IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CHIESI USA, INC. and CHIESI FARMACEUTICI S.P.A.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
HIKMA PHARMACEUTICALS USA INC., EUROHEALTH (U.S.A.) INC., and HIKMA PHARMACEUTICALS PLC,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Chiesi USA, Inc. and Chiesi Farmaceutici S.p.A. (collectively, "Chiesi" or "Plaintiffs") by and through their undersigned attorneys, for their Complaint against defendants Hikma Pharmaceuticals USA, Inc. ("Hikma USA"), EuroHealth (U.S.A.) Inc. ("EuroHealth") and Hikma Pharmaceuticals PLC ("Hikma PLC") (collectively, "Hikma" or "Defendants") hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent No. 7,049,328 ("the '328 patent" or "patent in suit") arising under the patent laws of the United States and Title 35 of the United States Code. The '328 patent is attached hereto as Exhibit A.

THE PARTIES

2. Chiesi USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 175 Regency Woods Place, Suite 600, Cary, North Carolina 27518. Chiesi USA, Inc. is a wholly owned subsidiary of Chiesi Farmaceutici S.p.A.

3. Chiesi USA, Inc. is the owner of New Drug Application ("NDA") No. 021825, which was approved by the U.S. Food and Drug Administration ("FDA") for the manufacture and sale of the deferiprone tablet product, Ferriprox®.

4. Chiesi Farmaceutici S.p.A. is a corporation organized and existing under the laws of Italy, having its principal place of business at Via Palermo, 26/A, 43122 Parma, Italy.

5. Chiesi Farmaceutici S.p.A. is the current owner and assignee of the patent in suit listed in FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") as covering the Ferriprox® product. The patent in suit and NDA were previously owned by Apotex, Inc. and Apo-Pharma USA, Inc.

6. Upon information and belief, Hikma USA was formally known as West-Ward Pharmaceutical Corp. and is a corporation organized under the laws of the State of Delaware under File No. 2264775, having its principal place of business at 246 Industrial Way West, Eatontown, NJ 07724.

7. Upon information and belief, Hikma USA is a wholly owned subsidiary of Hikma PLC through and with Hikma PLC's subsidiary, EuroHealth. Hikma PLC's 2019 Annual Report lists its "Ownership % Ordinary shares" of Hikma USA as 100%.[1]

8. Upon information and belief, Hikma USA is in the business of, among other things, the development, manufacturing, and marketing of generic medicines worldwide, including in the United States and in Delaware.

9. On information and belief, Defendant EuroHealth is a corporation organized and existing under the laws of the State of Delaware under File No. 2264777, having a principal place of business at 401 Industrial Way West, Eatontown, New Jersey 07724.

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[1] https://www.hikma.com/media/2733/2019-full-ar.pdf at p. 166; *see also* Hikma PLC's 2018 Annual Report, https://www.hikma.com/media/2187/hikma_ar2018_full-ar.pdf at p. 165.

10. Upon information and belief, EuroHealth is in the business of, among other things, trading pharmaceuticals and associated goods and services worldwide, including in the United States and in Delaware.

11. On information and belief, Defendant EuroHealth is a wholly owned subsidiary of Hikma PLC. Hikma PLC's 2019 Annual Report lists its "Ownership % Ordinary shares" of EuroHealth as 100%.[2]

12. Upon information and belief, Hikma PLC is a corporation organized and existing under the laws of England, having its principal place of business at 1 New Burlington Place, London, Greater London W1S 2HR, United Kingdom.

13. Upon information and belief, Hikma USA is an authorized U.S. Agent for EuroHealth and Hikma PLC. Upon information and belief, EuroHealth is an authorized U.S. agent for Hikma PLC. Upon information and belief, Hikma USA acts at the direction, and for the benefit, of Hikma PLC and EuroHealth, and is controlled and/or dominated by Hikma PLC and EuroHealth.

14. Upon information and belief, Hikma USA is an authorized U.S. Agent for Hikma PLC and EuroHealth with respect to Abbreviated New Drug Applications ("ANDAs") submitted to the FDA pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), including at least ANDA No. 213239 (deferiprone tablet, 500 mg.) ("Hikma's ANDA"). Upon information and belief, Hikma's ANDA included a paragraph IV certification under 21 U.S.C. § 355(j)(2)(A) ("paragraph IV certification") to the '328 patent.

