Superior Court of California

County of Orange

Case Number : 30-2019-01119045-CU-CO-CJC

Copy Request: 4426269

Request Type: Case Documents

Prepared for: cns

Number of documents: 1

Number of pages: 15

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ORANGE

30-2019-01119045-CU-CO-CJC
Judge John C. Gastelum

BLS Pharma, Inc.,

Plaintiff,

vs.

Inovio Pharmaceuticals, Inc., and Genetronics, Inc.;

Defendants.

Case No.

VERIFIED COMPLAINT FOR DAMAGES AND RESTITUTION BASED ON BREACH OF CONTRACT, INTENTIONAL MISREPRESENTATION, AND NEGLIGENT MISREPRESENTATION

Plaintiff BLS Pharma Inc., by and through its attorneys, based on its personal knowledge as to its own actions and on the independent investigation of counsel, alleges as follows:

I. NATURE OF THE CASE

1. This case arises from Defendants' breach of an agreement to supply proprietary components of a needleless injector that was being used by Plaintiff to develop a drug-device combination ("DDC") for injection of testosterone.

2. Testosterone treatment is the preferred treatment for patients with male hypogonadism and for transgender individuals transitioning from female to male. The testosterone treatment market is valued at between $1.3 and $1.8 billion annually.

3. This breach was committed immediately after a meeting where Plaintiff discussed with Defendants that the DDC would be used, in part, for the transgender indication, whereupon Defendants suddenly refused to supply the proprietary syringes. Defendants gave no valid reason for the breach.

4. Because of Defendants' breach, Plaintiff was unable to conduct planned clinical trials for the DDC and was ultimately prevented from bringing this product to market.

5. Following that breach, at least one similar, but inferior, drug-device combination for a testosterone injector has been brought to market and is currently earning hundreds of millions of dollars in revenue per year. This similar product is inferior in that it uses a needle, and so Plaintiff's DDC would have been able to capture a significant portion of the growing testosterone treatment market if not for Defendants' breach.

6. Plaintiff lost a substantial outlay in development costs and a significant, and reasonably ascertainable, amount of future profits, which are conservatively estimated at $72.9 million, due to and as a proximate result of Defendants' conduct.

II. JURISDICTION AND VENUE

7. This Court has jurisdiction over this action pursuant to California Constitution Article VI, § 10 and under California Code of Civil Procedure ("CCP") § 410.10. Jurisdiction is

proper in the Superior Court of California, County of Orange, because Defendants reside and/or conduct business in California.

8. Moreover, Defendants are doing, and at all relevant times have done, business in Orange County, and venue is proper under California Code of Civil Procedure § 395. Specifically, Plaintiff is located in Orange Country, the contracts at issue in this litigation were entered into in Orange County, and the obligations under the contract were to be performed in Orange County.

III. THE PARTIES

9. Plaintiff BLS Pharma Inc. ("BLS") is a Delaware corporation headquartered at 25422 Trabuco Road, Suite 105-348, Lake Forest, CA 92630.

10. Defendant Inovio Pharmaceuticals Inc. ("Inovio") is a Delaware corporation, headquartered in Plymouth Meeting, PA, that maintains two offices in California. Inovio is publicly traded on the NASDAQ stock exchange under the symbol "INO." Inovio describes itself as "a late-stage biotechnology company focused on the discovery, development, and commercialization of DNA-based immunotherapies and vaccines that transform the treatment and prevention of cancer and infectious disease."

