Sheila F. McShane, Esq.
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4500

Of Counsel:
Tony V. Pezzano, Esq.
Michael P. Dougherty, Esq.
CADWALADER, WICKERSHAM & TAFT LLP
One World Financial Center
New York, NY 10281
(212) 504-6000

Edward W. Murray, Esq.
Mary J. Morry, Esq.
MERCK & CO., INC.
RY28-320
P.O. Box 2000
Rahway, New Jersey 07065-0900
(732) 594-0436

Attorneys for Plaintiffs
MERCK & CO., INC. and
MERCK SHARP & DOHME CORP.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MERCK & CO., INC. and MERCK SHARP & DOHME CORP. Plaintiffs, v. HETERO DRUGS LTD., UNIT III, and HETERO USA INC. Defendants.	CIVIL ACTION NO.:____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merck & Co., Inc. and Merck Sharp & Dohme Corp., by way of Complaint against Hetero Drugs Ltd., Unit III and Hetero USA Inc., allege as follows:

THE PARTIES

1. Merck & Co., Inc. is a corporation organized and existing under the laws of the state of New Jersey, having its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889. Merck & Co., Inc. is a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve human and animal health.

2. Merck Sharp & Dohme Corp. is a subsidiary of Merck & Co., Inc. and is a corporation incorporated under the laws of the state of New Jersey, having its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

3. On information and belief, Hetero Drugs Ltd., Unit III is an Indian Corporation having a principal place of business at Hetero House, H. No. 8-3-166/7/1, Erragadda, Hyderabad – 500 018, A.P. India.

4. On information and belief, Hetero USA Inc. is a Delaware corporation having a principal place of business at 1035 Centennial Ave., Piscataway, New Jersey 08854.

5. On information and belief, Hetero USA Inc. is a wholly owned subsidiary of Hetero Drugs Ltd., Unit III.

6. On information and belief, Hetero Drugs Ltd., Unit III named Hetero USA Inc. as the authorized U.S. agent for Abbreviated New Drug Application ("ANDA") No. 90-060, which is the subject of this action, when that ANDA was filed on October 3, 2007.

7. On information and belief, the generic sales and marketing division in the U.S. of Hetero Drugs Ltd., Unit III is located in New Jersey.

8. On information and belief, the acts of Hetero USA Inc. complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of, and at least in part for the benefit of, Hetero Drugs Ltd., Unit III.

9. Hetero Drugs Ltd., Unit III and Hetero USA Inc. are referred to hereinafter, collectively, as "Hetero."

10. On information and belief, Hetero is in the business of developing and manufacturing generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

12. This Court has personal jurisdiction over Hetero because of its continuous and systematic contacts with the State of New Jersey.

13. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), (c), and (d), and/or 28 U.S.C. § 1400(b).

MERCK'S NDA AND ASSERTED PATENTS

14. Merck & Co., Inc. filed New Drug Application ("NDA") No. 20-788, by which the United States Food & Drug Administration ("FDA") first granted approval for a 1 mg tablet including the active ingredient finasteride. The finasteride tablets described in NDA No 20-788 are prescribed for the treatment of male pattern baldness and sold in the United States under the tradename "PROPECIA®".

15. Merck Sharp & Dohme Corp. is the owner of U.S. Patent Nos. 5,571,817 (the "'817 patent"), 5,547,957 (the "'957 patent), and 5,886,184 (the "'184 patent"), which are attached as Exhibits A, B, and C, respectively.

16. Merck & Co., Inc. and Merck Sharp & Dohme Corp. are hereinafter referred to collectively as "Merck."

CLAIM FOR RELIEF – COUNT I

17. Merck realleges, as if fully set forth herein, the averments contained in paragraphs 1-16.

18. Merck's '817 patent discloses and claims a method of treating androgenic alopecia which comprises orally administering to a human in need of such treatment a therapeutically effective amount of 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-en-3-one (i.e., finasteride).

19. Hetero's ANDA No. 90-060 seeks FDA approval to market 1 mg finasteride tablets "for the treatment of male pattern hair loss (androgenetic alopecia) in men only."

20. Hetero has filed in connection with ANDA No. 90-060 a certification with respect to the '817 patent under § 505(j)(2)(A)(vii)(IV) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355) seeking approval to sell finasteride 1 mg tablets prior to the expiration of the '817 patent.

21. On or about October 6, 2010, Hetero sent a notice to Merck in which Hetero represented that it had filed an ANDA for finasteride, including the certification with respect to the '817 patent, and that it sought approval of its ANDA prior to the expiration of that patent.

