

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

JULIE GOLLA,

Plaintiff,

v.

NOVO NORDISK INC.,

Defendant.

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Civil Action No. _____

COMPLAINT FOR DECLARATORY RELIEF

Plaintiff Julie Golla files this Complaint for Declaratory Relief in her favor and against Defendant Novo Nordisk Inc. (“Novo Nordisk”), and alleges as follows:

INTRODUCTION

1. Defendant Novo Nordisk, a pharmaceutical company that produces a replacement therapy treatment for the bleeding disorder hemophilia, is attempting to use a non-competition agreement to restrain its former employee, Julie Golla, from working in a different position at BioMarin related to a potential new, revolutionary gene therapy treatment for hemophilia that has not yet been approved by the U.S. Federal Drug Administration (“FDA”) and thus does not yet compete with Novo.

2. Novo Nordisk – along with several other companies – sells a replacement “factor VIII” therapy in which hemophilia patients receive intravenously the clotting protein (factor VIII) that their cells do not produce. Novo Nordisk’s replacement therapy requires infusions of Factor VIII multiple times a week.

3. Golla’s new employer, BioMarin, has developed a product, valoctocogene roxaparvovec, that, if approved by the FDA, may eliminate the need for regular infusions of Factor

VIII for those with severe hemophilia A. Specifically, BioMarin's therapy does not rely on Factor VIII but instead inserts a corrected gene into hemophilia patients' cells so the patients will begin producing the deficient clotting protein *on their own*.

4. Valoctocogene roxaparvovec has not been approved to be sold or even marketed. BioMarin recently filed a request for approval with the FDA. It is unknown when the FDA will approve valoctocogene roxaparvovec or if it will be approved at all.

5. Ms. Golla recently resigned from Novo Nordisk and informed Novo Nordisk that she intends to work as a Senior Account Manager – Hemophilia Gene Therapy at BioMarin. After completing training, Ms. Golla will educate members of the hemophilia community about gene therapy generally (not for hemophilia) until the FDA approves valoctocogene roxaparvovec. Prior to FDA approval, Ms. Golla will not be permitted to discuss valoctocogene roxaparvovec or promote it in any way. Nevertheless, upon information and belief, Novo Nordisk seeks to enforce the non-competition provision in Ms. Golla's agreement to prevent Ms. Golla from working at BioMarin.

6. Because BioMarin does not currently compete with Novo Nordisk, Ms. Golla should not be precluded from working in her anticipated role with BioMarin. Moreover, the noncompete agreement at issue should not prohibit her from working at BioMarin because it is overbroad. Ms. Golla, who only worked for Novo Nordisk for just over a year, did not receive any training from Novo Nordisk regarding hemophilia and during her employment at Novo Nordisk, she did not establish any new customer contacts in the region she will be assigned at BioMarin. Ms. Golla had knowledge regarding hemophilia and relationships in the hemophilia community in Texas from her prior employment.

7. Therefore, Ms. Golla seeks declaratory judgment that under the factual circumstances outlined herein, Ms. Golla's position at BioMarin does not violate the noncompetition provision. Alternatively, to the extent the Court believes that Ms. Golla's new position falls within the text of the noncompetition provision, the restrictive covenant is overbroad because there is no geographic limitation, the scope of activity to be restrained is not reasonable, and it is broader than necessary to protect Novo Nordisk's legitimate business interests. To the extent the Court finds that the noncompetition provision does lawfully prevent Ms. Golla's employment at BioMarin, Ms. Golla seeks a declaration that Novo Nordisk must pay her base salary during the one-year non-competition period in accordance with the agreement.

PARTIES

8. Plaintiff Ms. Golla is an individual residing in Harris County, Texas. Ms. Golla resided in Harris County, Texas when she signed the agreement, and she resided in Harris County, Texas during her entire employment at Novo Nordisk. At Novo Nordisk, Ms. Golla's sales territory included Texas, and at BioMarin, she will be focused solely on areas within Texas.