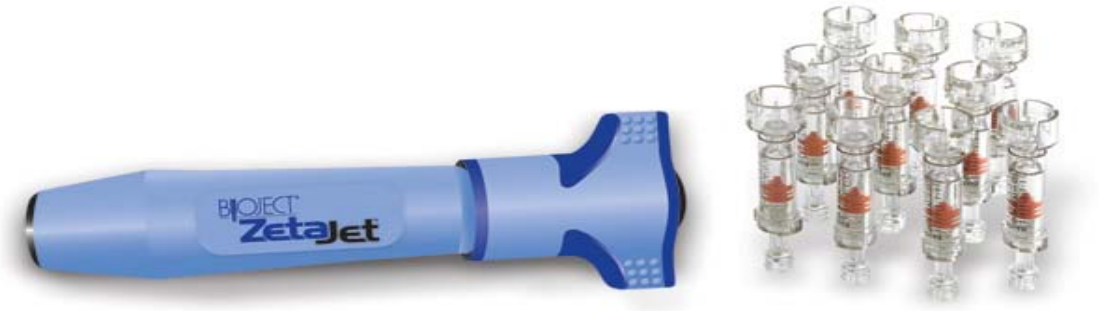
11. Defendant Genetronics, Inc. ("Genetronics") is a fully-owned subsidiary of Inovio. Genetronics is a Delaware corporation headquartered at 11494 Sorrento Valley Road, San Diego, CA 92121-1334.

IV. STATEMENT OF FACTS

12. The principal executives of Plaintiff BLS previously owned a company called Bioject Inc. ("Bioject"). Bioject developed a needleless injector technology called Zetajet.

13. Zetajet is a compact, reusable, spring-powered device that can deliver vaccines and injectable medication either subcutaneously or intramuscularly. Although it can be used by doctors, it is simple enough for patients to use for at-home injections. The ZetaJet device is capable of delivering three thousand to five thousand injections over a three to five-year period, after which the device must be replaced due to spring attenuation.

14. The Zetajet technology generally consists of two components: a reusable injector, and disposable needleless syringes that are inserted into the injector:



15. In March of 2016, an Asset Purchase Agreement was executed that sold the Bioject company to Defendant Genetronics. Both Defendants, Genetronics and Inovio, were signatories to that agreement and Inovio stock was part of the purchase price.

16. As part of that Asset Purchase Agreement, the intellectual property rights for the Zetajet injector were sold to Genetronics.

17. At around this same time, Plaintiff BLS was formed to continue the DDC development efforts that Bioject's executives started. As part of the Asset Purchase Agreement, Defendants were obligated to execute a license and supply agreement that would supply Zetajet units to Plaintiff upon request. This obligation was a material and critical part of the negotiations for the sale of the Bioject company and the Zetajet technology to Defendants. The owners of BLS already had plans to utilize the Zetajet technology for up to three future applications, including the testosterone DDC discussed herein, and had even sponsored two small studies on that project in 2013 and 2014. BLS would no longer be able to produce Zetajet on their own after the asset sale, and so the ability to obtain continued supply of the injectors from Inovio was crucial to continuation of that project and the future of BLS.

18. In accordance with that obligation, on April 26, 2016, an Exclusive License Agreement was executed between Defendant Genetronics and Plaintiff BLS.

19. The Exclusive License Agreement grants Plaintiff "an exclusive, perpetual, irrevocable, royalty-free, fully paid-up, non-transferable" right and license to "use, market, promote, sell and otherwise commercially exploit" the Zetajet technology for delivery of testosterone, as well as for two additional fields to be agreed-upon between the parties, worldwide.

20. The Exclusive License Agreement also states that, when requested by Plaintiff, Defendants would "negotiate in good faith" agreements to directly or indirectly supply Zetajet units to BLS at a price of production cost plus 15%. Under the Exclusive License Agreement, if Defendants cannot supply the Zetajet products, they must grant Plaintiff the right to make, or have made, the Zetajet product. This supply provision was material and critical to this Agreement, as without it, the licensing rights provided by the Exclusive License Agreement have no value.

21. During the following months thereafter, as more fully set forth below, Defendants agreed to directly supply Zetajet units to Plaintiff BLS by confirming their obligations to do so under the Asset Purchase Agreement and the Exclusive License Agreement, as well as through their acceptance of a purchase order for the units, their issuance of an invoice for the units, and their receipt for payment on the invoice for the Zetajet units.

22. Upon information and belief, Plaintiff states that the same personnel own and run both Inovio and Genetronics. When communicating with Defendants regarding the Exclusive License Agreement, Plaintiff communicated with personnel who identified themselves as Inovio executives or officers, but was in fact communicating with both of the Defendant entities regarding provision of the Zetajet units. Upon information and belief, Plaintiff alleges that Genetronics was the agent and/or alter-ego of Inovio regarding the contracts and transactions at issue in this Complaint.

