

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KERYX BIOPHARMACEUTICALS, INC.)
and PANION & BF BIOTECH, INC.,)
Plaintiffs,)
v.) C.A. No. _____
ZYDUS WORLDWIDE DMCC,)
ZYDUS PHARMACEUTICALS (USA) INC.)
and ZYDUS LIFESCIENCES LIMITED,)
Defendants.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Keryx Biopharmaceuticals, Inc. (“Keryx”) and Panion & BF Biotech, Inc. (“Panion”) (collectively, “Plaintiffs”), by their undersigned attorneys, for their Complaint against Defendants Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited (collectively, “Zydus”), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, arising from Zydus’s submission of Abbreviated New Drug Application (“ANDA”) No. 218192 (“Zydus’s ANDA”) to the United States Food and Drug Administration (“FDA”) seeking approval to commercially market generic versions of Keryx’s AURYXIA® (Ferric Citrate) Tablets (“Zydus’s Proposed Product”) before the expiration of United States Patent Nos. 7,767,851 (the “‘851 patent”); 8,093,423 (the “‘423 patent”); 8,299,298 (the “‘298 patent”); 8,338,642 (the “‘642 patent”); 8,609,896 (the “‘896 patent”); 8,754,257 (the “‘257 patent”); 8,754,258 (the “‘258 patent”); 8,846,976 (the “‘976 patent”); 8,901,349 (the “‘349 patent”); 9,050,316 (the “‘316 patent”); 9,387,191 (the “‘191 patent”); 9,328,133 (the “‘133 patent”); 9,757,416 (the “‘416

patent”), and 10,300,039 (the “039 patent”) (collectively, the “patents-in-suit”), owned by Plaintiffs.

THE PARTIES

2. Plaintiff Keryx is a corporation organized and existing under the laws of Delaware with a principal place of business at 245 First Street, Suite 1400, Cambridge, MA 02142.

3. Plaintiff Panion is a corporation organized and existing under the laws of Taiwan, with its principal place of business at 16F No. 3, Yuanqu Street, Nangang District, Taipei, Taiwan.

4. On information and belief, Zydus Worldwide DMCC is a company organized and existing under the laws of the United Arab Emirates, having a principal place of business at Unit No. 908, Armada Tower 2, Plot No. JLT-PH2-P2A, Jumeriah Lakes Tower, P.O. Box 113536, Dubai, United Arab Emirates.

5. On information and belief, Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 73 Route 31 North, Pennington, New Jersey, 08534.

6. On information and belief, Zydus Lifesciences Limited is a corporation organized and existing under the laws of India, with its principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad, Gujarat 382481, India.

7. On information and belief, Zydus is in the business of marketing, distributing, and/or selling pharmaceutical drugs, including generic pharmaceutical drugs manufactured by Zydus, throughout the United States, including in this Judicial District.

8. On information and belief, Zydus Worldwide DMCC submitted ANDA 218192 to the FDA.

9. On information and belief, Zydus Pharmaceuticals (USA) Inc. is in the business of marketing, distributing, and/or selling pharmaceutical drugs, including generic pharmaceutical drugs, throughout the United States, including in this Judicial District. On information and belief, Zydus Pharmaceuticals (USA) Inc. is acting as an agent for Zydus Worldwide DMCC with respect to the Zydus ANDA Product.

10. On information and belief, Zydus Pharmaceuticals (USA) Inc. and Zydus Worldwide DMCC are both wholly owned subsidiaries of Zydus Lifesciences Limited.

11. On information and belief, Zydus Lifesciences Limited is in the business of manufacturing pharmaceutical products, including generic pharmaceutical products, sold in the United States. In its answer to the complaint filed in *Novo Nordisk Inc. and Novo Nordisk A/S v. Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Ltd.*, C.A. No. 22-297-CFC (D. Del.) D.I. 14 (filed May 9, 2022), Zydus admitted that “Zydus Lifesciences manufactures pharmaceutical products, including generic pharmaceutical products, sold in the United States.”

12. On information and belief, Zydus Worldwide DMCC, in conjunction with or under the direction of Zydus Pharmaceuticals (USA) Inc. and/or Zydus Lifesciences Limited, developed Zydus’s Proposed Product and/or prepared ANDA No. 218192 for submission. On information and belief, upon receiving approval of ANDA No. 218192, Zydus Worldwide DMCC, in conjunction with or under the direction of Zydus Pharmaceuticals (USA) Inc. and/or Zydus Lifesciences Limited, will manufacture, sell, offer to sell, and/or import Zydus’s Proposed Product in the United States, including in this district.

THE PATENTS-IN-SUIT

13. On August 3, 2010, the USPTO duly and lawfully issued the ’851 patent, entitled, “Ferric Organic Compounds, Uses Thereof and Methods of Making Same.” The ’851 patent is

assigned to Panion. Keryx is the exclusive licensee of all rights in the '851 patent that are relevant to this litigation. A copy of the '851 patent is attached hereto as Exhibit A.

14. On January 10, 2012, the USPTO duly and lawfully issued the '423 patent, entitled, "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Method of Making Same." The '423 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '423 patent that are relevant to this litigation. A copy of the '423 patent is attached hereto as Exhibit B.

15. On October 30, 2012, the USPTO duly and lawfully issued the '298 patent, entitled, "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Method of Making Same." The '298 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '298 patent that are relevant to this litigation. A copy of the '298 patent is attached hereto as Exhibit C.

