IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| ABBOTT LABORATORIES, | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | C.A. No. 12-457 |
| | ) | |
| ROXANE LABORATORIES, INC., | ) | |
| | ) | |
| Defendant. | ) | |

**AMENDED COMPLAINT**

Plaintiff Abbott Laboratories, by way of Amended Complaint against Roxane Laboratories, Inc., states as follows:

**THE PARTIES**

1. Plaintiff Abbott Laboratories ("Abbott") is a corporation organized and existing under the laws of Illinois with its corporate headquarters at 100 Abbott Park Road, Abbott Park, Illinois 60064. Abbott is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. On information and belief, Defendant Roxane Laboratories, Inc. ("Roxane") is a corporation organized and existing under the laws of Nevada, having its principal place of business located at 1809 Wilson Road, Columbus, Ohio 43216.

**NATURE OF THE ACTION**

3. This is a civil action for patent infringement of United States Patent Number 7,148,359 B2 ("the '359 patent"), United States Patent Number 7,364,752 B1 ("the '752 patent"), United States Patent No. 5,648,497 ("the '497 patent"), United States Patent No. 6,037,157 ("the '157 patent"), and United States Patent No. 6,703,403 B2 ("the '403 patent"),

arising under the United States Patent Laws, Title 35, United States Code, §100, *et seq.*, and in particular under 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application ("ANDA") No. 202573, which Roxane filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA"), for approval to market a generic copy of Abbott's successful Norvir® tablets that are sold in the United States, and which Roxane subsequently amended.

## JURISDICTION AND VENUE

4. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Roxane.

6. On information and belief, Roxane formulates, develops, markets, and sells active pharmaceutical ingredients (API), solid oral dosage forms, pharmaceutical formulations, and/or pharmaceutical products containing such API or pharmaceutical formulations (collectively "Roxane's products"). Roxane routinely files ANDAs and seeks FDA approval to market its products in the United States.

7. On information and belief, Roxane, either directly or through one or more of its wholly owned subsidiaries, affiliates, agents, distributors, or parent corporation sells and/or distributes a substantial volume of Roxane's products in this judicial district. On information and belief, Roxane purposefully has conducted and continues to conduct substantial business in this judicial district, from which it has derived, directly or indirectly, substantial revenue.

8. On information and belief, this judicial district is a likely destination of products that will be manufactured and sold as a result of FDA approval of Roxane's ANDA No. 202573, which is the subject of this lawsuit.

9. This Court has personal jurisdiction over Roxane by virtue of, *inter alia*, its marketing and sales activities in this judicial district, including but not limited to the substantial, continuous and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of this judicial district.

10. Roxane has availed itself of this forum previously for the purpose of litigating a patent dispute. For example, Roxane has filed counterclaims for declaratory judgment in *Abbott Laboratories v. Roxane Laboratories, Inc.*, No. 10-998 and *GlaxoSmithKline LLC v. Roxane Laboratories, Inc.*, No. 11-542.

11. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

## BACKGROUND

12. Abbott is the holder of approved New Drug Application ("NDA") No. 22-417 for ritonavir tablets, which Abbott markets and sells under the trademark Norvir®. Abbott manufactures and sells Norvir® 100 mg tablets in the United States under NDA No. 22-417.

13. Roxane filed with the FDA ANDA No. 202573 under 21 U.S.C. § 355(j)(2)(B), seeking FDA approval to market ritonavir tablets 100 mg ("Roxane's generic ritonavir tablets"), which are generic copies of Abbott's Norvir® tablets.

14. Upon information and belief, ANDA No. 202573 seeks FDA approval of a pharmaceutical composition comprising ritonavir in a 100 mg dosage strength.

15. Upon information and belief, ANDA No. 202573 seeks FDA approval to market Roxane's generic ritonavir tablets in the United States.