23. Relying upon the Exclusive License Agreement and Defendants' obligation to supply the Zetajet units, BLS continued developing its DDC for injection of testosterone as

treatment for male hypogonadism and also to provide necessary testosterone for transgender individuals undergoing the transition from female to male.

24. Male hypogonadism, also known as testosterone deficiency, is a failure of the testes to produce the male sex hormone testosterone, sperm, or both. Testosterone replacement therapy is the recommended treatment for male hypogonadism, and Plaintiff's DDC would have provided such therapy in the comfort of the patient's own home via a simple, easy to use needle-free delivery system.

25. Testosterone therapy is also necessary for transgender individuals who are transitioning from female to male, in order to develop male secondary sex characteristics and suppress or minimize female secondary sex characteristics, and in order to provide lifetime maintenance of secondary male characteristics.

26. For both conditions, the need for testosterone supplements is chronic – the patient anticipates long-term use of the product.

27. The testosterone replacement therapy market is valued at between $1.3 to $1.8 billion annually. The market size is estimated to be growing at a 5% annual rate as measured by third party data sources that supply information to the pharmaceutical industry. The revenue potential for a new company offering an in-home, needle-free testosterone treatment delivery system, like BLS, was tremendous.

28. As part of the development of its DDC, BLS worked with Signet Healthcare Partners ("Signet"). In January of 2017, Signet discussed in an email with Defendants the probability of an upcoming clinical trial for the DDC. Defendants responded that they anticipated the supply of the Zetajet injector for that trial would "not be a problem." Signet stated that they would get an estimate of the necessary volumes.

29. On February 23, 2017, Signet advised Niranjan Sardesai, the Chief Operating Officer at Inovio, that they had met with the Food and Drug Administration regarding the DDC and "had a very positive meeting" and that the "committee guidance was very friendly and should provide a clear path to a product approval." Mr. Sardesai acknowledged receipt, wrote

that it sounded like a “good meeting,” and forwarded the email to his colleague, EJ Brandreth (“Brandreth”), a vice president at Defendant Inovio, who gave his congratulations.

30. At that referenced meeting, Plaintiff came to an agreement with the FDA that a Phase 3 Pharmacokinetic Study was necessary for approval for male hypogonadism, with between 100 and 200 patients.

31. In March of 2017, a third party inquired of Defendants about using the Zetajet product for testosterone therapy. Defendants responded that they do not sell the Zetajet on a commercial basis and that the “previous owners” of Bioject, meaning Plaintiff BLS, have an interest in pursuing a testosterone product “and we [Inovio] have an agreement to supply to them if this comes to fruition.” Defendants offered to put the third party in touch with BLS and forwarded the email string to Mark Logomasini (“Logomasini”), the President and CEO of BLS. This exchange demonstrated Defendants’ acknowledgement of their ongoing supply agreement obligations with BLS.

32. On March 31, 2017, Defendants emailed Plaintiff stating that they had not yet received the project details and asked if they still needed support. Plaintiff had a call with Defendants and confirmed that the testosterone DDC project was still going forward.

33. On April 7, 2017, Plaintiff emailed Defendants to ask about the inventory situation for Zetajet, advising that they "could be in the clinic," meaning clinical trials, with the requested study as soon as the fourth quarter of 2017. In that email, Plaintiff expressed its belief that the injector device stock already available to Plaintiff was generally fine but asked about the availability of the disposable, proprietary syringes. Plaintiff stated that "The forecast I gave you awhile back is reasonably accurate" regarding the number of syringes needed.

34. On April 10, 2017, Defendants requested a call with Plaintiff regarding the Zetajet syringe supply. Plaintiff had a call with Defendants on April 13, 2017, during which Defendants advised Plaintiff that Defendants could supply the syringes, as required by the Exclusive License Agreement.

