

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELENZA, INC., a Delaware corporation,)	
)	
Plaintiff,)	
)	
v.)	
)	
ALCON LABORATORIES HOLDING)	C.A. No. 15-348-GMS
CORPORATION, a Delaware corporation,)	
ALCON RESEARCH, LTD, a Delaware)	
corporation, and NOVARTIS AG, a Swiss)	
corporation,)	
)	
Defendants.)	

SECOND AMENDED COMPLAINT

INTRODUCTION AND SUMMARY

1. ELENZA, Inc. (“ELENZA”) is a company engaged in the development of intraocular accommodating lenses for the treatment of cataracts and other serious eye conditions. When ELENZA approached Alcon, Novartis’ predecessor corporation, in search of strategic investors to help it finance the development and exploitation of its technology and the commencement of manufacturing operations in 2010, Alcon identified the technology being developed by ELENZA as an important breakthrough in the field. Alcon signed a Non-Disclosure Agreement and on that basis conducted diligence, gaining access to ELENZA’s confidential information, including its trade secrets and product development plans. After learning the details of ELENZA’s technology, Alcon agreed to become an investor and committed to invest \$15 million in two tranches. At the time of its diligence and its investment in ELENZA, Alcon had no experience or expertise in any of the electro-active technologies being developed by ELENZA. Upon making its investment, Alcon took two seats on

ELENZA's Board of Directors and three seats on a newly created Joint Development Committee and, in those capacities, learned further details regarding ELENZA's confidential information. In the course of learning of ELENZA's trade secrets, confidential information, and product development plans, Alcon was acquired by and merged into Novartis AG ("Novartis") and became a division thereof and Novartis succeeded to all of the rights, obligations, and liabilities of Alcon. Novartis determined to itself develop and commercialize the technology invented by ELENZA and to eliminate ELENZA as a competitor in the market of electro-active intraocular lenses. In breach of its legal duties and its contractual obligations, Novartis refused to provide the second tranche of funding to ELENZA, secretly filed its own patent applications claiming ELENZA's technologies as its own, and commenced its own internal effort to develop and commercialize electro-active intraocular lens and to otherwise exploit ELENZA's confidential information and trade secrets. Novartis' conduct accomplished its goals by devastating ELENZA's position in the market and rendering it unable to finance the development and commercialization of its technology. ELENZA's damages exceed \$25 million.

THE PARTIES

2. ELENZA is a Delaware corporation with its principal place of business in Roanoke, Virginia. ELENZA was at all relevant times, and remains, in the business of developing and preparing to manufacture and commercialize accommodating intraocular lenses.

3. Alcon Holdings, Inc. was a Delaware corporation with its principal place of business in Fort Worth, Texas. Alcon Holdings Inc. is no longer in existence and was merged into Alcon Laboratories Holding Corporation, a Delaware corporation which, upon information and belief, is a subsidiary of Novartis AG. Alcon Laboratories Holding Corporation, Inc. succeeded to all of the rights, obligations, and liabilities of Alcon Holdings, Inc.

4. Alcon Research Ltd. is a Delaware corporation with its principal place of business in Ft. Worth, Texas. At all times prior to Alcon, Inc.'s merger with Novartis, alleged in more detail below, Alcon Holdings, Inc., Alcon Laboratories Holding Corporation, Inc., and Alcon Research Ltd. were wholly owned direct or indirect subsidiaries of Alcon, Inc. With respect to that time period prior to the merger of Novartis and Alcon, Inc., Alcon Holdings, Inc., Alcon Laboratories Holding Corporation, Inc., Alcon Research Ltd., and Alcon, Inc. are collectively referred to as "Alcon" unless otherwise indicated.

5. Novartis AG is a Swiss corporation with its principal place of business in Basel, Switzerland. Novartis is engaged in the business of developing and commercializing pharmaceuticals and other healthcare products. On or about December 15, 2010, the boards of Alcon, Inc. and Novartis agreed to merge their corporations. On February 25, 2011, Alcon, Inc. sent a proxy to its shareholders describing the proposed transaction and soliciting its shareholders' votes on the proposed transaction. The proxy stated that Alcon, Inc. was to merge into Novartis AG and thereupon cease to exist and that Novartis succeeded to all of the rights, obligations, and liabilities of Alcon, Inc. On or about April 8, 2011, the merger was completed. Alcon, Inc. ceased to exist as a separate corporate entity and became a division of Novartis, which succeeded to all of the rights, obligations, and liabilities of Alcon, Inc. Alcon, Inc., Alcon Holdings, Inc., Alcon Laboratories Holding Corporation Inc., Alcon Research Ltd., and Novartis are, with respect to allegations regarding the time period following Novartis' merger with Alcon, hereinafter collectively referred to as "Novartis" unless otherwise specified.

FACTS

6. Cataracts are a condition that affects 4 in 7 Americans and 67 % of the world population. Historically, those suffering from cataracts simply endured failed eyesight. In the last 50 years, surgical treatments have become available. These procedures involve an incision into the cornea to remove the patient's clouded lens and the replacement of the natural lens with a man-made polymer lens. Historically, however, the man-made lens inserted into the patient's eye has had a single focal length; *i.e.*, it could only provide vision for either distance or close-up viewing, but not both. The patient who has an intraocular implant must therefore continue to wear vision correction in order to maintain vision throughout the distance spectrum, from near to intermediate and far.