9. Defendant Novo Nordisk Inc. is a Delaware corporation with its principal place of business in Plainsboro, New Jersey. Novo Nordisk is a company that provides healthcare and pharmaceutical products and services, including in Harris County, Texas. Novo Nordisk has purposefully directed its activities at Texas, including by selling products and services in Texas, by selling products and services to Texas entities, and by employing Texas residents such as Ms. Golla. Novo Nordisk has otherwise purposefully availed itself of the benefits and privileges of operating and doing business in Texas. Novo Nordisk may be served by service of process through its registered agent, CT Corporation System, located at 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

JURISDICTION AND VENUE

10. This Court has jurisdiction pursuant to 28 U.S.C. § 1332 because this is an action between citizens of different states and the amount in controversy exceeds \$75,000. The amount in controversy includes, among other things, the compensation and benefits that Ms. Golla would be forced to forgo if the agreement is interpreted to prevent Ms. Golla from being employed by BioMarin and the amounts that Novo Nordisk is contractually obligated to pay to Ms. Golla (which exceeds \$75,000) if it enforces the noncompetition provision in the agreement.

11. This Court has personal jurisdiction over Novo Nordisk because Novo Nordisk purposely and contractually availed itself of the privileges and benefits of conducting business in Texas. Novo Nordisk regularly does business with and employs individuals in Texas, sells its products in Texas, and entered into a contract with a Texas resident that was to be substantially performed in Texas.

12. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) because all or a substantial part of the events giving rise to this Complaint occurred in Harris County, Texas. Among other things, the Agreement was executed and performed within this judicial district.

FACTUAL BACKGROUND

A. Hemophilia A Treatments

13. Hemophilia is a rare genetic disorder that occurs when an individual does not produce all (or an insufficient amount) of the blood-clotting proteins – “clotting factors” – needed for blood to clot to stop bleeding. Hemophilia patients are at risk for painful and/or potentially life-threatening bleeds from surface cuts and internal bleeding. In addition, patients with severe hemophilia can experience spontaneous bleeding, most frequently into joints, that causes progressive and debilitating joint damage.

14. The most common type of hemophilia is hemophilia A, which is caused by a lack of or deficiency in the clotting factor known as called Factor VIII.

15. Hemophilia A affects approximately 16,000 individuals in the United States and occurs much more frequently in males. About half of the hemophilia patient population is children.

16. The standard of care for patients with hemophilia A is a prophylactic regimen of replacement Factor VIII infusions administered intravenously up to two to three times per week or 100 to 150 infusions per year. Despite these regimens, many people continue to experience bleeds, resulting in progressive and debilitating joint damage, which can have a major impact on their quality of life.

17. There are currently approximately 20 different Factor VIII replacements on the market through various companies. While there are some differences among the Factor VIII replacement products (*e.g.*, storage options such as whether it requires refrigeration and can withstand extreme temperatures), they are often prescribed based on the doctor's preference and the patient's lifestyle needs. BioMarin does not market or sell any Factor VIII replacement products.

B. A Potentially Groundbreaking Hemophilia A Treatment

18. BioMarin is investigating a new, innovative treatment for adults with hemophilia A: gene therapy.

19. Gene therapy is a form of treatment designed to address a genetic problem by adding a corrected copy of the defective gene. The functional gene is inserted into a vector containing a small DNA sequence that acts as a delivery mechanism, providing the ability to deliver the functional gene to targeted cells. The cells can then use the information to build the functional proteins that the body needs, potentially reducing or eliminating the cause of the disease.

20. Upon information and belief, the FDA has approved gene therapy to treat only two disorders: hereditary blindness and spinal muscular atrophy. The FDA has not yet approved for use any gene therapies for hemophilia or determined that any gene therapies for hemophilia are safe or effective.

21. On December 23, 2019, BioMarin announced that it submitted a Biologics License Application (“BLA”) to the FDA for its investigational gene therapy, valoctocogene roxaparvovec. BioMarin needs a biologics license in order to market and sell valoctocogene roxaparvovec.

22. BioMarin’s BLA submission is the first FDA marketing application in the United States for a gene therapy treatment for hemophilia.

23. If approved by the FDA, valoctocogene roxaparvovec may provide qualifying hemophilia A patients with a treatment that could eliminate the need for regular Factor VIII infusions.