16. On March 24, 2011, Abbott received a letter on behalf of Roxane, dated March 21, 2011, purporting to be a "Patent Notice Pursuant to § 505(b)(3)(B) [21 USC § 355(b)(4)(B)]" for ANDA No. 202573 pursuant to section 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Roxane's March 24, 2011 Notice Letter notified Abbott that Roxane had filed ANDA No. 202573, seeking approval to market Roxane's generic ritonavir tablets prior to the expiration of the '359 and '752 patents.

17. On April 6, 2012, Abbott received a letter on behalf of Roxane, dated March 29, 2012, purporting to be a "Patent Notice Pursuant to § 505(j)(2)(B)(ii) [21 USC § 355(j)(2)(B)(ii)]" for ANDA No. 202573 pursuant to section 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Roxane's April 6, 2012 Notice Letter notified Abbott that Roxane had amended ANDA No. 202573, seeking approval to market Roxane's generic ritonavir tablets prior to, *inter alia*, the expiration of the '497 patent, the '157 patent, and the '403 patent.

## THE PATENTS-IN-SUIT

18. The '359 patent was duly and legally issued by the United States Patent and Trademark Office ("PTO") on December 12, 2006. Abbott is the owner by assignment of the '359 patent and has the right to sue for infringement thereof. Abbott lists the '359 patent in the Approved Drug Products With Therapeutic Equivalence Evaluations ("Orange Book") for NDA No. 22-417. The '359 patent is currently the subject of a reexamination proceeding pending at the PTO. A true and correct copy of the '359 patent is attached as Exhibit A.

19. The ’752 patent was duly and legally issued by the PTO on April 29, 2008. Abbott is the owner by assignment of the ’752 patent and has the right to sue for infringement thereof. Abbott lists the ’752 patent in the Orange Book for NDA No. 22-417. The ’752 patent is currently the subject of a reexamination proceeding pending at the PTO. A true and correct copy of the ’752 patent is attached as Exhibit B.

20. The ’497 patent was duly and legally issued by the PTO on July 15, 1997. Abbott is the owner by assignment of the ’497 patent and has the right to sue for infringement thereof. Abbott lists the ’497 patent in the Orange Book for NDA No. 22-417. The ’497 patent is currently the subject of a reexamination proceeding pending at the PTO. A true and correct copy of the ’497 patent is attached as Exhibit C.

21. The ’157 patent was duly and legally issued by the PTO on March 14, 2000. Abbott is the owner by assignment of the ’157 patent and has the right to sue for infringement thereof. Abbott lists the ’157 patent in the Orange Book for NDA No. 22-417. The ’157 patent is currently the subject of a reexamination proceeding pending at the PTO. A true and correct copy of the ’157 patent is attached as Exhibit D.

22. The ’403 patent was duly and legally issued by the PTO on March 9, 2004. Abbott is the owner by assignment of the ’403 patent and has the right to sue for infringement thereof. Abbott lists the ’403 patent in the Orange Book for NDA No. 22-417. The ’403 patent is currently the subject of a reexamination proceeding pending at the PTO. A true and correct copy of the ’403 patent is attached as Exhibit E.

## FACTS PERTINENT TO THE CLAIMS

23. Infection by the virus known as “HIV,” or human immunodeficiency virus, is a serious health problem affecting millions of patients around the globe. Norvir® tablets, sold by

Abbott throughout the United States, is a critical component of HIV treatment for many patients. Norvir® is approved for use in combination with other anti-retroviral agents for the treatment of HIV-1 infection. (Ex. F; Norvir® Labeling at Section 1, Indications and Usage.)

24. Abbott researchers made the unexpected discovery that ritonavir, the active ingredient in Norvir®, is capable of boosting the effectiveness of other HIV treatments, including drugs known as "protease inhibitors." Ritonavir accomplishes this feat by inhibiting a certain enzyme, known as "cytochrome P450 monooxygenase" ("CYP"), that normally metabolizes protease inhibitors, leading to the need for more frequent and higher doses than desired. This groundbreaking discovery transformed the treatment of HIV infections, allowing for the use of potent protease inhibitors at lower doses, and consequently fewer attendant side effects, when administered with ritonavir. This discovery was not the mere coadministration of ritonavir with a companion drug but rather was that the ritonavir and/or the companion drug could be administered in amounts which were previously understood to be ineffective. This unique innovation ushered in a new era in the treatment of HIV/AIDS.

