

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

LONZA GROUP AG,
Muenchensteinerstrasse 38
CH-4002
Basel, Switzerland,

Plaintiff,

v.

NORTHWEST BIOTHERAPEUTICS, INC.,
7600 Wisconsin Ave., 7th Floor
Bethesda, MD 20814
(Montgomery County),

Defendant.

Case No.: _____

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Lonza Group AG (“Lonza”), by its attorneys, files its Complaint against Defendant Northwest Biotherapeutics, Inc. (“Northwest”), and states as follows:

NATURE OF THE ACTION

1. This is an action arising under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*, and more specifically 35 U.S.C. § 271, *et seq.*, for patent infringement by Northwest of various United States Patents owned or exclusively licensed by Lonza relating to recombinant DNA methods, sequences, vectors, cell lines, and host cells.

PARTIES

2. Plaintiff Lonza Group AG is a corporation organized and existing under the laws of Switzerland, with its principal place of business at Muenchensteinerstrasse 38, CH-4002, Basel, Switzerland. Lonza’s predecessors include Alusuisse Lonza Group AG and Alusuisse Holdings

AG.

3. Defendant Northwest Biotherapeutics, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 7600 Wisconsin Avenue, 7th Floor, Bethesda, Maryland 20814.

JURISDICTION AND VENUE

4. This action arises under the Patent Laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a) and 1367.

5. This Court has personal jurisdiction over Defendant Northwest because it is a resident of the State of Maryland.

6. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. §§ 1400(b) because Defendant Northwest resides in the State of Maryland.

FACTS

7. Lonza directly and through its various subsidiaries and affiliates is a leading worldwide supplier of glutamine synthetase ("GS") gene expression systems that involve the use of patented processes for recombinant DNA methods, sequences, vectors, cell lines and host cells.

8. Lonza is the exclusive sub-licensee in and to U.S. Patent No. 5,122,464, entitled "Method for Dominant Selection in Eucaryotic Cells," which was duly and properly issued by the U.S. Patent and Trademark Office on June 16, 1992 in the name of Richard Wilson and Christopher Bebbington (the "Wilson '464 Patent"). A copy of the Wilson '464 Patent is attached hereto as Exhibit 1.

9. Lonza holds all right, title and interest in and to U.S. Patent No. 5,591,639, entitled "Recombinant DNA Expression Vectors," which was duly and properly issued by the U.S. Patent

and Trademark Office on January 7, 1997 in the name of Christopher Bebbington (the "Bebbington '639 Patent"). A copy of the Bebbington '639 Patent is attached hereto as Exhibit 2.

10. Lonza holds all right, title and interest in and to U.S. Patent No. 5,658,759, entitled "Recombinant DNA Expression Vectors," which was duly and properly issued by the U.S. Patent and Trademark Office on June 23, 1998 in the name of Christopher Bebbington (the "Bebbington '759 Patent"). A copy of the Bebbington '759 Patent is attached hereto as Exhibit 3.

11. Lonza is the exclusive sub-licensee in and to U.S. Patent No. 5,770,359, entitled "Recombinant DNA Sequences, Vectors Containing Them and Method for the Use Thereof," which was duly and properly issued by the U.S. Patent and Trademark Office on June 23, 1998 in the name of Richard Wilson and Christopher Bebbington (the "Wilson '359 Patent"). A copy of the Wilson '359 Patent is attached hereto as Exhibit 4.

12. Lonza is the exclusive sub-licensee in and to U.S. Patent No. 5,827,739, entitled "Recombinant DNA Sequences, Vectors Containing Them and Method for the Use Thereof," which was duly and properly issued by the U.S. Patent and Trademark Office on October 27, 1998 in the name of Richard Wilson and Christopher Bebbington (the "Wilson '739 Patent"). A copy of the Wilson '739 Patent is attached hereto as Exhibit 5.

