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UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF FLORIDA  
JACKSONVILLE DIVISION

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JOHNSON & JOHNSON  
VISION CARE, INC.,

Plaintiff,

v.

CIBA VISION CORPORATION,

Defendant.

Civil Action No. 3:04-cv-1297-J-20mmH

JURY TRIAL DEMANDED

**COMPLAINT**

Plaintiff Johnson & Johnson Vision Care, Inc. ("J&J Vision Care"), by its undersigned attorneys, complains of Defendant CIBA Vision Corporation ("CIBA"), and alleges as follows:

1. This Complaint comprises five counts. Counts I through V are for a declaratory judgment pursuant to 28 U.S.C. §§2201 and 2202 that United States Patent Nos. 5,760,100; 5,776,999; 5,789,461; 5,849,811 and 5,965,631 (collectively "the Nicolson patents," attached at Tabs A-E) are not infringed by Plaintiff and/or are invalid and/or are unenforceable. This case involves the same Nicolson patents that are at issue in *Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corporation*, Case No. 3:03-cv-800-J-99TEM, currently pending in this Court before Judge Corrigan.

**Parties**

2. Plaintiff J&J Vision Care is a corporation incorporated and existing under the laws of the State of Florida with its principal place of business at 7500 Centurion Parkway,

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Suite 100, Jacksonville, Florida 32256. J&J Vision Care is engaged in the business of manufacturing ophthalmic goods.

3. On information and belief, Defendant CIBA is a corporation incorporated and existing under the laws of the State of Delaware with its principal place of business at 11460 Johns Creek Parkway, Duluth, Georgia 30097. CIBA is engaged in the business of manufacturing ophthalmic goods.

4. On information and belief, CIBA is an owner by assignment of the Nicolson patents. CIBA is the owner of the Nicolson patents with the present right to sue and recover damages for infringement of the Nicolson patents.

#### **Jurisdiction and Venue**

5. Jurisdiction for Counts I through V arise under 28 U.S.C. §§1331, 1338(a), 2201 and 2202.

6. On information and belief, this Court has personal jurisdiction over CIBA because CIBA is doing business in the State of Florida and in this judicial district and division.

7. Venue in this Court is proper pursuant to 28 U.S.C. §§1391 and 1400(b).

#### **Background**

8. CIBA and J&J Vision Care are direct competitors in certain segments of the market of ophthalmic goods, including certain segments of the contact lens market.

9. The Nicolson patents generally concern contact lenses as well as methods of using, screening and forming extended wear contact lenses.

10. On information and belief, CIBA and Commonwealth Scientific and Industrial Research Organisation (“CSIRO”) are joint owners of the Nicolson patents. CSIRO is an Australian company having its principal place of business in Campbell, Australia.

11. On information and belief, CSIRO may not commence patent infringement litigation on the Nicolson patents unless CIBA waives its right to initiate patent litigation by failing to file a claim for infringement within ninety days of notice of alleged infringement. On information and belief, CIBA has been and will continue to be the party responsible for initiating patent litigation on the Nicolson patents in the United States.

12. J&J Vision Care has developed a new line of silicone hydrogel contact lenses. The new lenses will be sold under the Acuvue Advance name, and are “toric” lenses that correct for astigmatism (“Acuvue Advance toric”). Unlike regular spherical contact lenses, toric lenses, including Acuvue Advance toric, have two powers, created with curvatures at different angles. These lenses remain relatively stable on the eye when a patient blinks or looks around. Toric lenses are designed to minimize rotation on the eye.

13. The new Acuvue Advance toric lenses are daily wear lenses, *i.e.*, the lenses are put in and taken out of the eye every day. The Acuvue Advance toric lenses are made from a material called “galyfilcon A.”

14. As discussed below, J&J Vision Care has made meaningful preparations to manufacture, sell and use its Acuvue Advance toric contact lenses in the United States. Specifically, J&J Vision Care has been developing the Acuvue Advance toric lenses for several years. J&J Vision Care first filed for regulatory clearance of these lenses with the United States Food and Drug Administration (“FDA”) on July 28, 2003, and was granted FDA clearance on October 16, 2003. J&J Vision Care began limited manufacturing of its Acuvue Advance toric contact lenses in the last several months and is preparing for high volume manufacturing in December 2004 in Jacksonville to prepare for the upcoming full commercial launches, which are expected to be in the first half of 2005 in the United States.

