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Attorneys for Plaintiff
GLAUKOS CORPORATION

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

GLAUKOS CORPORATION, a Delaware Corporation, Plaintiff, v. IVANTIS, INC, a Delaware Corporation, Defendant.	Case No. 8:18-cv-00620 **COMPLAINT FOR PATENT INFRINGEMENT** **DEMAND FOR JURY TRIAL**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Glaukos Corporation ("Glaukos") brings this patent infringement action against Defendant Ivantis, Inc. ("Ivantis") and alleges as follows:

NATURE OF THE ACTION

1. This action concerns Ivantis's willful infringement of U.S. Patent Nos. 6,626,858 ("the '858 Patent") and 9,827,143 ("the '143 Patent") (collectively, the "Asserted Patents"), owned by Glaukos. The infringing Ivantis product is a medical device known as the Hydrus Microstent ("Hydrus"). By this action, Glaukos seeks redress for Ivantis's infringement as well as its imminent additional acts of future infringement. This Court has Federal Question jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) and jurisdiction under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

2. On information and belief, Ivantis currently manufactures the Hydrus at its facility in Irvine, California, for use outside of the safe harbor provided under 35 U.S.C. § 271(e)(1), including for commercial use in international markets. For example, on information and belief, Ivantis is currently supplying the Hydrus to physicians in Australia and New Zealand for commercial purposes not reasonably related to the development and submission of information to the U.S. Food and Drug Administration (FDA).

3. On information and belief, Ivantis plans to significantly expand its infringing conduct in 2018. In November of 2017, at the American Academy of Ophthalmology (AAO) conference, Ivantis publicly announced its plans to commercially launch the Hydrus, including a "Limited International Launch" in the first quarter of 2018 and a "U.S. Launch" early in the third quarter of 2018. *See* https://ois.net/ivantis-preparing-us-commercialization-hydrus/. In connection with Ivantis's U.S. commercial launch, Ivantis is engaging in and/or imminently will engage in further acts of infringement of one or more claims of each of the Asserted

Patents, including manufacturing, selling, offering for sale, using, and actively inducing and/or contributing to infringement by third parties.

4. By this action, Glaukos seeks all available remedies for Ivantis's willful infringement, including without limitation damages, damages enhancements for willfulness, injunctive relief requiring Ivantis to cease its infringing activities, and a judicial determination that Ivantis infringes and/or imminently will infringe one or more claims of each of the Asserted Patents.

THE PARTIES

5. Glaukos is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 229 Avenida Fabricante, San Clemente, California.

6. Ivantis identifies itself as a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 38 Discovery, Suite 150, Irvine, California.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1 et seq. This Court has federal question jurisdiction under 28 U.S.C. § 1331 and 28 U.S.C. § 1338(a) because this is a civil action arising under the Patent Act. This Court also has subject matter jurisdiction based on the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, because an immediate and substantial controversy exists between Glaukos and Ivantis with respect to Ivantis's current and/or imminent infringement of the Asserted Patents.

8. This Court has personal jurisdiction over Ivantis. Ivantis has continuous, systematic, and substantial contacts with this judicial district, including having a principal place of business within this judicial district.

9. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c), and 1400(b). Ivantis has a regular and established place of business in this district, and

substantial activities relating to its infringement described herein have occurred, and on information and belief will occur in the future, in this district.

GLAUKOS AND ITS GROUNDBREAKING PRODUCTS

10. For nearly twenty years, Glaukos has focused exclusively on research, development, and commercialization of its breakthrough products designed to transform treatment of the category of diseases known as glaucoma. In 2012, Glaukos became the first company to obtain FDA approval of a micro-stent for the treatment of glaucoma.

11. Glaucoma is one of the leading causes of blindness worldwide. The condition is usually caused by the excessive accumulation of fluid called aqueous humor in the front part of the eye. In a healthy eye, this fluid passes through mesh-like tissue called the trabecular meshwork, into a natural drainage channel in the eye known as Schlemm's canal. However, when fluid does not drain at the same rate at which it is produced, the result is often an undesirable increase of pressure in the eye. Over time, this pressure may damage the eye's optic nerve, the part of the eye that transmits images to the brain. Ultimately, this damage to the optic nerve can result in substantial vision impairment or complete blindness. The most common treatment for high eye pressure in glaucoma patients has traditionally been prescription eye drops. However, these medications are often ineffective due to high non-compliance rates, multiple side effects, and other factors. For decades, physicians have explored alternatives such as laser treatments and complicated surgical procedures, but many of these procedures have been unsuccessful or carried a high risk of infection or other side effects.