24. In clinical trials, BioMarin’s gene therapy treatment consisted of a single infusion into the patient’s body of a genetically engineered vehicle known as a “vector” that carries a gene that correctly manufactures Factor VIII. Upon injection, the vector is designed to go to the patient’s liver where it is absorbed by the patient’s liver cells. The vector deposits the functioning Factor VIII gene into the nucleus of the liver cells and the vector dissolves, leaving the functioning gene. With the functioning Factor VIII gene, the patient’s *own cells* began producing the Factor VIII protein. Thus, valoctocogene roxaparvovec is not a Factor VIII replacement; rather, it corrects the underlying cause of hemophilia A.

25. In contrast with Factor VIII replacement therapies, which require intravenous injections multiple times per week, the valoctocogene roxaparvovec clinical data has shown patients’ Factor VIII levels can remain at a therapeutic level for years.

26. Based on the draft product label submitted to the FDA, BioMarin estimates that, if approved, only about 10% of the hemophilia population will be eligible for its gene therapy treatment. For example, the clinical data submitted to the FDA involved only adults and patients with severe hemophilia A. Other hemophilia A patients may not qualify for valoctocogene roxaparvovec if their cells contain a certain vector or if they test positive for certain viruses.

27. Upon information and belief, the earliest the FDA will approve BioMarin's gene therapy treatment is the third quarter of 2020. However, the approval process could take longer due to various regulatory requirements or additional requests for information from the FDA. Moreover, there is no guarantee that the FDA will approve BioMarin's application at all.

C. Ms. Golla's Professional Experience

28. Ms. Golla has worked for pharmaceutical companies for more than 25 years. She also has significant experience launching new drugs. For example, from November 2013 through May 2014, Ms. Golla worked at Lundbeck USA, where she launched a new and novel antidepressant into the Houston market.

29. Ms. Golla began working in the hemophilia disease state in 2012 when she worked at Octapharma, Inc. as a Territory Business Manager. In that role, she managed sales growth and customer relations in Houston, Texas, Louisiana and Arkansas for that company's Factor VIII replacement therapy. During her employment at Octapharma, Ms. Golla received training regarding hemophilia and factor replacement therapies generally. She developed a deep knowledge of the hemophilia disease state and the corresponding market for hemophilia treatment.

30. Ms. Golla continued to work in hemophilia when she accepted a position at Accredo Specialty Pharmacy in May 2014 as a Bleeding Disorders Account Manager, covering Texas, Louisiana, Arkansas, Oklahoma, and Mississippi. In that role, she identified and developed relationships with Hemophilia Treatment Centers in order to grow and retain the company's

hemophilia patient base. Accredo selected Ms. Golla to serve as one of its two nationwide Hemophilia Team Representatives for the American Society of Hematology, the Infusion Nurse Society, and the Hemophilia Federation of America, a role she held for three years.

31. Also at Accredo, Ms. Golla became a certified facilitator for “Karing for Kids,” a hemophilia education program designed and implemented by Accredo that was conducted at hemophilia conferences. Ms. Golla received training for this role while at Accredo.

D. Ms. Golla’s Position at Novo Nordisk

32. In November 2018, Novo Nordisk hired Ms. Golla as a Senior Hemophilia Therapy Manager to promote its Factor VIII replacement therapies for hemophilia patients by meeting with hemophilia treatment centers and hematologists in her territory. Upon information and belief, Novo Nordisk hired Ms. Golla because of her expertise regarding hemophilia that she obtained during her employment at Octapharma and Accredo and because of her relationships with hemophilia treatment centers and practitioners that she knew from her employment at Octapharma and Accredo. Novo Nordisk assigned Ms. Golla Texas, Louisiana, Oklahoma, and New Mexico, substantially the same territory she had at Accredo.

33. Novo Nordisk did not provide Ms. Golla with any training on the hemophilia disease state. During the course of her employment at Novo Nordisk, Ms. Golla relied on her prior knowledge regarding hemophilia.

34. The only training Ms. Golla received from Novo Nordisk was on its Factor VIII replacement therapies, but Ms. Golla already had knowledge of the hemophilia disease state. Information regarding Novo Nordisk’s Factor VIII replacement therapies is available publicly, and it is not relevant to BioMarin anyway because valoctocogene roxaparvovec is a fundamentally different treatment.