16. On December 25, 2012, the USPTO duly and lawfully issued the '642 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '642 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '642 patent that are relevant to this litigation. A copy of the '642 patent is attached hereto as Exhibit D.

17. On December 17, 2013, the USPTO duly and lawfully issued the '896 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '896 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '896 patent that are relevant to this litigation. A copy of the '896 patent is attached hereto as Exhibit E.

18. On June 17, 2014, the USPTO duly and lawfully issued the '257 patent, entitled, "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '257 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '257 patent that are relevant to this litigation. A copy of the '257 patent is attached hereto as Exhibit F.

19. On June 17, 2014, the USPTO duly and lawfully issued the '258 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '258 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '258 patent that are relevant to this litigation. A copy of the '258 patent is attached hereto as Exhibit G.

20. On September 30, 2014, the USPTO duly and lawfully issued the '976 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '976 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '976 patent that are relevant to this litigation. A copy of the '976 patent is attached hereto as Exhibit H.

21. On December 2, 2014, the USPTO duly and lawfully issued the '349 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '349 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '349 patent that are relevant to this litigation. A copy of the '349 patent is attached hereto as Exhibit I.

22. On June 9, 2015, the USPTO duly and lawfully issued the '316 patent, entitled, "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '316 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '316 patent that are relevant to this litigation. A copy of the '316 patent is attached hereto as Exhibit J.

23. On May 3, 2016, the USPTO duly and lawfully issued the '133 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '133 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '133 patent that are relevant to this litigation. A copy of the '133 patent is attached hereto as Exhibit K.

24. On July 12, 2016, the USPTO duly and lawfully issued the '191 patent, entitled, "Ferric Citrate Dosage Forms." The '191 patent is assigned to Keryx. A copy of the '191 patent is attached hereto as Exhibit L.

25. On September 12, 2017, the USPTO duly and lawfully issued the '416 patent, entitled "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '416 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '416 patent that are relevant to this litigation. A copy of the '416 patent is attached hereto as Exhibit M.

26. On May 28, 2019, the USPTO duly and lawfully issued the '039 patent, entitled "Ferric Citrate Dosage Forms." The '039 patent is assigned to Keryx. A copy of the '039 patent is attached hereto as Exhibit N.

THE AURYXIA® (FERRIC CITRATE) DRUG PRODUCT

27. Keryx holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for ferric citrate, 210 mg tablets (NDA No. 205874), which it sells under the trade name AURYXIA®. AURYXIA® is an orally available, absorbable, iron-based medicine. AURYXIA® is FDA-approved for the control of serum phosphorus levels in adult patients with chronic kidney disease on dialysis, and for the treatment of iron deficiency anemia in adult patients with chronic kidney disease not on dialysis. The claims of the patents-in-suit cover, among other things, ferric citrate formulations, methods of controlling phosphate retention, methods of decreasing serum calcium levels, and methods of treating hyperphosphatemia.

28. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to AURYXIA®.

JURISDICTION AND VENUE

29. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

30. On information and belief, Zydus Worldwide DMCC, with the participation of Zydus Lifesciences Limited and Zydus Pharmaceuticals (USA) Inc., has submitted, caused to be submitted, or aided and abetted in the preparation of the Zydus ANDA. On information and belief, upon FDA approval of the Zydus ANDA, Zydus Worldwide DMCC, with the participation of Zydus Lifesciences Limited and Zydus Pharmaceuticals (USA) Inc., intends to commercially manufacture, import, market, offer for sale, and/or sell Zydus's Proposed Product throughout the United States including in this Judicial District.

31. This Court has personal jurisdiction over Zydus Worldwide DMCC because of, among other things, its systematic and continuous contacts with the State of Delaware. On information and belief, Zydus Worldwide DMCC purposefully has conducted and continues to conduct business, directly or through its parent, subsidiaries, affiliates and/or agents, including Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited, in this Judicial District, and this Judicial District is a likely destination of Zydus's Proposed Product.

32. On information and belief, Zydus Worldwide DMCC has been previously sued in this Judicial District and has not challenged personal jurisdiction. *See, e.g., Novo Nordisk Inc. and Novo Nordisk A/S v. Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Ltd.*, C.A. No. 22-297-CFC (D. Del.) (filed March 4, 2022); *UCB, Inc. v. Zydus Worldwide DMCC et al.*, C.A. No. 16-1023 (D. Del.) (filed Nov. 3, 2016).

33. On information and belief, Zydus Worldwide DMCC has availed itself of the jurisdiction of this Court by previously asserting claims in this Judicial District. *See, e.g., Pharmacyclics LLC v. Zydus Worldwide DMCC et al.*, C.A. No. 20-560 (D. Del. Apr. 24, 2020).

34. This Court has personal jurisdiction over Zydus Pharmaceuticals (USA) Inc. because of, among other things, its systematic and continuous contacts with the State of Delaware.

On information and belief, Zydus Pharmaceuticals (USA) Inc., directly or through its parent, subsidiaries, affiliates and/or agents, including Zydus Worldwide DMCC and Zydus Lifesciences Limited, regularly and continuously transacts business within Delaware, including by developing, manufacturing, importing, marketing, making and/or selling pharmaceutical products in Delaware. On information and belief, Zydus Pharmaceuticals (USA) Inc. derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware. On information and belief, Zydus Pharmaceuticals (USA) Inc. derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this Judicial District.