7. A number of companies have attempted through a variety of means to address the issue of the fixed focal length of intraocular lenses. The goal of such companies is to develop an accommodating lens; *i.e.*, a lens that can detect the distance that the patient seeks to view and instantly accommodate itself to that distance by changing its focal length in order to provide accurate vision. Such attempts include the development of "bifocal" intraocular lenses and mechanical accommodating lenses that require that the lenses actually move within the anterior chamber of the eye to adjust to different viewing distances, far and near. Companies that have developed such technologies include Visiogen and Eyeonics, both of which have been acquired by larger optical companies at prices of approximately \$400 million and \$700 million, respectively.

8. ELENZA chose to pursue a more promising approach that addressed the deficiencies of the prior mechanical accommodating lens. It developed technology that allowed the focal length of a lens to be changed by the application of an electrical impulse to the man-

made lens. Such an electrical impulse causes ELENZA's proprietary liquid crystal to realign its molecular structure which changes the optical focal length of the lens. This method involved the creation of a plethora of new and multi-faceted technologies, including but not limited to: (1) the lens itself, containing the liquid crystal and a separate accommodating lens that activates upon the electrification of the liquid crystal; (2) photo-sensors in communication with implantable microchips that can detect and measure the patient's pupil change as a trigger to implement the accommodating mechanism of the lens; (3) implantable batteries that can power the electrical charges that trigger the accommodating mechanism; (4) a radio-frequency charging mechanism that allows for the remote inductive charging of the implanted battery and wireless programmability of the system; and (5) software algorithms that correlate pupil changes with distant and near viewing.

9. After developing the core technologies required for its accommodating intraocular lens, ELENZA began looking for strategic investors to fund the manufacturing and clinical development of its device. Among the potential investors it approached was Alcon. Alcon currently has one of the largest market shares in the industry for fixed and multi-focal length implantable lenses, but no promising research and development programs for the development of accommodating intraocular lenses. At the very outset of the parties' discussions, on May 24, 2010, Alcon Research Ltd. (on behalf of itself and its affiliates) and ELENZA entered into a mutual non-disclosure agreement ("NDA") that prohibited each party from using or disclosing any of the information exchanged between them. More specifically, the agreement provided that the party receiving confidential information "agrees to keep, hold and maintain in confidence all such Confidential Information, of every kind and character, and not to disclose, directly or indirectly, to any third party, or otherwise make use of said Confidential Information

without the prior written consent of the disclosing party.” This confidentiality obligation “shall remain in effect for a period of five (5) years from the date of disclosure.”

10. Upon execution of the NDA and in reliance upon it, ELENZA gave Alcon and its engineers and lawyers (including Jonathan Prejean) access to all of ELENZA’s confidential information, including its trade secrets and proprietary development partners as part of its diligence to determine whether or not to invest in ELENZA. These materials included, but are not limited to: a technology summary, a product development plan, the ASIC design materials, the battery design and function materials, the sensor and algorithm designs, descriptions of the intellectual landscape of ELENZA and the industry, presentations regarding an implantable hermetically sealed ocular device, liquid crystal material selection presentations, and overviews of liquid crystal materials. During the course of these presentations, Alcon presented to ELENZA and acknowledged that it had absolutely no expertise in any of the areas of ELENZA’s expertise. Alcon reviewed ELENZA’s approach to the development of intraocular accommodating lenses and determined that it had promise. In the course of its evaluation and diligence, Alcon concluded that ELENZA would obtain approval for sales and distribution in the United States by 2016 and that annual sales would ramp from \$25 million in 2016 to \$178 million in 2020, and that other indications for ELENZA’s products would increase annual revenue by an additional \$186 million per year by 2017.

11. On or about February 7, 2011, ELENZA and Alcon Holdings Corporation, Inc., together with a series of smaller investors (collectively referred to as the “follow-on investors”) entered into a Stock Purchase Agreement (hereinafter, the “SPA”). Under the terms of the SPA, Alcon and the follow-on investors obligated themselves to purchase Series B shares of ELENZA in two equal but separate tranches, each consisting of \$11,307,906.11, of which \$7,499,999.41

was to be paid by Alcon. In exchange for its payment in the first tranche, Alcon was to receive 7,129,277 shares and become the holder of 24.3% of the outstanding shares of ELENZA. The second tranche was conditioned on two things; execution of definitive agreements reflecting the term sheets attached as Exhibits L (Sapphire Development Agreement) and M (Research License) to the SPA, and the successful completion of a clinical study establishing that ELENZA's microchip could detect patients' pupil dilation and constriction, and that ELENZA's algorithms correctly correlated such pupil dynamics to the patients' attempt to changes their viewing distance (the "Algorithm Milestone"). The criteria for the success or failure of the study were expressly set out in Exhibit C to the SPA. At the conclusion of the second tranche, Alcon was to own 34.4% of ELENZA. As part of the transaction, Alcon also received the right to appoint its designees to two seats on the ELENZA Board of Directors, the right to appoint its employees to three of the six positions on the Joint Scientific Advisory Board, and a right of first refusal to purchase ELENZA. By virtue of its express agreements, its actual and prospective stock ownership, its power to appoint two directors on the ELENZA Board of Directors, its power to appoint three of six members to the Joint Scientific Advisory Board, its right of first refusal to purchase ELENZA, and its receipt of the confidential, proprietary and trade secret information of ELENZA, Alcon owed duties to ELENZA to maintain the confidentiality of the information conveyed to it and not to use such information for its own benefit and to the detriment of ELENZA. Alcon appointed two of its employees, William Graham and Matthew Head, to serve as its designees on the ELENZA Board of Directors, both of whom thereafter served in that capacity.