35. Other than customers in New Mexico (a territory she will not be responsible for at BioMarin), Ms. Golla did not identify or develop any new customer contacts during her employment at Novo Nordisk.

36. In any case, Ms. Golla's contacts and relationships with hemophilia treatment centers and practitioners has limited utility. Hemophilia treatment is a specialized field with few treatment centers and treating practitioners in each region and whose identity is known in the industry and publicly available. For example, the Center for Disease Control's website contains a directory with the names and contact information for doctors and nurses who treat hemophilia throughout the United States. A list of hemophilia treatment centers is also published on the Center for Disease Control's website. Moreover, regulations restrict pharmaceutical sales representatives' access to and interactions with practitioners.

37. Relationships between sales representatives and practitioners and treatment centers are of greater significance for Factor VIII replacement products because Factor VIII products are therapeutically similar but have some differing attributes that may make a certain product more attractive to a particular patient.

38. Ms. Golla's base salary at Novo Nordisk at the time she resigned was more than \$75,000. Ms. Golla also received commissions based on her sales performance. She also received health care benefits.

E. Ms. Golla's New Position at BioMarin

39. BioMarin has hired Ms. Golla as a Senior Account Manager – Hemophilia Gene Therapy, and she is expected to start on January 21, 2020. Her territory will be the southern half of Texas, which includes Harris County. Ms. Golla's base salary at BioMarin will be in excess of \$75,000 a year.

40. Until the FDA approves valoctocogene roxaparvovec, regulations prohibit BioMarin from marketing the treatment in any way. Thus, Ms. Golla will not be promoting or selling valoctocogene roxaparvovec prior to FDA approval. After joining BioMarin, Ms. Golla will have an initial period of internal training during which she will receive instruction on how gene therapy works. She will not be trained on valoctocogene roxaparvovec other than receiving instruction that she should not answer any questions pertaining to valoctocogene roxaparvovec. After this initial period of internal training, Ms. Golla's role will be to educate healthcare providers, treatment centers, advocacy groups, and patients regarding gene therapy generally using approved materials. Consistent with applicable regulations, Ms. Golla will not focus on hemophilia or reference any specific products. In fact, Ms. Golla will not be permitted to answer any specific questions about valoctocogene roxaparvovec prior to FDA approval. Ms. Golla will conduct general gene therapy education until the FDA approves valoctocogene roxaparvovec. One of Ms. Golla's additional duties will be to survey the facilities she visits to ascertain their capabilities for supporting gene therapy treatments.

41. Only after – and if – the FDA approves valoctocogene roxaparvovec will Ms. Golla begin promoting it.

F. Novo Nordisk Seeks to Prevent Her From Working at BioMarin

42. Novo Nordisk required Ms. Golla to sign the “Confidentiality, Non-Compete and Employment Invention Agreement” (the “Agreement”) (attached as Exhibit A) at the outset of her employment. Among other things, Section 3 of the Agreement contains the following non-competition provision (the “Non-Compete”):

In addition, during my employment and for a period of twelve months following the termination of my employment for any reason, voluntary or involuntary, (the “Non-Compete Period”), I will not individually compete, or be employed by, work for, advise, provide services to, or assist in any way any competitor of the Company by

performing work involving or related to the disease state in which I worked or was involved. Also, I will not individually compete, or be employed by, work for, advise, provide services to, or assist in any way any competitor of the Company by working on, or having any involvement or communication with respect to, products that compete with or are the same as products that I worked on, was involved with, or about which I had access to any information, during the last twelve months of my employment with the Company. Said Non-Compete Period shall commence on the day upon which I shall actually leave my employment with the Company, even if such date is prior to the expiration of any non-working notice of termination given.

43. The Non-Compete in Section 3 of the Agreement does not contain a geographic restriction.

44. Section 4 of the Agreement suggests that the Non-Compete is worldwide.

45. The Agreement also provides that if Novo Nordisk enforces the Non-Compete, it will continue to pay Ms. Golla:

In the event that the Company enforces the restriction on employment in this section 3 following the termination of my employment, the Company shall continue to pay my base salary during the Non-Compete Period, offset and reduced by any wages, compensation or other amounts I earn during the Non-Compete Period (whether through employment, self-employment, consulting, contracting, or other services).

