

EXHIBIT A

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C. 20436**

In the Matter of

CERTAIN VAGINAL RING BIRTH
CONTROL DEVICES

Investigation No. 337-TA-_____

**AMENDED COMPLAINT OF FEMINA PHARMA INCORPORATED
UNDERSECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED**

COMPLAINANTS

Femina Pharma Incorporated
3470 E. Coast Ave.,
Suite H502
Miami, Florida 33137
Tel.: 202.669.5097

PROPOSED RESPONDENTS

Merck & Co., Inc.
One Merck Drive
Whitehouse Station, New Jersey 08889
USA

Schering Plough Corporation
2000 Galloping Hill Road
Kenilworth, New Jersey 07033
USA

Organon USA, Inc.
100 Rodolphe Street
Durham, North Carolina 27712
USA

N.V. Organon
Molenstraat 110
Oss, Netherlands
5340 BH

COUNSEL FOR COMPLAINANTS

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THE FUISZ-KUNDU GROUP LLP
1455 Pennsylvania Ave., N.W.
Suite 400
Washington, D.C. 20004
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F. 202.652.2309

CVS Caremark Corporation
One CVS Drive
Woonsocket, Rhode Island 02895
USA

CVS Pharmacy, Inc.
One CVS Drive
Woonsocket, Rhode Island 02895
USA

Proposed Respondents (Cont.)

Wal-Mart Stores, Inc.
702 S.W. 8th St.
Betonville, Arkansas 72716
USA

Walgreens Co.
200 Wilmont RD
Deerfield, Illinois 60015
USA

The Canamerican Drugs Inc.
D/B/A
www.77Canadapharmacy.com
www.medcentercanada.com
www.tigerdrugs.com
77 Canada Pharmacy
8-1421 St. James Street
Winnipeg, MB
R3H 0Y9
Canada

The Canamerican Global Inc.
D/B/A
www.canamericanglobal.com
77 Canada Pharmacy
8-1421 St. James Street
Winnipeg, MB
R3H 0Y9
Canada

Canadian Med Service
D/B/A
www.canadianmedservices.com
77 Canada Pharmacy
8-1421 St. James Street
Winnipeg, MB
R3H 0Y9
Canada

Proposed Respondents (Cont.)

Panther Meds Inc.
D/B/A
www.panthermeds.com
77 Canada Pharmacy
8-1421 St. James Street
Winnipeg, MB
R3H 0Y9
Canada

Canada Drugs Online
D/B/A
www.Canadadrugsonline.com
Unit #202A,
8322-130th Street, Surrey,
British Columbia, Canada V3W 8J9

Drug World Canada
D/B/A
www.drugworldcanada.com
Unit #202A,
8322-130th Street, Surrey,
British Columbia, Canada V3W 8J9

CanDrug Health Solutions Inc.
D/B/A
www.candrug.com
Unit #202A,
8322-130th Street, Surrey,
British Columbia, Canada V3W 8J9

Big Mountain Drugs
D/B/A
www.bigmountaindrugs.com
Unit #202A,
8322-130th Street, Surrey,
British Columbia, Canada V3W 8J9

Proposed Respondents (Cont.)

BestBuyRx.com

D/B/A

www.bestbuyrx.com

Unit #202A,

8322-130th Street, Surrey,

British Columbia, Canada V3W 8J9

Blue Sky Drugs

D/B/A

www.Blueskydrugs.com

Unit #202A,

8322-130th Street, Surrey,

British Columbia, Canada V3W 8J9

ABC Online Pharmacy

D/B/A

www.abconlinepharmacy.com

200-7382 Winston Street

Burnaby, British Columbia

V5A 2G9 Canada

Canadadrugs.com LP

D/B/A

www.Canadadrugs.com

24 Terracon Place

Winnipeg, Manitoba

Canada R2J 4G7

North Drug Store

D/B/A

www.northdrugstore.com

266 Graham Avenue,

P.O. Box 1074 Station Main,

Winnipeg, Manitoba,

R3C 2X4 Canada

Canada Pharmacy

D/B/A

www.CanadaPharmacy.com

477 Peace Portal Dr Suite #180

Blaine WA 98230

USA

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LIST OF EXHIBITS

1. Certified copy of U.S. Patent No. 6,086,909
2. Certified copy of inventor assignments to UMD, Inc.
3. Non-Certified copy of assignment from UMD, Inc. to Femina Pharma
Incorporated
4. **CONFIDENTIAL** – Purchase document for UMD, Inc. by Femina Pharma
Incorporated
5. U.S. Provisional Application No. 60/049,325.
6. Nuvaring Package
7. Nuvaring Package Insert
8. U.S. Patent No. 5,989,581
9. Exemplary claim chart for Nuvaring
10. **CONFIDENTIAL** – Declaration of Joseph M. Fuisz
11. **CONFIDENTIAL** – Kimberly-Clark – UMD Agreement
12. **CONFIDENTIAL** – Claim chart
13. Panjiva Report on Nuvaring Importation
14. 77canadapharmacy.com web page
15. 77canadapharmacy.com web page
16. medcentercanada.com web page
17. medcentercanada.com web page
18. Tigerdrugs.com web page
19. Tigerdrugs.com web page
20. Canamericanglobal.com web page

21. Canaamericanglobal.com web page
22. Canadianmedservice.com web page
23. Canadianmedservice.com web page
24. Panthermeds.com web page
25. Panthermeds.com web page
26. Canadadrugsonline.com web page
27. Canadadrugsonline.com web page
28. Drugworldcanada.com web page
29. Drugworldcanada.com web page
30. Candrug.com web page
31. Candrug.com web page
32. Bigmountaindrugs.com web page
33. Bigmountaindrugs.com web page
34. Bestbuyrx.com web page
35. Bestbuyrx.com web page
36. Blueskydrugs.com web page
37. Blueskydrugs.com web page
38. Abconlinpharmacy.com web page
39. Abonlinepharmacy.com web page
40. Canadadrugs.com web page
41. Canadadrugs.com web page
42. Northdrugstore.com web page
43. Northdrugstore.com web page

44. Canapharmacy.com web page
45. Canadapharmacy.com web page
46. www.nuvaring.com web page
47. Nuvaring Orange Book pages
48. Thompson-Delphion Patent Family and status
49. Country code index

APPENDIX

- A. Four (4) copies of the '909 patent file history
- B. Four copies references mentioned in prosecution history.
- C. **CONFIDENTIAL** - Three copies of '909 patent license agreements.

I. INTRODUCTION

1.1 Complainant Femina Pharma Incorporated (“Femina”) requests that the United States International Trade Commission commence an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (“Section 337”), to remedy the unlawful importation into the United States, the sale for importation, and/or the sale within the United States after importation by the owner, importer, consignee (or any agent of the owner, importer or consignee), of certain vaginal ring birth control devices known as the Nuvaring, (“accused product”) that infringes at least claim 1 of U.S. Patent No. 6,086,909 (“the ‘909 patent”), which is a valid and enforceable United States Patent owned by Femina.