13. Lonza holds all right, title and interest in and to U.S. Patent No. 5,879,936, entitled "Recombinant DNA Methods, Vectors and Host Cells," which was duly and properly issued by the U.S. Patent and Trademark Office on March 9, 1999 in the name of Christopher Bebbington and Geoffrey Yarranton (the "Bebbington '936 Patent"). A copy of the Bebbington '936 Patent is attached hereto as Exhibit 6.

14. Lonza holds all right, title and interest in and to U.S. Patent No. 5,891,693, entitled "Recombinant DNA Methods, Vectors and Host Cells," which was duly and properly issued by

the U.S. Patent and Trademark Office on April 6, 1999 in the name of Christopher Bebbington, Geoffrey Yarranton and Richard Wilson (the "Bebbington '693 Patent"). A copy of the Bebbington '693 Patent is attached hereto as Exhibit 7.

15. Lonza holds all right, title and interest in and to U.S. Patent No. 5,981,216, entitled "Transformed Myeloma Cell-Line and a Process for the Expression of a Gene Coding for a Eukaryotic Polypeptide Employing Same," which was duly and properly issued by the U.S. Patent and Trademark Office on November 9, 1999 in the name of John Kenten and Michael Boss (the "Kenten '216 Patent"). A copy of the Kenten '216 Patent is attached hereto as Exhibit 8.

16. Collectively, the Wilson '464 Patent, Bebbington '639 Patent, Bebbington '759 Patent, Wilson '359 Patent, Wilson '739 Patent, Bebbington '936 Patent, Bebbington '693 Patent, and Kenten '216 Patent are referred to herein as the "Lonza Patents."

17. As assignee or as exclusive licensee, Lonza owns all substantial rights in the Lonza Patents and is therefore deemed to be the effective patentee for purposes of enforcement of the Lonza Patents against infringers such as Northwest, with the right to recover damages for all past and future infringement of the Lonza Patents.

18. Medarex, Inc. ("Medarex") is the licensee or sub-licensee from Lonza or its subsidiaries and affiliates, of GS gene expression systems that use, employ or incorporate the patented and proprietary GS expression technology in the Lonza Patents. On information and belief, Medarex sold, licensed or otherwise transferred GS gene expression cell lines, vectors and systems that use, employ or incorporate the patented and proprietary GS expression technology in the Lonza Patents to Northwest, without legal right or authority, and without the knowledge, permission or approval of Lonza. Northwest has used and continues to hold the patented GS expression technology in the Lonza Patents, including vectors, cell lines and GS expression

systems technology and other GS materials.

19. Northwest makes, uses, markets, sells, and/or offers for sale autologous immunotherapy products and technologies for use in treatment of cancer and cancer treatment therapies. Northwest is or has been engaged in Phase II and Phase III clinical trials of dendritic cell-based cancer vaccine therapies. These therapies are known as "DCVax®" products, and include specifically a "DCVax®-Prostate" product. The DCVax®-Prostate product includes a prostate specific membrane antigen ("PSMA") product that, on information and belief, uses Lonza's patented GS expression technology.

20. Northwest's manufacture, use, marketing, selling, and/or offers to sell the DCVax®-Prostate product, and other infringing products or technologies, is not solely for uses reasonably related to the development and submission of information to the U.S. Food and Drug Administration.

21. Upon first learning of Northwest's acquisition and use of Lonza's patented technology, Lonza notified Northwest of the Lonza Patents and of the requirement to obtain a license for its possession and use of such proprietary and patented technology. After a delay caused by Northwest's financial difficulties and need to obtain additional capital, the parties entered into lengthy licensing negotiations based on Northwest's admitted possession and use of Lonza's GS expression system for manufacturing one of the components in its DCVax®-Prostate product. A comprehensive license agreement for Northwest's use of the Lonza Patents was drafted and negotiated between the parties but Northwest abruptly refused to execute the final agreement.