12. Glaukos's pioneering product, the iStent® Trabecular Micro Bypass Stent ("iStent"), transformed the glaucoma treatment landscape. Because the iStent represented an entirely new class of medical device (now known as "Micro-Invasive Glaucoma Surgery" or "MIGS"), the Glaukos team began working with the FDA in 2004 to design a first-of-its-kind pivotal clinical trial protocol to evaluate the safety

and efficacy of its MIGS device. During the approval process, Glaukos spent considerable time and resources recruiting patients for the study, and educating and training physicians on this revolutionary new class of treatment, and conducting clinical trials in the U.S. and abroad.

13. In 2012, the iStent became the first MIGS device to be approved by the FDA. With a length of approximately 1 millimeter and height of approximately 0.3 millimeters, Glaukos's iStent is believed to be the smallest medical device of any kind to be approved by the FDA. Inserted through a tiny corneal incision made during cataract surgery, the iStent allows fluid to drain through the stent from the anterior chamber in the front of the eye into Schlemm's canal. Once in place, the iStent is designed to restore natural fluid outflow and reduce pressure in the eye. The iStent has been implanted in over 300,000 eyes to date.

14. After pioneering the market for MIGS with the history-making approval and launch of the iStent, Glaukos continues to develop innovative glaucoma treatments. Glaukos's investigational devices currently under development include the iStent *inject*®, a system preloaded with two micro-scale stents (even smaller than the iStent), the iStent *infinite*™, a system preloaded with three micro-scale stents, and the iDose™, a drug-eluting implant.

15. Including the proceeds of its 2015 public offering, Glaukos raised in aggregate approximately $270 million in funding to bring its innovative MIGS devices to market. Since then, Glaukos has continued to invest heavily in research and development, spending $25.0 million in 2015, $29.2 million in 2016, and $38.9 million in 2017. In addition, Glaukos has historically expended, and continues to expend, significant time and money educating and training medical professionals, including programs designed to train surgeons on the iStent procedure. By the end of 2017, over 3,100 U.S. physicians had been fully trained by Glaukos representatives on the iStent procedure.

16. Glaukos is currently sponsoring more than twenty clinical trials in the U.S. and abroad, all evaluating current and potential future glaucoma therapies. Glaukos's MIGS technologies have been featured in more than 70 peer-reviewed articles appearing in leading clinical journals. To protect its substantial investments, Glaukos has built a portfolio of more than 200 issued, pending, or exclusively licensed patents.

IVANTIS'S KNOWING DISREGARD OF GLAUKOS'S PATENT RIGHTS

17. According to Ivantis's website, Ivantis was founded in 2007, three years after Glaukos began its groundbreaking pivotal trial for the iStent which ultimately led to FDA approval, and three years after the iStent achieved CE Mark clearance in Europe. By 2007, favorable data regarding the iStent's safety and efficacy had been published in leading publications and presented at industry conferences worldwide.

18. From the beginning, Ivantis was well aware of Glaukos's technology and patents. As the pioneer of the MIGS industry and the first company to obtain FDA approval for a MIGS device, Glaukos was at that time and continues to be a leader in MIGS. To date, Glaukos is the only company that has received FDA approval for a MIGS device that enhances drainage through Schlemm's canal to reduce pressure in the eye.

19. Ivantis designed the Hydrus to have this same mechanism of action, and has stated publicly that it views its targeting of Schlemm's canal as a "competitive advantage." At a recent presentation entitled "Ivantis Preparing US Commercialization," Ivantis described the size of the U.S. market as $164 million annually and growing, "thanks in large part to the great effort by Glaukos in building this category to date." *See* https://ois.net/ivantis-preparing-us-commercialization-hydrus/.

20. The '858 Patent had already issued by 2007 and was readily identifiable by any search for intellectual property covering stenting of Schlemm's

canal. Indeed, the '858 Patent has been repeatedly cited during prosecution of Ivantis's own patent applications. The '143 Patent issued from the same parent application as the '858 Patent. Additionally, the '143 Patent was the subject of a Glaukos press release dated November 30, 2017, which noted that "the newly issued patent covers ocular devices and methods of surgically implanting the devices at least partially within Schlemm's canal to facilitate the flow of aqueous humor." On information and belief, Ivantis closely monitors press releases regarding Glaukos.

