

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

REGENXBIO INC. and THE TRUSTEES)	
OF THE UNIVERSITY OF)	
PENNSYLVANIA,)	
)	
Plaintiffs,)	C.A. No. 23-667 (RGA)
)	
v.)	JURY TRIAL DEMANDED
)	
SAREPTA THERAPEUTICS, INC.,)	
SAREPTA THERAPEUTICS THREE,)	
LLC, and CATALENT INC.)	
)	
Defendants.)	

**DEFENDANT CATALENT INC.’S ANSWER TO COMPLAINT FOR PATENT
INFRINGEMENT AND FOR DECLARATORY JUDGMENT
OF PATENT INFRINGEMENT**

Defendant Catalent Inc. (“Catalent”), by and through its undersigned counsel, hereby submits its Answer to the Complaint for Patent Infringement and for Declaratory Judgment of Patent Infringement (“Complaint”) (D.I. 1) filed by RegenxBio Inc. (“Regenx”) and The Trustees of The University of Pennsylvania (“UPenn”) (collectively, “Plaintiffs”) as follows:

NATURE OF ACTION¹

1. Catalent admits that the Complaint purports to be an action for infringement of United States Patent No. 11,680,274 (“the ’274 patent”) instituted under the Patent Laws of the United States, 35 U.S.C. §§ 271 (a)-(c), and for a declaratory judgment of infringement of the ’274 patent under the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Catalent admits that the Complaint alleges that Catalent infringes the ’274 patent through its alleged manufacture

¹ For convenience and clarity, Catalent’s Answer uses the same headings as the Complaint. Catalent does not admit any allegations contained in the Complaint’s headings.

and use of an adeno-associated virus (“AAV”) technology gene therapy product, referred to as SRP-9001. Catalent admits that Exhibit A purports to be a copy of the ’274 patent. Catalent denies that it has infringed any claim of the ’274 patent or that the claims of the ’274 patent are valid. Catalent denies any remaining allegations in Paragraph 1.

THE PARTIES

2. Upon information and belief, Catalent admits the allegations of Paragraph 2.
3. Upon information and belief, Catalent admits the allegations of Paragraph 3.
4. Upon information and belief, Catalent admits the allegations of Paragraph 4.
5. Catalent denies that Regenx’s NAV[®] Technology Platform is entitled to patent protection. Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.
6. Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.
7. Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.
8. Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.
9. Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.
10. Catalent admits that Catalent Inc. is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 14 Schoolhouse Road, Somerset, NJ 08873. Catalent denies any remaining allegations in Paragraph 10.

11. Catalent admits that Catalent Inc. is a global contract development and manufacturing organization focused on helping pharmaceutical, biotech, and consumer health innovators develop, deliver and supply superior products that improve people's lives. Catalent denies any remaining allegations in Paragraph 11.

12. Catalent admits it is not a party to any license agreement with Regenx and/or UPenn. Catalent denies that it needs a license to the '274 patent to conduct its business. Catalent denies any remaining allegations in Paragraph 12.

JURISDICTION AND VENUE

13. Paragraph 13 contains a legal conclusion to which no response is required. To the extent a response is required, Catalent admits that Plaintiffs have brought an action arising under the patent laws of the United States, Title 35, of the United States Code. Catalent denies that this Court has subject matter jurisdiction over Plaintiffs' claims directed to any of Catalent's activities that have been solely for uses reasonably related to the development and submission of information to the FDA. To the extent Plaintiffs' claims are directed to Catalent's activities that are protected by the Safe Harbor provision of 35 U.S.C. § 271(e)(1), the Court lacks subject matter jurisdiction. Catalent denies any remaining allegations in Paragraph 13.

14. Paragraph 14 contains a legal conclusion to which no response is required. To the extent a response is required, Catalent admits that Plaintiffs have brought an action arising under the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the patent laws of the United States for a declaratory judgment. Catalent denies that this Court has subject matter jurisdiction over Plaintiffs' claims directed to any of Catalent's activities that have been solely for uses reasonably related to the development and submission of information to the FDA. To the extent Plaintiffs' claims are directed to Catalent's activities that are protected by the Safe Harbor

provision of 35 U.S.C. § 271(e)(1), the Court lacks subject matter jurisdiction. Catalent denies any remaining allegations in Paragraph 14.