22. Since that time, Lonza has repeatedly requested that Northwest either cease and desist from, or obtain a license from Lonza for, Northwest's possession and use of the patented GS expression technology. Although Northwest has obtained and continues to hold Lonza's patented

GS expression technology and other GS materials, Northwest has refused and failed to enter into any license agreement with Lonza regarding any or all of the Lonza Patents.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 5,122,464

23. Lonza incorporates herein each and every allegation set forth in paragraphs 1 through 22, above.

24. Northwest has infringed and continues to infringe the Wilson '464 Patent by Northwest's making, using, marketing, selling, and/or offering for sale the DCVax®-Prostate product and other infringing products or technologies in the United States without authority or license from Lonza.

25. Northwest has contributorily infringed and/or induced others to infringe and continues to contributorily infringe and/or induce others to infringe the Wilson '464 Patent by Northwest's making, using, marketing, selling, and/or offering for sale the DCVax®-Prostate product and other infringing products or technologies in the United States without authority or license from Lonza.

26. Upon information and belief, Northwest's infringement of the Wilson '464 Patent has been and continues to be willful.

27. Lonza has been damaged by Northwest's infringement of the Wilson '464 Patent and will continue to suffer irreparable injury for which there is no adequate remedy at law unless the infringement is preliminarily and permanently enjoined by the Court.

COUNT II – INFRINGEMENT OF U.S. PATENT NO. 5,591,639

28. Lonza incorporates herein each and every allegation set forth in paragraphs 1 through 27, above.

29. Northwest has infringed and continues to infringe the Bebbington '639 Patent by Northwest's making, using, marketing, selling, and/or offering for sale the DCVax®-Prostate

product and other infringing products or technologies in the United States without authority or license from Lonza.

30. Northwest has contributorily infringed and/or induced others to infringe and continues to contributorily infringe and/or induce others to infringe the Bebbington '639 Patent by Northwest's making, using, marketing, selling, and/or offering for sale the DCVax®-Prostate product and other infringing products or technologies in the United States without authority or license from Lonza.

31. Upon information and belief, Northwest's infringement of the Bebbington '639 Patent has been and continues to be willful.

32. Lonza has been damaged by Northwest's infringement of the Bebbington '639 Patent and will continue to suffer irreparable injury for which there is no adequate remedy at law unless the infringement is preliminarily and permanently enjoined by the Court.

COUNT III – INFRINGEMENT OF U.S. PATENT NO. 5,658,759

33. Lonza incorporates herein each and every allegation set forth in paragraphs 1 through 32, above.

34. Northwest has infringed and continues to infringe the Bebbington '759 Patent by Northwest's making, using, marketing, selling, and/or offering for sale the DCVax®-Prostate product and other infringing products or technologies in the United States without authority or license from Lonza.

35. Northwest has contributorily infringed and/or induced others to infringe and continues to contributorily infringe and/or induce others to infringe the Bebbington '759 Patent by Northwest's making, using, marketing, selling, and/or offering for sale the DCVax®-Prostate product and other infringing products or technologies in the United States without authority or

license from Lonza.

36. Upon information and belief, Northwest's infringement of the Bebbington '759 Patent has been and continues to be willful.

37. Lonza has been damaged by Northwest's infringement of the Bebbington '759 Patent and will continue to suffer irreparable injury for which there is no adequate remedy at law unless the infringement is preliminarily and permanently enjoined by the Court.

COUNT IV – INFRINGEMENT OF U.S. PATENT NO. 5,770,359

38. Lonza incorporates herein each and every allegation set forth in paragraphs 1 through 37, above.

39. Northwest has infringed and continues to infringe the Wilson '359 Patent by Northwest's making, using, marketing, selling, and/or offering for sale the DCVax®-Prostate product and other infringing products or technologies in the United States without authority or license from Lonza.

40. Northwest has contributorily infringed and/or induced others to infringe and continues to contributorily infringe and/or induce others to infringe the Wilson '359 Patent by Northwest's making, using, marketing, selling, and/or offering for sale the DCVax®-Prostate product and other infringing products or technologies in the United States without authority or license from Lonza.