1.2 The accused product, Nuvaring, is a prescription only vaginal ring birth control device that is manufactured outside of the United States and imported into the United States for sale. On information and belief, all of the named respondents are involved in the manufacture, importation, sale for importation or sale after importation of Nuvaring. On information and belief, Nuvaring is manufactured by N.V. Organon, which is a wholly owned subsidiary of Merck & Co. and related to Organon USA, Inc., N.V. Organon, and Schering Plough Corporation (collectively “the Merck Respondents”). On information and belief, Nuvaring is manufactured outside of the United States in Oss, Netherlands.

1.3 On information and belief, Nuvaring is sold for or after importation by CVS Caremark Corporation and CVS Pharmacy, Inc. (collectively the “CVS Respondents”), Wal-Mart Stores, Inc, (the “Wal-Mart Respondent”) and Walgreens Co. (the “Walgreens Respondent”).

1.4 On information and belief, Nuvaring is also sold for or after importation by numerous on-line pharmacies (“On-line Pharmacy Respondents”). The On-line Pharmacy Respondents include:

- (i) The Canamerican Drugs Inc. D/B/A www.77Canadapharmacy.com, www.medcentercanada.com , www.tigerdrugs.com;
- (ii) The Canamerican Global Inc. D/B/A www.canamericanglobal.com;
- (iii) Canadian Med Service D/B/A www.canadianmedservices.com;
- (iv) Panther Meds Inc. D/B/A www.pathermeds.com;
- (v) Canada Drugs Online D/B/A www.Canadadrugsonline.com;
- (vi) Drug World Canada D/B/A www.drugworldcanada.com;
- (vii) CanDrug Health Solutions Inc. D/B/A www.candrug.com;
- (viii) Big Mountain Drugs D/B/A www.bigmountaindrugs.com;
- (ix) BestBuyRx.com D/B/A www.bestbuyrx.com;
- (x) Blue Sky Drugs D/B/A www.Blueskydrugs.com;
- (xi) ABC Online Pharmacy D/B/A www.abconlinepharmacy.com;
- (xii) Canadadrugs.com LP D/B/A www.canadadrugs.com;
- (xiii) North Drug Store D/B/A www.northdrugstore.com; and
- (xiv) Canada Pharmacy D/B/A www.candapharmacy.com.

1.5 Collectively, the Respondents have engaged in violations of Section 337 through the unlicensed importation into the United States, the sale for importation, and/or the sale within the United States after importation of the accused product that infringe at least claim 1 of the ‘909 patent.

1.6 A certified copy of the '909 patent accompany this Complaint as Exhibit 1.

1.7 Femina owns by assignment the entire right, title, and interest in and to the '909 patent by way of assignment from the inventors to UMD Inc. and through a subsequent assignment from UMD Inc. to Femina. A certified copy of the assignment as recorded at the U.S. Patent and Trademark office from the inventors to UMD, Inc. accompanies this Complaint as Exhibit 2. The assignment from UMD Inc. to Femina is not recorded at the U.S. Patent and Trademark Office. A true and accurate copy of the assignment from UMD, Inc. to Femina accompanies this Complaint as Exhibit 3.

1.8 As required by Section 337(a)(2) and defined in Section 337(a)(3), an industry in the United States exists relating to product and intellectual property, which is covered by the '909 patent.

1.9 Complainant seeks a general and/or limited exclusion order, pursuant to Section 337(d), permanently excluding the accused products from entry into the United States. Complainant also seeks to cease and desist the importation into the United States, the sale for importation, and/or the sale within the United States after importation of the accused products. Complainant also requests that the cease and desist order directs each respondent and its related entities and agents to cease demonstrating, selling, offering for sale, and using the accused products and to cease transferring, moving, or shipping their United States inventory of the accused products.

II. COMPLAINANT

2.1 UMD Inc. was founded in 1996 by a number of well know inventors and medical scientists to develop new drug delivery systems and technologies with a primary focus on women's health. The chairman and founder of UMD, as well as an inventor on the '909 patent, is Donald C. Harrison, M.D. Dr. Harrison is the managing member of Charter Life Sciences. In addition to his work at the University of Cincinnati, Dr. Harrison is a former chief of cardiology at Stanford and former co-director of the Falk Cardiac Research Center at Stanford. He is an author of seven books and over five hundred scientific articles and reviews. Another inventor of the '909 patent is Wolfgang Ritschel, MD PhD, Professor Emeritus of Pharmacokinetics and Biopharmaceutics at the University of Cincinnati Winkle College of Pharmacy and Adjunct Professor of Pharmacology at the College of Medicine. Dr. Ritschel authored twelve textbooks and over 400 scientific articles prior to his passing in February 2010. Another inventor of the '909 patent is Roger A. Stern, PhD. Dr. Stern is a serial entrepreneur specializing in the medical device field. He is a named inventor on over forty US patents. Another inventor of the '909 patent is James H. Liu, M.D. Dr. Liu is the Arthur H. Bill Professor and Chair of the Department of Obstetrics and Gynecology, University Hospitals Case Medical Center, and the Department of Reproductive Biology, Case Western Reserve University.

2.2 Women's healthcare products are unique in that they can offer women many health advantages over traditional unisex drug delivery technologies. Largely, because of the male dominated sales market there is a bias against female specific health care technologies which the original inventors and UMD had to fight against. UMD made

significant investment in plant, equipment, employment or labor and capital as well as making a substantial investment in exploiting the technology claimed in the '909 patent. These included a number of license agreements and development of product. In addition, UMD was in contact with at least the Merck Respondent at various times in its product development. Despite its considerable efforts, however, UMD was unable to overcome the bias against female specific health care technologies, and was therefore unable to compete against these larger companies.

2.3 Femina is an American company founded in 2009. It is located at 3470 E. Coast Ave., Suite H502, Miami, Florida. Femina specializes in women health technologies and had the specialized knowledge and experience needed to advance the technology of the '909 patent in a very competitive market. Femina's president since its founding is Joseph Fuisz who is a named inventor on five issued United States drug delivery patents, one issued United States patent relating to medical devices, and various patents pending in the drug delivery field. Joseph Fuisz has substantial experience in the licensing of drug delivery technologies, through, inter alia, his service as senior vice president for business development of MonoSol Rx, LLC, an oral thin film drug delivery company. A director and shareholder of Femina, is Richard C. Fuisz, M.D., (father of Joseph Fuisz) who is a well known inventor and businessman in the drug delivery field having founded the publicly traded quick dissolve tablet company, Fuisz Technologies. Richard Fuisz has been a successful inventor in drug delivery and is credited with making substantial contributions to particle coating technologies, quick dissolve tablets, oral thin films, buccal sheets and many other inventions.

2.4 To facilitate the continued development of its drug delivery technology, UMD was absorbed into the pre-existing Femina entity by way of a purchase of all of the assets of UMD whereby the UMD owners were provided with an ownership position in Femina. Thus on February 20, 2010, Femina acquired all of the rights, title and interest in the assets (tangible and intangible), third-party agreements, permits, and books and records of UMD in return for preferred shares in Femina. See CONFIDENTIAL Exhibit 4. This transaction thus included all rights title and interest to the '909 patent, agreements involving the '909 patent and all permits, records and books related to the '909 patent and its product development. See Exhibit 3 and CONFIDENTIAL Exhibit 4.