15. Upon information and belief, Hikma PLC, by itself and/or through its wholly owned subsidiaries, is in the business of, among other things, the development, manufacturing, and

[2] https://www.hikma.com/media/2733/2019-full-ar.pdf at pg. 166; *see also* Hikma PLC's 2018 Annual Report, https://www.hikma.com/media/2187/hikma_ar2018_full-ar.pdf at p. 165.

marketing of generic pharmaceutical products for marketing, sale, and distribution throughout the United States, including in Delaware.

16. Upon information and belief, Defendants operate in concert as integrated parts of the same business group, and enter into agreements with each other that are not arm's length.

17. Upon information and belief, Defendants operate as a single integrated business with respect to the regulatory approval, manufacturing, importation, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in Delaware. Hikma PLC's 2018 Annual Report describes Hikma USA and EuroHealth as subsidiaries and states that "Hikma [PLC]'s fixed and intangible assets are held in various subsidiaries."[3] Hikma PLC's 2019 Annual Report further states that Hikma PLC's subsidiaries "submit[] a Group reporting package to Hikma [PLC]'s central accounting team."[4]

18. Upon information and belief, Hikma PLC controls Hikma USA's importation, sale, and/or distribution of products. For example, Hikma PLC announced its launch of "Everolimus Tablets . . . in the United States through its US affiliate, Hikma Pharmaceuticals USA Inc."[5]

19. Upon information and belief, Defendants derive substantial revenue from the sale of generic pharmaceutical products throughout the United States, including in Delaware. In its 2019 Annual Report, Hikma PLC reported that its "[g]enerics core gross profit . . . [was] $326 million" even though "the US retail generics market remain[s] challenging."[6]

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[3] https://www.hikma.com/media/2575/hikma_ar2018_full-ar.pdf at pg. 76.

[4] https://www.hikma.com/media/2733/2019-full-ar.pdf at pg. 112; *see also* Hikma PLC's 2018 Annual Report, https://www.hikma.com/media/2575/hikma_ar2018_full-ar.pdf at pg. 113.

[5] https://www.hikma.com/newsroom/article-i4716-hikma-expands-generics-portfolio-with-everolimus-tablets-launch/.

[6] https://www.hikma.com/media/2733/2019-full-ar.pdf at pg. 25; *see also* Hikma PLC's 2018 Annual Report, https://www.hikma.com/media/2187/hikma_ar2018_full-ar.pdf at pg. 30.

20. Upon information and belief, Defendants have submitted Hikma's ANDA to the FDA, seeking approval to market 500 mg deferiprone tablets (the "ANDA Product") throughout the United States, including in Delaware, before the expiration of the patent in suit.

JURISDICTION AND VENUE

21. This is a complaint for patent infringement. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

22. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b). Venue is proper against Hikma PLC as to which federal venue statutes do not apply.

23. This Court has personal jurisdiction over Hikma USA at least because, upon information and belief: (i) Hikma USA is incorporated in Delaware; (ii) Hikma USA does business in Delaware and maintains continuous and systematic contacts with Delaware; (iii) Hikma USA, together with its parent Hikma PLC and EuroHealth, is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of Delaware; (iv) Hikma USA, together with Hikma PLC and EuroHealth, has committed, induced, or contributed to acts of patent infringement in Delaware by submitting Hikma's ANDA that includes a paragraph IV certification (a technical act of infringement under 35 U.S.C. § 271(e)(2)(A)) that Hikma seeks to import, offer for sale, and sell its ANDA Product throughout the United States, including in this judicial district, before the expiration of the patent in suit; (v) Hikma USA (under its current name or previously as West-Ward Pharmaceutical Corp.) has previously submitted to the jurisdiction of this Court and/or has availed itself of Delaware's legal protections in at least seven (7) prior litigations.[7]

[7] *Takeda Pharms. U.S.A., Inc. v. Mylan Pharms. et al.*, No. 19-cv-02216-RGA (D. Del. 2019); *Hikma Pharms. USA Inc., et al. v. Micro Labs Ltd. et al.*, 19-cv-00883-CFC-CJB (D. Del. 2019); *Hikma Pharms. USA Inc., et al. v. Granules Pharms., Inc.*, No. 18-cv-00085-CFC (D. Del. 2018);