41. Upon information and belief, Northwest's infringement of the Wilson '359 Patent has been and continues to be willful.

42. Lonza has been damaged by Northwest's infringement of the Wilson '359 Patent and will continue to suffer irreparable injury for which there is no adequate remedy at law unless the infringement is preliminarily and permanently enjoined by the Court.

COUNT V – INFRINGEMENT OF U.S. PATENT NO. 5,827,739

43. Lonza incorporates herein each and every allegation set forth in paragraphs 1 through 42, above.

44. Northwest has infringed and continues to infringe the Wilson '739 Patent by Northwest's making, using, marketing, selling, and/or offering for sale the DCVax®-Prostate product and other infringing products or technologies in the United States without authority or license from Lonza.

45. Northwest has contributorily infringed and/or induced others to infringe and continues to contributorily infringe and/or induce others to infringe the Wilson '739 Patent by Northwest's making, using, marketing, selling, and/or offering for sale the DCVax®-Prostate product and other infringing products or technologies in the United States without authority or license from Lonza.

46. Upon information and belief, Northwest's infringement of the Wilson '739 Patent has been and continues to be willful.

47. Lonza has been damaged by Northwest's infringement of the Wilson '739 Patent and will continue to suffer irreparable injury for which there is no adequate remedy at law unless the infringement is preliminarily and permanently enjoined by the Court.

COUNT VI – INFRINGEMENT OF U.S. PATENT NO. 5,879,936

48. Lonza incorporates herein each and every allegation set forth in paragraphs 1 through 47, above.

49. Northwest has infringed and continues to infringe the Bebbington '936 Patent by Northwest's making, using, marketing, selling, and/or offering for sale the DCVax®-Prostate product and other infringing products or technologies in the United States without authority or license from Lonza.

50. Northwest has contributorily infringed and/or induced others to infringe and continues

to contributorily infringe and/or induce others to infringe the Bebbington '936 Patent by Northwest's making, using, marketing, selling, and/or offering for sale the DCVax®-Prostate product and other infringing products or technologies in the United States without authority or license from Lonza.

51. Upon information and belief, Northwest's infringement of the Bebbington '936 Patent has been and continues to be willful.

52. Lonza has been damaged by Northwest's infringement of the Bebbington '936 Patent and will continue to suffer irreparable injury for which there is no adequate remedy at law unless the infringement is preliminarily and permanently enjoined by the Court.

COUNT VII – INFRINGEMENT OF U.S. PATENT NO. 5,891,693

53. Lonza incorporates herein each and every allegation set forth in paragraphs 1 through 52, above.

54. Northwest has infringed and continues to infringe the Bebbington '693 Patent by Northwest's making, using, marketing, selling, and/or offering for sale the DCVax®-Prostate product and other infringing products or technologies in the United States without authority or license from Lonza.

55. Northwest has contributorily infringed and/or induced others to infringe and continues to contributorily infringe and/or induce others to infringe the Bebbington '693 Patent by Northwest's making, using, marketing, selling, and/or offering for sale the DCVax®-Prostate product and other infringing products or technologies in the United States without authority or license from Lonza.

56. Upon information and belief, Northwest's infringement of the Bebbington '693 Patent has been and continues to be willful.

57. Lonza has been damaged by Northwest's infringement of the Bebbington '693 Patent and will continue to suffer irreparable injury for which there is no adequate remedy at law unless the infringement is preliminarily and permanently enjoined by the Court.

COUNT VIII – INFRINGEMENT OF U.S. PATENT NO. 5,981,216

58. Lonza incorporates herein each and every allegation set forth in paragraphs 1 through 57, above.

59. Northwest has infringed and continues to infringe the Kenten '216 Patent by Northwest's making, using, marketing, selling, and/or offering for sale the DCVax®-Prostate product and other infringing products or technologies in the United States without authority or license from Lonza.

