

FILED

UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF FLORIDA  
JACKSONVILLE DIVISION

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JOHNSON & JOHNSON VISION  
CARE, INC.,

CIVIL ACTION NO.: 3:05-cv-135-J-12MMH

Plaintiff,

JURY TRIAL DEMANDED

v.

CIBA VISION CORPORATION,

Defendant.

**COMPLAINT FOR DAMAGES, DECLARATORY AND INJUNCTIVE RELIEF**

Plaintiff, Johnson & Johnson Vision Care, Inc. ("Johnson & Johnson"), 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.

2. The parties to this case currently have two other patent infringement matters pending in this Court before Judge Corrigan: *Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corporation*, Case No. 3:03-cv-800-J-99TEM and *Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corporation*, Case No. 3:04-cv-1297-J-32TEM. Those two cases primarily relate to Johnson & Johnson's first two silicone hydrogel contact lens products -- the ACUVUE ADVANCE with HYDRACLEAR lenses -- and the Nicolson patents. Hereinafter, those cases

are singularly and/or collectively referred to as the “Acuvue Advance Case” or “Acuvue Advance Cases.”

3. As described in detail below, the present case relates to Johnson & Johnson’s newest silicone hydrogel contact lens product -- the Phoenix contact lens -- and CIBA’s Nicolson patents.

### **PARTIES**

4. Plaintiff Johnson & Johnson is a corporation incorporated and existing under the laws of the State of Florida with its principal place of business at 7500 Centurion Parkway, Suite 100, Jacksonville, Florida 32256. Johnson & Johnson is engaged in the business of manufacturing ophthalmic goods.

5. 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.

6. 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.

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

8. 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.

### **JURISDICTION AND VENUE**

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

10. 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.

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

### **BACKGROUND**

12. CIBA and Johnson & Johnson are direct competitors in certain segments of the market for ophthalmic goods, including certain segments of the contact lens market.

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

### **Development of Johnson & Johnson's Silicone Hydrogel Contact Lenses**

14. Prior to completing the development of its Phoenix lenses at issue in this case, Johnson & Johnson developed silicone hydrogel materials and manufacturing processes for its ACUVUE ADVANCE with HYDRACLEAR line of contact lenses. Johnson & Johnson markets two types of ACUVUE ADVANCE with HYDRACLEAR contact lenses: spherical lenses and toric lenses. Spherical lenses are used to correct various ocular conditions such as myopia (nearsightedness) and hyperopia (farsightedness). Toric lenses are used primarily to correct astigmatism. Toric lenses differ from spherical lenses in that they have two powers which are created by curvatures at different angles. The Acuvue Advance Cases relate to the ACUVUE ADVANCE with HYDRACLEAR spherical and toric lenses.

15. One characteristic of a contact lens is its oxygen transmissibility. Generally, it relates to the amount of oxygen that can pass through a certain thickness of the lens. This characteristic is measured as a value commonly referred to as Dk/t. The Nicolson patents contain limitations claiming various Dk/t values.

16. Johnson & Johnson used the polarographic method to measure the oxygen transmissibility value of its ACUVUE ADVANCE with HYDRACLEAR lenses. Certain powers of both the spherical and toric lenses have a Dk/t value of 85.

17. Johnson & Johnson has continued its development of silicone hydrogel contact lenses. This development was done under the project name "Phoenix" and resulted in the Phoenix lenses. Certain powers of the Phoenix lenses have a Dk/t value higher than 85 when tested using the polarographic method.

**Johnson & Johnson's Preparation for Commercial Launch of the Phoenix Lenses**

18. As discussed below, Johnson & Johnson has made meaningful preparations to manufacture, sell and use its Phoenix contact lenses in the United States. Specifically, Johnson & Johnson has been developing the Phoenix lenses for several years. Johnson & Johnson first filed for regulatory clearance of these lenses with the United States Food and Drug Administration ("FDA") on August 20, 2004, and was granted FDA clearance on October 29, 2004. Johnson & Johnson began manufacturing its Phoenix contact lenses last year and is currently producing approximately 30,000 lenses per day in Jacksonville, Florida to prepare for the upcoming domestic commercial launch, which is expected to occur in the first half of 2005.

19. Johnson & Johnson has already invested a substantial amount of time, money and planning into the production and sales of its Phoenix contact lenses. Johnson & Johnson has over 400 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 that are separate from those processes for ACUVUE ADVANCE with HYDRACLEAR. The production line is operating, and is currently producing more than 30,000 lenses per day. Johnson & Johnson has incurred millions of dollars in costs relating to research and development, testing, regulatory approval, manufacturing and marketing of these lenses.