25. In fact, there are several known AIDS drugs that are not approved for monotherapy but that are approved for administration with ritonavir. The reason is because these other HIV drugs would be toxic in dosage amounts necessary for them to be effective for the treatment of AIDS when used alone. Ritonavir, however, allows them to be administered in lower amounts that are safe and translate into effective levels in the bloodstream. This is due to ritonavir's remarkable ability to inhibit CYP and thereby allow for the other HIV agent to be available in the bloodstream in effective amounts. This discovery has been a breakthrough in AIDS treatment.

26. The importance of ritonavir did not go unnoticed. In 1997, Dale Kempf, Daniel Norbeck, Hing Sham, and Chen Zhao of Abbott Laboratories were awarded the 1997 National Inventor of the Year Award by the Intellectual Property Owners Association for their invention of Norvir®. (Ex. H.) Since 1974, this award has been given to distinguished inventors who have benefited the nation's economy and made a significant impact on society. According to IPO, the criteria used to judge the nominated candidates for the award include originality of concept, ingenuity in bringing the concept to market, societal benefit and commercial success. This award was followed in 1999 by the Pharmaceutical Research and Manufacturers of America's presentation of the Discoverers Award to Dale Kempf and Daniel Norbeck for their efforts in developing Norvir® and helping save the lives of AIDS patients. (Ex. I.) In addition, these Abbott chemists were also awarded the 2002 Industrial Innovation Award from the American Chemical Society for discovering the pioneering boosting effect of ritonavir. (Ex. J.)

27. The '157 patent claims, *inter alia*, methods of improving the pharmacokinetics of a drug that is metabolized by CYP comprising administering to a human in need of treatment of a therapeutically effective amount of a combination of the drug and ritonavir. (*E.g.*, '157 patent, claim 1.) The '403 patent claims, *inter alia*, methods of improving the pharmacokinetics of a drug that is metabolized by CYP comprising co-administering to a human being treated with the drug and an amount of ritonavir effective to inhibit CYP. (*E.g.*, '403 patent, claim 3.) Thus, the patents claim the administration of ritonavir to patients suffering from HIV infection in combination with other anti-retroviral agents.

28. The specifications of the '157 and '403 patents disclose co-administration of ritonavir with a drug that is metabolized by CYP, for example, HIV protease inhibitors, in order to improve the pharmacokinetics of the drug and thus provide a useful treatment for HIV

infection or AIDS ("Acquired Immune Deficiency Syndrome") in humans. (*E.g.*, '157 patent, col. 1, l. 49 – col. 2, l. 52; '403 patent, col. 1, l. 53 – col. 2, l. 52.) The '157 and '403 patents further disclose that ritonavir improves such drug's pharmacokinetics by inhibiting CYP. (*E.g.*, '157 patent, col. 1, l. 49 – col. 2, l. 52; '403 patent, col. 1, l. 53 – col. 2, l. 52.) This effect is reflected in the Norvir® labeling, which not only directs the use of Norvir® in combination with other anti-retroviral agents for the treatment of HIV-1 infection, but also describes ritonavir as an inhibitor of CYP, including cytochrome P450 3A ("CYP3A"), and discloses ritonavir's effect on various protease inhibitors. For example, the Norvir® labeling states that taking Norvir® may lead to increased plasma concentrations of concomitant medications, and that higher plasma concentrations can result in increased or prolonged therapeutic or adverse effects. (Ex. F at Section 5.1.) The Norvir® labeling further directs prescribers to refer to the full prescribing information of other protease inhibitors for details on co-administration. (Ex. F at Section 7.)