35. On April 24, 2017, Plaintiff emailed Defendants and stated that it would like to move forward with the Zetajet syringe order. Plaintiff requested an order of 25,000 syringes for the clinical testing of the DDC. Plaintiff stated that “BLS will cover the full cost of the order plus 15% in accordance with the terms of the purchase agreement.” Defendants replied: "That sounds fine” and that they were confirming the purchase number and the availability. Later that day, Defendants emailed “We came up with about $21 per box, so we will put together an invoice for you with the specifics.”

36. On April 26, 2017, Defendants confirmed the pricing at “$21.50 per kit” with a total cost of $24,725. Defendants stated, “Please send a PO [purchase order], and we will get started on our end.” Plaintiff emailed a purchase order number “to get this on the books” and stated that it would issue a formal written purchase order the next day.

37. On April 27, 2017, Plaintiff sent a formal purchase order for 25,000 Zetajet syringes to Defendants, at the price of $24,725, to be shipped in eight to twelve weeks.

38. On June 21, 2017 Plaintiff asked Defendants for an estimated time on when the syringes would be ready. Defendants stated that the order had moved from a status of "Not started" to "In process" and that they would “get a better feel of sterilization dates….” Defendants also asked if a payment for the syringes had yet been sent. Plaintiff stated that it had not yet received an invoice from Defendants but "Please just send it over and I'll get it taken care of."

39. On a date between June 21, 2017 and June 30, 2017, Plaintiff received an invoice, which was dated May 4, 2017 but had not been previously received, from Defendants for the Zetajet syringes at the price of $24,725.

40. On August 29, 2017, Plaintiff stated that it would be sending out a check for the syringes that week. Defendants responded that they “did not want to make your parts without the up front payment, that was our agreement, yes? Please send check asap." Plaintiff responded that it did not realize the payment was required up front, but asked that Defendants “Please just confirm they have the ability to make them -- Our timelines are fine, I will get the check out this

week." Defendants responded that "We can get them [referring to the syringes]" and stated their recollection of Plaintiff's offer to make payment in advance. Plaintiff responded that the check would be sent that week and Plaintiff's owner Logomasini also discussed meeting with Defendant Inovio's Vice President Brandreth in person to discuss other opportunities. Brandreth responded that lunch the following Friday "sounded good" and that Logomasini "must stop by and see the new device facility, it is impressive." At this point, discussions between the parties were still amicable and there was no indication or suggestion of any kind that there was a problem with the order.

41. On Friday, September 1, 2017, Plaintiff confirmed to Defendants that it had mailed the check for the syringes, and that Defendants would have it by the following Tuesday. BLS's owner Logomasini also asked if the upcoming in-person meeting could be changed from the next Friday to Thursday instead.

42. In summary, as of September 1, 2017, Defendants repeatedly acknowledged their obligation to supply the syringes, Plaintiff had sent Defendants a purchase order, Defendants had sent Plaintiff an invoice, and Plaintiff had tendered payment for the order of 25,000 syringes to be used in the clinical trials for the DDC. At that time, Defendants had not made any attempt to rescind or contest their obligations to supply Plaintiff under this invoiced agreement or under the Asset Purchase Agreement and the Exclusive License Agreement. To the contrary, every representation by Defendants was amicable, positive and confirmed that they would timely supply the Zetajets to Plaintiff. In fact, to this point, all parties conducted themselves in a manner consistent with the Exclusive License Agreement and Defendants affirmed their agreement to supply the Zetajet syringes to Plaintiff through words and/or conduct.

43. On Thursday, September 7, 2017, Logomasini from Plaintiff met in person with Brandreth from Inovio for lunch. During this meeting, Logomasini and Brandreth discussed the logistics of the syringe supply, including the possibility of BLS taking over the manufacturing of the supply, if necessary, as per the Exclusive License Agreement. Plaintiff was particularly excited about the positive reception that the transgender indication had received from the FDA,

and so it was during this meeting, that Plaintiff described to an employee of Defendants that the DDC would be used for transgender patients as well as for hypogonadism.

44. The following Monday, September 11, 2017, Defendants requested a call with Plaintiff. During that call, Defendants advised Plaintiff that they were rejecting the syringe order, would not authorize BLS to take over manufacturing of the syringes, that their legal department would be sending a letter terminating the relationship, and that they would return the check previously-issued by BLS for payment.