35. This Court has personal jurisdiction over Zydus Lifesciences Limited because of, among other things, its systematic and continuous contacts with the State of Delaware. On information and belief, Zydus Lifesciences Limited, directly or through its parent, subsidiaries, affiliates and/or agents, including Zydus Pharmaceuticals (USA) Inc. and Worldwide DMCC, regularly and continuously transacts business within Delaware, including by developing, manufacturing, importing, marketing, making and/or selling pharmaceutical products in Delaware. On information and belief, Zydus Lifesciences Limited derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware. On information and belief, Zydus Lifesciences Limited derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this Judicial District.

36. On information and belief, Zydus intends to engage in a future course of conduct that includes acts of patent infringement in Delaware. These acts will lead to foreseeable harm and injury to Plaintiffs in Delaware and in this Judicial District. For example, on information and

belief, Zydus will work towards the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including Zydus's Proposed Product, throughout the United States, including in Delaware and in this Judicial District, prior to the expiration of the patents-in-suit.

37. On information and belief, both Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited have previously been sued in this Judicial District and have not challenged personal jurisdiction. *See, e.g., Novo Nordisk Inc. and Novo Nordisk A/S v. Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Ltd.*, C.A. No. 22-297-CFC (D. Del.) (filed March 4, 2022); *Acadia Pharmaceuticals Inc. v. Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited*, C.A. No. 22-1386-GBW (D. Del.) (filed Oct. 21, 2022); *Pharmacyclics LLC et al. v. Zydus Worldwide DMCC et al.*, C.A. No. 18-275 (D. Del.) (filed Feb. 16, 2018).

38. On information and belief, Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited have previously availed themselves of the jurisdiction of this Judicial District by bringing counterclaims in this Judicial District. *Acadia Pharmaceuticals Inc. v. Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited*, C.A. No. 22-1386-GBW (D. Del.) (filed Oct. 21, 2022).

39. In the alternative, this Court has personal jurisdiction over Zydus Worldwide DMCC and Zydus Lifesciences Limited because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Plaintiffs' claims arise under federal law; (b) Zydus Worldwide DMCC and Zydus Lifesciences Limited are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) Zydus Worldwide DMCC and Zydus Lifesciences Limited have sufficient contacts with the United States as a whole, including, but not limited to,

preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Zydus Worldwide DMCC and Zydus Lifesciences Limited satisfies due process.

40. Venue is proper for Zydus Pharmaceuticals (USA) Inc. in this Court under 28 U.S.C. §§ 1391 and/or 1400(b), including because, among other things, Zydus Pharmaceuticals (USA) Inc. is subject to personal jurisdiction in this Judicial District, as set forth above; and has committed acts of infringement and, upon information and belief, will commit further acts of infringement in this Judicial District.

41. Venue is proper for Zydus Worldwide DMCC and Zydus Lifesciences Limited pursuant to 28 U.S.C. §§ 1391(c)(3) including because, *inter alia*, Zydus Worldwide DMCC and Zydus Lifesciences Limited are foreign corporations.

42. On information and belief, Zydus Pharmaceuticals (USA) Inc., Zydus Worldwide DMCC, and Zydus Lifesciences Limited have been previously sued in this Judicial District and have not challenged venue. *See, e.g., See, e.g., Novo Nordisk Inc. and Novo Nordisk A/S v. Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Ltd.*, C.A. No. 22-297-CFC (D. Del.) (filed March 4, 2022) D.I. 14 (answer filed on behalf of Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited, formerly known as Cadila Healthcare Limited, not challenging venue); *Acadia Pharmaceuticals Inc. v. Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited*, C.A. No. 22-1386-GBW (D. Del.) (filed Oct. 21, 2022), D.I. 11 (answer filed on behalf of Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited, not challenging venue).

ACTS GIVING RISE TO THIS SUIT

43. Pursuant to Section 505 of the FFDCA, Zydus filed Zydus's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Zydus's Proposed Product before the patents-in-suit expire.

44. On information and belief, following FDA approval of Zydus's ANDA, Zydus will manufacture, use, offer to sell, or sell Zydus's Proposed Product throughout the United States, or import such generic products into the United States.

45. On information and belief, in connection with the filing of its ANDA as described above, Zydus provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Zydus's Paragraph IV Certification"), alleging that the claims of the '851, '423, '191, and '039 patents (the "certified patents") are invalid, unenforceable, and/or will not be infringed by the activities described in Zydus's ANDA.

46. No earlier than February 9, 2023, Zydus sent written notice of its Paragraph IV Certification to Plaintiffs ("Zydus's Notice Letter"). Zydus's Notice Letter alleged that the claims of the certified patents are invalid and/or will not be infringed by the activities described in Zydus's ANDA. Zydus's Notice Letter also informed Plaintiffs that Zydus seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Zydus's Proposed Product before the certified patents expire. Plaintiffs received Zydus's Notice Letter no earlier than February 10, 2023.

47. The certified patents expire on or after February 18, 2024. The '298, '642, '896, '257, '258, '976, '349, '316, '133, and '416 patents expire on February 18, 2024. Therefore, because Zydus is seeking approval of the Zydus ANDA Product before the expiration of the certified patents, Zydus is necessarily also seeking approval of the Zydus ANDA Product before the expiration of the '298, '642, '896, '257, '258, '976, '349, '316, '133, and '416 patents.