15. Paragraph 15 contains a legal conclusion to which no response is required. To the extent a response is required, Catalent admits that venue is proper in this District for purposes of this action only. Catalent denies any remaining allegations in Paragraph 15.

16. Paragraph 16 contains a legal conclusion to which no response is required. To the extent a response is required, Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

17. Paragraph 17 contains a legal conclusion to which no response is required. To the extent a response is required, Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

18. Paragraph 18 contains a legal conclusion to which no response is required. To the extent a response is required, Catalent admits that this Court has personal jurisdiction over Catalent Inc. for purposes of this action only. Catalent denies any remaining allegations in Paragraph 18.

19. Paragraph 19 contains a legal conclusion to which no response is required. To the extent a response is required, Catalent admits that this Court has personal jurisdiction over Catalent Inc. for purposes of this action only. Catalent is without knowledge or information sufficient to form a belief as to the truth of the remaining matters asserted in this paragraph and therefore denies them.

FACTUAL BACKGROUND

Background Technology

20. Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

21. Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

22. Paragraph 22 contains a legal conclusion to which no response is required. To the extent a response is required, Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

The Patent-in-Suit

23. Catalent admits that the '274 Patent is titled "Method of Increasing the Function of an AAV Vector." Catalent admits that the '274 Patent on its face lists June 20, 2023 as the issue date. Catalent admits that the '274 Patent on its face names Luk Vandenberghe, Guangping Gao, and James M. Wilson as inventors. Catalent admits that the '274 Patent on its face names The Trustees of the University of Pennsylvania as the assignee. Catalent is without knowledge or information sufficient to form a belief as to the truth of the remaining matters asserted in this paragraph and therefore denies them.

24. Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

25. Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

26. Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

27. Catalent denies that it has infringed any claim of the '274 patent or that the claims of the '274 patent are valid. Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

28. Catalent denies that it has infringed any claim of the '274 patent or that the claims of the '274 patent are valid. Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

Count I
(Infringement of the '274 Patent)

29. Catalent restates as if fully set forth herein each of the foregoing paragraphs.

30. Catalent denies the allegations in Paragraph 30.

31. Catalent denies the allegations in Paragraph 31.

32. Catalent denies the allegations in Paragraph 32.

33. Catalent denies the allegations in Paragraph 33.

34. Catalent denies the allegations in Paragraph 34.

35. Catalent denies that it has infringed any claim of the '274 patent or that the claims of the '274 patent are valid. Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

36. Catalent denies the allegations in Paragraph 36.

37. Catalent denies the allegations in Paragraph 37.

38. Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

39. Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

40. Catalent denies the allegations in Paragraph 40.

41. Catalent admits that it became aware of the '274 patent no later than the date of filing of the Complaint. Catalent denies the remaining allegations in Paragraph 41.

42. Catalent denies the allegations in Paragraph 42.

43. Catalent denies the allegations in Paragraph 43.

44. Catalent denies the allegations in Paragraph 44.

Count II
(Declaratory Judgment of Infringement of the '274 Patent)

45. Catalent restates as if fully set forth herein each of the foregoing paragraphs.

46. Catalent denies the allegations in Paragraph 46.

47. Catalent denies the allegations in Paragraph 47.

48. Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

49. Catalent is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

50. Catalent denies the allegations in Paragraph 50.

51. Paragraph 51 states a request for relief to which no response is required. To the extent a response is required, Catalent denies the allegations in Paragraph 51.

JURY TRIAL DEMAND

Catalent admits that Plaintiffs have demanded a jury trial pursuant to Federal Rule of Civil Procedure 38(b) but denies that they are entitled to one.

PRAYER FOR RELIEF

Catalent denies that Plaintiffs are entitled to the relief requested or to any other relief.

Catalent denies all allegations of the Complaint not specifically admitted above.