45. Defendants gave no reason -legal or otherwise - for breaching the agreement to sell Plaintiff the necessary syringes. When asked about the reasons, Defendants stated that "We don't need transgender, we have Gates." Upon information and belief, Defendants meant they did not see sufficient benefit in supporting the transgender community, as Defendants already were supporting a different publicizable public interest effort through a separate and unrelated project with the Gates Foundation.

46. Defendants would not change their decision and continued their refusal to supply the necessary Zetajet syringes.

47. In the months following, Plaintiff diligently attempted to find another supplier for needleless syringes or other devices that would work like the Zetajet device and which could be obtained at a price that would make continuation of the testosterone DDC project possible. Due to the propriety nature of these devices and the exacting specifications necessary, there were no such suppliers available.

48. Plaintiff invested significant time, money, and effort into developing the DDC, meeting with the FDA, and preparing for clinical trials. Defendants' breach of the invoice and purchase order to supply the syringes, as well as their breach of the terms of the Asset Purchase Agreement and the Exclusive License Agreement, prevented Plaintiff from both conducting clinical trials and bringing the DDC to market.

49. At least one other drug-device combination for testosterone injections, a product called "Xyosted" which was developed by Antares Pharma, Inc., obtained FDA approval in the

interim. Accordingly, Plaintiffs' DDC had a very high probability of FDA approval and could, in fact, have used the materials submitted in connection with Xyosted to accelerate the FDA approval process under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, which allows for reliance on clinical data or literature produced by other entities for a faster route to approval.

50. However, Xyosted is inferior to Plaintiff's DDC as it does not use a needless injection system, but instead uses a small needle for injection via a single weekly shot. Plaintiff's DDC would have had the benefit to consumers of being able to control their testosterone levels from the comfort of their own house without the stress, anxiety, and expense that comes with a needle-based system. Because of this, Plaintiff's DDC would have also allowed for more frequent, smaller doses of testosterone to be utilized, which would have allowed patients to maintain a more continuous baseline level of testosterone without spikes or drops in that level that can cause physical and emotional difficulties.

51. Because of these superior attributes, Plaintiff's DDC would have been able to capture a significant share of the market, were it not for Defendants' breach, which proximately caused Plaintiff's damages. Moreover, expert analysis indicates that the testosterone treatment market was a growing one, and the success of Plaintiff's DDC was not necessarily predicated on taking customers from Xyosted.

52. But for Defendants' failure to supply the syringes, Plaintiff would have obtained FDA approval, as a clear path was created with the prior approval of the Xyosted product, and thereafter marketed and sold its DDC commercially.

53. Plaintiff's preliminary investigation and initial expert analysis indicates that it lost at least $72,900,000 in net-present-value profits it would have obtained from selling the DDC. These lost profits are reasonably ascertainable due to significant market information available, including by comparison to the actual and projected revenue of Xyosted.

54. Due to the passage of time without clinical approval, the suspension of the project's fund-raising process which cannot easily be restarted, the loss of key personnel who

have since moved on to other ventures, and the ability of other products such as Xyosted to establish uncontested market recognition, the opportunity to market Plaintiff's DDC has now been lost.

FIRST CLAIM FOR RELIEF

Breach of Contract

55. Plaintiff incorporates and realleges, as though fully set forth herein, each of the paragraphs set forth above.

56. Plaintiff and Defendants formed valid written contracts in the Asset Purchase Agreement and the Exclusive License Agreement.

57. The Asset Purchase Agreement obligated Defendants to execute a license and supply agreement to supply physical Zetajet units, including both the injectors and proprietary syringes, to Plaintiff upon request.

58. The Exclusive License Agreement obligated Defendants to negotiate, in good faith, to directly or indirectly supply Zetajet units to BLS at a price of production cost plus 15%.

59. Defendants breached these obligations when they refused to supply syringes to Plaintiff.

60. Further, the purchase order from Plaintiff, invoice from Defendants, and payment tendered by Plaintiff for an order of 25,000 Zetajet syringes, show agreement between the parties sufficient to evidence a contract for sale of goods.