48. In Zydus's Notice Letter, Zydus offered to provide access to certain confidential information and materials within Zydus's ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Zydus's offer of confidential access was conditioned on terms identified in Zydus's Notice Letter. The terms and conditions of Zydus's offer of confidential access were unreasonable and beyond those that would apply under a protective order, including those that applied in the protective order in related multi-district litigation. *See In re Auryxia Patent Litig.*, MDL No. 19-2896-LPS, C.A. Nos. 18-1986, 18-2012, 19-220, 19-1445, 19-884, and 19-885, D.I. 43 (Protective Order filed Oct. 16, 2019). The restrictions Zydus sought to impose on access to its ANDA contravened 21 U.S.C. § 355(j)(5)(C)(i)(III). Plaintiffs and Zydus have been negotiating conditions under which Plaintiffs could access Zydus's ANDA but were unable to reach an agreement before the filing of this Complaint. To date, Zydus has not provided any portion of its ANDA to Plaintiffs.

49. This Complaint is being filed before expiration of the forty-five days from the date Plaintiffs received Zydus's Notice Letter.

COUNT I
Infringement of the '851 Patent

50. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-49 as if fully set forth herein.

51. Zydus's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Zydus's Proposed Product, prior to the expiration of the '851 patent, constitutes infringement of one or more of the claims of the '851 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including claim 1.

52. Zydus's commercial manufacture, use, offer for sale, sale and/or importation of the Zydus ANDA Product and/or its active ingredient prior to expiration of the '851 patent, and

Zydus's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '851 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

53. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will infringe at least claim 1 of the '851 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Zydus's Proposed Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of at least claim 1 of the '851 patent, under 35 U.S.C. § 271(a), (b), and/or (c). Such infringement is imminent because, among other things, Zydus has notified Plaintiffs of the submission of Zydus's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Product before the expiration of the '851 patent.

54. Upon information and belief, use of the Zydus ANDA Product in accordance with and as directed by Zydus's proposed labeling for that product would infringe at least claim 1 of the '851 patent. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will actively induce infringement of at least claim 1 of the '851 patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import the Zydus ANDA Product in the United States. Upon information and belief, upon FDA approval of the Zydus ANDA, Zydus will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '851 patent and with knowledge that its acts are encouraging infringement.

55. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will contributorily infringe at least claim 1 of the '851 patent under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the Zydus ANDA Product in the United States. Upon information

and belief, Zydus knows that the Zydus ANDA Product constitutes a material part of the invention, is especially made or adapted for use in infringing the '851 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

56. A justiciable controversy exists between the parties hereto as to the infringement of the '851 patent.

57. Plaintiffs will be substantially and irreparably damaged and harmed if Zydus's infringement of the '851 patent is not enjoined.

58. Plaintiffs do not have an adequate remedy at law.

59. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II
Infringement of the '423 Patent

60. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-49 as if fully set forth herein.

61. Zydus's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Zydus's Proposed Product, prior to the expiration of the '423 patent, constitutes infringement of one or more of the claims of the '423 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including claim 7.

62. Such infringement is imminent because, among other things, Zydus has notified Plaintiffs of the submission of Zydus's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Product before the expiration of the '423 patent.

63. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will actively induce infringement of one or more claims of the '423 patent under 35 U.S.C. § 271(b), including claim 7, by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import Zydus's Proposed Product in the United States. On information and belief, upon FDA approval of Zydus's ANDA, Zydus will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '423 patent and with knowledge that its acts are encouraging infringement.

64. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will contributorily infringe one or more claims of the '423 patent under 35 U.S.C. § 271(c), including claim 7, by offering to sell, selling, and/or importing Zydus's Proposed Product in the United States. Zydus's Proposed Product is a material for use in practicing method claims in the '423 patent that constitutes a material part of those claims' inventions. On information and belief, Zydus knew and knows that Zydus's Proposed Product is especially made or adapted for use in infringing one or more claims of the '423 patent, and that Zydus's Proposed Product is not a staple article or commodity with a substantial non-infringing use.

65. A justiciable controversy exists between the parties hereto as to the infringement of the '423 patent. Plaintiffs will be substantially and irreparably damaged and harmed if Zydus's infringement of the '423 patent is not enjoined.

66. Plaintiffs do not have an adequate remedy at law.

67. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT III
Infringement of the '298 Patent

68. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-49 as if fully set forth herein.

69. Zydus's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Zydus's Proposed Product, prior to the expiration of the '298 patent, constitutes infringement of one or more of the claims of the '298 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including claim 1.

70. Zydus's commercial manufacture, use, offer for sale, sale and/or importation of the Zydus ANDA product and/or its active ingredient prior to expiration of the '298 patent, and Zydus's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '298 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

71. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will infringe at least claim 1 of the '298 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Zydus's Proposed Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of at least claim 1 of the '298 patent, under 35 U.S.C. § 271(a), (b), and/or (c). Such infringement is imminent because, among other things, Zydus has notified Plaintiffs of the submission of Zydus's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Product before the expiration of the '851 patent, which expires on the same date as the '298 patent.