DEFENSES

By alleging the Defenses set forth below, Catalent does not agree or concede that it bears the burden of proof or the burden of persuasion on any of these issues, whether in whole or in part.

For its Defenses to the Complaint, Catalent alleges as follows:

FIRST DEFENSE
(Non-Infringement)

Catalent has not infringed and is not infringing any claim of the '274 patent, either literally or under the doctrine of equivalents.

SECOND DEFENSE
(Safe Harbor)

Catalent's activities are immune or otherwise protected from suit under the Safe Harbor provision of 35 U.S.C. § 271(e)(1), which states that "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs"

THIRD DEFENSE
(Prosecution History Estoppel)

The '274 patent is limited by amendment, the prior art and/or statements made during its prosecution before the United States Patent and Trademark Office such that Plaintiffs are now estopped and/or otherwise precluded from maintaining that such claims of the '274 patent are of sufficient scope to cover the products accused of infringement in this case, either literally or under the doctrine of equivalents.

FOURTH DEFENSE
(Prosecution Laches)

The '274 patent is unenforceable due to the unreasonable and unexplained delay in prosecution of the '274 patent resulting in prejudice to Catalent.

FIFTH DEFENSE
(Equitable Estoppel)

Plaintiffs' claims for relief are barred in whole or in part by the doctrine of equitable estoppel.

SIXTH DEFENSE
(Invalidity)

The '274 patent is invalid for failure to comply with the conditions of patentability, including but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112.

SEVENTH DEFENSE
(Double Patenting)

The '274 patent is invalid for obviousness-type double patenting.

EIGHTH DEFENSE
(No Injunctive Relief)

Plaintiffs are not entitled to injunctive relief because any alleged injury to Plaintiffs is neither immediate nor irreparable, Plaintiffs have an adequate remedy at law, and the public interest is not served by the granting of an injunction.

NINTH DEFENSE
(Failure to State a Claim)

The Complaint fails to state a claim upon which relief may be granted.

TENTH DEFENSE
(Subject Matter Jurisdiction)

The Court lacks subject matter jurisdiction over the Complaint to the extent Plaintiffs' claims are directed to Catalent's activities that are protected by the Safe Harbor provision of 35 U.S.C. § 271(e)(1).

ELEVENTH DEFENSE
(No Damages)

Plaintiffs have incurred no damages as a result of the alleged infringement, which Catalent denies.

RESERVATION OF ADDITIONAL DEFENSES

Catalent reserves any and all additional defenses available under Title 35 of the United States Code, or otherwise in law or equity, now existing, or later arising, as may be discovered.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

Jack B. Blumenfeld (#1014)
Megan E. Dellinger (#5739)
Derek J. Fahnestock (#4705)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@morrisonichols.com
mdellinger@morrisonichols.com
dfahnestock@morrisonichols.com

OF COUNSEL:

Andrew M. Berdon
Robert B. Wilson
Anastasia M. Fernands
QUINN EMANUEL URQUHART &
SULLIVAN LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849 7000

Attorneys for Defendant Catalent Inc.

August 10, 2023

CERTIFICATE OF SERVICE

I hereby certify that on August 10, 2023, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on August 10, 2023, upon the following in the manner indicated:

Susan E. Morrison, Esquire
Casey M. Kraning, Esquire
FISH & RICHARDSON P.C.
222 Delaware Avenue 17th Floor
Wilmington, DE 19801
Attorneys for Plaintiff REGENXBIO Inc.

VIA ELECTRONIC MAIL

Brian D. Coggio, Esquire
Jeremy T. Saks, Esquire
FISH & RICHARDSON P.C.
7 Times Square 20th Floor
New York, NY 10036
Attorneys for Plaintiff REGENXBIO Inc.

VIA ELECTRONIC MAIL

Amy M. Dudash, Esquire
MORGAN, LEWIS & BOCKIUS LLP
1201 North Market Street, Suite 2201
Wilmington, DE 19801
*Attorneys for Plaintiff The Trustees of the University
of Pennsylvania*

VIA ELECTRONIC MAIL

/s/ Derek J. Fahnestock

Derek J. Fahnestock (#4705)