29. For example, the Norvir® labeling directs prescribers to the Prezista® (darunavir) labeling for details on co-administration of ritonavir and darunavir. (Ex. F at Section 7.) The Prezista® label, which states that darunavir must be administered with ritonavir and other anti-retroviral agents, also describes ritonavir's favorable pharmacokinetics effect. (Ex. G at Section 1.) The Prezista® labeling specifically states that Prezista® must be co-administered with ritonavir to exert its therapeutic effect and warns that failure to correctly co-administer darunavir with ritonavir results in insufficient plasma levels of darunavir. (Ex. G at Section 2.)

30. The Norvir® labeling similarly directs prescribers to consult labeling for other anti-retroviral agents, including Reyataz® (atazanavir), Lexiva® (fosamprenavir), indinavir, Invirase® (saquinavir), and Aptivus® (tipranavir) when co-administered with ritonavir. (Ex. F at Section 7.)

31. Based on the Norvir® labeling, physicians and healthcare professionals prescribing and administering ritonavir to treat HIV-1 infection understand and intend that ritonavir, when co-administered with certain drugs, like darunavir, improves the pharmacokinetics of the co-administered drug, thereby requiring a reduced dosage relative to that which would be necessary if administered without ritonavir.

32. Upon information and belief, Roxane has copied, and includes in its own proposed labeling for its proposed generic ritonavir tablets, the above-mentioned portions of the Norvir® FDA-approved labeling. Thus, upon information and belief, Roxane's proposed drug labeling contains descriptions indicating ritonavir's use in combination with other anti-retroviral agents for the treatment of HIV-1 infection. Therefore, the proposed products and labeling in ANDA No. 202573, if approved and marketed in the United States, would result in Roxane knowingly and intentionally encouraging, promoting, and inducing infringement of the Abbott patents-in-suit.

**FIRST COUNT FOR PATENT INFRINGEMENT**
**UNITED STATES PATENT NO. 7,148,359 B2**

33. Paragraphs 1-32 are incorporated herein by reference.

34. On information and belief, Roxane filed ANDA No. 202573 in order to obtain approval to market Roxane's generic ritonavir tablets in the United States before the expiration of the '359 patent. On information and belief, Roxane filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '359 patent are purportedly invalid and/or not infringed.

35. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 202573 seeking approval for the commercial marketing of Roxane's generic ritonavir tablets

before the expiration date of the ’359 patent constitutes infringement of one or more claims of the ’359 patent, either literally or under the doctrine of equivalents.

36. Upon FDA approval of ANDA No. 202573, Roxane will infringe one or more claims of the ’359 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Roxane’s generic ritonavir tablets, and by actively inducing others under § 271(b), unless this Court orders that the effective date of any FDA approval of ANDA No. 202573 shall be no earlier than the expiration date of the ’359 patent and any additional periods of exclusivity.

37. The offering to sell, sale, making, and/or importation of Roxane’s generic ritonavir tablets would actively induce infringement of at least one of the claims of the ’359 patent, either literally or under the doctrine of equivalents. Roxane has knowledge and is aware of Abbott’s ’359 patent, as evidenced by Roxane’s March 24, 2011 Notice Letter.

38. Abbott will be irreparably harmed if Roxane is not enjoined from infringing or actively inducing infringement of at least one claim of the ’359 patent. Pursuant to 35 U.S.C. § 283, Abbott is entitled to a permanent injunction against further infringement. Abbott does not have an adequate remedy at law.

**SECOND COUNT FOR PATENT INFRINGEMENT**
**UNITED STATES PATENT NO. 7,364,752 B1**

39. Paragraphs 1-38 are incorporated herein by reference.

40. On information and belief, Roxane filed ANDA No. 202573 in order to obtain approval to market Roxane’s generic ritonavir tablets in the United States before the expiration of the ’752 patent. On information and belief, Roxane filed with the FDA, pursuant to 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '752 patent are purportedly invalid and/or not infringed.

41. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 202573 seeking approval for the commercial marketing of Roxane's generic ritonavir tablets before the expiration date of the '752 patent constitutes infringement of one or more claims of the '752 patent, either literally or under the doctrine of equivalents.

42. Upon FDA approval of ANDA No. 202573, Roxane will infringe one or more claims of the '752 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Roxane's generic ritonavir tablets, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 202573 shall be no earlier than the expiration date of the '752 patent and any additional periods of exclusivity.

43. On information and belief, Roxane knows and intends that physicians will prescribe and patients will take Roxane's generic ritonavir tablets for which approval is sought in ANDA No. 202573 to treat HIV infection, and therefore will infringe at least one claim in the '752 patent.

44. On information and belief, Roxane had knowledge of the '752 patent and, by its promotional activities and package insert for Roxane's generic ritonavir tablets, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '752 patent, either literally or under the doctrine of equivalents.

45. The offering to sell, sale, and/or importation of Roxane's generic ritonavir tablets would actively induce or contribute to infringement of at least one of the claims of the '752 patent, either literally or under the doctrine of equivalents. Roxane has knowledge and is aware of Abbott's '752 patent, as evidenced by Roxane's March 24, 2011 Notice Letter.

46. Abbott will be irreparably harmed if Roxane is not enjoined from infringing and actively inducing and contributing to infringement of at least one claim of the '752 patent. Pursuant to 35 U.S.C. § 283, Abbott is entitled to a permanent injunction against further infringement. Abbott does not have an adequate remedy at law.

**THIRD COUNT FOR PATENT INFRINGEMENT**
**UNITED STATES PATENT NO. 5,648,497**

47. Paragraphs 1-46 are incorporated herein by reference.

48. On information and belief, Roxane filed ANDA No. 202573 in order to obtain approval to market Roxane's generic ritonavir tablets in the United States before the expiration of the '497 patent. On information and belief, Roxane filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '497 patent are purportedly invalid and/or not infringed.

49. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 202573 seeking approval for the commercial marketing of Roxane's generic ritonavir tablets before the expiration date of the '497 patent constitutes infringement of one or more claims of the '497 patent, either literally or under the doctrine of equivalents.

50. Upon FDA approval of ANDA No. 202573, Roxane will infringe one or more claims of the '497 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Roxane's generic ritonavir tablets, and by actively

inducing others under § 271(b), unless this Court orders that the effective date of any FDA approval of ANDA No. 202573 shall be no earlier than the expiration date of the '497 patent and any additional periods of exclusivity.

51. The offering to sell, sale, making, and/or importation of Roxane's generic ritonavir tablets would actively induce infringement of at least one of the claims of the '497 patent, either literally or under the doctrine of equivalents. Roxane has knowledge and is aware of Abbott's '497 patent, as evidenced by Roxane's April 6, 2012 Notice Letter.

52. Abbott will be irreparably harmed if Roxane is not enjoined from infringing or actively inducing infringement of at least one claim of the '497 patent. Pursuant to 35 U.S.C. § 283, Abbott is entitled to a permanent injunction against further infringement. Abbott does not have an adequate remedy at law.

**FOURTH COUNT FOR PATENT INFRINGEMENT**
**UNITED STATES PATENT NO. 6,037,157**

53. Paragraphs 1-52 are incorporated herein by reference.

54. On information and belief, Roxane filed ANDA No. 202573 in order to obtain approval to market Roxane's generic ritonavir tablets in the United States before the expiration of the '157 patent. On information and belief, Roxane filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '157 patent are purportedly invalid and/or not infringed.

55. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 202573 seeking approval for the commercial marketing of Roxane's generic ritonavir tablets before the expiration date of the '157 patent constitutes infringement of one or more claims of the '157 patent, either literally or under the doctrine of equivalents.