46. On January 7, 2020, Ms. Golla notified Novo Nordisk of her resignation and intent to begin employment with BioMarin. In her resignation letter, Ms. Golla explained the scope of her new position at BioMarin as well as her beliefs that the BioMarin position does not violate the Non-Compete and that the Non-Compete is unenforceable to the extent that it purports to prohibit her from working at BioMarin as a Senior Account Manager – Hemophilia Gene Therapy. Ms. Golla requested that Novo Nordisk acknowledge and confirm that it would not seek to enforce the Non-Compete, that the Non-Compete does not prohibit her from working at BioMarin as a Senior Account Manager – Hemophilia Gene Therapy, and that she is lawfully entitled to work at

BioMarin as a Senior Account Manager – Hemophilia Gene Therapy. Ms. Golla also asked if Novo Nordisk will seek to enforce the Non-Compete and, if so, whether it will pay her salary.

47. Ms. Golla specifically requested that Novo Nordisk provide the requested information by 5:00 p.m. Eastern Standard Time on January 8, 2020 and advised that, in the event Novo Nordisk did not provide the requested information by that time, she would assume that Novo Nordisk would seek to enforce the noncompete, take the position that she is prohibited from working for BioMarin in the position for which she was hired, and would not pay her the salary required by the Agreement.

48. Novo Nordisk responded to Ms. Golla's resignation letter and accepted her resignation but did not provide a response to the specific requests set forth above by 5:00 p.m. Eastern Standard Time on January 8, 2020.

49. A live controversy has arisen and now exists between the parties concerning their respective rights and obligations under the Agreement.

GOVERNING LAW

50. Section 13 of the Agreement provides that it will be governed by New Jersey law.

51. However, Texas law applies to the Agreement under applicable precedent. *See Exxon Mobil Corp. v. Drennen*, 452 S.W.3d 319 (2014); *DeSantis v. Wackenhut Corp.*, 793 S.W.2d 670 (1990).

52. Texas has the most significant relationship with the parties and their transaction. Novo Nordisk hired Ms. Golla to work from its office in Houston. She interviewed with Novo Nordisk via Skype; Ms. Golla was in Houston and the Novo Nordisk manager was in Alabama. , Ms. Golla signed the Agreement with Novo Nordisk in Houston, and Ms. Golla's work was primarily to be performed in Texas, along with the surrounding states of Louisiana, New Mexico,

and Oklahoma. Ms. Golla is a resident of Texas and targeted customers in Texas during her employment. Texas has a materially greater interest in determination of this issue than New Jersey.

53. Application of New Jersey law would be contrary to a fundamental policy of Texas.

COUNT I

Declaratory Judgment That Ms. Golla's Position At BioMarin Does Not Violate The Agreement

54. Ms. Golla repeats and re-alleges the allegations set forth in Paragraphs 1 – 53 as if fully set forth herein.

55. Ms. Golla's employment at BioMarin does not violate the Agreement.

56. BioMarin does not sell a product that competes with any product Novo Nordisk sells. It is unknown if the FDA will approve valoctocogene roxaparvovec at all and if it does, it is unknown when it will be approved or what the indication will be. Currently, BioMarin prohibited from selling and even marketing valoctocogene roxaparvovec. Thus, BioMarin is not a competitor of Novo Nordisk.

57. Because BioMarin is not currently a competitor of Novo Nordisk, her employment at BioMarin does not violate the Agreement.

58. Ms. Golla's role at BioMarin educating the community about gene therapy generally does not violate the Agreement.

59. Novo Nordisk claims that the Non-Compete prevents Ms. Golla from working at BioMarin. Novo Nordisk's effort to prevent Ms. Golla from working for BioMarin educating the community and practitioners about gene therapy injures Ms. Golla as it hampers her professional development, purports to prevent her from working in a disease state in which she has worked for multiple years prior to joining Novo Nordisk, prevents her from working at the cutting edge of scientific development, and places her at risk of losing her compensation and benefits at BioMarin for at least twelve months, and potentially longer if she is unable to find work.