20. Johnson & Johnson's marketing preparations began late last year and have moved quickly to accommodate the upcoming commercial launch. Johnson & Johnson has exhibited Phoenix lenses to eye care professionals in Europe. In or about February 2005, Johnson & Johnson will begin distributing Phoenix lenses to a limited number of trained eye care professionals in the United States who will participate in a new product advisory panel and can fit their patients with the Phoenix lenses.

**Johnson & Johnson Reasonably Apprehends Suit by CIBA Related to the Phoenix Lenses**

21. As described below, Johnson & Johnson has a reasonable apprehension of being sued by CIBA for the Phoenix lenses' alleged infringement of the Nicolson patents. In two separate lawsuits, CIBA has accused Johnson & Johnson's silicone hydrogel contact lenses of infringing at least three of the Nicolson patents. In the first Acuvue Advance Case filed in this Court, *Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp.*, Case No. 3:03-cv-800-J-99TEM, CIBA accused Johnson & Johnson's first silicone hydrogel lens of infringing three of the Nicolson patents. Subsequently, in June 2004, CIBA filed a complaint against Johnson & Johnson in the U.S. District Court for the Northern District of Georgia captioned *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 Georgia lawsuit has now been dismissed.

22. CIBA's actions give rise to Johnson & Johnson's reasonable apprehension of being sued for its latest silicone hydrogel contact lenses. CIBA has already accused Johnson & Johnson's ACUVUE ADVANCE lenses of infringement based on a lower oxygen transmissibility value than the Phoenix lenses. In view of CIBA bringing infringement claims against the ACUVUE ADVANCE lenses, Johnson & Johnson understands CIBA's position to be that lenses with a Dk/t value of at least 85 (as measured by the polarographic method) infringe the Nicolson patents. Consequently, Johnson & Johnson was and is apprehensive that CIBA will sue Johnson & Johnson for alleged infringement of the Nicolson patents by its new Phoenix contact lenses.

23. In addition, Johnson & Johnson and CIBA held discussions in 2002 relating to a potential patent cross-licensing and arbitration agreement relating to patents held by both parties concerning contact lens technology, including the Nicolson patents. At a September 2002 meeting concerning this potential agreement, Johnson & Johnson representatives indicated that any cross-licensing arrangement would have to include the Nicolson patents. Johnson & Johnson informed CIBA that it was investigating different formulations for contact lenses. CIBA responded with its position that the Nicolson patents were pioneering patents covering a broad scope such that any working extended wear contact lens would infringe the claims of the Nicolson patents.

24. After the meeting, CIBA wrote to Johnson & Johnson concerning the potential cross-licensing agreement, but failed to include any discussion of a potential license to the Nicolson patents. Johnson & Johnson then reiterated its interest in "the right to practice under

the Nicholson [sic] patents, should it turn out that we need a license under those patents,” and followed-up with another proposal. CIBA responded to these proposals by stressing that “CIBA Vision has no desire to license” its Nicholson patents, and indicated that in CIBA’s view, Johnson & Johnson’s proposal on the Nicholson patents was “a non-starter.” In its discussion of the Nicholson 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.”

25. CIBA then made a “proposal” to Johnson & Johnson concerning the Nicholson patents with royalty provisions Johnson & Johnson considered so exorbitant as to have been economically unfeasible. CIBA also rejected Johnson & Johnson’s proposal to arbitrate any future patent disputes. Johnson & Johnson declined CIBA’s licensing proposal regarding the Nicholson patents. The parties engaged in no further negotiations relating to the Nicholson patents.

26. The next communication from CIBA relating to the Nicholson patents, dated May 2003, recognized that earlier discussions between the parties had ended “on a negative note.” CIBA referred Johnson & Johnson 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 sued B&L for infringing the Nicholson patents based on its sale of B&L’s silicone hydrogel contact lenses. CIBA enclosed a copy of a ruling from the B&L litigation concerning the scope of the Nicholson patents. CIBA also reiterated its previous request to obtain samples of Johnson & Johnson’s lenses, threatening to use those samples “solely for the purposes of determining whether infringement will occur upon sale.”

27. In addition to CIBA's allegations in two patent lawsuits against Johnson & Johnson's silicone hydrogel contact lenses and CIBA's litigation with B&L concerning its silicone hydrogel contact lenses, Johnson & Johnson 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.

28. Recognizing that it had a reasonable apprehension of being sued by CIBA for its first silicone hydrogel contact lenses -- the ACUVUE ADVANCE with HYDRACLEAR spherical lenses -- Johnson & Johnson filed the first Acuvue Advance Case in this Court in September 2003, seeking a declaratory judgment of non-infringement, invalidity and unenforceability of the Nicolson patents. CIBA moved to dismiss the Complaint on the basis that Johnson & Johnson had not alleged the existence of an actual controversy. The Court denied CIBA's motion, and that case is currently pending in this Court before Judge Corrigan.