12. Exhibit L to the SPA was the Sapphire Development Agreement, which set forth certain rights and obligations of the parties as ELENZA continued to develop its accommodating

intraocular lens. These included, for example, the formation of a Joint Scientific Advisory Board with scientists from both ELENZA and Alcon to oversee and guide the development of the product. Exhibit L expressly provided that “as between ELENZA and Alcon, ELENZA will have exclusive rights to any EA IOL (electro-active intraocular lens) or other intraocular implant product that directly results from the Sapphire project” and that “ELENZA will have exclusive rights to use all such know-how and other technical information in connection with the commercialization of any EA IOL or other intraocular implant products directly resulting from the Sapphire project, as well as exclusive rights to use all such know-how and other technical information that is directed to liquid crystal-based optics that utilize polarization-insensitive liquid crystal materials.” Despite the fact that ELENZA was at all relevant times ready, willing and able to enter into the joint development agreement described in Exhibit L, no formal Sapphire Development Agreement was ever entered into by the parties and Exhibit L was never executed.

13. Exhibit M to the SPA contemplated that the parties would enter into a formal license agreement which, had it been entered, would have allowed Alcon to disclose to its third party collaborators certain product specifications and a set of information that the parties agreed constituted ELENZA’s trade secrets, though it specifically provided that Alcon was not to have any access to ELENZA’s liquid crystal technology. Exhibit M expressly acknowledged the trade secret status and protection for ELENZA’s confidential and proprietary information and know-how regarding: (1) lithium ion rechargeable battery design and testing; (2) ASIC design and testing; (3) algorithm on pupil changes; (4) sensor design and performance; (5) encapsulation process, glass bonding at low temperature, laser welding and laser fusion bonding; (6) microcircuit design and assembly process, including placement of battery, ASICs, antenna for

communications and remote charging with minimal power loss; (7) electro-active cell for tunable, switchable add power. Despite the fact that ELENZA was at all relevant times ready, willing and able to enter into the license agreement described in Exhibit M, the formal license agreement was never entered into by the parties and Exhibit M was never executed.

14. In addition, Exhibit F to the SPA granted Alcon a right of first refusal to purchase ELENZA upon various triggers, which right of first refusal required Alcon to pay to ELENZA \$5,000,000 upon "Proof of Science" (defined in Exhibit L as the establishment of technical feasibility of a completed functional prototype of the product) and an additional \$7,500,000 upon "Proof of Concept" (defined in Exhibit L as the successful completion of clinical studies of 60 clinical implants with 6 months' follow up assessment). The payment for the right of first refusal, together with the money committed to be invested in the Series B financing, would have been sufficient to finance ELENZA through the development, manufacture, testing, and approval of its electro-active intraocular lens.

15. The SPA requires that, with respect to any dispute arising out of or related to the stock purchase agreement, "the parties consent to the exclusive jurisdiction of, and venue in, the federal and state courts of Delaware." The SPA also provides that the prevailing party in any such dispute shall be entitled to its attorneys' fees.

16. After execution of the SPA, Novartis acquired Alcon and merged Alcon into it, thereby succeeding to all of Alcon's rights, obligations, and liabilities.

17. After entering into the SPA, and without executing the Sapphire Development Agreement referenced in Exhibit L, the parties formed a de facto Joint Development Committee to oversee their venture or enterprise. ELENZA conducted the clinical study described in the SPA as a pre-condition to the closing of the second tranche of the SPA. The SPA and the Joint

Development Committee established in advance the criteria contemplated to be used to test the success of the study, which was designed to determine: (1) whether pupil dynamics was a reliable indicator of a patient's effort to change the focusing distance of his or her vision; (2) whether ELENZA's sensor could reliably detect such pupil changes; and (3) whether ELENZA's algorithm accurately converted such detected dynamics into the appropriate adjustment to the focal length of the lens. After over a year of preparation and the expenditure of \$1.7 million, the test was conducted among 350 volunteer patients. The study was a success in all aspects. The ELENZA Board of Directors, which at the time included two Novartis appointees, determined that all of the criteria had been satisfied. Likewise, the ELENZA Medical Advisory Board determined that the clinical study was a success in all respects. Similarly, various third parties, including Helbling Technik AG, a well-known contract development and engineering company in the optical field, determined that the study was a success in all respects.

18. After completion of the Novartis acquisition and merger with Alcon, a Novartis lawyer, Jonathan Prejean (who had previously conducted the intellectual property due diligence on Alcon's potential investment into ELENZA) began attending the meetings of the Joint Development Committee. When the issue of whether the clinical trials had satisfied the relevant criteria came to the attention of the Joint Development Committee, the lawyer from Novartis argued for the first time that the pre-defined criteria were flawed, too vague, and not susceptible to objective measurement. When the Joint Development Committee was scheduled to vote on the question of whether the study had met the criteria that would require Novartis to fund the second tranche of its investment, Mr. Prejean announced that Novartis had determined not to make its second tranche investment and that therefore the vote was unnecessary.