22. Because Hetero seeks approval of its ANDA to engage in the commercial manufacture, use or sale of a drug the use of which is claimed in the '817 patent before its expiration, Hetero has infringed the '817 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

23. If Hetero were to commercially market the 1 mg finasteride tablets of its ANDA No. 90-060 in the United States prior to the expiration of the '817 patent, Hetero would also induce infringement of the '817 patent under 35 U.S.C. § 271(b) and/or be liable as a contributory infringer under § 271(c).

24. Merck is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Hetero's ANDA be a date that is not earlier than the November 5, 2013, expiration date of the '817 patent, or any later expiration of exclusivity to which Merck is or becomes entitled.

25. Upon information and belief, Hetero was aware of the existence of the '817 patent and was aware that the filing of its ANDA and certification with respect to the '817 patent constituted an act of infringement of that patent.

26. This case is an exceptional one, and Merck is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

CLAIM FOR RELIEF – COUNT II

27. Merck realleges, as if fully set forth herein, the averments contained in paragraphs 1-16.

28. Merck's '957 patent discloses and claims a method of treating male pattern baldness, and a method of arresting and reversing male pattern baldness, comprising orally administering to a male person having a balding area or to a bald or balding male person, a

dosage of 0.05 to 3.0 mgs/day of 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-en-3-one (i.e., finasteride).

29. Hetero's ANDA No. 90-060 seeks FDA approval to market 1 mg finasterirde tablets "for the treatment of male pattern hair loss (androgenetic alopecia) in men only."

30. Hetero has filed in connection with ANDA No. 90-060 a certification with respect to the '957 patent under § 505(j)(2)(A)(vii)(IV) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355) seeking approval to sell finasteride 1 mg tablets prior to the expiration of the '957 patent.

31. On or about October 6, 2010, Hetero sent a notice to Merck in which Hetero represented that it had filed an ANDA for finasteride, including the certification with respect to the '957 patent, and that it sought approval of its ANDA prior to the expiration of that patent.

32. Because Hetero seeks approval of its ANDA to engage in the commercial manufacture, use or sale of a drug the use of which is claimed in the '957 patent before its expiration, Hetero has infringed the '957 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

33. If Hetero were to commercially market the 1 mg finasteride tablets of its ANDA No. 90-060 in the United States prior to the expiration of the '957 patent, Hetero would also induce infringement of the '957 patent under 35 U.S.C. § 271(b) and/or be liable as a contributory infringer under § 271(c).

34. Merck is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Hetero's ANDA be a date that is not earlier than the October 15, 2013, expiration date of the '957 patent, or any later expiration of exclusivity to which Merck is or becomes entitled.

35. Upon information and belief, Hetero was aware of the existence of the '957 patent and was aware that the filing of its ANDA and certification with respect to the '957 patent constituted an act of infringement of that patent.

36. This case is an exceptional one, and Merck is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

CLAIM FOR RELIEF – COUNT III

37. Merck realleges, as if fully set forth herein, the averments contained in paragraphs 1-16.

38. Merck's '184 patent discloses and claims the product 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-en-3-one (i.e., finasteride) in polymorphic Form II and a process for producing that product.

39. Hetero's ANDA No. 90-060 seeks FDA approval to market 1 mg finasteride tablets "for the treatment of male pattern hair loss (androgenetic alopecia) in men only."

40. Hetero has filed in connection with ANDA No. 90-060 a certification with respect to the '184 patent under § 505(j)(2)(A)(vii)(IV) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355) seeking approval to sell finasteride 1 mg tablets prior to the expiration of the '184 patent.

41. On or about October 6, 2010, Hetero sent a notice to Merck in which Hetero represented that it had filed an ANDA for finasteride, including the certification with respect to the '184 patent, and that it sought approval of its ANDA prior to the expiration of that patent.

42. Soon after receipt of the Hetero notice, counsel for Hetero and Merck negotiated a confidential access agreement by which Merck could gain access to, as agreed upon by the parties, Hetero's complete ANDA, related Drug Master File ("DMF") and an agreed upon number of Hetero's finasteride tablets and quantity of active pharmaceutical ingredient ("API") for such tablets whereby Merck might ascertain whether Hetero's proposed finasteride tablets would not infringe Merck's '184 patent as alleged in Hetero's notice.