60. Northwest has contributorily infringed and/or induced others to infringe and continues to contributorily infringe and/or induce others to infringe the Kenten '216 Patent by Northwest's making, using, marketing, selling, and/or offering for sale the DCVax®-Prostate product and other infringing products or technologies in the United States without authority or license from Lonza.

61. Upon information and belief, Northwest's infringement of the Kenten '216 Patent has been and continues to be willful.

62. Lonza has been damaged by Northwest's infringement of the Kenten '216 Patent and will continue to suffer irreparable injury for which there is no adequate remedy at law unless the infringement is preliminarily and permanently enjoined by the Court.

COUNT IX – CONVERSION

63. Lonza incorporates herein each and every allegation set forth in paragraphs 1 through 62, above.

64. Lonza's GS gene expression systems for recombinant DNA methods, sequences,

vectors, cell lines and host cells are the property of Lonza, directly or as exclusive licensee.

65. Lonza has the right to possession of the GS expression systems because it is the legal right, title and interest holder to the GS expression systems, materials and technology described herein.

66. Northwest wrongfully obtained Lonza's GS expression systems, materials and technology without compensation to Lonza.

67. Upon information and belief, Northwest has or will wrongfully profit from its conversion of Lonza's property and has therefore caused damages and irreparable harm to Lonza.

68. Northwest's conduct was intentional, willfully and wantonly reckless, malicious and/or grossly negligent, which justifies an award of punitive damages.

COUNT X – UNJUST ENRICHMENT

69. Lonza incorporates herein each and every allegation set forth in paragraphs 1 through 68, above.

70. By its improper acquisition of Lonza's GS gene expression systems for recombinant DNA methods, sequences, vectors, cell lines and host cells, Northwest has obtained a valuable benefit.

71. Lonza, the proper right, title, and interest holder in the GS expression systems described herein, has not received compensation for Northwest's acquisition of these systems, material and technology.

72. Lonza has sustained economic loss from the compensation it would have received had Northwest obtained a license for the GS expression systems.

73. It would be inequitable for Northwest to retain the benefits of the wrongfully obtained Lonza GS expression systems, materials and technology, at the expense of Lonza.

74. Upon information and belief, Northwest has or will wrongfully profit by being unjustly enriched by Lonza's property and has therefore caused damages and irreparable harm to Lonza.

WHEREFORE, Plaintiff Lonza Group AG prays for judgment as follows:

A. Enter judgment that Northwest has infringed, contributorily infringed and/or actively induced others to infringe the Lonza Patents;

B. Enter judgment that Northwest's infringement of the Lonza Patents is willful;

C. Enter preliminary and permanent injunctions permanently enjoining Northwest, its parents, subsidiaries, affiliates, officers, directors, servants, managers, employees, agents, successors and assigns, and all persons in active concert or participation with any of them, from infringing, contributorily infringing, and/or actively inducing others to infringe the Lonza Patents and that Northwest be ordered to destroy or offer up to Lonza for destruction any and all DCVax®-Prostate product and/or any other products within the scope of the claims of the Lonza Patents that are within Northwest's possession, custody or control;

D. Award Lonza all damages sufficient to compensate it for Northwest's infringement of the Lonza Patents, including lost profits and price erosion, but in no case less than a reasonable royalty, together with pre-judgment and post-judgment interest and costs, pursuant to 35 U.S.C. § 284;

E. Award Lonza increased damages, pursuant to 35 U.S.C. § 284, in an amount not less than three times the amount of actual damages awarded to it, by reason of Northwest's willful infringement of the Lonza Patents, and punitive damages for those claims for which punitive damages are recoverable;

F. Declare this case exceptional under 35 U.S.C. § 285 and award Lonza its interest,

costs, and attorneys' fees on all claims;

G. Award Lonza all other legal and equitable relief to which it proves itself entitled;

and

H. Grant such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff Lonza Group AG hereby demands a jury trial in this action on all issues so triable.

Dated: November 27, 2007

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