19. On information and belief, at the time that Novartis was preventing the vote regarding the success of the clinical study, it had already commenced its own internal development effort to develop and exploit the technologies invented by ELENZA and to capture for itself 100% of the anticipated revenues from the commercialization of ELENZA's technologies. At the time that it prevented any meaningful vote on the Algorithm Milestone, Novartis was already at work preparing a provisional patent application that included the trade secrets and other confidential information that Novartis had learned from ELENZA during the course of its diligence and its participation on the Board of Directors and the Joint Development Committee. On February 23, 2012, without alerting ELENZA to the fact, Novartis then filed a provisional patent application No. 61/602,281 that sought to patent for itself ELENZA's technologies, including the use of nematic liquid crystal materials to form an electro-active lens, the hermetic sealing of electronics without damaging them or impairing their function in order to maintain biocompatibility inside the human eye, and electrical voltage amplifiers designed to consume a minimum amount of electrical power and fit into microminiaturized electronic chips suitable for implantation into the human eye. This provisional patent application resulted in published patent application No. 13/775,517. Novartis' filing of the patent application permanently and irrevocably damaged ELENZA by publicly disclosing ELENZA's trade secrets and by creating "prior art" that threatened to undermine all of ELENZA's subsequent patent filings.

20. Five months later, still without having disclosed its patent application to ELENZA and knowing that such application would soon publish and become public, Novartis entered into a "Clarification Agreement" with ELENZA. That agreement recited that both parties wished to dissolve their relationship, including "any contractual or implied partnership." Among other

things, the Clarification Agreement (1) terminated all special rights of Novartis as an ELENZA investor; (2) set forth that both parties could use the clinical study data, provided that Exhibits L and M were never entered into and were, in any event, terminated; (3) terminated the Joint Development Committee; (4) removed the Novartis members of the ELENZA Board of Directors; and (5) terminated Novartis' right of first refusal. The Clarification Agreement also provided, among other things, that the parties did not jointly develop any intellectual property, that ELENZA's pupil detection algorithm and pupil sensor design (including any approaches, algorithm components, and formulae) was exclusive to ELENZA and that Novartis had no rights in any of it, and that ELENZA had the exclusive right to commercialize any electro-active intraocular lens product "having either (1) an optic that changes optical power using polarization-insensitive and/or nematic liquid crystals or (2) a sensor using papillary response as a physiological trigger and which shall include the first generation product of such Sapphire Project and all second and later generations thereof and improvements thereto." Finally, the Clarification Agreement also contained a confidentiality provision pursuant to which the parties agreed that each "will not disclose to any Third Party any confidential, proprietary and/or non-public information of the other party exchanged between the parties during the collaborative period between the parties ending in December 31, 2011." The "Clarification Agreement" did not contain any releases of any liability by any party.

21. Approximately one year after execution of the "Clarification Agreement," Novartis' patent application became public. ELENZA's business was devastated. Deprived of its anticipated capital by Novartis' breach of its funding obligations contained in the Stock Purchase Agreement, ELENZA found it impossible to raise capital to replace that wrongfully withheld by Novartis. Potential investors incorrectly concluded that ELENZA's clinical study

and its product had failed and concluded from Novartis' patent filing that Novartis, a much larger and better funded business than ELENZA, was going to compete with ELENZA to develop an accommodating intraocular lens. As a consequence of these developments, the enterprise value of ELENZA was devastated and ELENZA can now no longer find funding to complete manufacturing and clinical development of its intraocular lens.

22. On information and belief, Novartis is now actively involved in the exploitation of ELENZA's confidential information, including its trade secrets, to develop an electro-active accommodating intraocular lens based on the inventions of ELENZA. On information and belief, Novartis has approached at least three of ELENZA's subcontractors—Aurolab, Front Edge Technologies, and Helbling Technik—to enlist them in Novartis' effort to develop an electro-active IOL using the confidential information and trade secrets provided to Novartis by ELENZA. Aurolab was responsible for the final stages of ELENZA's manufacturing process, including assembling the final lens. Front Edge designed the miniaturized batteries that powered ELENZA's IOL. Most importantly, Helbling Technik was ELENZA's primary development partner and possessed detailed knowledge concerning all aspects of its IOL. Furthermore, as part of Novartis' ongoing development effort, John Campin and George Pettit, two Alcon employees intimately involved with the Joint Development Committee and Alcon's work with ELENZA, filed (and assigned to Novartis) two additional patent applications that both disclose and reflect the use of ELENZA's confidential information and trade secrets, each of which has recently been published. Thus, US 2014/0156000 A1 and WO 2014/084958 A1, both of which claim a priority date of November 30, 2012, disclose an electro-active IOL that relies on a microprocessor and photodiodes, as does ELENZA's device. The applications also disclose various methods of manually triggering the IOL, one of which directly implicates ELENZA's claimed trade secrets.

A third patent application—publication No. US 2014/0171957 A1, which was filed by Alcon Research Ltd. and claims a priority date of December 19, 2012—also suggests that Novartis has continued to utilize various aspects of ELENZA’s research concerning surgical methods and tools for inserting the IOL into the eye.

23. Generally, sophisticated entities engaged in joint development projects with potential competitors or other third parties who wish to commence an independent development effort will isolate and segregate those employees engaged in the independent effort from any contact with or information concerning the joint development effort underway with the potential competitor. This process, referred to as creating a “clean room,” is specifically designed to prevent misuse of a potential competitor’s confidential information. Novartis did the opposite; it staffed its internal development effort with precisely those employees and consultants most intimately familiar with ELENZA and its confidential information and trade secrets, including but not limited to John Campin, George Pettit, Dr. Andrew Maxwell (the former Chairman of ELENZA’s Medical Advisory Board), and William Graham (one of Alcon’s two appointees to ELENZA’s Board of Directors). Novartis’ failure to segregate the individuals who had access to ELENZA’s technology from its own internal efforts to develop an electro-active intraocular lens, contrary to industry custom, indicates that its misuse of ELENZA’s confidential information is intentional. Finally, on July 15, 2014, Novartis announced that it had licensed technology from Google, Inc. to aid in the development of a “smart” lens capable of accommodation, with plans to develop an accommodating intraocular lens. Accordingly, Novartis has both disclosed and used confidential information acquired from ELENZA in the course of developing its own accommodating electro-active lens.

