States, the Proposed Hospira Pegfilgrastim Product prior to the expiration

of the ’707 Patent, Defendants will infringe one or more claims of the ’707 Patent under 35 U.S.C. § 271(a), (b), (c), and/or (g).

71. An actual controversy has arisen and now exists between the parties concerning whether the Proposed Hospira Pegfilgrastim Product will infringe one or more claims of the ’707 Patent.

72. Amgen is entitled to a declaratory judgment that Defendants will infringe one or more claims of the ’707 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Hospira Pegfilgrastim Product prior to the expiration of the ’707 Patent.

73. Amgen is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Proposed Hospira Pegfilgrastim Product prior to the expiration of the ’707 Patent. Amgen does not have an adequate remedy at law.

74. The manufacture, use, offer for sale, or sale within the United States and/or importation into the United States, of the Proposed Hospira Pegfilgrastim Product before the expiration of the ’707 Patent will cause injury to Amgen, entitling Amgen to damages under 35 U.S.C. § 284.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests that this Court enter judgment in their favor against Defendants and grant the following relief:

A. a judgment that Defendants have infringed directly, contributed to, or induced the infringement of one or more claims of the ’707 Patent under 35 U.S.C. § 271(e)(2)(C) by submitting to FDA the Hospira aBLA and any amendment(s) or supplementation(s) thereto;

B. a preliminary and/or permanent injunction that enjoins Defendants, their officers, partners, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, other related business entities, and those persons in active concert or participation with any of them from infringing the ’707 Patent, or contributing to or inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of a product that infringes, or the use or manufacture of which infringes the ’707 Patent, in accordance with 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283;

C. a judgment declaring that the manufacture, use, offer to sell, sale, distribution, or importation of the products described in the Hospira aBLA would constitute infringement of one or more claims of the ’707 Patent, or inducement of or contribution to such conduct, by Defendants pursuant to 35 U.S.C. § 271(a), (b), (c), and/or (g);

D. a judgment compelling Defendants to pay to Amgen damages adequate to compensate for Defendants’ infringement, in accordance with 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284;

E. a declaration that this is an exceptional case and an award to Plaintiffs of their attorneys’ fees and costs pursuant to 35 U.S.C. § 285;

F. such other and further relief as this Court may deem to be just and proper.

DEMAND FOR A JURY TRIAL

Plaintiffs hereby demand a jury trial on all issues so triable.

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Dated: February 11, 2020

/s/ Robert W. Whetzel

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