2.5. Starting on or about February 2010, Femina began the process of identifying partnership opportunities, obtaining licenses to facilitate the further use and/or development of the technology, as well as identifying unlicensed uses of its patented technology. Femina has also identified other partners for the technology as set forth in CONFIDENTIAL Exhibit 10. In that capacity, Femina has identified Nuvaring as an infringing product.

III. PROPOSED RESPONDENTS

A. Merck Respondents

3.1 On information and belief, the accused product was developed by N.V. Organon, which is a biopharmaceutical company engaged in the marketing and manufacture of prescription medicines. On information and belief, the company was founded in on or about 1923 and became N.V. Organon on or about 1969. On information and belief, the company is headquartered in Oss, Netherlands with an additional office in Roseland, New Jersey. On information and belief, on November 19, 2007, Organon Biosciences N.V. became a subsidiary of Schering-Plough Corporation. On information and belief, on November 2009, Schering-Plough merged with Merck & Co. Respondent Merck & Co., Inc. is a company organized and existing under the laws of Delaware with its principal place of business at One Merck Drive Whitehouse Station, NJ 08889. On information and belief, Schering Plough Corporation is a wholly-owned subsidiary of Merck & Co. with a principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. On information and belief, proposed respondent Organon USA, Inc. is a wholly-owned subsidiary of Merck & Co. with a principal place of business at 56 Livingstone Ave, Roseland NJ 07068. On information and belief, proposed respondent N.V. Organon is a wholly-owned subsidiary of Merck & Co. with a principal place of business at Molenstraat 110, Oss, the Netherlands. On information and belief, N.V. Organon manufactures the infringing product Nuvaring, which is imported and sold into the United States through Merck, Schering Plough and Organon USA. On information and belief, the proposed Merck Respondents manufacture the accused product, import the accused product into the United States, sell the accused product for

importation into the United States, and/or sell the accused products after they have been imported into the United States.

B. Non-Merck U.S. Entities

3.3 On information and belief, the proposed respondent CVS Caremark Corporation is a company organized and existing under the laws of Delaware with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. On information and belief, proposed respondent CVS Pharmacy Corporation is a wholly-owned subsidiary of CVS Caremark Corporation with a principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. On information and belief, the proposed CVS Respondents sell the accused products after they have been imported into the United States.

3.4 On information and belief, the proposed respondent Wal-Mart Stores, Inc. is a company organized and existing under the laws of Delaware with its principal place of business at 702 S.W. 8th St., Bentonville, Arkansas 72716. On information and belief, the proposed Wal-Mart Respondent sells the accused products after they have been imported into the United States.

3.5 On information and belief, the proposed respondent Walgreen Co. is a company organized and existing under the laws of Illinois with its principal place of business at 200 Wilmont Rd., Deerfield Illinois 60015. On information and belief, the proposed Walgreen Respondent sells the accused products after they have been imported into the United States.

C. On-Line Pharmacies

3.6 Proposed respondent Canamerican Drugs Inc. is also identified with www.77canadapharmacy.com (Exhibit 14), www.medcentercanada.com (Exhibit 16) and www.tigerdrugs.com (Exhibit 18) and is run out of 8-1421 St. James Street, Winnipeg, MB, R3H 0Y9 Canada. These web sites advertise Nuvaring. Exhibits 15, 17 and 19. As set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 800.545.1106 (www.77canadapharmacy.com) where an individual taking orders indicated that the Nuvaring product was sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States. On information and belief, the proposed respondent Canamerican Drugs Inc. respondent imports the accused product into the United States, sell the accused product for importation into the United States, and/or sell the accused products after they have been imported into the United States.

3.7 Proposed respondent Canamerican Global Inc. is identified with www.canamericanglobal.com and is also run out of 8-1421 St. James Street, Winnipeg, MB, R3H 0Y9 Canada. Exhibit 20. This site also identifies Canamerican Global Inc. who can also be reached at 8-1421 St. James Street, Winnipeg, MB, R3H 0Y9 Canada. The web site advertises Nuvaring. Exhibit 21. As set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 888.788.1112 (www.canamericanglobal.com) where an individual taking orders indicated that the Nuvaring product was sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States. On information and belief, the proposed respondent Canamerican Drugs Inc. respondent imports the accused product into the United States, sell the accused

product for importation into the United States, and/or sell the accused products after they have been imported into the United States.

3.8 Proposed respondent Canadian Med Services. is identified with www.canadianmedservices.com and is also run out of 8-1421 St. James Street, Winnipeg, MB, R3H 0Y9 Canada. Exhibit 22. This site also identifies Canadian Med Services who can also be reached at 8-1421 St. James Street, Winnipeg, MB, R3H 0Y9 Canada. The web site advertises Nuvaring. Exhibit 23. As set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 888.600.4955 (www.canadianmedservices.com) where an individual taking orders explained that Nuvaring is offered from Canada and is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States. On information and belief, the proposed respondent Canadian Med Services respondent imports the accused product into the United States, sell the accused product for importation into the United States, and/or sell the accused products after they have been imported into the United States.

3.9 Proposed respondent Panther Meds Inc. is identified with www.panthermeds.com and is also run out of 8-1421 St. James Street, Winnipeg, MB, R3H 0Y9 Canada. Exhibit 24. The web site advertises Nuvaring. Exhibit 25. As set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 866.353.2236 (www.panthermeds.com) where an individual taking orders named Marco answered the phone again (which was the same Marco as www.canamericanglobal.com). The individual taking orders reconfirmed that Nuvaring product is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States. On information and belief, the proposed respondent Panther Meds Inc.

respondent imports the accused product into the United States, sell the accused product for importation into the United States, and/or sell the accused products after they have been imported into the United States.

3.10 Proposed respondent Canada Drugs Online is also identified as www.canadadrugsonline.com and is identified as being run out of Unit 202A, 8322-130th St, Surrey, British Columbia, Canada V3W8J9. Exhibit 26. The web site advertises Nuvaring. Exhibit 27. As set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 877.900.3784 (www.canadadrugsonline.com) where an individual taking orders indicated that the Nuvaring product is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States. On information and belief, the proposed respondent Canada Drugs Online respondent imports the accused product into the United States, sell the accused product for importation into the United States, and/or sell the accused products after they have been imported into the United States.

3.11 Proposed respondent Drug World Canada is also identified as www.drugworldcanada.com and is identified as being run out of Unit 202A, 8322-130th St, Surrey, British Columbia, Canada V3W8J9. Exhibit 28. The web site advertises Nuvaring. Exhibit 29. As set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 866.485.7979 (www.drugworldcanada.com) where an individual taking orders indicated that the Nuvaring product is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States. On information and belief, the proposed respondent Drug World Canada respondent imports the accused product into the United States, sell the accused product for importation into

the United States, and/or sell the accused products after they have been imported into the United States.