29. In December 2004, Johnson & Johnson filed the second Acuvue Advance Case seeking a similar declaration from this Court based on its reasonable apprehension of being sued by CIBA for its second silicone hydrogel contact lens -- the ACUVUE ADVANCE toric lenses. That case also is currently pending before Judge Corrigan. CIBA has not yet filed a response to this complaint.

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

30. 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, Johnson & Johnson provides a summary of the actions that are in the public record.

31. Specifically, CIBA failed to disclose material prior art to the PTO during both the original prosecution and the reexamination. This material prior art includes an FDA 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 claims in the Nicolson patents, but were not submitted to the PTO.

32. 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 lenses it recreated in accordance with the Nandu patent, CIBA failed to do so, and also withheld material information concerning the thickness of these recreated lenses. This information was known to CIBA inventors, was material to the patentability of the lenses, but was not provided to the PTO.

33. 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. CIBA's statement was knowingly false in light of the existence of B&L's publicly disclosed work.

34. 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**

35. Paragraphs 1-34 of the Complaint are incorporated herein by reference.

36. CIBA’s actions and statements have caused Johnson & Johnson 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”).

37. Johnson & Johnson’s Phoenix contact lenses do not infringe any valid claim of the ‘100 patent. Consequently, Johnson & Johnson’s manufacture, sale, use or other activities with respect to Phoenix contact lenses do not infringe, contributorily infringe or induce infringement of any valid claim of the ‘100 patent.

38. Johnson & Johnson has not infringed, contributorily infringed or induced infringement of any valid claim of the ‘100 patent.

39. 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.

40. 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 30-34 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**

41. Paragraphs 1-34 of the Complaint are incorporated herein by reference.

42. CIBA's actions and statements have caused Johnson & Johnson 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").

43. Johnson & Johnson's Phoenix contact lenses do not infringe any valid claim of the '999 patent. Consequently, Johnson & Johnson's manufacture, sale, use or other activities with respect to Phoenix contact lenses do not infringe, contributorily infringe or induce infringement of any valid claim of the '999 patent.

44. Johnson & Johnson has not infringed, contributorily infringed or induced infringement of any valid claim of the '999 patent.

45. 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.

46. 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 30-34 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**

47. Paragraphs 1-34 of the Complaint are incorporated herein by reference.

48. CIBA's actions and statements have caused Johnson & Johnson 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").

49. Johnson & Johnson's Phoenix contact lenses do not infringe any valid claim of the '461 patent. Consequently, Johnson & Johnson's manufacture, sale, use or other activities with respect to Phoenix contact lenses do not infringe, contributorily infringe or induce infringement of any valid claim of the '461 patent.

50. Johnson & Johnson has not infringed, contributorily infringed or induced infringement of any valid claim of the '461 patent.

51. 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.

52. 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 30-34 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**

53. Paragraphs 1-34 of the Complaint are incorporated herein by reference.

54. CIBA's actions and statements have caused Johnson & Johnson 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").

55. Johnson & Johnson's Phoenix contact lenses do not infringe any valid claim of the '811 patent. Consequently, Johnson & Johnson's manufacture, sale, use or other activities with respect to Phoenix contact lenses do not infringe, contributorily infringe or induce infringement of any valid claim of the '811 patent.

56. Johnson & Johnson has not infringed, contributorily infringed or induced infringement of any valid claim of the '811 patent.

57. 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.

58. 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 30-34 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**

59. Paragraphs 1-34 of the Complaint are incorporated herein by reference.

60. CIBA's actions and statements have caused Johnson & Johnson 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").

61. Johnson & Johnson's Phoenix contact lenses do not infringe any valid claim of the '631 patent. Consequently, Johnson & Johnson's manufacture, sale, use or other activities with respect to Phoenix contact lenses do not infringe, contributorily infringe or induce infringement of any valid claim of the '631 patent.

62. Johnson & Johnson has not infringed, contributorily infringed or induced infringement of any valid claim of the '631 patent.

63. 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.

64. 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 30-34 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 Johnson & Johnson 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 Johnson & Johnson's Phoenix 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 Johnson & Johnson its reasonable attorney fees pursuant to 35 U.S.C. § 285 and its costs; and

F. Award Johnson & Johnson such other and further relief as the Court deems just.

**DEMAND FOR JURY TRIAL**

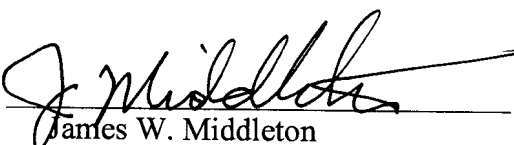
Johnson & Johnson demands trial by jury of all issues so triable as of right by a jury.

Respectfully submitted,

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**EXHIBITS**

**NOT SCANNED-**

**REFER TO  
COURT FILE**