

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PRECISION BIOSCIENCES, INC. and)	
DUKE UNIVERSITY,)	
)	
Plaintiffs,)	C.A. No. _____
)	
v.)	
)	JURY TRIAL DEMANDED
LONZA GROUP LTD., LONZA SALES)	
LTD., LONZA BIOLOGICS plc, LONZA)	
INC., LONZA WALKERSVILLE, INC. and)	
LONZA BIOLOGICS, INC.,)	
)	
Defendants.)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Precision BioSciences, Inc. and Duke University hereby file this Complaint for Patent Infringement against defendants Lonza Group Ltd., Lonza Sales Ltd., Lonza Biologics plc, Lonza Inc., Lonza Walkersville, Inc. and Lonza Biologics, Inc., alleging as follows, on personal knowledge as to their own activities and on information and belief as to all other matters:

Parties

1. Precision BioSciences, Inc. (“Precision”) is a Delaware corporation having a principal place of business at 302 East Pettigrew Street, Dibrell Building, Suite A-100, Durham, North Carolina 27701.
2. Duke University (“Duke”) is an educational, research and health care institution and a North Carolina nonprofit corporation located in Durham, North Carolina.
3. Upon information and belief, Lonza Group Ltd. (“Lonza Group”) is a corporation organized under the laws of Switzerland with its principal place of business located at Muenchensteinerstrasse 38, CH-4002, Basel, Switzerland.

4. Upon information and belief, Lonza Sales Ltd. (“Lonza Sales”) is a corporation organized under the laws of Switzerland with its principal place of business located at Muenchensteinerstrasse 38, CH-4002, Basel, Switzerland.

5. Upon information and belief, Lonza Biologics plc (“Lonza Biologics UK”) is a public limited company organized under the laws of Great Britain with its principal place of business located at 228 Bath Road, Slough, Berkshire, SL1 4DX United Kingdom.

6. Upon information and belief, Lonza Inc. (“Lonza USA”) is a corporation organized under the laws of New York with its principal place of business located at 90 Boroline Road, Allendale, New Jersey 07401.

7. Upon information and belief, Lonza Walkersville, Inc. (“Lonza Walkersville”) is a corporation organized under the laws of Delaware with its principal place of business located at 8830 Biggs Ford Road, Walkersville, Maryland 21793.

8. Upon information and belief, Lonza Biologics, Inc. (“Lonza Biologics USA”) is a corporation organized under the laws of Delaware with its principal place of business located at 101 International Drive, Portsmouth, New Hampshire 03801.

9. Upon information and belief, Lonza Group, Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville, Lonza Biologics USA, and other Lonza affiliates are operated by Lonza Group as a single business group headquartered in Basel, Switzerland known as “Lonza.” Lonza Group, Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville, Lonza Biologics USA and other Lonza affiliates act in concert with one another under Lonza Group’s direction and control and present themselves to the marketplace as a unified entity, “Lonza,” that is “a global leader in the production and support of active pharmaceutical

ingredients, both chemically and biotechnologically, as well as in microbial control,” according to www.lonza.com.

10. According to the “Lonza 2012 Annual Report,” the activities of “Lonza” (which include Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville, Lonza Biologics USA and other Lonza affiliates) are organized into four operating divisions that are managed by a “Management Committee.” The “Management Committee,” according to the “Lonza 2012 Annual Report,” is “responsible for leading Lonza and for developing and implementing the Lonza strategy after approval by the Board of Directors. It supports and coordinates the activities of the divisions and corporate functions.”

11. In the “Lonza 2012 Annual Report,” Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville and Lonza Biologics USA are identified as “Subsidiaries,” defined as follows: “A subsidiary is an enterprise controlled by Lonza Group Ltd. Control exists when the Company has the power, directly or indirectly, to govern the financial and operating policies of an enterprise so as to obtain benefits from its activities.”

12. Financial statements of Lonza Group, Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville and Lonza Biologics USA, along with other Lonza affiliates, are presented in the “Lonza 2012 Annual Report” on a consolidated basis.