3.12 Proposed respondent CanDrug Health Solutions Inc. is also identified as www.candrug.com and is identified as being run out of Unit 202A, 8322-130th St, Surrey, British Columbia, Canada V3W8J9. Exhibit 30. The web site advertises Nuvaring. Exhibit 31. As set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 888.488.3784 (www.candrug.com) where an individual taking orders indicated that the Nuvaring product is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States. On information and belief, the proposed respondent CanDrug Health Solutions Inc. respondent imports the accused product into the United States, sell the accused product for importation into the United States, and/or sell the accused products after they have been imported into the United States.

3.13 Proposed respondent Big Mountain Drugs is also identified as www.bigmountaindrugs.com and is identified as being run out of Unit 202A, 8322-130th St, Surrey, British Columbia, Canada V3W8J9. Exhibit 32. The web site advertises Nuvaring. Exhibit 33. As set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 877.223.9977 (www.bigmountaindrugs.com) where an individual taking orders indicated that the Nuvaring product is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States. On information and belief, the proposed respondent Big Mountain Drugs respondent imports the accused product into the United States, sell the accused product for importation into

the United States, and/or sell the accused products after they have been imported into the United States.

3.14 Proposed respondent BestbuyRX.com is also identified as www.bestbuyrx.com and is identified as being run out of Unit 202A, 8322-130th St, Surrey, British Columbia, Canada V3W8J9. Exhibit 34. The web site advertises Nuvaring. Exhibit 35. As set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 877.745.9217 (www.bestbuyrx.com) where an individual taking orders indicated that the Nuvaring product is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States. On information and belief, the proposed respondent BestbuyRX respondent imports the accused product into the United States, sell the accused product for importation into the United States, and/or sell the accused products after they have been imported into the United States.

3.15 Proposed respondent Blue Sky Drugs is also identified as www.blueskydrugs.com and is identified as being run out of Unit 202A, 8322-130th St, Surrey, British Columbia, Canada V3W8J9. Exhibit 36. The web site advertises Nuvaring. Exhibit 37. As set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 877.995.7387 (www.blueskydrugs.com) where an individual taking orders indicated that the Nuvaring product is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States. On information and belief, the proposed respondent Blue Sky Drugs respondent imports the accused product into the United States, sell the accused product for importation into the

United States, and/or sell the accused products after they have been imported into the United States.

3.16 Proposed respondent ABC Online Pharmacy is also identified as www.abconlinepharmacy.com and is identified as being run out of 200-7382 Winston Street, Burnaby, British Columbia, Canada V5A 2G9. Exhibit 38. The web site advertises Nuvaring. Exhibit 39. As set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 866.299.3784 (www.abconlinepharmacy.com) where an individual taking orders indicated that the Nuvaring product is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States. On information and belief, the proposed respondent ABC Online Pharmacy respondent imports the accused product into the United States, sell the accused product for importation into the United States, and/or sell the accused products after they have been imported into the United States.

3.17 Proposed respondent Canada Drugs LP is also identified as www.canadadrugs.com and is identified as being run out of 24 Terracon Place, Winnipeg, Manitoba, R2J 4G7 Canada. Exhibit 40. The web site advertises Nuvaring. Exhibit 41. As set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 800.226.3784 (www.canadadrugs.com) where an individual taking orders indicated that the Nuvaring product is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States. On information and belief, the proposed respondent Canada Drugs LP respondent imports the accused product into the United States, sell the accused product for importation into the United States, and/or sell the accused products after they have been imported into the United States.

3.18 Proposed respondent North Drug Store is also identified as www.northdrugstore.com and is identified as being run out of 266 Graham Avenue, P.O. Box 1074 Station Main, Winnipeg, Manitoba, R3C 2X4 Canada. Exhibit 42. The web site advertises Nuvaring. Exhibit 43. As set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 866.940.3784 (www.northdrugstore.com) where an individual taking orders indicated that the Nuvaring product is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States. On information and belief, the proposed respondent North Drug Store respondent imports the accused product into the United States, sell the accused product for importation into the United States, and/or sell the accused products after they have been imported into the United States.

3.19 Proposed respondent Canada Pharmacy is also identified as www.canadapharmacy.com and is identified as being run out of 477 Peace Portal Drive, Suite 180, Blaine Washington 98230. Exhibit 44. The web site advertises Nuvaring. Exhibit 45. As set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 888.269.2168 (www.canadapharmacy.com) where an individual taking orders indicated that the Nuvaring product is sold into the United States from Canada. The individual confirmed that Nuvaring has been sold by the website into the United States. On information and belief, the proposed respondent Canada Pharmacy respondent imports the accused product into the United States, sell the accused product for importation into the United States, and/or sell the accused products after they have been imported into the United States.

IV. THE TECHNOLOGY AND PRODUCTS AT ISSUE

A. '909 Patent and Nuvaring

4.1 The '909 Patent is entitled "Device and Method for Treatment of Dysmenorrhea" and issued July 11, 2000. The '909 Patent issued from U.S. Patent Application No. 09/249,963, filed on February 12, 1999, which is a continuation-in-part of U.S. Patent Application No. 09/079,897, filed on May 15, 1998. The '909 Patent claims priority to Provisional Application No. 60/049,325, filed on June 11, 1997. A Certified copy of the '909 patent is at Exhibit 1. A certified copy of the file history is at Appendix A and the references cited therein at Appendix B. A separate copy of Provisional Application No. 60/049,325 is at Exhibit 5.

4.2 The '909 patent describes and claims a medicated intravaginal device, such as a vaginal ring, for transvaginal delivery of a pharmaceutical agent to the uterus of a female. The patent also describes delivery systems other than a vaginal ring such as a medicated intrauterine tampon, tampon-like device, vaginal pessary or vaginal sponge. In the human female there is a unique vaginal-to-uterine circulatory system which has allowed a drug delivery system to be developed that allows administration of the drug to the uterine muscle while largely bypassing liver metabolism. And as described in the '909 patent, suitable pharmaceutical agents are those that are absorbable through the vaginal mucosa into this unique circulation system between the vagina and uterus. The drug delivery system described in the '909 patent allows delivery of the drug transvaginally in lower concentrations than those needed for systemic treatment and thus provides for lower systemic concentration and fewer side effects.

4.3 As stated above, one of the drug delivery systems described in the '909 patent is a vaginal ring. In particular, as stated in the '909 patent:

Another example of a suitable controlled release drug delivery system for the present invention is the vaginal ring. Vaginal rings usually consist of an inert elastomer ring coated by another layer of elastomer containing the drug to be delivered. The rings can be easily inserted, left in place for the desired period of time (e.g., up to 7 days), then removed by the user. The ring can optionally include a third, outer, rate-controlling elastomer layer which contains no drug. Optionally, the third ring can contain a second drug for a dual release ring. The drug can be incorporated into polyethylene glycol throughout the silicone elastomer ring to act as a reservoir for drug to be delivered.

909 patent at Col 13:1-9. The vaginal ring is of particular significance to this investigation since the Nuvaring is a vaginal ring that contacts the vagina and delivers pharmaceutical agents such as progestin and estrogen into a female's bloodstream.