56. Upon FDA approval of ANDA No. 202573, Roxane will infringe one or more claims of the ’157 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Roxane’s generic ritonavir tablets, and by actively inducing others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 202573 shall be no earlier than the expiration date of the ’157 patent and any additional periods of exclusivity.

57. The offering to sell, sale, making, and/or importation of Roxane’s generic ritonavir tablets would actively induce infringement of at least one of the claims of the ’157 patent, either literally or under the doctrine of equivalents. Roxane has knowledge and is aware of Abbott’s ’157 patent, as evidenced by Roxane’s April 6, 2012 Notice Letter.

58. Abbott will be irreparably harmed if Roxane is not enjoined from infringing or actively inducing infringement of at least one claim of the ’157 patent. Pursuant to 35 U.S.C. § 283, Abbott is entitled to a permanent injunction against further infringement. Abbott does not have an adequate remedy at law.

**FIFTH COUNT FOR PATENT INFRINGEMENT**
**UNITED STATES PATENT NO. 6,703,403 B2**

59. Paragraphs 1-58 are incorporated herein by reference.

60. On information and belief, Roxane filed ANDA No. 202573 in order to obtain approval to market Roxane’s generic ritonavir tablets in the United States before the expiration of the ’403 patent. On information and belief, Roxane filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the ’403 patent are purportedly invalid and/or not infringed.

61. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 202573 seeking approval for the commercial marketing of Roxane's generic ritonavir tablets before the expiration date of the '403 patent constitutes infringement of one or more claims of the '403 patent, either literally or under the doctrine of equivalents.

62. Upon FDA approval of ANDA No. 202573, Roxane will infringe one or more claims of the '403 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Roxane's generic ritonavir tablets, and by actively inducing others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 202573 shall be no earlier than the expiration date of the '403 patent and any additional periods of exclusivity.

63. The offering to sell, sale, making, and/or importation of Roxane's generic ritonavir tablets would actively induce infringement of at least one of the claims of the '403 patent, either literally or under the doctrine of equivalents. Roxane has knowledge and is aware of Abbott's '403 patent, as evidenced by Roxane's April 6, 2012 Notice Letter.

64. Abbott will be irreparably harmed if Roxane is not enjoined from infringing or actively inducing infringement of at least one claim of the '403 patent. Pursuant to 35 U.S.C. § 283, Abbott is entitled to a permanent injunction against further infringement. Abbott does not have an adequate remedy at law.

**SIXTH COUNT FOR DECLARATORY JUDGMENT AS TO THE '359 PATENT**

65. Paragraphs 1-64 are incorporated herein by reference.

66. On information and belief, Roxane has made substantial preparations to sell ritonavir tablets labeled for the same indications and the same dosage and methods of use as the Norvir® product sold by Abbott.

67. Upon further information and belief, Roxane intends to commence sales of such ritonavir tablets immediately upon receiving approval from the FDA.

68. The manufacture, importation, sale, and offer for sale of ritonavir tablets, once approved by the FDA, would infringe one or more claims of the ’359 patent.

69. Roxane’s threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe one or more claims of the ’359 patent.

70. Abbott will be substantially and irreparably damaged and harmed if Roxane’s threatened infringement is not enjoined. Abbott does not have an adequate remedy at law.

**SEVENTH COUNT FOR DECLARATORY JUDGMENT AS TO THE ’752 PATENT**

71. Paragraphs 1-70 are incorporated herein by reference.

72. On information and belief, Roxane has made substantial preparations to sell ritonavir tablets labeled for the same indications and the same dosage and methods of use as the Norvir® product sold by Abbott.

73. Upon further information and belief, Roxane intends to commence sales of such ritonavir tablets immediately upon receiving approval from the FDA.

74. The manufacture, importation, sale, and offer for sale of ritonavir tablets, once approved by the FDA, would infringe one or more claims of the ’752 patent.

75. Roxane’s threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe one or more claims of the ’752 patent.

76. Abbott will be substantially and irreparably damaged and harmed if Roxane's threatened infringement is not enjoined. Abbott does not have an adequate remedy at law.