21. The Asserted Patents were co-invented by Dr. Reay Brown and Dr. Mary Lynch, and were acquired by Glaukos in 2006 while Glaukos was in the early stages of the regulatory review process. Further illustrating Ivantis's knowledge of the foundational technologies described in the Asserted Patents and their relevance to Ivantis's product, Ivantis's own website refers to the patents by stating, "Dr. Brown has been awarded 15 patents for new instruments to improve glaucoma and cataract surgery."

22. The relevance of Glaukos's patent portfolio to the Hydrus is well known not only to Ivantis but also to industry analysts. For example, a recent industry analyst report discussed the likelihood of litigation by Glaukos against Ivantis. The report further noted, "Glaukos has strong intellectual property in the trabecular meshwork space, highlighted by its most recent IP win, a five-year extension (through April 2025) for one of its key patents [the '858 Patent] involving the trabecular meshwork." On information and belief, Ivantis closely monitors industry analyst reports.

23. Notwithstanding Ivantis's specific knowledge of the Asserted Patents and their applicability to the Hydrus, Ivantis has never sought or received authorization from Glaukos to practice the Asserted Patents. Instead, without authorization, Ivantis has proceeded to design its products and its regulatory activity closely tracking the technical, commercial, and regulatory path forged by Glaukos and the iStent. As noted above, Ivantis touts that it targets the same pathway as the

iStent and that it will attempt to take advantage of the market built by Glaukos. Further, in its pending FDA submission, Ivantis seeks the same indication for which the iStent® was approved: patients with mild-to-moderate primary open angle glaucoma undergoing cataract surgery.

24. On information and belief, the Hydrus is manufactured at Ivantis's assembly facility in Irvine, California, and Ivantis is currently exporting the product for commercial use in at least two countries outside the United States.

25. Ivantis has stated that it has sufficient resources to commercially launch in the U.S. promptly upon FDA approval, which Ivantis has repeatedly represented it anticipates occurring early in the third quarter of 2018 or "mid-2018." In 2017, Ivantis solicited and raised an additional approximately $25 million, including for the specific purpose of "support[ing] US commercialization of the Hydrus Microstent upon its anticipated 2018 US Food and Drug Administration (FDA) approval." *See* http://www.market wired.com/ press-release/ivantis-raises-25-million-series-c-fund-future-us-commercialization-hydrus-microstent-2186951.htm. Ivantis recently hired a VP of Marketing, a Senior Director of Market Development, a Director of Manufacturing, a Manufacturing Supervisor, a Senior Manufacturing Engineer, a Senior Manufacturing Assembler, and on information and belief is currently filling other new manufacturing-related positions for its assembly facility, which is located in Irvine. Therefore, in addition to Ivantis's past and present acts of infringement, in light of Ivantis's statements that it plans an imminent, commercial launch of its Hydrus product to United States customers, a substantial controversy also exists with respect to future acts of infringement by Ivantis, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

OVERVIEW OF THE INFRINGING HYDRUS PRODUCT

26. Public admissions by Ivantis, including on its website and in presentations made at industry conferences, confirm that the Hydrus incorporates the very same foundational technology described and claimed in the Asserted

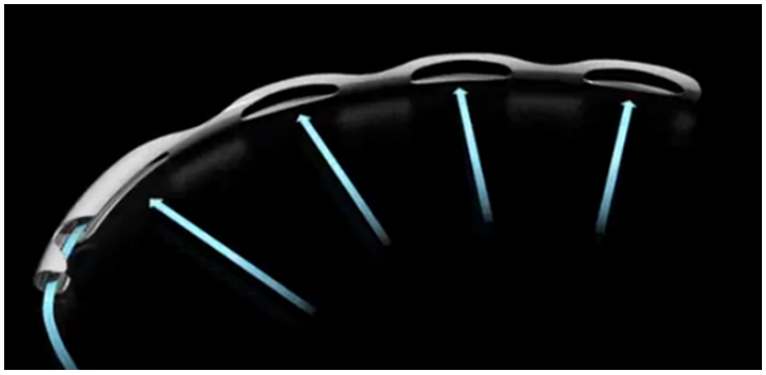
Patents, despite Ivantis's knowledge of the Asserted Patents. For example, and by way of illustration only:

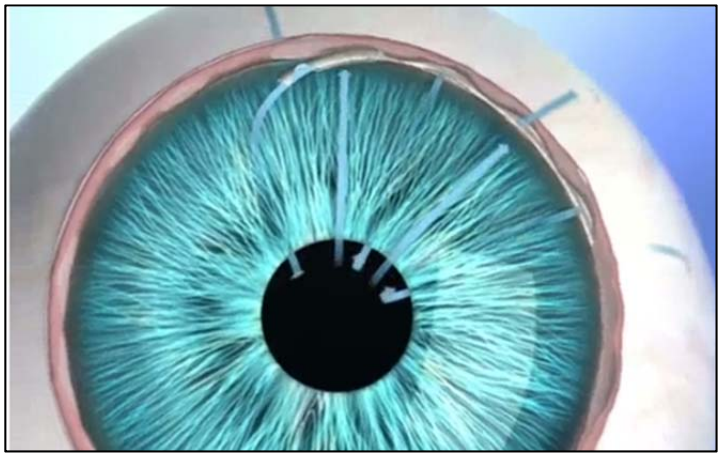
27. Ivantis describes the Hydrus as an aqueous humor shunt device configured to maintain patency of Schlemm's canal and reduce intraocular pressure.

28. According to Ivantis's product marketing materials, the Hydrus includes a proximal inlet portion and a distal outlet portion, and is made of biocompatible nitinol. Ivantis describes the Hydrus as being 8 mm long and crescent-shaped, with a proximal inlet portion of approximately 2 mm.

29. Ivantis further describes the Hydrus as including a proximal inlet portion designed to be received by the anterior chamber of the eye. *See, e.g.*, http://ois.net/ivantis-goes-after-canal-based-migs/ (Ivantis CEO: the "proximal end" of the Hydrus "resides in the anterior chamber, where aqueous humor enters the body of the device"). According to Ivantis's product marketing materials, the Hydrus's distal portion is designed to be received and retained at least partially circumferentially within a portion of Schlemm's canal. Ivantis sometimes refers to this portion of the Hydrus as a "scaffold." *See* http://www.ivantisinc.com/faq.php (describing the Hydrus as including a "'scaffold' designed to be inserted into the primary fluid canal (called Schlemm's canal) of the eye.").

30. Ivantis's website contains animations depicting aqueous humor flowing from the proximal portion of the Hydrus in the anterior chamber of the eye, across the trabecular meshwork, and through to the distal portion in Schlemm's canal, and aqueous humor flowing from the anterior chamber through openings of the Hydrus and exiting towards the collecting channels of the eye:





http://www.ivantisinc.com/hydrus-procedure.php (screen captures).

31. The following image from Ivantis's website depicts the Hydrus from both sides, illustrating that the distal portion that is received in Schlemm's canal has multiple fenestrations or portals, and comprises an at least partially open trough-like channel open posteriorly toward the collecting channels.

http://www.ivantisinc.com/hydrus-procedure.php.

32. Ivantis knowingly encourages use of the Hydrus system in accordance with Glaukos's patented inventions, including without limitation through Ivantis's published studies, oral and slide presentations at conferences and other events, demonstrative videos, the Ivantis website, and other marketing materials.

CLAIM ONE FOR INFRINGEMENT OF U.S. PATENT NO. 6,626,858

33. Glaukos re-alleges and incorporates by reference the allegations contained in paragraphs 1-32 above.

34. On September 30, 2003, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '858 Patent, entitled "Shunt Device and Method for Treating Glaucoma." A copy of the '858 Patent is attached as Exhibit A.

35. Dr. Mary G. Lynch and Dr. Reay H. Brown are co-inventors of the '858 Patent, the rights to which they each assigned to GMP Vision Solutions, Inc. ("GMP"). On December 12, 2006, GMP assigned the rights to Glaukos, which is the present assignee of all rights to the '858 Patent.

36. Ivantis currently does and/or imminently will infringe the '858 Patent in violation of 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making, using, offering to sell, and/or selling within the United States and/or importing into the United States, without license or authority, the Hydrus product.

37. Ivantis currently does and/or imminently will infringe the '858 Patent in violation of 35 U.S.C. § 271(b) by actively inducing infringement of the '858 Patent, literally or under the doctrine of equivalents, with knowledge of the '858 Patent by, among other things, knowingly aiding and abetting, assisting and encouraging others, including without limitation, end users of Ivantis's products, to directly infringe the '858 Patent with knowledge that such conduct infringes the '858 Patent.

38. Ivantis currently does and/or imminently will infringe the '858 Patent in violation of 35 U.S.C. § 271(c) by contributing to infringement of the '858 Patent, literally or under the doctrine of equivalents, by, among other things, selling, offering to sell and/or importing in the United States, without license and authority, Hydrus products or components thereof, with knowledge of the '858 Patent and knowing that such products and/or components are especially made or especially adapted for use in the infringement of the '858 Patent, are a material part of the invention, and are not staple articles or commodities of commerce suitable for substantial non-infringing use.