Jurisdiction and Venue

13. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action arises under the patent laws of the United States, 35 U.S.C. § 101, *et seq.*

14. This Court may exercise personal jurisdiction over Lonza Group consistent with the U.S. Constitution and 10 Del. Code § 3104. Upon information and belief, Lonza Group (directly and/or through affiliates under its direction and control that function in concert as

“Lonza”) has imported into the United States and has used, offered for sale and sold the GS Xceed™ Gene Expression System and CHOK1SV GS Knock-out host cell line in the United States, including in Delaware. Further, upon information and belief, Lonza Group regularly does or solicits business in Delaware and derives substantial revenue from Lonza services or products used or consumed in Delaware. Upon information and belief, Lonza Group has entered into and performed contracts with corporations domiciled in Delaware. Lonza Group has availed itself of the benefits of asserting and litigating a claim in the United States District for the District of Delaware for infringement of patents allegedly relating to its GS gene expression system and GS gene expression technology. Upon information and belief, Lonza Group operates an interactive website at www.lonza.com which permits users, including residents of Delaware, to order and to purchase products via the Internet from Lonza Group affiliates functioning as “Lonza” under Lonza Group’s direction and control. In addition, upon information and belief, the Delaware activities of Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville, Lonza Biologics and other Lonza affiliates, functioning in concert under Lonza Group’s direction and control as a part of a single business group known as “Lonza,” may be attributed to Lonza Group for purposes of personal jurisdiction under principles of agency.

15. This Court may exercise personal jurisdiction over Lonza Sales consistent with the U.S. Constitution and 10 Del. Code § 3104. Upon information and belief, Lonza Sales is the owner of the CHOK1SV GS Knock-out host cell line, and Lonza Sales (directly and/or through other Lonza Group affiliates that function in concert under Lonza Group’s direction and control as “Lonza”) has imported into the United States and has used, offered for sale and sold the GS Xceed™ Gene Expression System and CHOK1SV GS Knock-out host cell line in the United States, including in Delaware. Further, upon information and belief, Lonza Group regularly does

or solicits business in Delaware and derives substantial revenue from Lonza services or products used or consumed in Delaware. Upon information and belief, Lonza Sales has entered into and performed contracts with corporations domiciled in Delaware. Upon information and belief, via an interactive website operated by Lonza Group at www.lonza.com, users, including residents of Delaware, can order and purchase Lonza products from Lonza Sales via the Internet. In addition, upon information and belief, the Delaware activities of Lonza Group, Lonza Biologics UK, Lonza USA, Lonza Walkersville, Lonza Biologics and other Lonza affiliates, functioning in concert with Lonza Sales under Lonza Group's direction and control as a part of a single business group known as "Lonza," may be attributed to Lonza Sales for purposes of personal jurisdiction under principles of agency.

16. This Court may exercise personal jurisdiction over Lonza Biologics UK consistent with the U.S. Constitution and 10 Del. Code § 3104. Upon information and belief, the CHOK1SV GS Knock-out host cell line is manufactured by Lonza Biologics UK. Upon information and belief, Lonza Biologics UK (directly and/or through other Lonza Group affiliates that function in concert under Lonza Group's direction and control as "Lonza") has imported into the United States and has used, offered for sale and sold the GS XceedTM Gene Expression System and CHOK1SV GS Knock-out host cell line in the United States, including in Delaware. Further, upon information and belief, Lonza Biologics UK regularly does or solicits business in Delaware and derives substantial revenue from Lonza services or products used or consumed in Delaware. Upon information and belief, Lonza Biologics UK has entered into and performed contracts with corporations domiciled in Delaware. In addition, upon information and belief, the Delaware activities of Lonza Group, Lonza Sales, Lonza USA, Lonza Walkersville, Lonza Biologics and other Lonza affiliates, functioning in concert with Lonza

Biologics UK under Lonza Group's direction and control as a part of a single business group known as "Lonza," may be attributed to Lonza Biologics UK for purposes of personal jurisdiction under principles of agency.

17. This Court may exercise personal jurisdiction over Lonza USA consistent with the U.S. Constitution and 10 Del. Code § 3104. Upon information and belief, Lonza USA (directly and/or through other Lonza Group affiliates that function in concert under Lonza Group's direction and control as "Lonza") has imported into the United States and has used, offered for sale and sold the GS XceedTM Gene Expression System and CHOK1SV GS Knock-out host cell line in the United States, including in Delaware. Upon information and belief, Lonza USA has entered into and performed contracts with Delaware corporations. Further, upon information and belief, Lonza USA regularly does or solicits business in Delaware and derives substantial revenue from Lonza services or products used or consumed in Delaware. Upon information and belief, Lonza USA has entered into and performed contracts with corporations domiciled in Delaware. In addition, upon information and belief, the Delaware activities of Lonza Group, Lonza Sales, Lonza Biologics UK, Lonza Walkersville, Lonza Biologics and other Lonza affiliates functioning in concert with Lonza USA under Lonza Group's direction and control as a part of a single business group known as "Lonza," may be attributed to Lonza USA for purposes of personal jurisdiction under principles of agency.