72. Upon information and belief, use of the Zydus ANDA Product in accordance with and as directed by Zydus's proposed labeling for that product would infringe at least claim 1 of the '298 patent. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will actively induce infringement of at least claim 1 of the '298 patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import the Zydus ANDA Product in the United States. Upon information and belief, upon FDA approval of the Zydus ANDA, Zydus will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '298 patent and with knowledge that its acts are encouraging infringement.

73. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will contributorily infringe at least claim 1 of the '298 patent under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the Zydus ANDA Product in the United States. Upon information and belief, Zydus knows that the Zydus ANDA Product constitutes a material part of the invention, is especially made or adapted for use in infringing the '298 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

74. A justiciable controversy exists between the parties hereto as to the infringement of the '298 patent.

75. Plaintiffs will be substantially and irreparably damaged and harmed if Zydus's infringement of the '298 patent is not enjoined.

76. Plaintiffs do not have an adequate remedy at law.

77. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT IV
Infringement of the '642 Patent

78. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-49 as if fully set forth herein.

79. Zydus's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Zydus's Proposed Product, prior to the expiration of the '642 patent, constitutes infringement of one or more of the claims of the '642 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including claims 1, 8, 10, and 17.

80. Zydus's commercial manufacture, use, offer for sale, sale and/or importation of the Zydus ANDA product and/or its active ingredient prior to expiration of the '642 patent, and Zydus's inducement of and/or contribution to such conduct, would further infringe at least claims 1, 8, 10, and 17 of the '642 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

81. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will infringe at least claims 1, 8, 10, and 17 of the '642 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Zydus's Proposed Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of at least claims 1, 8, 10, and 17 of the '642 patent, under 35 U.S.C. § 271(a), (b), and/or (c). Such infringement is imminent because, among other things, Zydus has notified Plaintiffs of the submission of Zydus's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Product before the expiration of the '851 patent, which expires on the same date as the '642 patent.

82. Upon information and belief, use of the Zydus ANDA Product in accordance with and as directed by Zydus's proposed labeling for that product would infringe at least claims 1, 8, 10, and 17 of the '642 patent. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will actively induce infringement of at least claims 1, 8, 10, and 17 of the '642 patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import the Zydus ANDA Product in the United States. Upon information and belief, upon FDA approval of the Zydus ANDA, Zydus will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '642 patent and with knowledge that its acts are encouraging infringement.

83. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will contributorily infringe at least claims 1, 8, 10, and 17 of the '642 patent under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the Zydus ANDA Product in the United States. Upon information and belief, Zydus knows that the Zydus ANDA Product constitutes a material part of the invention, is especially made or adapted for use in infringing the '642 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. A justiciable controversy exists between the parties hereto as to the infringement of the '642 patent.

84. Plaintiffs will be substantially and irreparably damaged and harmed if Zydus's infringement of the '642 patent is not enjoined.

85. Plaintiffs do not have an adequate remedy at law.

86. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT V
Infringement of the '896 Patent

87. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-49 as if fully set forth herein.

88. Zydus's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Zydus's Proposed Product, prior to the expiration of the '896 patent, constitutes infringement of one or more of the claims of the '896 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including claim 1.

89. Zydus's commercial manufacture, use, offer for sale, sale and/or importation of the Zydus ANDA product and/or its active ingredient prior to expiration of the '896 patent, and Zydus's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '896 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

90. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will infringe at least claim 1 of the '896 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Zydus's Proposed Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of at least claim 1 of the '896 patent, under 35 U.S.C. § 271(a), (b), and/or (c). Such infringement is imminent because, among other things, Zydus has notified Plaintiffs of the submission of Zydus's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Product before the expiration of the '851 patent, which expires on the same date as the '896 patent.

91. Upon information and belief, use of the Zydus ANDA Product in accordance with and as directed by Zydus's proposed labeling for that product would infringe at least claim 1 of the '896 patent. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will actively induce infringement of at least claim 1 of the '896 patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import the Zydus ANDA Product in the United States. Upon information and belief, upon FDA approval of the Zydus ANDA, Zydus will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '896 patent and with knowledge that its acts are encouraging infringement.

92. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will contributorily infringe at least claim 1 of the '896 patent under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the Zydus ANDA Product in the United States. Upon information and belief, Zydus knows that the Zydus ANDA Product constitutes a material part of the invention, is especially made or adapted for use in infringing the '896 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

93. A justiciable controversy exists between the parties hereto as to the infringement of the '896 patent.

94. Plaintiffs will be substantially and irreparably damaged and harmed if Zydus's infringement of the '896 patent is not enjoined.

95. Plaintiffs do not have an adequate remedy at law.

96. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT VI
Infringement of the '257 Patent

97. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-49 as if fully set forth herein.

98. Zydus's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Zydus's Proposed Product, prior to the expiration of the '257 patent, constitutes infringement of one or more of the claims of the '257 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including claim 1.

99. Zydus's commercial manufacture, use, offer for sale, sale and/or importation of the Zydus ANDA product and/or its active ingredient prior to expiration of the '257 patent, and Zydus's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '257 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

100. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will infringe at least claim 1 of the '257 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Zydus's Proposed Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of at least claim 1 of the '257 patent, under 35 U.S.C. § 271(a), (b), and/or (c). Such infringement is imminent because, among other things, Zydus has notified Plaintiffs of the submission of Zydus's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Product before the expiration of the '851 patent, which expires on the same date as the '257 patent.