39. Ivantis's activities are willful. Ivantis is aware of the '858 Patent, including from its monitoring of Glaukos and Glaukos's technology for stenting Schlemm's canal, because the '858 Patent has been cited repeatedly during prosecution of Ivantis patent applications, and from industry analyst reports discussing the '858 patent. Ivantis's knowledge is also confirmed by Ivantis's reference on its website to '858 Patent co-inventor Dr. Brown's patents. Ivantis further has knowledge of the '858 Patent as a result of this complaint. With

knowledge of the '858 Patent, Ivantis is deliberately and consciously making and commercializing a product that mimics the '858 Patent's claims and teachings.

40. Ivantis's willful infringement of the '858 Patent will cause and continue to cause irreparable harm to Glaukos unless and until Ivantis's infringing activities are enjoined by this Court.

CLAIM TWO FOR INFRINGEMENT OF U.S. PATENT NO. 9,827,143

41. Glaukos re-alleges and incorporates by reference the allegations contained in paragraphs 1-40 above.

42. On November 28, 2017, the USPTO duly and legally issued the '143 Patent, entitled "Shunt Device and Method for Treating Ocular Disorders." A copy of the '143 Patent is attached as Exhibit B.

43. Dr. Mary G. Lynch and Dr. Reay H. Brown are co-inventors of the '143 Patent, the rights to which they each assigned to GMP Vision Solutions, Inc. ("GMP"). On December 12, 2006, GMP assigned the rights to Glaukos, which is the present assignee of all rights to the '143 Patent.

44. Ivantis currently does and/or imminently will infringe the '143 Patent in violation of 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making, using, offering to sell, and/or selling within the United States and/or importing into the United States, without license or authority, the Hydrus product.

45. Ivantis currently does and/or imminently will infringe the '143 Patent in violation of 35 U.S.C. § 271(b) by actively inducing infringement of the '143 Patent, literally or under the doctrine of equivalents, with knowledge of the '143 Patent and knowledge that it will induce infringement of the '143 Patent, by, among other things, knowingly aiding and abetting, assisting and encouraging others, including without limitation, end users of Ivantis's products, to directly infringe the '143 Patent with knowledge that such conduct infringes the '143 Patent.

46. Ivantis currently does and/or imminently will infringe the '143 Patent in violation of 35 U.S.C. § 271(c) by contributing to infringement of the '143 Patent,

literally or under the doctrine of equivalents, by, among other things, selling, offering to sell and/or importing in the United States, without license and authority, Hydrus products or components thereof, with knowledge of the '143 Patent and knowing that such products and/or components are especially made or especially adapted for use in the infringement of the '143 Patent, are a material part of the invention, and are not staple articles or commodities of commerce suitable for substantial non-infringing use.

47. Ivantis's activities are willful. Ivantis is aware of the '143 Patent, including from its continued monitoring of Glaukos and Glaukos's technology for stenting Schlemm's canal, because the '858 Patent (from which the '143 Patent issued as a continuation) has been cited repeatedly during prosecution of Ivantis patent applications and discussed by industry analysts, from Glaukos's press release identifying the '143 Patent, and as further confirmed by Ivantis's reference on its website to '143 Patent co-inventor Dr. Brown's patents. Ivantis further has knowledge of the '143 Patent as a result of this complaint. With knowledge of the '143 Patent, Ivantis is deliberately and consciously making and commercializing a product that mimics the '143 Patent's claims and teachings.

48. Ivantis's willful infringement of the '143 Patent will cause and continue to cause irreparable harm to Glaukos unless and until Ivantis's infringing activities are enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Glaukos requests entry of judgment in its favor and against Defendant as follows:

A. Judgment in its favor on all claims for relief;

B. A declaration of infringement by Ivantis based on one or more claims of the Asserted Patents;

C. A declaration that Ivantis's infringement is willful;

D. An order enjoining Ivantis from infringement of the Asserted Patents;

E. Damages for infringement, with interest and trebled, pursuant to 35 U.S.C. § 284;

F. Costs and reasonable expenses to the fullest extent permitted by law;

G. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285, and an award of attorney's fees and costs; and

H. Such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff Glaukos Corporation hereby demands a trial by jury on each of its claims so triable.

Dated: April 14, 2018

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By: /s/ *Lisa S. Glasser*

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