24. This Court has personal jurisdiction over Hikma PLC at least because, upon information and belief: (i) Hikma PLC manufactures generic pharmaceutical products that are imported, distributed, and sold throughout the United States and thus avails itself of the privileges and benefits of the laws and commerce of the United States and Delaware; (ii) Hikma PLC does business in Delaware and maintains continuous and systematic contacts with Delaware at least through its subsidiaries; (iii) Hikma PLC is in the business of developing and manufacturing generic pharmaceutical products, directly or indirectly, and in partnership or agency with its subsidiary Hikma USA and/or EuroHealth for importation, sale, and/or distribution in the State of Delaware; (iv) Hikma PLC derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in Delaware; (v) for the same reasons as alleged above, Hikma PLC, together with Hikma USA, has committed, induced, or contributed to acts of patent infringement in Delaware; and (vi) Hikma PLC has previously submitted to the jurisdiction of this Court and/or has availed itself of Delaware legal protections in at least six (6) prior litigations.[8]

25. This Court has personal jurisdiction over EuroHealth at least because, upon information and belief: (i) EuroHealth is involved in the manufacture of generic pharmaceutical products that are imported, distributed, and sold throughout the United States and thus avails itself of the privileges and benefits of the laws and commerce of the United States and Delaware; (ii) EuroHealth does business in Delaware and maintains continuous and systematic contacts with

Astellas Pharma Inc., et al. v. Zydus Pharms. (USA) Inc., 16-cv-01120-CFC (D. Del. 2016); *Endo Pharms. Inc., et al. v. West-Ward Pharms. Int'l Ltd., et al.*, No. 14-cv-01387-RGA (D. Del. 2014); *Takeda Pharms. U.S.A., Inc. v. Hikma Pharms. USA Inc. et al.*, No. 14-cv-01268-RGA-SRF (D. Del. 2014); *Hospira, Inc. v. Eurohealth Int'l Sarl et al.*, No. 14-cv-00487-GMS (D. Del. 2014).

[8] *Astellas Pharma Inc., et al. v. Roxane Labs., Inc., et al.*, No. 17-cv-0054-CFC (D. Del. 2017); *Takeda Pharms. U.S.A., Inc., v. Hikma Pharms. USA Inc. et al.*, No. 14-cv-01268-RGA-SRF (D. Del. 2014); *Forest Labs., LLC et al. v. Hikma Pharms. LLC et al.*, No. 14-cv-01266-MSG-SRF (D. Del. 2014); *Forest Labs., LLC et al. v. Sigmapharm Labs. LLC et al.*, No. 14-cv-01119-MSG (D. Del. 2014); *Cephalon Inc. v. Eurohealth Int'l Sarl et al.*, No. 14-cv-01045-GMS (D. Del. 2014); *Hospira Inc., et al. v. Eurohealth Int'l Sarl et al.*, No. 14-cv-01008-GMS (D. Del. 2014).

Delaware; (iii) EuroHealth is in the business of developing and manufacturing generic pharmaceutical products, directly or indirectly, and in partnership or agency with its subsidiary Hikma USA for importation, sale, and/or distribution in the State of Delaware; (iv) EuroHealth derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in Delaware; (v) for the same reasons as alleged above, EuroHealth, together with Hikma USA and Hikma PLC, has committed, induced, or contributed to acts of patent infringement in Delaware; and (vi) EuroHealth has previously submitted to the jurisdiction of this Court and/or has availed itself of Delaware legal protections in at least four (4) prior litigations.[9]

26. This Court has personal jurisdiction over Defendants at least because, upon information and belief, if Hikma's ANDA receives final FDA approval, the ANDA Product will be manufactured, sold, distributed, and/or used by Defendants in Delaware, prescribed by physicians practicing in Delaware, and/or administered to patients in Delaware.

FACTS AS TO ALL COUNTS

27. The '328 patent is entitled "Use For Deferiprone," and was issued by the U.S. Patent Office to inventors Michael Spino and Antonio Piga (the "Inventors") on May 23, 2006.