**EIGHTH COUNT FOR DECLARATORY JUDGMENT AS TO THE '497 PATENT**

77. Paragraphs 1-76 are incorporated herein by reference.

78. On information and belief, Roxane has made substantial preparations to sell ritonavir tablets labeled for the same indications and the same dosage as the Norvir® product sold by Abbott.

79. Upon further information and belief, Roxane intends to commence sales of such ritonavir tablets immediately upon receiving approval from the FDA.

80. The manufacture, importation, sale, and offer for sale of ritonavir tablets, once approved by the FDA, would infringe one or more claims of the '497 patent.

81. Roxane's threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe one or more claims of the '497 patent.

82. Abbott will be substantially and irreparably damaged and harmed if Roxane's threatened infringement is not enjoined. Abbott does not have an adequate remedy at law.

**NINTH COUNT FOR DECLARATORY JUDGMENT AS TO THE '157 PATENT**

83. Paragraphs 1-82 are incorporated herein by reference.

84. On information and belief, Roxane has made substantial preparations to sell ritonavir tablets labeled for the same indications and the same dosage as the Norvir® product sold by Abbott.

85. Upon further information and belief, Roxane intends to commence sales of such ritonavir tablets immediately upon receiving approval from the FDA.

86. The manufacture, importation, sale, and offer for sale of ritonavir tablets, once approved by the FDA, would infringe one or more claims of the ’157 patent.

87. Roxane’s threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe one or more claims of the ’157 patent.

88. Abbott will be substantially and irreparably damaged and harmed if Roxane’s threatened infringement is not enjoined. Abbott does not have an adequate remedy at law.

**TENTH COUNT FOR DECLARATORY JUDGMENT AS TO THE ’403 PATENT**

89. Paragraphs 1-88 are incorporated herein by reference.

90. On information and belief, Roxane has made substantial preparations to sell ritonavir tablets labeled for the same indications and the same dosage as the Norvir® product sold by Abbott.

91. Upon further information and belief, Roxane intends to commence sales of such ritonavir tablets immediately upon receiving approval from the FDA.

92. The manufacture, importation, sale, and offer for sale of ritonavir tablets, once approved by the FDA, would infringe one or more claims of the ’403 patent.

93. Roxane’s threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe one or more claims of the ’403 patent.

94. Abbott will be substantially and irreparably damaged and harmed if Roxane’s threatened infringement is not enjoined. Abbott does not have an adequate remedy at law.

## PRAYER FOR RELIEF

WHEREFORE, Abbott respectfully requests that this Court enter judgment in its favor as follows:

1) declaring that, under 35 U.S.C. § 271(e)(2)(A), Roxane's submission to the FDA of ANDA No. 202573 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Roxane's generic ritonavir tablets before the expiration of the '359 patent was an act of infringement of the '359 patent;

2) declaring that Roxane's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Roxane's generic ritonavir tablets would constitute infringement of the '359 patent;

3) declaring that, under 35 U.S.C. § 271(e)(2)(A), Roxane's submission to the FDA of ANDA No. 202573 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Roxane's generic ritonavir tablets before the expiration of the '752 patent was an act of infringement of the '752 patent;

4) declaring that Roxane's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Roxane's generic ritonavir tablets would constitute infringement of the '752 patent;

5) declaring that, under 35 U.S.C. § 271(e)(2)(A), Roxane's submission to the FDA of ANDA No. 202573 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Roxane's generic ritonavir tablets before the expiration of the '497 patent was an act of infringement of the '497 patent;

6) declaring that Roxane's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Roxane's generic ritonavir tablets would constitute infringement of the '497 patent;

7) declaring that, under 35 U.S.C. § 271(e)(2)(A), Roxane's submission to the FDA of ANDA No. 202573 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Roxane's generic ritonavir tablets before the expiration of the '157 patent was an act of infringement of the '157 patent;