15. Tests conducted using the polarographic method by J&J Vision Care demonstrate that certain powers of Acuvue Advance toric contact lenses have an approximate oxygen transmissibility value of 85 barrers/mm. In view of these test results, J&J Vision Care understands CIBA's position to be that such lenses infringe the Nicolson patents. In another lawsuit in this Court, CIBA has accused J&J Vision Care's Acuvue Advance Brand Contact Lenses With Hydraclear ("Acuvue Advance with Hydraclear")—also made from galyfilcon A—of infringement based on an oxygen transmissibility value of 85 determined by the polarographic method. Consequently, J&J Vision Care was and is apprehensive that CIBA will sue J&J Vision Care for alleged infringement of its new Acuvue Advance toric contact lenses.

16. J&J Vision Care has already invested a substantial amount of time, money and planning into the production and sales of its Acuvue Advance toric contact lenses. J&J Vision Care has over 100 people in its Jacksonville facility working on the manufacture, production and marketing of these lenses, has purchased the necessary equipment and supplies and has developed and implemented manufacturing processes. The production line is operating, and will shortly be producing over 18,000 lenses a day. J&J Vision Care has incurred millions of dollars in costs relating to research and development, testing, regulatory approval expenses, manufacturing and marketing of these lenses.

17. J&J Vision Care's marketing preparations began this year and have moved quickly to accommodate the upcoming commercial launches. J&J Vision Care has exhibited Acuvue Advance toric lenses to consumers, eye care professionals and sales representatives. J&J Vision Care recently began distributing Acuvue Advance toric lenses to a limited number of trained eye care professionals who participated in a new product advisory panel.

18. Based on CIBA's ongoing litigation with J&J Vision Care, J&J Vision Care has a reasonable apprehension of being sued by CIBA for the Acuvue Advance toric's alleged infringement of the Nicolson patents. In two separate lawsuits, CIBA has accused J&J Vision Care of infringing at least three of the Nicolson patents. First, in a case filed in this Court, *Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp.*, Case No. 3:03-cv-800-J-99TEM, CIBA has accused J&J Vision Care's daily wear Acuvue Advance with Hydraclear lenses of infringing three of the Nicolson patents. Subsequently, in June 2004, CIBA filed a complaint against J&J Vision Care in the U.S. District Court for the Northern District of Georgia, *CIBA Vision Corp. v. Johnson & Johnson Vision Care, Inc.*, Case No. 2:04-cv-01150 RWS, accusing the same lenses of infringing the same Nicolson patents. The Acuvue Advance toric lens is made of galyfilcon A, the same material as the Acuvue Advance with Hydraclear lenses, and has the same oxygen transmissibility values. Thus, based on CIBA's current assertions of infringement against lenses made from the same material, J&J Vision Care has a reasonable apprehension that it will be sued for infringement of the Nicolson patents for its new Acuvue Advance toric lenses.

19. CIBA's prior dealings with J&J Vision Care have also given rise to J&J Vision Care's reasonable apprehension of being sued. In 2002, J&J Vision Care and CIBA had discussions relating to a potential patent arbitration and cross-licensing agreement relating to patents held by both parties concerning contact lens technology, including the Nicolson patents. At a September 2002 meeting on this potential agreement with CIBA, J&J Vision Care representatives indicated that any cross-licensing arrangement would have to include the Nicolson patents. J&J Vision Care informed CIBA that it was investigating different formulations for contact lenses. CIBA responded that CIBA's position was that the Nicolson

patents were pioneering patents with such a broad scope that any working extended wear contact lens would infringe the claims of the Nicolson patents.

20. After the meeting, CIBA wrote to J&J Vision Care concerning the potential cross-licensing agreement, but failed to include any discussion of a potential license to the Nicolson patents. J&J Vision Care responded, reiterating J&J Vision Care's interest in "the right to practice under the Nicholson [sic] patents, should it turn out that we need a license under those patents." J&J followed up with another proposal. CIBA responded to these proposals by stressing that "CIBA Vision has no desire to license" its Nicolson patents, and indicated that in CIBA's view, J&J Vision Care's proposal on the Nicolson patents was "a non-starter." In its discussion of the Nicolson patents, CIBA also specifically threatened that in any litigation, "CIBA Vision will seek an injunction pursuant to 35 U.S.C. §283 that takes and keeps Johnson & Johnson off of the market until the last of CIBA Vision's patents expire." CIBA concluded that it did "not see any options to proceed with negotiation, mediation or arbitration."