24. On March 31, 2015, Patent No. US 8,992,610 B2 issued to ELENZA. The patent claims several technologies fundamental to the development of a functioning electro-active IOL, and details the design of ELENZA's electro-active IOL.

**FIRST CLAIM FOR RELIEF
FOR MISAPPROPRIATION OF TRADE SECRETS
AGAINST ALL DEFENDANTS**

25. ELENZA restates and incorporates paragraphs 1 through 24 above as though fully set forth herein.

26. The following technologies constitute ELENZA trade secrets, as previously admitted by Alcon: (1) lithium ion rechargeable battery design and testing; (2) ASIC design and testing; (3) algorithm on pupil changes; (4) sensor design and performance; (5) encapsulation process, glass bonding at low temperature, laser welding and laser fusion bonding; (6) microcircuit design and assembly process, including placement of battery, ASICs, antenna for communications and remote charging with minimal power loss; (7) electro-active cell for tunable, switchable add power. In addition, as the project advanced, additional trade secrets were developed including, but not limited to, the physical properties required of the liquid crystal in the lens, the development of a solid-state ceramic battery, and the design of a surgical injector intended to aid in the implantation of the EA IOL.

27. Each of the technologies described in the preceding paragraph derives independent economic value from not being generally known to the public or to other persons who can derive value from its disclosure and each was and is the subject of reasonable efforts to maintain its secrecy.

28. Novartis gained knowledge of the trade secrets described in paragraph 26, and such knowledge was acquired under circumstances giving rise to a duty to maintain its secrecy and limit its use and/or was derived through a person who owed and breached a duty to ELENZA to maintain its secrecy or limit its use.

29. Without the express or implied consent of ELENZA, Novartis has disclosed all or a portion of the trade secrets they acquired under the circumstances described above and/or continued to use all or a portion of the trade secrets it acquired under the circumstances described above.

30. ELENZA has been damaged by Novartis' misappropriation of the trade secrets described in paragraph 26, and Novartis has been unjustly enriched by their misappropriation of the foregoing trade secrets.

31. Novartis' actions alleged above were willful and malicious, were undertaken and performed by it with the intent to harm ELENZA, with a conscious recklessness and indifference to the rights of ELENZA and to the foreseeable effects of its conduct. Its conduct was wanton, willful, malicious, and outrageous, and breached the trust and confidence placed in it by ELENZA.

**SECOND CLAIM FOR RELIEF
FOR BREACH OF CONTRACT
AGAINST ALL DEFENDANTS**

32. ELENZA restates and incorporates paragraphs 1 through 24 above as though fully set forth herein.

33. The SPA was a valid and enforceable contract supported by adequate consideration. In the SPA, Novartis committed itself to purchase \$15 million of ELENZA Series B shares subject only to the conditions set forth in the Stock Purchase Agreement. ELENZA

was ready, willing, and able to execute agreements reflecting the terms of Exhibits L and M to the SPA and had achieved in its patient study the Algorithm Milestone described in Section 2.1(c) of the SPA.

34. Rather than allow the Joint Development Committee to hold a meaningful vote on the question of whether the Algorithm Milestone had been achieved, Novartis instead announced in advance that it had no intent to close on the second tranche of its \$15 million investment.

35. ELENZA performed all conditions required to be performed by it under the SPA, or its performance of such conditions was excused.

36. Novartis' announcement of its intent not to perform its stock purchase obligation, and its refusal to so perform, constituted a breach of the SPA. As a consequence of Novartis' refusal to fund its second tranche investment, the follow-on investors likewise failed to invest.

37. In addition, Novartis' filing of its various patent applications and its use of the confidential information disclosed to it pursuant to the May 24, 2010 NDA constitutes a breach of the terms of that NDA and a breach of the confidentiality and other provisions of the Clarification Agreement.

38. Finally, Novartis' refusal to negotiate and finalize in good faith the agreements outlined in Exhibits L and M constitutes a breach of the SPA.

39. Novartis' breach of its obligation to purchase the second tranche of its Series B shares of ELENZA damaged ELENZA in an amount to be proven at trial, but in no event less than \$25,000,000 comprised of the \$7.5 million that Novartis refused to invest, \$5 million that the follow-on investors failed to invest, and \$12.5 million that Novartis committed itself to pay for the Right of First Refusal to purchase ELENZA. In addition, Novartis' breach of its

confidentiality obligations contained in the May 24, 2010 NDA and in the Clarification Agreement has damaged ELENZA in an amount to be determined at trial.

**THIRD CLAIM FOR RELIEF IN THE ALTERNATIVE
FOR BREACH OF THE SPA'S COVENANT OF GOOD FAITH AND FAIR DEALING
AGAINST ALL DEFENDANTS**

40. ELENZA restates and incorporates paragraphs 1 through 24 above as though fully set forth herein.

41. Implied in the SPA was a covenant of good faith and fair dealing, precluding Novartis from acting in a manner that would render ELENZA's performance of its conditions more difficult or impossible, deprive ELENZA of the benefit of its bargain, or both.