8) declaring that Roxane's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Roxane's generic ritonavir tablets would constitute infringement of the '157 patent;

9) declaring that, under 35 U.S.C. § 271(e)(2)(A), Roxane's submission to the FDA of ANDA No. 202573 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Roxane's generic ritonavir tablets before the expiration of the '403 patent was an act of infringement of the '403 patent;

10) declaring that Roxane's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Roxane's generic ritonavir tablets would constitute infringement of the '403 patent;

11) ordering that the effective date of any FDA approval of Roxane's generic ritonavir tablets shall be no earlier than the expiration date of the '359 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

12) ordering that the effective date of any FDA approval of Roxane's generic ritonavir tablets shall be no earlier than the expiration date of the '752 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

13) ordering that the effective date of any FDA approval of Roxane's generic ritonavir tablets shall be no earlier than the expiration date of the '497 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

14) ordering that the effective date of any FDA approval of Roxane's generic ritonavir tablets shall be no earlier than the expiration date of the '157 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

15) ordering that the effective date of any FDA approval of Roxane's generic ritonavir tablets shall be no earlier than the expiration date of the '403 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

16) enjoining Roxane and all persons acting in concert with Roxane, from commercially manufacturing, using, offering for sale, or selling Roxane's generic ritonavir tablets within the United States or importing into the United States Roxane's generic ritonavir tablets, until the expiration of the '359 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

17) enjoining Roxane and all persons acting in concert with Roxane, from commercially manufacturing, using, offering for sale, or selling Roxane's generic ritonavir tablets within the United States or importing into the United States Roxane's generic ritonavir tablets, until the expiration of the '752 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

18) enjoining Roxane and all persons acting in concert with Roxane, from commercially manufacturing, using, offering for sale, or selling Roxane's generic ritonavir tablets within the United States or importing into the United States Roxane's generic ritonavir tablets, until the expiration of the '497 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

19) enjoining Roxane and all persons acting in concert with Roxane, from commercially manufacturing, using, offering for sale, or selling Roxane's generic ritonavir tablets within the United States or importing into the United States Roxane's generic ritonavir tablets, until the expiration of the '157 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

20) enjoining Roxane and all persons acting in concert with Roxane, from commercially manufacturing, using, offering for sale, or selling Roxane's generic ritonavir tablets within the United States or importing into the United States Roxane's generic ritonavir tablets, until the expiration of the '403 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B)

21) enjoining Roxane and all persons acting in concert with Roxane, from seeking, obtaining, or maintaining approval of ANDA No. 202573 until the expiration of the '359 patent, and any additional periods of exclusivity;

22) enjoining Roxane and all persons acting in concert with Roxane, from seeking, obtaining, or maintaining approval of ANDA No. 202573 until the expiration of the '752 patent, and any additional periods of exclusivity;

23) enjoining Roxane and all persons acting in concert with Roxane, from seeking, obtaining, or maintaining approval of ANDA No. 202573 until the expiration of the ’497 patent, and any additional periods of exclusivity;

24) enjoining Roxane and all persons acting in concert with Roxane, from seeking, obtaining, or maintaining approval of ANDA No. 202573 until the expiration of the ’157 patent, and any additional periods of exclusivity;

25) enjoining Roxane and all persons acting in concert with Roxane, from seeking, obtaining, or maintaining approval of ANDA No. 202573 until the expiration of the ’403 patent, and any additional periods of exclusivity;

26) declaring this to be an exceptional case and awarding Abbott its attorney fees under 35 U.S.C. § 285;

27) declaring the ’359 patent valid and enforceable;

28) declaring the ’752 patent valid and enforceable;

29) declaring the ’497 patent valid and enforceable;

30) declaring the ’157 patent valid and enforceable;

31) declaring the ’403 patent valid and enforceable;

32) awarding Abbott its costs and expenses in this action; and

33) awarding Abbott any further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Jeremy A. Tigan*

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