21. CIBA then made a "proposal" to J&J Vision Care concerning the Nicolson patents with royalty provisions J&J Vision Care considered so exorbitant as to have been economically unfeasible. CIBA also rejected J&J Vision Care's proposal to arbitrate any future patent disputes. J&J Vision Care declined CIBA's licensing proposal regarding the Nicolson patents. The parties engaged in no further negotiations relating to the Nicolson patents.

22. The next communication from CIBA relating to the Nicolson patents was in May 2003, and recognized that earlier discussions between the parties had ended "on a negative note." CIBA referred J&J Vision Care to CIBA's patent litigation with Bausch & Lomb ("B&L") in the U.S. District Court for the Northern District of Georgia in which CIBA was suing B&L for infringing the Nicolson patents with its sale of B&L's extended wear silicone

hydrogel soft disposable contact lens. CIBA enclosed a copy of a ruling from the B&L litigation concerning the scope of the Nicolson patents. CIBA also reiterated its previous request to obtain samples of J&J Vision Care's lenses, threatening to use those samples "solely for the purposes of determining whether infringement will occur upon sale."

23. In addition to CIBA's two patent lawsuits against J&J Vision Care and the B&L contact lens litigation, J&J Vision Care is also aware that CIBA (through its wholly-owned subsidiary, Wesley Jessen Corporation) had sued B&L in the District of Delaware for infringing a patent relating to contact lens materials. In that lawsuit, CIBA obtained a permanent injunction preventing B&L from manufacturing or selling its extended wear silicone hydrogel lenses until the patent at issue in that case expires in 2005.

24. Recognizing that it had a reasonable apprehension of being sued by CIBA for its Acuvue Advance with Hydraclear lenses, J&J Vision Care filed a declaratory judgment lawsuit in this Court in September 2003. CIBA moved to dismiss the Complaint on the basis that J&J had not alleged the existence of an actual controversy. The Court denied CIBA's motion, and that case is currently pending before Judge Corrigan.

#### **CIBA's Actions In The Patent Office**

25. During the original prosecution and during the reexamination of the Nicolson patents, CIBA knowingly submitted false information or failed to disclose material information to the U.S. Patent and Trademark Office ("PTO"). Many of the facts germane to these actions are confidential, and cannot be set forth in the public record. Nevertheless, J&J Vision Care provides a summary of the actions that are in the public record.

26. Specifically, CIBA failed to disclose material prior art to the PTO during both the original prosecution and the reexamination. This material prior art includes a 510(k)

submission by B&L, a B&L lens in development, and an article entitled “Surface Characterization of Oxidized Silicone Hydrogel” by Dr. George Grobe. These references were known by CIBA inventors as disclosing information material to the patentability of the Nicolson claims, but were not submitted to the PTO.

27. CIBA also failed to disclose material information concerning a prior art patent, known as the “Nandu patent,” which was the basis for the PTO’s rejection of the Nicolson patent claims. Despite a request by the PTO for CIBA to disclose oxygen permeability values for the Nandu patent that CIBA had recreated, CIBA failed to do so, and also withheld material information concerning the thickness of the lenses used during the recreation. This information was known to CIBA inventors, was material to the patentability of the lenses, but was not provided to the PTO.

28. Moreover, during the reexamination of the patents-in-suit, one of the inventors, Paul Nicolson signed an affidavit in which he stated that CIBA discovered the need for surface modification of silicone hydrogels to achieve ophthalmic compatibility of the inner and outer surfaces of the lens. This statement was knowingly false in light of the existence of B&L’s publicly disclosed work.

29. CIBA also knowingly failed to disclose to the PTO that the materials CIBA disclosed in Example A of the patents-in-suit were not novel, but were developed by two CIBA employees who were not listed as inventors of the patent. CIBA also failed to disclose that the lens materials disclosed in Example A were not stable and had poor shelf life, a fact known by CIBA prior to filing the patent application. However, the Nicolson patent applications each expressly state that the inventive contact lenses have “high dimensional stability and shelf life.” This was a materially false statement.