101. Upon information and belief, use of the Zydus ANDA Product in accordance with and as directed by Zydus's proposed labeling for that product would infringe at least claim 1 of the '257 patent. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will actively induce infringement of at least claim 1 of the '257 patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import the Zydus ANDA Product in the United States. Upon information and belief, upon FDA approval of the Zydus ANDA, Zydus will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '257 patent and with knowledge that its acts are encouraging infringement.

102. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will contributorily infringe at least claim 1 of the '257 patent under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the Zydus ANDA Product in the United States. Upon information and belief, Zydus knows that the Zydus ANDA Product constitutes a material part of the invention, is especially made or adapted for use in infringing the '257 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

103. A justiciable controversy exists between the parties hereto as to the infringement of the '257 patent.

104. Plaintiffs will be substantially and irreparably damaged and harmed if Zydus's infringement of the '257 patent is not enjoined.

105. Plaintiffs do not have an adequate remedy at law.

106. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT VII
Infringement of the '258 Patent

107. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-49 as if fully set forth herein.

108. Zydus's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Zydus's Proposed Product, prior to the expiration of the '258 patent, constitutes infringement of one or more of the claims of the '258 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including claim 1.

109. Zydus's commercial manufacture, use, offer for sale, sale and/or importation of the Zydus ANDA product and/or its active ingredient prior to expiration of the '258 patent, and Zydus's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '258 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

110. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will infringe at least claim 1 of the '258 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Zydus's Proposed Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of at least claim 1 of the '258 patent, under 35 U.S.C. § 271(a), (b), and/or (c). Such infringement is imminent because, among other things, Zydus has notified Plaintiffs of the submission of Zydus's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Product before the expiration of the 851 patent, which expires on the same date as the '258 patent.

111. Upon information and belief, use of the Zydus ANDA Product in accordance with and as directed by Zydus's proposed labeling for that product would infringe at least claim 1 of the '258 patent. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will actively induce infringement of at least claim 1 of the '258 patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import the Zydus ANDA Product in the United States. Upon information and belief, upon FDA approval of the Zydus ANDA, Zydus will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '258 patent and with knowledge that its acts are encouraging infringement.

112. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will contributorily infringe at least claim 1 of the '258 patent under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the Zydus ANDA Product in the United States. Upon information and belief, Zydus knows that the Zydus ANDA Product constitutes a material part of the invention, is especially made or adapted for use in infringing the '258 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

113. A justiciable controversy exists between the parties hereto as to the infringement of the '258 patent.

114. Plaintiffs will be substantially and irreparably damaged and harmed if Zydus's infringement of the '258 patent is not enjoined.

115. Plaintiffs do not have an adequate remedy at law.

116. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT VIII
Infringement of the '976 Patent

117. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-49 as if fully set forth herein.

118. Zydus's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Zydus's Proposed Product, prior to the expiration of the '976 patent, constitutes infringement of one or more of the claims of the '976 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including claim 1.

119. Such infringement is imminent because, among other things, Zydus has notified Plaintiffs of the submission of Zydus's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Product before the expiration of the '851 patent, which expires on the same date as the '976 patent.

120. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will actively induce infringement of one or more claims of the '976 patent under 35 U.S.C. § 271(b), including claim 1, by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import Zydus's Proposed Product in the United States. On information and belief, upon FDA approval of Zydus's ANDA, Zydus will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '976 patent and with knowledge that its acts are encouraging infringement.

121. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will contributorily infringe one or more claims of the '976 patent under 35 U.S.C. § 271(c), including claim 1, by offering to sell, selling, and/or importing Zydus's Proposed Product in the United States. Zydus's Proposed Product is a material for use in practicing method claims in the '976

patent that constitutes a material part of those claims' inventions. On information and belief, Zydus knew and knows that Zydus's Proposed Product is especially made or adapted for use in infringing one or more claims of the '976 patent, and that Zydus's Proposed Product is not a staple article or commodity of commerce with a substantial non-infringing use.

122. A justiciable controversy exists between the parties hereto as to the infringement of the '976 patent.

123. Plaintiffs will be substantially and irreparably damaged and harmed if Zydus's infringement of the '976 patent is not enjoined.

124. Plaintiffs do not have an adequate remedy at law.

125. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT IX
Infringement of the '349 Patent

126. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-49 as if fully set forth herein.

127. Zydus's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Zydus's Proposed Product, prior to the expiration of the '349 patent, constitutes infringement of one or more of the claims of the '349 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including claim 1.

128. Such infringement is imminent because, among other things, Zydus has notified Plaintiffs of the submission of Zydus's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Product before the expiration of the '851 patent, which has the same expiration date as the '349 patent.

129. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will actively induce infringement of one or more claims of the '349 patent under 35 U.S.C. § 271(b), including claim 1, by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import Zydus's Proposed Product in the United States. On information and belief, upon FDA approval of Zydus's ANDA, Zydus will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '349 patent and with knowledge that its acts are encouraging infringement.

130. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will contributorily infringe one or more claims of the '349 patent under 35 U.S.C. § 271(c), including claim 1, by offering to sell, selling, and/or importing Zydus's Proposed Product in the United States. Zydus's Proposed Product is a material for use in practicing method claims in the '349

patent that constitutes a material part of those claims' inventions. On information and belief, Zydus knew and knows that Zydus's Proposed Product is especially made or adapted for use in infringing one or more claims of the '349 patent, and that Zydus's Proposed Product is not a staple article or commodity of commerce with a substantial non-infringing use.

