IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SAN ROCCO THERAPEUTICS, LLC, Plaintiff, v. BLUEBIRD BIO, INC. and THIRD ROCK VENTURES, LLC, Defendants.	)	C.A. No. 21-1478-RGA **JURY TRIAL DEMANDED** **PUBLIC VERSION**

SECOND AMENDED AND SUPPLEMENTAL COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff San Rocco Therapeutics, LLC ("SRT"), formerly known as Errant Gene Therapeutics, LLC, for its Complaint against Defendants Bluebird Bio, Inc. ("Bluebird") and Third Rock Ventures, LLC ("Third Rock") (collectively, "Defendants") hereby alleges, on knowledge as to its own actions, and upon information and belief as to all other matters, as follows:

NATURE OF THE CASE

1. This is an action for infringement of U.S. Patent Nos. 7,541,179 ("the '179 Patent") and 8,058,061 ("the '061 Patent") (collectively, the "Patents-in-Suit") pursuant to the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*., including §§ 271(a), 271(b), and/or 271(c).

2. SRT has an exclusive commercial license to the '179 and '061 Patents, titled "Vector Encoding Human Globin Gene And Use Thereof In Treatment of Hemoglobinopathies," which claim recombinant vectors that are used in the treatment of hemoglobinopathies, such as Sickle Cell Disease and Beta Thalassemia.

3. SRT is a biopharmaceutical company, established in 1993 by its founder and CEO, Mr. Patrick Girondi, after his son was diagnosed with Beta Thalassemia, a rare inherited blood disorder. Since that time, and for the greater part of nearly three decades, SRT has dedicated itself

to developing treatments for life-threatening diseases, with a special focus on rare diseases (commonly referred to as orphan diseases), through the use of gene therapy — a scientific technique that treats genetic disorders by modifying, replacing, and/or inactivating mutated genes responsible for causing the disease.

4. As a result of its tireless efforts, SRT has successfully developed recombinant vectors that can be used in gene therapy treatment of rare genetic diseases, such as Sickle Cell Disease and Beta Thalassemia (also referred to as β-thalassemia). Indeed, SRT became the first company to obtain Orphan Drug Designation for Beta Thalassemia in the United States and Europe, and the first to produce a commercial batch (sufficient for 8-10 patients) of gene therapy for Beta Thalassemia.

5. SRT brings this action to protect its rights and investment in its innovations embodied in the '179 and '061 Patents infringed by Bluebird's betibeglogene autotemcel (beti-cel) gene therapy (formerly, marketed as ZYNTEGLO® and LENTIGLOBIN®), which is manufactured using (and containing) the BB305 lentiviral vector (hereinafter "the BB305 Vector" or "Infringing Drug Product").

6. SRT brings this action against Third Rock for inducing infringement of the '179 and '061 Patents by, among other things, actively and knowingly aiding and abetting Bluebird's infringement of the '179 and '061 Patents. With knowledge of SRT's exclusive (worldwide) license to the '179 and '061 Patents, Third Rock actively induced, and possessed the specific intent to cause, urge, encourage, and aid in Bluebird's direct infringement of the '179 and '061 Patents.

THE PARTIES

7. SRT is a Delaware limited liability company with its principal place of business at 308 East Emily Street, Tampa, Florida 33603.

8. Bluebird is a Delaware corporation with business offices located at 60 Binney Street, Cambridge, Massachusetts 02142, and at 188 East Blaine Street, Suite 300, Seattle, Washington 98102.

9. Third Rock is a Delaware limited liability company with business offices located at 29 Newbury Street, 3rd Floor, Boston, Massachusetts 02116, and at 499 Illinois Street, Suite 110, San Francisco, California 94158.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq*., including §§ 271(a), 271(b), and/or 271(c).

11. This Court has subject matter jurisdiction over the matters asserted herein pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. This Court has personal jurisdiction over Bluebird and Third Rock at least because Bluebird and Third Rock are each incorporated in the State of Delaware.

13. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(a), 1391(c), and 1400(b) because Bluebird and Third Rock are each incorporated in this District and therefore "reside" in this District.

THE PATENTS-IN-SUIT

14. On June 2, 2009, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '179 Patent, entitled "Vector Encoding Human Globin Gene and Use

Thereof in Treatment of Hemoglobinopathies," to inventors ("Inventors" and each an "Inventor") Michel Sadelain, Stefano Rivella, Chad May, and Joseph Bertino, and the '179 Patent was assigned to Memorial Sloan-Kettering Cancer Center ("MSKCC"). A true and correct copy of the '179 Patent is attached as Exhibit A.

15. The '179 Patent issued from U.S. Patent Application No. 10/188,221, which claims priority to Provisional Application Nos. 60/301,861 filed on June 29, 2001 and 60/302,852 filed on July 2, 2001.

16. On November 15, 2011, the USPTO issued the '061 Patent, entitled "Vector Encoding Human Globin Gene and Use Thereof in Treatment of Hemoglobinopathies," to Inventors Michel Sadelain, Stefano Rivella, Chad May, and Joseph Bertino, and the '061 Patent was assigned to MSKCC. A true and correct copy of the '061 Patent is attached as Exhibit B.

17. The '061 Patent issued from U.S. Patent Application No. 12/433,412, which is a division of Application No. 10/188,221 filed on July 1, 2002, now the '179 Patent. The '061 Patent claims priority to Provisional Application Nos. 60/301,861 filed on June 29, 2001 and 60/302,852 filed on July 2, 2001.

SRT has an Exclusive Commercial License to the '179 and '061 Patents

18. Pursuant to a settlement agreement executed on November 2, 2020 (the "Settlement Agreement"), MSKCC granted SRT an [redacted] to the intellectual property listed in a [redacted] D.I. 16, [Dfs' Br.], Ex. C at 2(a) of the Settlement Agreement.

19. Under the Settlement Agreement, SRT has the right to exclude others from making, having made, using, importing, selling, or offering for sale in the United States any lentiviral

vector, gene therapy treatment, or drug product that is covered by a valid claim of the Patents-in-Suit, which are the intellectual property licensed in the [redacted].

20. Under the Settlement Agreement, SRT has the right to exclude others from commercializing or engaging in commercialization activities using a lentiviral vector that is within the scope of a valid claim of the Patents-in-Suit.

21. The intellectual property licensed in the 2005 Agreement is set forth under Exhibit A thereto, and includes: U.S. Patent Application No. 10/188,221, filed on July 1, 2002, "Vector Encoding Human Globin Gene and Use thereof in Treatment of Hemoglobinopathies;" U.S. Provisional Applications Nos. 60/301,861, filed on June 29, 2001 and 60,302,852 filed on July 2, 2001; and International Application No. PCT/US2002/020988.

22. The 2005 Agreement further provides that the patent rights shall mean all of the following intellectual property: (a) the United States and foreign patents and patent applications listed in Exhibit A; (b) the United States and foreign patents issued from the applications listed in Exhibit A and from divisionals and continuations of these applications; (c) claims of U.S. and foreign continuation-in-part applications, and of the resulting patents, which are directed to the subject matter specifically described in the U.S. and foreign patent applications listed in Exhibit A; and (d) any reissues or re-examinations of patents described in (a), (b), or (c), above.

23. The '179 Patent issued from U.S. Patent Application No. 10/188,221, which is listed in Exhibit A to the 2005 Agreement. The '061 Patent is a Division of U.S. Application No. 10/188,221 filed on July 1, 2002, now the '179 Patent. The '179 and '061 Patents claim priority to U.S. Provisional Application Nos. 60/301,861 and 60/302,852, which are listed in Exhibit A to the 2005 Agreement.

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