42. Novartis breached the covenant of good faith and fair dealing when it refused to continue funding ELENZA, despite the success of its clinical study, thus precluding the Joint Development Committee from voting on the question of whether the Algorithm Milestone had been achieved.

43. ELENZA was damaged by Novartis' breach of the covenant of good faith and fair dealing in an amount to be determined at trial.

**FOURTH CLAIM FOR RELIEF
FOR INTENTIONAL MISREPRESENTATION
AGAINST ALL DEFENDANTS**

44. ELENZA restates and incorporates paragraphs 1 through 24 above as though fully set forth herein.

45. Novartis and its employees were duty bound to disclose all facts relevant to the deliberations of the Joint Development Committee, the impending vote on the Algorithm Milestone, Novartis's refusal to fund the second investment tranche, and the relationship

between Novartis and ELENZA. The duty arose both from the obligations imputed to commercial entities engaged in business transactions and from the formation of a joint venture or enterprise dedicated to the common purpose of developing an electro-active intraocular lens. Despite the lack of any formal development agreement, Novartis and ELENZA created the Joint Development Committee to govern their interaction, which was composed of an equal number of Novartis and ELENZA employees. Novartis provided substantial funding for the project, in addition to purchasing millions of ELENZA shares, indicating that Novartis would share in any losses resulting from the project. In return, Novartis received a license to use the data generated by the clinical study. More importantly, Novartis also held a right of first refusal to purchase ELENZA should the joint venture or enterprise prove successful, which granted Novartis both a proprietary interest in the project and a right to share in any profits generated, thus supplementing the proprietary interests and rights to share in the profits accruing to Novartis as a significant stakeholder. Consequently, the parties' conduct in the absence of an executed Sapphire Development Agreement, the rights awarded to Novartis under the SPA, and the significant quantity of ELENZA shares held by Novartis resulted in the formation of a joint venture or enterprise.

46. At all times relevant hereto, Jonathan Prejean was acting in the course and scope of his authority as an employee for Novartis, which is therefore liable for his conduct on a respondeat superior basis.

47. At some point after the formation of the parties' joint venture or enterprise, Novartis began to prepare a provisional patent application claiming for itself the trade secrets and other confidential information of ELENZA. Prejean, while serving as a de facto member of the Joint Development Committee, was aware of the provisional application. The failure of both

Novartis and Prejean to disclose Novartis' intentions to the Joint Development Committee or ELENZA, particularly during the Committee's final meeting on December 16, 2011, was intentional and rendered materially misleading the statements of Novartis' employees to the Committee concerning the validity of the clinical study, the Algorithm Milestone vote, and the decision not to close the second tranche of the Series B financing.

48. The failure of Novartis and Prejean to disclose these facts was intentional, and they intended that ELENZA rely upon their omissions.

49. ELENZA relied upon the statements and omissions of Prejean and other Novartis employees in not voting on the Algorithm Milestone. Concealing the preparation of the patent application secured additional time for Novartis to continue developing a functional electro-active intraocular lens in secret using ELENZA's technology, while simultaneously hindering ELENZA's own progress. By abandoning its commitment to fund the second investment tranche, but not disclosing the planned patent application coopting ELENZA's trade secrets, Novartis gave potential investors the impression that ELENZA's technology was not viable. Thus, the omissions of Novartis and Prejean before the Joint Development Committee inhibited ELENZA's ability to obtain alternate financing in the wake of Novartis' sudden withdrawal. Had Prejean and Novartis disclosed the anticipated filing of the patent application, ELENZA would have successfully taken steps with Novartis and the United States Patent and Trademark Office to prevent the application from publishing. ELENZA was therefore damaged in an amount to be proven at trial.

**FIFTH CLAIM FOR RELIEF
FOR AFFIRMATIVE MISREPRESENTATION
AGAINST ALL DEFENDANTS**

50. ELENZA restates and incorporates paragraphs 1 through 24 above as though fully set forth herein.

51. After announcing that Novartis would not fund the second tranche of its investment obligation, and after secretly filing its patent application, Novartis and Prejean and Gregg Brown (both acting within the course and scope of their authority at Novartis) negotiated the “Clarification Agreement” with ELENZA. The Clarification Agreement sought to define and address the various relationships between Novartis and ELENZA, including the disposition of various rights attendant to Novartis’ purchase of the Series B stock.

52. At the time they negotiated the Clarification Agreement with ELENZA, both Brown and Prejean knew that Novartis had already filed a provisional patent application claiming for itself the trade secrets and confidential information of ELENZA. ELENZA had neither knowledge nor access to knowledge regarding the provisional patent application. Thus, Prejean and Brown’s statements concerning Alcon’s purported commitment in the Clarification Agreement to maintain the confidentiality of ELENZA’s confidential, proprietary, and non-public information were overt misrepresentations, given their knowledge that Novartis had *already* disclosed the relevant material. Because ELENZA’s information was already disclosed in the provisional patent application, the confidentiality clause itself also constitutes an affirmative misrepresentation.

53. Brown and Prejean’s affirmative misrepresentations were intentional, and were intended to induce ELENZA’s acquiescence to the terms of the proposed Clarification Agreement. The same misrepresentations were also intended to prevent ELENZA from

becoming aware of the provisional patent application, allowing Novartis additional time to develop a functional electro-active intraocular lens using ELENZA's technology.