61. Defendants breached that contract by refusing to sell the necessary Zetajet syringes to Plaintiff.

62. Plaintiff relied on these contracts in developing the DDC and undertaking preparatory work for clinical trials and marketing the product.

63. Because of these breaches, Plaintiff was unable to complete clinical trials for the DDC and bring it to market.

64. As a proximate result of the breach of contract, Plaintiff was damaged in the amount of money expended in developing the DDC and preparing the DDC for clinical trials, which is

approximately $170,571, and in the amount of lost profits that would otherwise have been made from sales of the DDC.

65. The amount of lost profits is reasonably ascertainable and may be proven by expert analysis. Plaintiff's initial investigation shows that amount to be no less than $72,900,000.

SECOND CLAIM FOR RELIEF

Fraud and Intentional Misrepresentation

66. Defendants represented to Plaintiff that the following facts were true: that they would supply Zetajet units and syringes to Plaintiff upon request, that they would negotiate in good faith to directly or indirectly supply Zetajet units and syringes to Plaintiff at a price of production cost plus 15%, and that they would supply 25,000 Zetajet syringes to Plaintiff, at the price of $24,725.

67. The above statements were untrue, as Defendants did not supply the Zetajet syringes to Plaintiff.

68. Defendants made these representations with the knowledge and belief that these representations were false, or with reckless indifference to the truth.

69. Defendants had the intent to induce Plaintiff to act and rely on these false representations.

70. Plaintiff reasonably relied on these representations, both when its principal executives sold the company Bioject and the rights to the Zetajet technology to Defendants, and in planning and proceeding with its DDC testosterone project.

71. As a proximate result of Defendants' intentional misrepresentation, on which Plaintiff reasonably relied, Plaintiff was harmed in the amount of money expended in developing the DDC and preparing the DDC for clinical trials, which is approximately $170,571, and in the amount of lost profits that would otherwise have been made from sales of the DDC.

72. The amount of lost profits is reasonably ascertainable and may be proven by expert analysis. Plaintiff's initial investigation shows that amount to be no less than $72,900,000.

THIRD CLAIM FOR RELIEF

Negligent Misrepresentation

73. Defendants represented to Plaintiff that the following facts were true: that they would supply Zetajet units and syringes to Plaintiff upon request, that they would negotiate in good faith to directly or indirectly supply Zetajet units and syringes to Plaintiff at a price of production cost plus 15%, and that they would supply 25,000 Zetajet syringes to Plaintiff, at the price of $24,725.

74. The above statements were untrue, as Defendants did not supply the Zetajet syringes to Plaintiff.

75. Defendants had no reasonable grounds for believing these representations were true.

76. Defendants had the intent to induce Plaintiff to act and rely on these false representations.

77. Plaintiff reasonably relied on these representations, both when its principal executives sold the company Bioject and the rights to the Zetajet technology to Defendants, and in planning and proceeding with its DDC testosterone project.

78. As a proximate result of Defendants' negligent misrepresentation, on which Plaintiff reasonably relied, Plaintiff was harmed in both the amount of money expended in developing the DDC and preparing the DDC for clinical trials, which is approximately $170,571, and in the amount of lost profits that would otherwise have been made from sales of the DDC.

79. The amount of lost profits is reasonably ascertainable and may be proven by expert analysis. Plaintiff's initial investigation shows that amount to be no less than $72,900,000.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff prays for relief as set forth below:

A. Actual damages, compensatory damages, statutory damages, punitive or treble damages, restitution, and such other relief as provided by the laws cited herein, in an amount subject to proof at trial;

B. Pre-judgment and post-judgment interest on such monetary relief;

C. The costs of bringing this suit, including reasonable attorneys' fees to the extent permitted by law; and

D. All other relief to which Plaintiff may be entitled at law or in equity.

DEMAND FOR JURY TRIAL

Plaintiff hereby requests a jury trial on any and all claims so triable.

DATED: December 17, 2019

HARTLEY LLP

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