43. Despite repeated requests by Merck's counsel to Hetero, Hetero did not produce the ANDA and DMF until November 10, 2010. Further, on November 18, 2010, Hetero represented that samples of its finasteride tablets and API would be delivered to Merck's counsel on November 19, 2010, which is the last business day before the expiry of the 45 day period provided for in § 505(j)(4)(B)(iii) of the Federal Food, Drug and Cosmetic Act. Analysis of the physical properties of the tablets and API is necessary to ascertain whether Hetero's finasteride tablets are within the scope of the '184 patent. Because the samples have not been produced in a timely manner, Merck's technical experts have been unable to conduct the requisite tests to ascertain whether Hetero's tablets are within the scope of the '184 patent.

44. The delay in obtaining the requisite and agreed upon number of Hetero finasteride tablets and quantity of API is not due to action or inaction on the part of Merck but is traceable to Hetero, its agents, or others over which Merck has and had no control.

45. According to Hetero's notice, its proposed finasteride tablets would not infringe the '184 patent because they contain polymorphic crystalline Form I of finasteride, not Form II, as called for by the '184 patent.

46. It is Merck's present belief, subject to confirmation upon a complete examination of Hetero's finasteride tablets and API by technical experts, that Hetero's polymorphic crystalline Form I of finasteride may convert into polymorphic Form II, for

example, upon at least the blending, mixing, milling and wet granulation steps of Hetero's manufacturing process.

47. On information and belief, Hetero has infringed the '184 patent pursuant to 35 U.S.C. § 271(e)(2)(A) because Hetero seeks approval of its ANDA to engage in the commercial manufacture, use or sale of finasteride tablets claimed in the '184 patent before its expiration. Merck has a proper basis for its cause of action for infringement of the '184 patent, as it is Merck's present belief, subject to confirmation upon a complete examination by technical experts, that Hetero's finasteride tablets may contain polymorphic crystalline Form II finasteride rather than purely crystalline Form I finasteride.

48. On information and belief, if Hetero were to commercially make, use, offer to sell, or sell the 1 mg finasteride product of its ANDA No. 90-060 within the United States, or import such product into the United States, prior to the expiration of the '184 patent, Hetero would also infringe the '184 patent under 35 U.S.C. §271(a).

49. On November 12, 2010, Hetero submitted to the FDA a request pursuant to 21 C.F.R. § 314.95(f) to re-set the beginning of the 45 day period provided for in § 505(j)(4)(B)(iii) of the Federal Food, Drug and Cosmetic Act to November 10, 2010, to allow Hetero more time to produce samples of its finasteride tablets and API and to allow Merck adequate time to test those samples. As of the filing date of this complaint, the FDA has not responded to Hetero's request.

50. Accordingly, in order to protect its statutory entitlement to a 30 month stay, Merck resorts to the judicial process and the aid of discovery under appropriate judicial safeguards to obtain such information as is required to present to the Court evidence that Hetero's proposed finasteride tablets fall within the scope of the '184 patent and would infringe

the '184 patent upon the FDA's approval of Hetero's ANDA and commercial marketing of the proposed tablets.

51. Merck is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Hetero's ANDA be a date that is not earlier than the November 19, 2012, expiration date of the '184 patent, or any later expiration of exclusivity to which Merck is or becomes entitled.

52. On information and belief, Hetero was aware of the existence of the '184 patent and was aware that the filing of its ANDA and certification with respect to the '184 patent constituted an act of infringement of that patent.

53. This case is an exceptional one, and Merck is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

54. Merck requests that:

a. Judgment be entered that Hetero has infringed the '817, '957 and '184 patents by submitting the aforesaid ANDA;

b. Judgment be entered that this is an exceptional case and Merck is entitled to its reasonable attorney fees pursuant to 35 U.S.C. § 285;

c. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Hetero, its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or

importation into the United States, of drug compounds claimed in or the use of which is claimed in the '817, '957 and '184 patents;

d. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 90-060 be a date which is not earlier than the later of November 5, 2013, the expiration date of the '817 patent, October 15, 2013, the expiration date of the '957 patent, November 19, 2012, the expiration date of the '184 patent, or any later expiration of exclusivity to which Merck is or becomes entitled; and

e. For such other and further relief as the Court may deem just and proper under the circumstances.

Dated: November 19, 2010

Respectfully submitted,

By: /s/ Sheila F. McShane

Sheila F. McShane, Esq.
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4500

Of Counsel:

Tony V. Pezzano, Esq.
Michael P. Dougherty, Esq.
CADWALADER, WICKERSHAM & TAFT LLP
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Edward W. Murray, Esq.
Mary J. Morry, Esq.
MERCK & CO., INC.
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P.O. Box 2000
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(732) 594-0436

Attorneys for Plaintiffs
MERCK & CO., INC. and
MERCK SHARP & DOHME CORP.