**COUNT I: DECLARATION OF NON-INFRINGEMENT,  
INVALIDITY AND UNENFORCEABILITY  
OF U.S. PATENT NO. 5,760,100**

30. Paragraphs 1-29 of the Complaint are incorporated herein by reference.

31. CIBA's actions and statements have caused J&J Vision Care to have a reasonable apprehension of facing suit by CIBA for direct patent infringement, contributory infringement and/or inducement of infringement of U.S. Patent No. 5,760,100 ("100 patent").

32. J&J Vision Care's Acuvue Advance toric contact lenses do not infringe any valid claim of the '100 patent. Consequently, J&J Vision Care's manufacture, sale, use or other activities with respect to Acuvue Advance toric contact lenses do not infringe, contributorily infringe or induce infringement of any valid claim of the '100 patent.

33. J&J Vision Care has not infringed, contributorily infringed or induced infringement of any valid claim of the '100 patent.

34. All claims of the '100 patent are invalid because of a failure to meet one or more of the conditions for patentability specified in Title 35 of the United States Code, including but not limited to Sections 101, 102, 103 and/or 112.

35. All claims of the '100 patent are unenforceable because of inequitable conduct in the United States Patent and Trademark Office during the original prosecution of the application that led to the '100 patent and during the reexamination of the '100 patent. As described in Paragraphs 25-29 above, CIBA knowingly made material false statements to the PTO and knowingly withheld material information from the PTO with an intent to deceive the PTO.

**COUNT II: DECLARATION OF NON-INFRINGEMENT,  
INVALIDITY AND UNENFORCEABILITY  
OF U.S. PATENT NO. 5,776,999**

36. Paragraphs 1-29 of the Complaint are incorporated herein by reference.

37. CIBA's actions and statements have caused J&J Vision Care to have a reasonable apprehension of facing suit by CIBA for direct patent infringement, contributory infringement and/or inducement of infringement of U.S. Patent No. 5,776,999 ("999 patent").

38. J&J Vision Care's Acuvue Advance toric contact lenses do not infringe any valid claim of the '999 patent. Consequently, J&J Vision Care's manufacture, sale, use or other activities with respect to Acuvue Advance toric contact lenses do not infringe, contributorily infringe or induce infringement of any valid claim of the '999 patent.

39. J&J Vision Care has not infringed, contributorily infringed or induced infringement of any valid claim of the '999 patent.

40. All claims of the '999 patent are invalid because of a failure to meet one or more of the conditions for patentability specified in Title 35 of the United States Code, including but not limited to Sections 101, 102, 103 and/or 112.

41. All claims of the '999 patent are unenforceable because of inequitable conduct in the United States Patent and Trademark Office during the original prosecution of the application that led to the '999 patent and during the reexamination of the '999 patent. As described in Paragraphs 25-29 above, CIBA knowingly made material false statements to the PTO and knowingly withheld material information from the PTO with an intent to deceive the PTO.

**COUNT III: DECLARATION OF NON-INFRINGEMENT,  
INVALIDITY AND UNENFORCEABILITY  
OF U.S. PATENT NO. 5,789,461**

42. Paragraphs 1-29 of the Complaint are incorporated herein by reference.

43. CIBA's actions and statements have caused J&J Vision Care to have a reasonable apprehension of facing suit by CIBA for direct patent infringement, contributory infringement and/or inducement of infringement of U.S. Patent No. 5,789,461 ("461 patent").

44. J&J Vision Care's Acuvue Advance toric contact lenses do not infringe any valid claim of the '461 patent. Consequently, J&J Vision Care's manufacture, sale, use or other activities with respect to Acuvue Advance toric contact lenses do not infringe, contributorily infringe or induce infringement of any valid claim of the '461 patent.

45. J&J Vision Care has not infringed, contributorily infringed or induced infringement of any valid claim of the '461 patent.

46. All claims of the '461 patent are invalid because of a failure to meet one or more of the conditions for patentability specified in Title 35 of the United States Code, including but not limited to Sections 101, 102, 103 and/or 112.

47. All claims of the '461 patent are unenforceable because of inequitable conduct in the United States Patent and Trademark Office during the original prosecution of the application that led to the '461 patent and during the reexamination of the '461 patent. As described in Paragraphs 25-29 above, CIBA knowingly made material false statements to the PTO and knowingly withheld material information from the PTO with an intent to deceive the PTO.