28. The Inventors assigned the entire right, title, and interest in the '328 patent to Apotex, Inc. by way of assignments dated May 26, 2006 and June 13, 2006, respectively, which assigned the entire right, title, and interest in the '328 patent to Apotex Technologies Inc. by way of assignment dated May 17, 2016. Apotex Technologies, Inc. thereafter assigned the entire right, title, and interest in the '328 patent back to Apotex, Inc. Apotex, Inc. assigned the entire right, title, and interest in the '328 patent to Chiesi Farmaceutici S.p.A. by way of assignment dated January 8, 2020.

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[9] *Fresenius Kabi USA, LLC et al. v. Eurohealth Int'l Sarl*, 18-cv-00835-LPS (D. Del. 2018); *Cephalon Inc. v. Sandoz Inc. et al.*, No. 15-cv-00178-GMS (D. Del. 2015); *Hospira Inc. et al. v. Eurohealth Int'l Sarl et al.*, 14-cv-01008-GMS (D. Del. 2014); *Helsinn Healthcare SA et al. v. Eurohealth Int'l Sarl et al.*, No. 13-cv-01612-GMS (D. Del. 2013).

29. As of the date of this Complaint, Chiesi Farmaceutici S.p.A. holds the entire right, title, and interest in the '328 patent, including the right to enforce the '328 patent against potential infringers and to seek damages.

30. The '328 patent is valid, enforceable, and has not expired.

31. Chiesi's Ferriprox® is sold and marketed under NDA No. 021825.

32. NDA No. 021825 pertains to Ferriprox® 500 and 1000 mg tablets.

33. The product Ferriprox® and its FDA-approved use are covered by at least one claim of the '328 patent.

34. As alleged above, the '328 patent is listed in the FDA's Orange Book in conjunction with NDA No. 021825.

35. According to Chiesi's label under "Indications and Usage," Ferriprox® "is an iron chelator indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate." It also states that Ferriprox®'s "[a]pproval is based on a reduction in serum ferritin levels."

36. The Ferriprox® label under "Clinical Studies" teaches patients and physicians that clinical studies using Ferriprox® treatment resulted in "at least a 20% reduction in serum ferritin" in 50% of subjects and some subjects that were assessed had "an increase in cardiac MRI T2* from a mean at baseline of 11.8 ± 4.9 ms to a mean of 15.1 ± 7.0 ms after approximately one year of treatment."

37. The Ferriprox® label under "Dosage and Administration" describes using "25 mg/kg to 33 mg/kg body weight, orally, three times per day, for a total daily dose of 75 mg/kg to 99 mg/kg body weight."

38. Defendants sent a letter addressed to Chiesi USA, Inc., received on February 25, 2020, purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) of the FD&C Act, 21 U.S.C. § 355(j)(5)(C), and 21 C.F.R. § 314.95 of Title 21 of the Code of Federal Regulations, regarding Hikma's ANDA (the "Notice Letter"). The Notice Letter was signed by Imron T. Aly of the law firm Schiff Hardin LLP on behalf of Hikma USA.

39. Defendants' Notice Letter states that Hikma's ANDA has been submitted under § 355(j)(1) and (2)(A) of the FD&C Act, with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of a 500 mg deferiprone tablet product before the expiration of the '328 patent. The FDA's Orange Book lists the patent expiration for the '328 patent as June 28, 2021.

40. Upon information and belief, Hikma's ANDA was submitted under § 355(j) of the FD&C Act with a paragraph IV certification alleging that the '328 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the ANDA Product.

41. In view of Defendants' Notice Letter and paragraph IV certification regarding the '328 patent contained in Hikma's ANDA, Defendants had knowledge of the '328 patent at least since the date on which Defendants filed Hikma's ANDA with the FDA.

42. Upon information and belief, the prescribing information for the ANDA Product will recommend the same Indication and Usage as Ferriprox®.

43. Upon information and belief, the prescribing information for the ANDA Product will teach the same Clinical Studies as Ferriprox®.

44. Upon information and belief, the prescribing information for the ANDA Product will recommend the same Dosage and Administration as Ferriprox®.

45. Upon information and belief, administration of the ANDA Product, like Ferriprox®, will be used for the reduction of iron concentration in patients with transfusional iron overload due to thalassemia syndromes when other chelation therapy has failed.