4.4 Claim 1 of the '909 patent recites as follows:

1. A medicated intravaginal device for a transvaginal delivery of a pharmaceutical agent to the uterus of a female subject,

wherein said device is a vaginal tampon, vaginal tampon-like device, vaginal ring, vaginal pessary or vaginal sponge,

wherein said device is impregnated with a pharmaceutical composition comprising the pharmaceutical agent;

wherein said device, when inserted intravaginally, maintains contact with the vaginal epithelium and releases said pharmaceutical agent, and

wherein the concentration of said pharmaceutical agent released from the medicated device to the vaginal epithelium is sufficient for transvaginal delivery of a therapeutically effective dose of said pharmaceutical agent to the uterus of the female subject.

4.5 This system has been adopted by the proposed respondents for use in a vaginal ring birth control device marked as Nuvaring. Photographs of the packaging and

device as set forth at Exhibit 6. The internal product information as provided at www.nuvaring.com is set forth at Exhibit 7. Because the device is only available in the United States by prescription, it is not practical to submit the imported article. As set forth in the Nuvaring insert the product is manufactured by N.V. Organon for Organon U.S.A., Inc. Exhibit 7. The product is described as follows:

DESCRIPTION

NuvaRing® (etonogestrel/ethinyl estradiol vaginal ring) is a non-biodegradable, flexible, transparent, colorless to almost colorless, combination contraceptive vaginal ring containing two active components, a progestin, etonogestrel (13-ethyl-17-hydroxy-11-methylene-18,19-dinor-17 α -pregn-4-en-20-yn-3-one) and an estrogen, ethinyl estradiol (19-nor-17 α -pregna-1,3,5(10)-trien-20-yne-3,17-diol). When placed in the vagina, each ring releases on average 0.120 mg/day of etonogestrel and 0.015 mg/day of ethinyl estradiol over a three-week period of use. NuvaRing® is made of ethylene vinylacetate copolymers (28% and 9% vinylacetate) and magnesium stearate and contains 11.7 mg etonogestrel and 2.7 mg ethinyl estradiol. NuvaRing® is latex-free. NuvaRing® has an outer diameter of 54 mm and a cross-sectional diameter of 4 mm. The molecular weights for etonogestrel and ethinyl estradiol are 324.46 and 296.40, respectively.

The structural formulas are as follows:

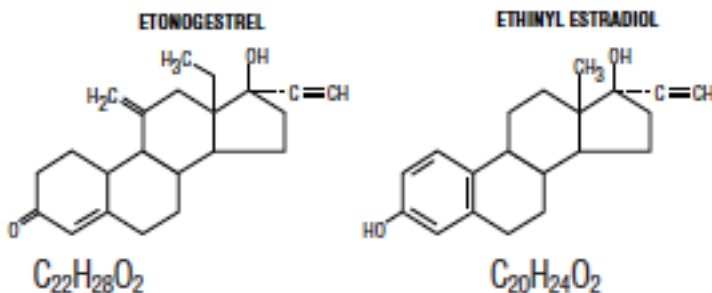


Exhibit 7. The pharmacokinetic absorption of the product is described as follows:

Pharmacokinetics

Absorption

Etonogestrel: Etonogestrel released by NuvaRing® is rapidly absorbed. The bioavailability of etonogestrel after vaginal administration is approximately 100%. The serum etonogestrel and ethinyl estradiol concentrations observed during three weeks of NuvaRing® use are summarized in Table I.

Ethinyl estradiol: Ethinyl estradiol released by NuvaRing® is rapidly absorbed. The bioavailability of ethinyl estradiol after vaginal administration is approximately 56%, which is comparable to that with oral administration of ethinyl estradiol. The serum ethinyl estradiol concentrations observed during three weeks of NuvaRing® use are summarized in Table I.

TABLE I: MEAN (SD) SERUM ETONOGESTREL AND ETHINYL ESTRADIOL CONCENTRATIONS (n=16).

| | 1 week | 2 weeks | 3 weeks |
|---------------------------|------------|------------|------------|
| etonogestrel (pg/mL) | 1578 (408) | 1476 (362) | 1374 (328) |
| ethinyl estradiol (pg/mL) | 19.1 (4.5) | 18.3 (4.3) | 17.6 (4.3) |

The pharmacokinetic profile of etonogestrel and ethinyl estradiol during use of NuvaRing® is shown in Figure 1.

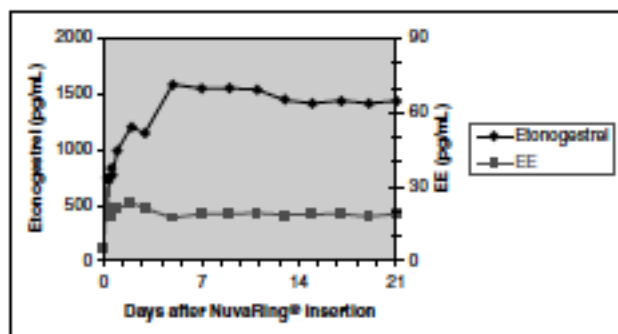


Figure 1. Mean serum concentration-time profile of etonogestrel and ethinyl estradiol during three weeks of NuvaRing® use.

4.6 On information and belief and as set forth in Exhibit 9, the accused Nuvaring product infringes at least claim 1 of the '909 patent.

For example, the preamble of claim 1 requires: A medicated intravaginal device for a transvaginal delivery of a pharmaceutical agent to the uterus of a female subject.

The Nuvaring product information states:

NuvaRing® (etonogestrel/ethinyl estradiol vaginal ring) is a non-biodegradable, flexible, transparent, colorless to almost colorless, combination contraceptive vaginal ring

Excerpt from Exhibit 7 at 1.

Next, claim 1 requires: wherein said device is a vaginal tampon, vaginal tampon-like device, vaginal ring, vaginal pessary or vaginal sponge, wherein said device is impregnated with a pharmaceutical composition comprising the pharmaceutical agent.

The Nuvaring product information states:

NuvaRing® (etonogestrel/ethinyl estradiol vaginal ring) is a non-biodegradable, flexible, transparent, colorless to almost colorless, combination contraceptive vaginal ring containing two active components, a progestin, etonogestrel (13-ethyl-17-hydroxy-11-methylene-18,19-dinor-17 α -pregn-4-en-20-yn-3-one) and an estrogen, ethinyl estradiol (19-nor-17 α -pregna-1,3,5(10)-trien-20-yne-3, 17-diol). When placed in the vagina, each ring releases on average 0.120 mg/day of etonogestrel and 0.015 mg/day of ethinyl estradiol over a three-week period of use.

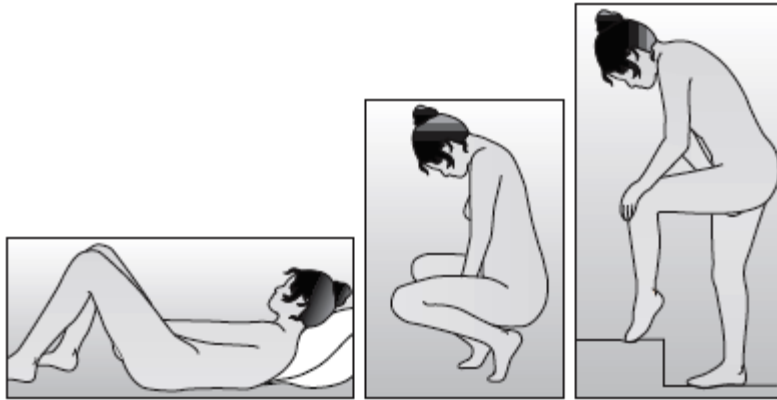
Exerpt from Exhibit 7 at 1.