54. ELENZA relied upon the statements of Prejean and Brown in executing the Clarification Agreement. Absent such misrepresentations, ELENZA would have successfully taken steps with Novartis and the United States Patent and Trademark Office to prevent the provisional patent application from being published. Moreover, as discussed above, Novartis' continuing deceptions concerning the provisional patent application inhibited ELENZA's ability to secure alternate sources of financing, as potential investors believed that Novartis had identified ELENZA's technology as flawed. ELENZA was damaged thereby in an amount to be proven at trial.

55. Novartis, Prejean, and Brown's actions alleged above were undertaken and performed by them with the intent to harm ELENZA, with a conscious recklessness and indifference to the rights of ELENZA and to the foreseeable effects of their conduct. Their conduct was wanton, willful, malicious, and outrageous and breached the trust and confidence placed in them by ELENZA.

**SIXTH CLAIM FOR RELIEF
FOR INTERFERENCE WITH CONTRACT
AGAINST NOVARTIS**

56. ELENZA restates and incorporates paragraphs 1 through 24 above as though fully set forth herein.

57. Novartis AG knew of Alcon Holding Corporation's obligations under the SPA, including but not limited to the obligation to make the second tranche investment in the Series B

financing. Novartis knew of Alcon's obligations to maintain the confidentiality and not to use the ELENZA trade secrets and other confidential information.

58. On information and belief, Novartis instructed Alcon Holdings Corporation, Inc. to refuse to make its second tranche investment in ELENZA and the \$12.5 million payment for the right of first refusal. Novartis intended by its instruction that Alcon Holdings Corporation Inc. would breach its obligations under the Stock Purchase Agreement and the right of first refusal. Novartis caused Alcon to use and/or disclose the ELENZA trade secret and confidential information. Novartis' conduct was in fact a significant factor in causing Alcon's breach of its funding and confidentiality obligations.

59. Novartis' instruction to Alcon was without justification and was wrongful in that it was not made to advance any legitimate economic interest of either Alcon or Novartis but was made instead to further Alcon and Novartis' misappropriation of the ELENZA trade secrets and as a consequence of Novartis' decision to develop internally at Alcon or Novartis what ELENZA had been developing under the terms of the various agreements between it and Alcon.

60. ELENZA was damaged by Novartis' conduct in that Alcon breached its funding obligation and its confidentiality obligations.

61. Novartis' actions alleged above were undertaken and performed by it with the intent to harm ELENZA, with a conscious recklessness and indifference to the rights of ELENZA and to the foreseeable effects of its conduct. Its conduct was wanton, willful, malicious and outrageous.

**SEVENTH CLAIM FOR RELIEF
FOR INFRINGEMENT OF U.S. PATENT NO. 8,992,610
AGAINST ALL DEFENDANTS**

62. ELENZA restates and incorporates paragraphs 1 through 24 above as though fully set forth herein.

63. This is a claim for patent infringement arising under the patent laws of the United States, Title 35, United States Code, including 35 U.S.C. §§ 271 and 281-285. Federal courts have exclusive subject matter jurisdiction over claims of patent infringement under 28 U.S.C. §§ 1331 and 1338(a). ELENZA, therefore, will immediately seek removal of this action pursuant to 28 U.S.C. § 1454 to the U.S. District Court for the District of Delaware, which has personal jurisdiction over Defendants. Venue is proper in that district pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b).

64. On March 31, 2015, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,992,610 (“the ‘610 Patent”), entitled “Hermetically Sealed Implantable Ophthalmic Devices and Methods of Making Same,” to Ronald D. Blum, Amitava Gupta, Jean-Noel Fehr, Jean-Christophe Roulet, Urban Schnell, Walter Doll, and Roland Michaely. A true and correct copy of the ‘610 Patent is attached hereto as Exhibit A.

65. ELENZA is the owner of all rights, title, and interest in and to the ‘610 Patent, including all rights to sue and recover for past and future infringement.

66. Upon information and belief, Novartis is developing implantable electro-active intraocular lens products in the United States based on the exploitation of ELENZA’s trade secrets and other confidential information. By making and/or using such products in the United States in connection with its research and development activities, Novartis has directly infringed, and continues to directly infringe, one or more claims of the ‘610 Patent.

67. Novartis has had notice of the '610 Patent since at least the filing of this amended complaint. Upon information and belief, Novartis' continued infringement of the '610 Patent is willful.

68. Upon information and belief, Novartis has been infringing and will continue to infringe one or more claims of the '610 Patent through the aforesaid acts, and will continue to do so unless enjoined by the court. Upon information and belief, Novartis' wrongful conduct has caused and will continue to cause ELENZA to suffer irreparable harm resulting from the loss of its lawful patent rights to exclude others from making, using, selling, offering to sell, and/or importing the patented technology.