46. Pursuant to 21 U.S.C. § 355(b)(1), the '328 patent was submitted to the FDA with NDA No. 021825.

47. Plaintiffs request entry of judgment that any final approval of Hikma's ANDA shall be effective no earlier than the expiration date of the '328 patent, or any later expiration of exclusivity for the '328 patent to which Plaintiffs are or may become entitled. *See* 21 U.S.C. § 355(c)(3)(C).

FIRST COUNT

(Defendants' Infringement of the '328 Patent)

48. Plaintiffs repeat and re-allege each of the foregoing paragraphs as if fully set forth herein.

49. Upon information and belief, Defendants prepared Hikma's ANDA.

50. Upon information and belief, Defendants submitted Hikma's ANDA to the FDA pursuant to § 505(j) of the FD&C Act (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market the ANDA Product prior to the expiration of the '328 patent.

51. Upon information and belief, Hikma's ANDA is based upon Ferriprox® deferiprone tablet product, as its reference listed drug.

52. Upon information and belief, the ANDA Product is a 500 mg deferiprone tablet.

53. Upon information and belief, Defendants submitted Hikma's ANDA with a paragraph IV certification to the '328 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of the ANDA Product throughout the United States before the expiration of the '328 patent.

54. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

55. Upon information and belief, as of the date of the Notice Letter Defendants were aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

56. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(a), Defendants sent a copy of the Notice Letter to Chiesi USA, Inc. at 175 Regency Woods Place, Suite 600, Cary, North Carolina 27518, which was received on February 25, 2020.

57. Under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of Hikma's ANDA with a paragraph IV certification to the '328 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '328 patent constitutes infringement of one or more claims of the '328 patent, including at least claims 1, 2, and 4-10.

58. Upon information and belief, Defendants will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States the ANDA Product if Hikma's ANDA ever receives final FDA approval.

59. Upon information and belief, Defendants' commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of the ANDA Product would infringe, directly and/or indirectly, one or more of the '328 patent claims under 35 U.S.C. § 271.

60. Upon information and belief, Defendants' commercial offering for sale and/or sale of the ANDA Product would induce and/or contribute to third-party infringement of one or more claims of the '328 patent under 35 U.S.C. § 271.

61. Defendants had knowledge of the '328 patent since at least the time they filed Hikma's ANDA with a paragraph IV certificate and are knowingly infringing the '328 patent.

62. Defendants' statements of the factual and legal bases for its opinion regarding the non-infringement of the '328 patent contained in Defendants' Notice Letter are devoid of any objective good-faith basis in either the facts or the law.

63. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '328 patent, actively inducing infringement of the '328 patent, and/or contributing to infringement by others of the '328 patent.

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

65. The acts of infringement of the '328 patent set forth above will cause Plaintiffs to suffer irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

66. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an Order of this Court that the effective date of the FDA's final approval of Hikma's ANDA be a date that is not earlier than the expiration date of the '328 patent, or any later expiration of exclusivity for the '328 patent to which Plaintiffs are or may become entitled.

67. This action is being commenced within forty-five (45) days from the date Plaintiffs received Defendants' Notice Letter, which Plaintiffs received on February 25, 2020.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendants have infringed the '328 patent by submitting to the FDA Hikma's ANDA with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '328 patent;

(B) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product before the expiration of the '328 patent (including any regulatory extension), would directly and/or indirectly infringe the '328 patent;

(C) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of Hikma's ANDA shall be no earlier than the date on which the '328 patent expires (including any regulatory extension);

(D) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Defendants, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United

States of the ANDA Product until the expiration of the '328 patent (including any regulatory extension);

(E) A judgment declaring that the '328 patent is valid and enforceable;

(F) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Plaintiffs damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of Hikma's ANDA, prior to the expiration of the '328 patent (including any regulatory extension);

(G) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Plaintiffs damages if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of Hikma's ANDA, prior to the expiration of the '328 patent (including any regulatory extension);

(H) A judgment, pursuant to 35 U.S.C. § 285, declaring that this is an exceptional case and awarding Plaintiffs their attorneys' fees and costs;

(I) Such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Karen Jacobs

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