60. There is therefore a real and substantial controversy between Ms. Golla and Novo Nordisk regarding whether Ms. Golla's employment at BioMarin violates the Agreement such that a declaration of rights is both necessary and appropriate.

61. Ms. Golla's injury can be resolved by a declaratory judgment that her position at BioMarin does not violate the Agreement.

COUNT II
Declaratory Judgment That The Non-Compete is Unenforceable

62. Ms. Golla repeats and re-alleges the allegations set forth in Paragraphs 1 – 61 as if fully set forth herein.

63. The Non-Compete is unenforceable because it does not contain a geographic restriction as required by Texas Business and Commercial Code § 15.50. Alternatively, if the Non-Compete contains a worldwide geographic scope, it is unenforceable because it seeks to restrict Ms. Golla from working in areas that were outside her territory at Novo Nordisk.

64. In addition, the Non-Compete cannot be enforced to prohibit Ms. Golla from working at BioMarin as a Senior Account Manager – Hemophilia Gene Therapy during the Non-Compete Period.

65. Novo Nordisk claims the Non-Compete lawfully prohibits Ms. Golla from working at BioMarin as a Senior Account Manager – Hemophilia Gene Therapy anywhere in the world during the Non-Compete Period.

66. There is therefore a real and substantial controversy between Ms. Golla and Novo Nordisk regarding whether the enforceability of the Non-Compete such that a declaration of rights is both necessary and appropriate in order to establish the enforceable scope of the Non-Compete.

67. A justiciable controversy exists between Ms. Golla and Novo Nordisk regarding the enforceable scope, if any, of the Non-Compete and whether Ms. Golla can work for BioMarin as a Senior Account Manager – Hemophilia Gene Therapy.

68. Ms. Golla's injury can be resolved by a declaratory judgment that the Non-Compete is unenforceable or that it does not prevent Ms. Golla from working at BioMarin as a Senior Account Manager – Hemophilia Gene Therapy.

COUNT III

Declaratory Judgment of Novo Nordisk's Obligation to Pay Ms. Golla's Base Salary

69. Ms. Golla repeats and re-alleges the allegations set forth in Paragraphs 1 – 68 as if fully set forth herein.

70. To the extent the Non-Compete prevents Ms. Golla's employment at BioMarin, Novo Nordisk has an obligation to pay Ms. Golla her salary during the Non-Compete Period, which was her base salary at the time of her resignation from Novo Nordisk. Novo Nordisk has no excuse justifying nonpayment and Ms. Golla has been injured by Novo Nordisk's repudiation of its contractual obligation.

71. There is therefore a real and substantial controversy between Ms. Golla and Novo Nordisk regarding Novo Nordisk's obligation to pay Ms. Golla her base salary such that a declaration of rights is both necessary and appropriate.

72. Ms. Golla's injury can be resolved by a declaratory judgment that if Novo Nordisk prevents Ms. Golla from being gainfully employed at BioMarin, Novo Nordisk must pay Ms. Golla her base salary during the Non-Compete Period.

ATTORNEY'S FEES AND COSTS

73. Ms. Golla is entitled to recover its reasonable and necessary attorney's fees and costs under Chapters 37 and 38 of the Texas Civil Practices and Remedies Code, the Federal

Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and all other applicable statutes, case law, and rules.

PRAYER FOR RELIEF

WHEREFORE, Ms. Golla requests a judgment against Novo Nordisk as follows:

1. For a judgment declaring that Ms. Golla's employment at BioMarin does not violate the Agreement;
2. For a judgment declaring that the Non-Compete cannot be enforced to prohibit Ms. Golla's employment at BioMarin;
3. Alternatively, if the Non-Compete does prevent Ms. Golla's employment at BioMarin, for a judgment declaring that Novo Nordisk must pay Ms. Golla's base salary during the Non-Compete Period;
4. For reasonable attorney's fees and costs; and
5. All other and further relief, legal or equitable, that this Court deems proper.

Dated: January 8, 2020

Respectfully submitted,

/s/ Matthew W. Ray

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