**COUNT IV: DECLARATION OF NON-INFRINGEMENT,  
INVALIDITY AND UNENFORCEABILITY  
OF U.S. PATENT NO. 5,849,811**

48. Paragraphs 1-29 of the Complaint are incorporated herein by reference.

49. CIBA's actions and statements have caused J&J Vision Care to have a reasonable apprehension of facing suit by CIBA for direct patent infringement, contributory infringement and/or inducement of infringement of U.S. Patent No. 5,849,811 ("811 patent").

50. J&J Vision Care's Acuvue Advance toric contact lenses do not infringe any valid claim of the '811 patent. Consequently, J&J Vision Care's manufacture, sale, use or other activities with respect to Acuvue Advance toric contact lenses do not infringe, contributorily infringe or induce infringement of any valid claim of the '811 patent.

51. J&J Vision Care has not infringed, contributorily infringed or induced infringement of any valid claim of the '811 patent.

52. All claims of the '811 patent are invalid because of a failure to meet one or more of the conditions for patentability specified in Title 35 of the United States Code, including but not limited to Sections 101, 102, 103 and/or 112.

53. All claims of the '811 patent are unenforceable because of inequitable conduct in the United States Patent and Trademark Office during the original prosecution of the application that led to the '811 patent and during the reexamination of the '811 patent. As described in Paragraphs 25-29 above, CIBA knowingly made material false statements to the PTO and knowingly withheld material information from the PTO with an intent to deceive the PTO.

**COUNT V: DECLARATION OF NON-INFRINGEMENT,  
INVALIDITY AND UNENFORCEABILITY  
OF U.S. PATENT NO. 5,965,631**

54. Paragraphs 1-29 of the Complaint are incorporated herein by reference.

55. CIBA's actions and statements have caused J&J Vision Care to have a reasonable apprehension of facing suit by CIBA for direct patent infringement, contributory infringement and/or inducement of infringement of U.S. Patent No. 5,965,631 ("631 patent").

56. J&J Vision Care's Acuvue Advance toric contact lenses do not infringe any valid claim of the '631 patent. Consequently, J&J Vision Care's manufacture, sale, use or other activities with respect to Acuvue Advance toric contact lenses do not infringe, contributorily infringe or induce infringement of any valid claim of the '631 patent.

57. J&J Vision Care has not infringed, contributorily infringed or induced infringement of any valid claim of the '631 patent.

58. All claims of the '631 patent are invalid because of a failure to meet one or more of the conditions for patentability specified in Title 35 of the United States Code, including but not limited to Sections 101, 102, 103 and/or 112.

59. All claims of the '631 patent are unenforceable because of inequitable conduct in the United States Patent and Trademark Office during the original prosecution of the application that led to the '631 patent. As described in Paragraphs 25-29 above, CIBA knowingly made material false statements to the PTO and knowingly withheld material information from the PTO with an intent to deceive the PTO.

WHEREFORE, Plaintiff respectfully requests that this Court:

A. Declare that J&J Vision Care does not infringe any valid and enforceable claim of United States Patent Nos. 5,760,100; 5,776,999; 5,789,461; 5,849,811 and 5,965,631;

B. Permanently enjoin and restrain CIBA and each of its officers, agents, servants, employees and those persons in active concert or participation with them from asserting that J&J Vision Care's Acuvue Advance for toric contact lenses infringe United States Patent Nos. 5,760,100; 5,776,999; 5,789,461; 5,849,811 and/or 5,965,631;

C. Declare that all claims of United States Patent Nos. 5,760,100; 5,776,999; 5,789,461; 5,849,811 and 5,965,631 are invalid;

D. Declare that all claims of United States Patent Nos. 5,760,100; 5,776,999; 5,789,461; 5,849,811 and 5,965,631 are unenforceable.

E. Award J&J Vision Care its reasonable attorney fees and costs; and

F. Award J&J Vision Care such other and further relief as the Court deems just.

#### **DEMAND FOR JURY TRIAL**

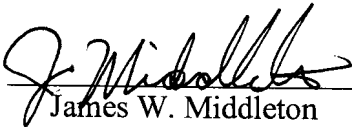
J&J Vision Care demands trial by jury of all issues so triable as of right by a jury.

Respectfully submitted,

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