Next, claim 1 requires: wherein said device, when inserted intravaginally, maintains contact with the vaginal epithelium and releases said pharmaceutical agents.

The Nuvaring product information states:

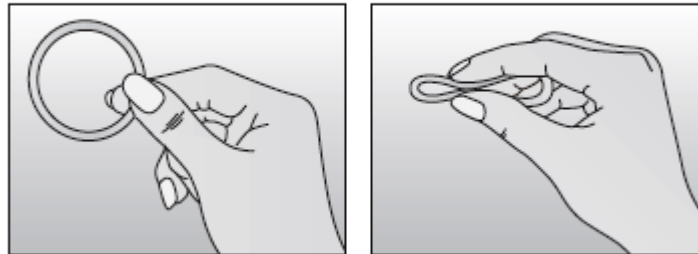
How do I insert NuvaRing®?

1. Each NuvaRing® comes in a reclosable foil pouch. After washing and drying your hands, remove NuvaRing® from its foil pouch. Keep the foil pouch for proper disposal of the ring after use. Choose the position that is most comfortable for you. For example, lying down, squatting, or standing with one leg up (Figures 1a, 1b, and 1c, respectively).



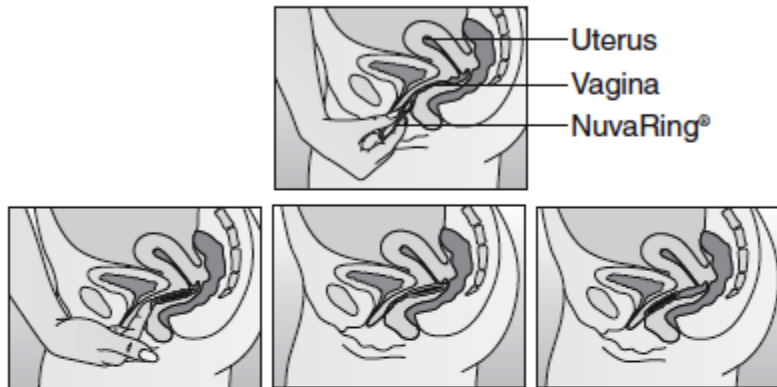
Figures 1a, 1b, and 1c. Positions for NuvaRing® insertion.

2. Hold NuvaRing® between your thumb and index finger (Figure 2a) and press the opposite sides of the ring together (Figure 2b).



Figures 2a and 2b. Holding NuvaRing® and pressing the sides together.

3. Gently push the folded ring into your vagina (Figures 3a and 3b). The exact position of NuvaRing® in the vagina is not important for it to work (Figures 3c and 3d).



Figures 3a, 3b, 3c, and 3d. Inserting and positioning of NuvaRing®.

Although some women may be aware of NuvaRing® in the vagina, most women do not feel it once it is in place. If you feel discomfort, NuvaRing® is probably not inserted back far enough in the vagina. Use your finger to gently push the NuvaRing® farther into your vagina. **There is no danger of NuvaRing® being pushed too far up in the vagina or getting lost.** NuvaRing® can be inserted only as far as the end of the vagina, where the cervix (the narrow, lower end of the uterus) will block NuvaRing® from going any farther.

4. Once inserted, keep NuvaRing® in place for three weeks in a row.

Excerpt from Exhibit 7 at 5.

Finally, claim 1 requires: wherein the concentration of said pharmaceutical agent released from the medicated device to the vaginal epithelium is sufficient for transvaginal delivery of a therapeutically effective dose of said pharmaceutical agent to the uterus of the female subject. The Nuvaring product information states:

NuvaRing® (etonogestrel/ethinyl estradiol vaginal ring) is a non-biodegradable, flexible, transparent, colorless to almost colorless, combination contraceptive vaginal ring containing two active components, a progestin, etonogestrel (13-ethyl-17-hydroxy-11-methylene-18,19-dinor-17 α -pregn-4-en-20-yn-3-one) and an estrogen, ethinyl estradiol (19-nor-17 α -pregna-1,3,5(10)-trien-20-yne-3, 17-diol). When placed in the vagina, each ring releases on average 0.120 mg/day of etonogestrel and 0.015 mg/day of ethinyl estradiol over a three-week period of use.

Excerpt from Exhibit 7 at 1.

NuvaRing® contains a combination of a progestin and estrogen, two kinds of female hormones. You insert the ring in your vagina and leave it there for three weeks. After the ring is inserted, it releases a continuous low dose of hormones into your body. You then remove it for a one-week ring-free period.

Excerpt from Exhibit 7 at 5. The Nuvaring website further states that; “NuvaRing® contains 2 types of hormones: estrogen and progestin, which work together to prevent your ovaries from producing mature eggs. These are the same hormones found in the Pill, and they work the same way in your body even though they are administered differently with NuvaRing®.” And “With NuvaRing®, hormone release is activated once the ring comes into contact with your vagina. The hormones are then absorbed and distributed into your bloodstream.” Excerpt from Nuvaring website (Exhibit 46):

http://www.nuvaring.com/Consumer/aboutNuvaRing_/howDoesItWork/index.asp. In addition, it is well known that NuvaRing works by stopping ovulation and altering the cervical mucus and lining of the uterus. *See, e.g.*, Exhibits 46, <http://women.emedtv.com/nuvaring/nuvaring.html> and <http://www.drugs.com/nuvaring.html>

4.7 As set forth in Exhibit 13, the Nuvaring product is shipped into the United States from Rotterdam, Netherlands to New York, New York by Schering-Plough Corporation.

4.8 The remaining On-line Pharmacy Respondents sell the accused Nuvaring product into the United States, sell the accused Nuvaring product for importation into the United States, and/or sell the accused Nuvaring products after they have been imported into the United States.

B. Related Merck Patent

4.9 As shown above, infringement is clear from the Nuvaring product information and website. Moreover, on information and belief and as set forth in Exhibit 9, evidence of infringement by the accused Nuvaring product is also demonstrated given that at least claim 1 of Merck's U.S. Patent No. 5,989,581 (the '581 patent") infringes claim 1 of the '909 patent. The Nuvaring product is registered in the Orange Book, which lists products that have been approved by the U.S. Food and Drug Administration under Section 505. The Orange Book registration for Nuvaring is attached as Exhibit 47 and was filed by Organon USA, Inc. The Orange Book registration identifies the product as a vaginal ring with active ingredients of ethinyl estradiol and etonogestrel. The Orange Book also lists applicable patent exclusivity for the product as being the '581 patent. A copy of the '581 patent is attached as Exhibit 8.