18. This Court may exercise personal jurisdiction over Lonza Walkersville consistent with the U.S. Constitution and 10 Del. Code § 3104. Lonza Walkersville is incorporated under Delaware law. Lonza Walkersville has appointed National Corporate Research, Ltd., 615 S. Dupont Highway, Dover, Delaware 19901 as its agent for service of process in Delaware. As a corporation domiciled in Delaware, Lonza Walkersville regularly avails itself of the benefits of

conducting business in Delaware and of the benefits of Delaware law. Further, upon information and belief, Lonza Walkersville, directly and/or through other Lonza Group affiliates functioning in concert as “Lonza” under the direction and control of Lonza Group, has imported into the United States and has used, offered for sale and sold the GS Xceed™ Gene Expression System and CHOK1SV GS Knock-out host cell line in the United States, including in Delaware. Upon information and belief, Lonza Walkersville has entered into and performed contracts with Delaware corporations.

19. This Court may exercise personal jurisdiction over Lonza Biologics USA consistent with the U.S. Constitution and 10 Del. Code § 3104. Lonza Biologics USA is incorporated under Delaware law. Lonza Biologics USA has appointed National Corporate Research, Ltd., 615 S. Dupont Highway, Dover, Delaware 19901 as its agent for service of process in Delaware. As a corporation domiciled in Delaware, Lonza Biologics USA regularly avails itself of the benefits of conducting business in Delaware and of the benefits of Delaware law. Upon information and belief, Lonza Biologics USA, directly and/or through other Lonza Group agents and affiliates functioning in concert as “Lonza” under the direction and control of Lonza Group, has imported into the United States and has used, offered for sale and sold the GS Xceed™ Gene Expression System and CHOK1SV GS Knock-out host cell line in the United States, including in Delaware. Upon information and belief, Lonza Biologics USA has entered into and performed contracts with corporations domiciled in Delaware.

20. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b).

Infringement of U.S. Patent No. 8,377,674

21. United States Patent No. 8,377,674 (the “674 patent”), entitled “Method for Producing Genetically-Modified Cells with Rationally-Designed Meganucleases with Altered

Sequence Specificity,” was duly and legally issued by the United States Patent and Trademark Office on February 19, 2013. A copy of the ’674 patent is attached hereto as Exhibit 1.

22. Duke is the owner by assignment of the ’674 patent.

23. Precision is the exclusive licensee of the ’674 patent, with Duke retaining a substantial proprietary interest therein.

24. On July 10, 2012, via a “News Release” entitled “Lonza Launches Next Generation GS Gene Expression System™,” Lonza Group announced the launch of its new GS Xceed™ Gene Expression System. According to Lonza Group’s “News Release,” “[t]he key element of the new system is the CHOK1SV GS Knock-out host cell line, which is a derivative of Lonza’s suspension adapted CHOK1SV host cell line in which both alleles of the endogenous glutamine synthetase gene have been ‘knocked out.’” Lonza Group announced in the “News Release” that “[t]his advanced expression platform will now be available for use globally in all major pharmaceutical and biotechnology markets. . . .” Further, according to the Lonza Group’s announcement, “[t]he new system is . . . available worldwide, allowing multinational companies global access to the system in all pharmaceutical and biotechnology markets.” A copy of the “News Release” is attached hereto as Exhibit 2.

25. Upon information and belief, the Lonza CHOK1SV GS Knock-out host cell line and GS Xceed™ Gene Expression System are made outside the United States using Collectis bioresearch engineered meganucleases.

26. Upon information and belief, subsequent to the issuance of the ’674 patent on February 19, 2013, Lonza Group, Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville and/or Lonza Biologics USA, directly and/or through other Lonza Group affiliates acting in concert as “Lonza” under the direction and control of Lonza Group, have imported into

the United States the Lonza CHOK1SV GS Knock-out host cell line and GS Xceed™ Gene Expression System.

27. Upon information and belief, subsequent to the issuance of the '674 patent on February 19, 2013, Lonza Group, Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville and/or Lonza Biologics USA, directly and/or through other Lonza Group affiliates acting in concert as "Lonza" under the direction and control of Lonza Group, have used, sold and/or offered to sell the Lonza CHOK1SV GS Knock-out host cell like and GS Xceed™ Gene Expression System in the United States.

28. Upon information and belief, the Lonza CHOK1SV GS Knock-out host cell line and GS Xceed™ Gene Expression System are made outside the United States using a method of producing genetically-modified cells with rationally-designed meganucleases with altered sequence specificity as described in one or more claims of the '674 patent, including but not limited to Claim 7 of the '674 patent.