69. ELENZA is entitled to recover damages adequate to compensate for Novartis' infringement of the '610 Patent.

**EIGHTH CLAIM FOR RELIEF
FOR BREACH OF FIDUCIARY DUTY
AGAINST ALL DEFENDANTS**

70. ELENZA restates and incorporates paragraphs 1 through 24 and 45 above as though fully set forth herein.

71. Alcon (and after its acquisition, Novartis), one of the largest and most dominant players in the ophthalmology market, was a strategic investor to ELENZA; its conduct with respect to ELENZA would communicate to third parties and other potential other investors more effectively than any other source the status of ELENZA and its technology. After having entered into the SPA and having funded the first tranche of the investment required to be made under the SPA, Novartis owned 24.4% of the outstanding stock of ELENZA, with the right upon funding the second tranche to increase its interest to 34%. In addition, as Lead Investor in the Series B

Investment set out in the SPA, Novartis knew that its conduct with respect to its investment in ELENZA would impact the investment decisions made by the follow-on investors in the Series B round, who together with Alcon comprised 68% of the outstanding shares of ELENZA (and 76% after the closing of the second tranche, had it occurred). In addition, Novartis had a right of first refusal to purchase all of the outstanding shares of ELENZA. Moreover, Novartis had the power to appoint two members of ELENZA's Board of Directors, and did so, appointing Matthew Head and William Graham on or about March 18, 2011. In addition to these two appointees to the ELENZA Board of Directors, Novartis employed a third board member, Dr. Lindstrom, as a consultant, and also employed the Chairman of ELENZA's Medical Advisory Board, Dr. Andrew Maxwell, as a Novartis consultant. Novartis had the right to appoint and control 50% of the Joint Development Committee, the management group that controlled ELENZA's only asset, its research and development of an electro-active intraocular lens. Accordingly, Novartis had the power to deadlock the JDC and effectively halt ELENZA's research and development, or to direct that research and development as it saw fit. Novartis was also effectively ELENZA's only source of capital after execution of the SPA and was able to control the activities of ELENZA by dictating what activities it would fund and what activities it would not fund. Novartis exercised the power it had over ELENZA. At the very outset of its relationship, it dictated to ELENZA that it abandon its existing research and development into an aperture-based electro-active lens and pursue instead ELENZA's next generation design. Similarly, it was only at the insistence of Novartis that ELENZA spent the time, money and resources to conduct the PCCS study, requiring multiple changes in the study design to meet criteria dictated by its clinical study group. When Alcon determined not to fund the second tranche of its Series B investment, no other investor funded its second tranche investment. Finally, when it suited Novartis' purposes,

Novartis insisted that William Graham resign his position as ELENZA board member and that Dr. Maxwell resign his position as Chairman of the Medical Advisory Board, both in order to assist Novartis in its own, competitive, development effort.

72. By virtue of the foregoing facts, Novartis owed ELENZA fiduciary duties of loyalty, care and candor.

73. Novartis breached its duties of loyalty by usurping for itself (and to the detriment of ELENZA) the opportunity to develop and commercialize an electro-active accommodating intraocular lens, the very product that ELENZA was in the process of developing and commercializing by attempting to patent for itself the confidential information and trade secrets of ELENZA and by recruiting for its own development efforts ELENZA's Board member and the Chairman of its Medical Advisory Board. Novartis breached the duty of candor by not informing ELENZA of its own internal development efforts, by its use of ELENZA confidential information and trade secrets, by its breach of its agreements with ELENZA, and by its attempts to enlist ELENZA's suppliers into Novartis wrongful development efforts.

74. ELENZA has been damaged by the foregoing conduct in an amount to be proven at trial.

75. Novartis' actions alleged above were undertaken and performed by it with the intent to harm ELENZA, with a conscious recklessness and indifference to the rights of ELENZA and to the foreseeable effects of its conduct. Its conduct was wanton, willful, malicious and outrageous.

DEMAND FOR JURY TRIAL

ELENZA, Inc. hereby demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, ELENZA prays for judgment against Defendants as follows:

1. Permanently enjoining Novartis and its parents, subsidiaries, affiliates, successors, and assigns, and each of their officers, directors, employees, representatives, agents, attorneys, and all persons acting in concert or active participation with them, or on their behalf, or within their control, from making, importing, using, offering for sale, selling, or causing to be sold any product or service falling within the scope of any claim of the '610 Patent, or otherwise infringing any claim of the '610 Patent;
2. Declaring that the '610 Patent is valid and enforceable against Novartis and that Novartis has directly and willfully infringed one or more claims of the '610 Patent literally and/or under the doctrine of equivalents;
3. For an accounting, including a post-verdict accounting, to determine the damages to be awarded to ELENZA as a result of all of Novartis' making, importing, using, offering for sale, selling, or causing to be sold any product or service falling within the scope of any claim of the '610 Patent, or otherwise infringing any claim of the '610 Patent;
4. For damages according to proof at trial, including damages due to Novartis' infringement of the '610 Patent pursuant to 35 U.S.C. § 284;
5. For treble damages due to Novartis' willful infringement of the '610 Patent pursuant to 35 U.S.C. § 284;
6. For exemplary and punitive damages in an amount to be determined at trial;

7. For ELENZA's attorneys' fees in pursuing the claims asserted herein, including attorneys' fees pursuant to 35 U.S.C. § 285;
8. For interest and costs of suit, including pre-judgment and post-judgment interest and costs pursuant to 35 U.S.C. § 284; and
9. For such other and further relief that the Court deems just and proper.

ASHBY & GEDDES, PA

/s/ Andrew D. Cordo

John G. Day (#2403)
Andrew D. Cordo (#4534)
F. Troupe Mickler IV (#5361)
500 Delaware Ave., 8th Floor
Wilmington, DE 19801
(302) 654-1888

Attorneys for the Plaintiff

Of Counsel:
KING & SPALDING
Timothy T. Scott
Geoffrey M. Ezgar
601 California Avenue
Palo Alto, CA 94304
(650) 422-6700

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