4.10 The '581 patent is entitled "Drug Delivery System for Two or More Active Substances" and was filed on April 8, 1998 by Akzo Nobel N.V., a predecessor in interest to the Merck respondents. The '581 patent claims priority under 35 U.S.C. §119 to European Patent Office 97201098 filed on April 11, 1997.

4.11 The '909 Patent was filed on May 15, 1990 approximately 5 weeks after the '581 patent, but is entitled to the benefit of the U.S. provisional filing of June 11, 1997, prior to the April 8, 1998 United States filing date of the '581 patent. On information and belief, for the purpose of determining prior art, *the In re Hilmer* doctrine and the invention outside of the U.S. prevents the use of the '581 patent as prior art to the '909 patent. Moreover, on information and belief, the Merck Respondents are estopped

from alleging that the accused product is not covered by the '581 patent by virtue of their listing the '581 patent in the Orange Book for the purpose of gaining FDA exclusivity.

V. THE '909 PATENT

A. Identification of the Patent and Ownership by Femina

5.1 The '909 Patent is entitled "Device and Method for Treatment of Dysmenorrhea" and issued July 11, 2000. The '909 Patent issued from U.S. Patent Application No. 09/249,963, filed on February 12, 1999, which is a continuation-in-part of U.S. Patent Application No. 09/079,897, filed on May 15, 1998. The '909 Patent claims priority to Provisional Application No. 60/049,325, filed on June 11, 1997.

Exhibits 1 and 5 as well as Appendix A.

5.2 Femina is the owner of the '909 patent as set forth in the Certified copies of the assignments filed with the U.S. Patent and Trademark Office as well as the true and accurate assignment from UMD to Femina. Exhibits 2 and 3.

5.3 Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by Appendix containing: (A) Four copies of the file history of the '909 Patent, (B) four copies of each patent and applicable pages of each technical reference mentioned in that prosecution history, and (C) Three CONFIDENTIAL copies of pending license covering the '909 patent.

B. Non-Technical Description of the Patented Invention¹

5.4 The '909 patent relates to an intravaginal drug delivery system coating an appropriate pharmaceutical agent incorporated into a pharmaceutically acceptable carrier whereby the pharmaceutical agent is released into the vagina and absorbed through the vaginal mucosal.

C. Foreign Counterparts of the '909 Patent

5.5 The foreign counter-parts to the '909 patent as listed in the Thompson-Delphion database and their associated status is set forth in Exhibit 48. An index of the country codes used there in is set forth in Exhibit 49.

VI. UNLAWFUL AND UNFAIR ACTS OF PROPOSED RESPONDENTS

6.1 On information and belief, proposed Merck Respondents' accused Nuvaring product directly infringe (35 U.S.C. §271(a)) and contributes to and/or induces others to infringe (35 U.S.C. §271(b) and (c)) at least claim 1 of the '909 patent. Discovery may reveal that proposed respondents infringe additional claims of the asserted patents. A representative claim charts applying independent claim 1 is attached as Exhibit 9.

6.2 On information and belief, proposed CVS Respondents, the Wal-Mart Respondent, the Walgreen Respondent and the On-line Pharmacy Respondents directly infringe (35 U.S.C. §271(a)) and contributes to and/or induces others to infringe (35

¹ The content of this Complaint, including this section (i.e., "Non-Technical Description of the Patented Invention"), does not, and is not intended to, construe either the specification or claims of the '909 Patent.

U.S.C. §271(b) and (c)) at least claim 1 of the '909 patent. Discovery may reveal that proposed respondents infringe additional claims of the asserted patents.

6.2.1 The proposed respondents' use, sale, offer for sale and/or importation of the accused Nuvaring directly infringe at least claim 1 of the '909 patent.

6.3 On information and belief, there is no substantial non-infringing use for the accused Nuvaring product.

6.4 The proposed respondents will be given notice of their infringement of the '909 patent by at least the service and filing of this Complaint as well as through the sending or a courtesy copy to each Respondent simultaneously with this filing.

6.5 In addition, on or about May 20, 2010 Merck was provided with notice of infringement of the '909 patent and the accused Nuvaring product. CONFIDENTIAL Exhibit 10. Further, on information and belief, the proposed Merck respondents knowingly sell to and induced other respondents to sell and import Nuvaring into the United States and for use in the United States.

6.6 On information and belief, the accused products is manufactured at least in Oss Norway (Exhibit 6) and imported into the United States, sold for importation, sold within the United States after importation by the proposed Merck respondents. Exhibit 13.

6.7 On information and belief, the accused products when imported into the United States are classified under the Pharmaceutical Appendix to Chapter 85 of the 2008 Harmonized Tariff Schedule of the United States. Femina believes that the unlawful importation occurs under one or more of the following subheadings: Etonogestryl 54048-10-1 and Ethinyl Estradiol 57-63-6. Exemplary photo of the product and of the package

insert are attached to this Complaint as Exhibits 5 and 6. Discovery may reveal additional products that infringe.

VII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE

7.1 On information and belief, the Merck Respondents manufacture the infringing Nuvaring Product in Oss, Netherlands. Exhibit 6. Moreover, as set forth in Exhibit 13, Nuvaring is imported into the United States from the Netherlands by Schering Plough Corporation. For example, on August 9, 2010 a 3,333kg shipment of Nuvaring was shipped from the Netherlands to New York, New York for Schedring Plough Corporation.

7.2 As set forth in the CONFIDENTIAL Exhibit 10, on or about December 2010, the CVS Pharmacy at 9578 Harding Avenue, Surfside Florida 33154 area had the accused Nuvaring product in stock.

7.3 As set forth in CONFIDENTIAL Exhibit 10, on or about January 5, 2010, Walgreens at 100 Lincoln Road, Miami Beach, Florida had the accused Nuvaring product in stock.

7.4 As set forth in CONFIDENTIAL Exhibit 10, on or about January 5, 2010, Walmart at 300 West Copans Road, Pompano Beach, Florida had the accused Nuvaring product in stock.

7.5 With respect to the Canamerican Drugs Inc. respondents, as set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 800.454.1106 (www.77pharmacy.com) where an individual taking orders explained that Nuvaring is offered from Canada and is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States.

7.6 With respect to the Canamerican Global Inc. respondent, as set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 888.788.1112 (www.canamericanglobal.com) where an individual taking orders explained that Nuvaring is offered from Canada and is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States.

7.7 With respect to the Canadian Med Services. respondent as set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 888.600.4955 (www.canadianmedservices.com) where an individual taking orders explained that Nuvaring is offered from Canada and is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States.

7.8 With respect to the Panther Meds Inc. respondent, as set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 866.353.2236 (www.panthermeds.com) where an individual taking orders explained that Nuvaring is offered from Canada and is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States.

7.9 With respect to the Canada Drugs Online respondent, as set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 877.900.3784 (www.canadadrugsonline.com) where an individual taking orders explained that Nuvaring is offered from Canada and is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States.

7.10 With respect to the Drug World Canada respondent, as set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 866.485.7979 (www.drugworldcanada.com) where an individual taking orders explained that Nuvaring

is offered from Canada and is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States.