131. A justiciable controversy exists between the parties hereto as to the infringement of the '349 patent.

132. Plaintiffs will be substantially and irreparably damaged and harmed if Zydus's infringement of the '349 patent is not enjoined.

133. Plaintiffs do not have an adequate remedy at law.

134. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT X
Infringement of the '316 Patent

135. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-49 as if fully set forth herein.

136. Zydus's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Zydus's Proposed Product, prior to the expiration of the '316 patent, constitutes infringement of one or more of the claims of the '316 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including claim 1.

137. Zydus's commercial manufacture, use, offer for sale, sale and/or importation of the Zydus ANDA product and/or its active ingredient prior to expiration of the '316 patent, and Zydus's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '316 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

138. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will infringe at least claim 1 of the '316 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Zydus's Proposed Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of at least claim 1 of the '316 patent, under 35 U.S.C. § 271(a), (b), and/or (c). Such infringement is imminent because, among other things, Zydus has notified Plaintiffs of the submission of Zydus's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Product before the expiration of the '851 patent, which has the same expiration date as the '316 patent.

139. Upon information and belief, use of the Zydus ANDA Product in accordance with and as directed by Zydus's proposed labeling for that product would infringe at least claim 1 of the '316 patent. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will actively induce infringement of at least claim 1 of the '316 patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import the Zydus ANDA Product in the United States. Upon information and belief, upon FDA approval of the Zydus ANDA, Zydus will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '316 patent and with knowledge that its acts are encouraging infringement.

140. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will contributorily infringe at least claim 1 of the '316 patent under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the Zydus ANDA Product in the United States. Upon information and belief, Zydus knows that the Zydus ANDA Product constitutes a material part of the invention, is especially made or adapted for use in infringing the '316 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

141. A justiciable controversy exists between the parties hereto as to the infringement of the '316 patent.

142. Plaintiffs will be substantially and irreparably damaged and harmed if Zydus's infringement of the '316 patent is not enjoined.

143. Plaintiffs do not have an adequate remedy at law.

144. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XI
Infringement of the '191 Patent

145. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-49 as if fully set forth herein.

146. Zydus's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Zydus's Proposed Product, prior to the expiration of the '191 patent, constitutes infringement of one or more of the claims of the '191 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including claims 1, 6, 11 and 16.

147. Zydus's commercial manufacture, use, offer for sale, sale and/or importation of the Zydus ANDA product and/or its active ingredient prior to expiration of the '191 patent, and Zydus's inducement of and/or contribution to such conduct, would further infringe at least claims 1, 6, 11 and 16 of the '191 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

148. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will infringe at least claims 1, 6, 11 and 16 of the '191 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Zydus's Proposed Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of at least claims 1, 6, 11 and 16 of the '191 patent, under 35 U.S.C. § 271(a), (b), and/or (c). Such infringement is imminent because, among other things, Zydus has notified Plaintiffs of the submission of Zydus's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Product before the expiration of the '191 patent.

149. Upon information and belief, use of the Zydus ANDA Product in accordance with and as directed by Zydus's proposed labeling for that product would infringe at least claims 1, 6, 11 and 16 of the '191 patent. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will actively induce infringement of at least claims 1, 6, 11 and 16 of the '191 patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import the Zydus ANDA Product in the United States. Upon information and belief, upon FDA approval of the Zydus ANDA, Zydus will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '191 patent and with knowledge that its acts are encouraging infringement.

150. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will contributorily infringe at least claims 1, 6, 11 and 16 of the '191 patent under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the Zydus ANDA Product in the United States. Upon information and belief, Zydus knows that the Zydus ANDA Product constitutes a material part of the invention, is especially made or adapted for use in infringing the '191 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

151. A justiciable controversy exists between the parties hereto as to the infringement of the '191 patent.

152. Plaintiffs will be substantially and irreparably damaged and harmed if Zydus's infringement of the '191 patent is not enjoined.

153. Plaintiffs do not have an adequate remedy at law.

154. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XII
Infringement of the '133 Patent

155. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-49 as if fully set forth herein.

156. Zydus's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Zydus's Proposed Product, prior to the expiration of the '133 patent, constitutes infringement of one or more of the claims of the '133 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including claims 1, 8, 10, and 17.

157. Zydus's commercial manufacture, use, offer for sale, sale and/or importation of the Zydus ANDA product and/or its active ingredient prior to expiration of the '133 patent, and Zydus's inducement of and/or contribution to such conduct, would further infringe at least claims 1, 8, 10, and 17 of the '133 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

158. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will infringe at least claims 1, 8, 10, and 17 of the '133 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Zydus's Proposed Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of at least claims 1, 8, 10, and 17 of the '133 patent, under 35 U.S.C. § 271(a), (b), and/or (c). Such infringement is imminent because, among other things, Zydus has notified Plaintiffs of the submission of Zydus's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Product before the expiration of the '851 patent, which has the same expiration date as the '133 patent.

159. Upon information and belief, use of the Zydus ANDA Product in accordance with and as directed by Zydus's proposed labeling for that product would infringe at least claims 1, 8, 10, and 17 of the '133 patent. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will actively induce infringement of at least claims 1, 8, 10, and 17 of the '133 patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import the Zydus ANDA Product in the United States. Upon information and belief, upon FDA approval of the Zydus ANDA, Zydus will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '133 patent and with knowledge that its acts are encouraging infringement.

160. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will contributorily infringe at least claims 1, 8, 10, and 17 of the '133 patent under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the Zydus ANDA Product in the United States. Upon information and belief, Zydus knows that the Zydus ANDA Product constitutes a material part of the invention, is especially made or adapted for use in infringing the '133 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

161. A justiciable controversy exists between the parties hereto as to the infringement of the '133 patent.

162. Plaintiffs will be substantially and irreparably damaged and harmed if Zydus's infringement of the '133 patent is not enjoined.

163. Plaintiffs do not have an adequate remedy at law.

164. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XIII
Infringement of the '416 Patent

165. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-49 as if fully set forth herein.

166. Zydus's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Zydus's Proposed Product, prior to the expiration of the '416 patent, constitutes infringement of one or more of the claims of the '416 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including claims 1 and 23.

167. Such infringement is imminent because, among other things, Zydus has notified Plaintiffs of the submission of Zydus's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Product before the expiration of the '851 patent, which has the same expiration date as the '416 patent.

168. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will actively induce infringement of one or more claims of the '416 patent under 35 U.S.C. § 271(b), including claims 1 and 23, by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import Zydus's Proposed Product in the United States. On information and belief, upon FDA approval of Zydus's ANDA, Zydus will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '416 patent and with knowledge that its acts are encouraging infringement.

169. Unless enjoined by this Court, upon FDA approval of Zydus's ANDA, Zydus will contributorily infringe one or more claims of the '416 patent under 35 U.S.C. § 271(c), including claims 1 and 23, by offering to sell, selling, and/or importing Zydus's Proposed Product in the

United States. Zydus's Proposed Product is a material for use in practicing method claims in the '416 patent that constitutes a material part of those claims' inventions. On information and belief, Zydus knew and knows that Zydus's Proposed Product is especially made or adapted for use in infringing one or more claims of the '416 patent, and that Zydus's Proposed Product is not a staple article or commodity of commerce with a substantial non-infringing use.

170. A justiciable controversy exists between the parties hereto as to the infringement of the '416 patent.

171. Plaintiffs will be substantially and irreparably damaged and harmed if Zydus's infringement of the '416 patent is not enjoined.

172. Plaintiffs do not have an adequate remedy at law.

173. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XIV
Infringement of the '039 Patent

174. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-49 as if fully set forth herein.

175. Zydus's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Zydus's Proposed Product, prior to the expiration of the '039 patent, constitutes infringement of one or more of the claims of the '039 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, including claims 1, 4, 5, 8, 11, 14 and 15.

176. Such infringement is imminent because, among other things, Zydus has notified Plaintiffs of the submission of Zydus's ANDA seeking approval to engage in the commercial

manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Product before the expiration of the '039 patent.

177. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will actively induce infringement of one or more claims of the '039 patent under 35 U.S.C. § 271(b), including claims 1, 4, 5, 8, 11, 14 and 15, by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import Zydus's Proposed Product in the United States. On information and belief, upon FDA approval of the Zydus ANDA, Zydus will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '039 patent and with knowledge that its acts are encouraging infringement.

178. Unless enjoined by this Court, upon FDA approval of the Zydus ANDA, Zydus will contributorily infringe one or more claims of the '039 patent under 35 U.S.C. § 271(c), including claims 1, 4, 5, 8, 11, 14 and 15, by offering to sell, selling, and/or importing Zydus's Proposed Product in the United States. Zydus's Proposed Product is a material for use in practicing method claims in the '039 patent that constitutes a material part of those claims' inventions. On information and belief, Zydus knew and knows that Zydus's Proposed Product is especially made or adapted for use in infringing one or more claims of the '039 patent, and that Zydus's Proposed Product is not a staple article or commodity of commerce with a substantial non-infringing use.

179. A justiciable controversy exists between the parties hereto as to the infringement of the '039 patent.

180. Plaintiffs will be substantially and irreparably damaged and harmed if Zydus's infringement of the '039 patent is not enjoined.

181. Plaintiffs do not have an adequate remedy at law.

182. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Zydus has infringed the patents-in-suit by submitting ANDA No. 218192 to the FDA;

B. A Declaratory Judgment under 28 U.S.C. § 2201 that the commercial manufacture, use, offer to sell, sale, or importation Zydus's Proposed Product will directly infringe, induce, and/or contribute to infringement of the patents-in-suit;

C. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of FDA approval of ANDA No. 218192 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Zydus, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing Zydus's Proposed Product, or from directly infringing or actively inducing or contributing to the infringement of claims of the patents-in-suit, until after the expiration of the patents-in-suit or any later expiration of exclusivity to which Plaintiffs are or become entitled;

F. To the extent that Zydus has committed any acts with respect to the devices, compositions, formulations, processes, and methods of use and administration claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Plaintiffs damages for such acts, together with interest;

G. If Zydus engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Zydus's Proposed Product prior to the expiration of the

patents-in-suit, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

I. A Judgment finding that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Plaintiffs their attorneys' fees incurred in this action;

J. A Judgment awarding Plaintiffs their costs and expenses incurred in this action; and

L. Such further and other relief as this Court may deem just and proper.

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