29. Upon information and belief, Lonza Group, Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville and/or Lonza Biologics USA have infringed and are infringing the '674 patent in violation of 35 U.S.C. § 271(g) by, directly and/or through other Lonza affiliates acting in concert as "Lonza" under Lonza Group's direction and control, importing the Lonza CHOK1SV GS Knock-out host cell line and GS Xceed™ Gene Expression System into the United States and/or by using, offering to sell and/or selling the Lonza CHOK1SV GS Knock-out host cell line and GS Xceed™ Gene Expression System in the United States subsequent to the issuance of the '674 patent.

30. As a result of the infringement of the '674 patent by Lonza Group, Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville and/or Lonza Biologics USA, Precision

and Duke have suffered and continue to suffer injury to their business and property in an amount to be determined as damages.

31. Unless an injunction is issued enjoining Lonza Group, Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville, Lonza Biologics USA, and their respective officers, agents, servants, employees and attorneys, and all those persons and entities in active concert and participation with them, from infringing the '674 patent, Precision and Duke will be irreparably harmed.

32. Prior to the filing of this action, Lonza Group, Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville and Lonza Biologics USA, directly and/or through other Lonza affiliates acting in concert as "Lonza" under Lonza Group's direction and control, were notified of the '674 patent, the application from which the '674 patent issued, and the infringing nature of their activities. On September 20, 2012, Precision notified them of U.S. Patent Application No. 13/532,190 (the "'190 application"), the application from which the '674 patent later issued, and provided to them at that time a copy of the unpublished claims then pending in the '190 application. On December 11, 2012, after publication of the '190 application on October 18, 2012, Precision notified them that a Notice of Allowance had been issued by the United States Patent and Trademark Office with respect to the '190 application, and, on January 31, 2013, Precision notified them that the '674 patent was expected to issue on February 19, 2013. Upon information and belief, Lonza Group, Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville and Lonza Biologics USA, directly and/or through other Lonza affiliates acting in concert as "Lonza" under Lonza Group's direction and control, received actual notice of the published '190 application prior to the issuance of the '674 patent. Since the '674 patent issued on February 19, 2013, Precision has on numerous occasions notified them, orally and in writing,

of the '674 patent and the infringing nature of their activities described herein, and Precision has requested that the infringing Lonza CHOK1SV GS Knock-out host cell line be withdrawn from the United States market.

33. Upon information and belief, Lonza Group, Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville, and/or Lonza Biologics USA have willfully infringed and are willfully infringing the '674 patent by importing the Lonza CHOK1SV GS Knock-out host cell line and GS XceedTM Gene Expression System into the United States and using, offering to sell and/or selling the Lonza CHOK1SV GS Knock-out host cell line and GS XceedTM Gene Expression System into the United States with full knowledge of the '674 patent and/or the published application from which the '674 patent issued and with reckless disregard for the infringing nature of such activities.

34. Upon information and belief, Lonza Group, Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville, and/or Lonza Biologics USA, directly and/or through other Lonza Group affiliates acting in concert as "Lonza" under the direction and control of Lonza Group, imported the Lonza CHOK1SV GS Knock-out host cell line and GS XceedTM Gene Expression System into the United States and/or used, offered to sell and/or sold the Lonza CHOK1SV GS Knock-out host cell line and GS XceedTM Gene Expression System in the United States after receiving actual notice of the published '190 application. The invention claimed in the '674 patent is substantially the same as claimed in the published '190 application.

Prayer for Relief

WHEREFORE, Precision and Duke respectfully request entry of judgment that includes:

- A. A finding that Lonza Group, Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville and Lonza Biologics USA have infringed the '674 patent;

- B. A preliminary and permanent injunction enjoining Lonza Group, Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville, and Lonza Biologics USA, and their respective officers, agents, servants, employees and attorneys, and all those persons and entities in active concert with them, from infringing the '674 patent;
- C. An award of damages in favor of Precision and Duke and against Lonza Group, Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville, and Lonza Biologics USA, such damages being in an amount sufficient to fully compensate Precision and Duke for infringement of the '674 patent by Lonza Group, Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville and Lonza Biologics USA;
- D. An award of a reasonable royalty pursuant to 35 U.S.C. § 154(d) in favor of Precision and Duke and against Lonza Group, Lonza Sales, Lonza Biologics UK, Lonza USA, Lonza Walkersville and/or Lonza Biologics USA as established by the evidence;
- E. A finding that the infringement of the '674 patent has been willful;
- F. Pursuant to 35 U.S.C. §284, an award of enhanced damages up to three times the amount of compensatory damages awarded;
- G. An assessment of prejudgment and post-judgment interest;
- H. A finding by the Court that this is an exceptional case under 35 U.S.C. § 285 and an award to Precision and Duke of their costs, expenses and attorneys' fees in this action; and
- I. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Precision and Duke hereby demand trial by jury as to all issues triable by jury as of right.

Respectfully submitted,

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