7.11 With respect to the CanDrug Health Solutions Inc. respondent, as set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 888.488.3784 (www.candrug.com) where an individual taking orders explained that Nuvaring is offered from Canada and is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States.

7.12 With respect to the Big Mountain Drugs respondent, as set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 877.223.9977 (www.bigmountaindrugs.com) where an individual taking orders explained that Nuvaring is offered from Canada and is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States.

7.12 With respect to the BestbuyRX.com respondent, as set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 877.745.9217 (www.bestbuyrx.com) where an individual taking orders explained that Nuvaring is offered from Canada and is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States.

7.13 With respect to the Blue Sky Drugs respondent, as set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 877.995.7387 (www.blueskydrugs.com) where an individual taking orders explained that Nuvaring is offered from Canada and is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States.

7.14 With respect to the proposed ABC Online Pharmacy respondent, as set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 866.299.3784 (www.abconlinepharmacy.com) where an individual taking orders explained that Nuvaring is offered from Canada and is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States.

7.15 With respect to the proposed Canada Drugs LP respondent, as set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 800.226.3784 (www.canadadrugs.com) where an individual taking orders explained that Nuvaring is offered from Canada and is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States.

7.16 With respect to the proposed North Drug Store respondent, as set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 866.940.3784 (www.northdrugstore.com) where an individual taking orders explained that Nuvaring is offered from Canada and is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States.

7.17 With respect to the proposed Canada Pharmacy respondent, as set forth in CONFIDENTIAL Exhibit 10, a phone call was placed to 888.269.2168 (www.canadapharmacy.com) where an individual taking orders explained that Nuvaring is offered from Canada and is sold into the United States. The individual confirmed that Nuvaring has been sold by the website into the United States.

II. LICENSE

8.1 There are two pending licenses under the '909 patent copies of which are attached as CONFIDENTIAL Appendix C.

8.2 On or about, November 2001, Kimberly-Clark Corporation, Kimberly-Clark Worldwide Inc. and UMD, Inc entered into a Joint Development Agreement relating to the technology claimed in the '909 patent. CONFIDENTIAL Exhibit 11. The Joint Development Agreement was terminated in part on or about December 21, 2005 at which point all rights associated with the '909 patent reverted to UMD, Inc. In February 2010, Femina purchased all of the assets of UMD, Inc., including all rights under the Kimberly-Clark Agreement. CONFIDENTIAL Exhibit 4.

III. DOMESTIC INDUSTRY

9.1 A domestic industry, as defined by 19 U.S.C. § 1337(a)(3)(A), (B) and (C), exists with respect to the Complainant's activities in the United States related to articles protected by the '909 patent by reasons of Complainant's, UMD Inc. and/or Kimberly-Clark Corporation and Kimberly-Clark Worldwide Inc.'s (a) significant investment in plant and equipment, (b) significant employment of labor and capital and (c) substantial investment in the exploitation of the '909 patent, such as substantial engineering activities, patent procurement, licensing efforts, R&D activities, consultation, manufacturing, product sales, sales support, licensing and operations.

9.2 UMD Inc. was an American company founded in 1996. Since its inception UMD Inc. operated in the U.S. with facilities in Cincinnati Ohio.

9.3 Femina is an American company founded in 2009. Femina is located at 34700 E. Coast Ave., Suite H502, Miami, Florida.

9.4 Kimberly-Clark Corporation was a Delaware corporation having an office at 351 Phelps Drive, Irving Texas 75308. Kimberly-Clark Worldwide, Inc., was a wholly owned subsidiary with offices at 401 North Lake Street, Neenah, Wisconsin 54957.

A. Technical Prong

9.5 As required by Section 337(a)(2) and defined by section 337(a)(3), an industry in the United States exists in connection with articles protected by the '909 Patent. For example, but not limited to, the UMD/Kimberly-Clark medicated tampon products that are covered in whole or in part by at least claims 1 and 16 of the '909 patent. Representative claim charts applying claims 1 and 16 of the '909 patent is attached as CONFIDENTIAL Exhibit 12.

9.6 A domestic industry exists through substantial investment in the '909 Patent through the research and development and licensing efforts made by UMD, Inc., Kimberly-Clark Corporation, Kimberly-Clark Worldwide, Inc. and/or Femina and UMD. See CONFIDENTIAL Exhibit 12.

B. Economic Prong

9.7 Femina's conducts, UMD Inc.'s conduct, Kimberly-Clark Corporation's conduct, and/or Kimberly-Clark Worldwide, Inc.'s conduct amounts to a significant domestic industry activities in the United States relating to its domestic industry products. Because the Femina, UMD, Inc., Kimberly-Clark Corporation and/or Kimberly-Clark Worldwide, Inc. products and/or activities are covered in whole or in part by at least one

claim of the '909 Patent, the following investment information shows the existence of a domestic industry. CONFIDENTIAL Exhibit 10.

9.8 Femina, UMD, Inc., Kimberly-Clark Corporation and/or Kimberly-Clark Worldwide, Inc. domestic industry activities include the significant investment in plant and equipment, significant employment of labor and capital and substantial investment in its exploitation, including engineering, R&D and licensing efforts. Femina continues to conduct many activities in the United States relating to the '909 patent including significant investment in employment of labor and capital and substantial investment in its exploitation, including partnering and licensing efforts. CONFIDENTIAL Exhibit 10.

XI. RELATED LITIGATION

10.1 The '909 patent has not been the subject of any court or agency litigation in the United States or overseas.

XII. REQUESTED RELIEF

11.1 WHEREFORE, by reason of the foregoing, Complainant requests that the United States International Trade Commission:

(a) Institute and immediate Investigation, pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, into the unlawful importation into the United States the sale for importation, and/or sale within the United States after importation by the proposed respondents and others of the accused Nuvaring product that infringes at least one claim of United States Patent No. 6,086,909;

(b) Determine that there has been a violation of Section 337;

(c) Issue a permanent general exclusion order, pursuant to Section 337(d) of the Tariff Act of 1930, as amended, excluding from entry into the United States

of the accused product and any discovered variants thereof that infringe one or more claims of United States Patent No. 6,086,909;

(d) In the alternative, issue a permanent limited exclusion order, pursuant to Section 337(d) of the Tariff Act of 1930, as amended, excluding from entry into the United States all Nuvaring and any discovered variants thereof that are manufactured, imported, or sold by or on behalf of the proposed respondents, their affiliates, subsidiaries, successors, or assigns, and components thereof, that infringe one or more claims of United States Patent No. 6,086,909;

(e) Issue permanent cease and desist orders, pursuant to Section 337(f) of the Tariff Act of 1930, as amended, directing each proposed respondent, its affiliates, subsidiaries, successors, or assigns, from marketing, demonstrating, distributing, offering for sale, selling, or otherwise transferring, including the movement or shipment of inventory, in the United States, or transferring outside the United States for sale in the United States all Nuvaring and any discovered variants thereof that infringe one or more claims of United States Patent No. 6,086,909; and

(f) Issue such further relief as the Commission deems just and proper based on the facts determined by the Investigation and the authority of the Commission.

Respectfully submitted,

THE FUISZ-KUNDU GROUP LLP

Dated: _____, 2011

By: _____

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