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*Attorneys for Plaintiff
LifeCell Corporation*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

LIFECELL CORPORATION,	:	
	:	
Plaintiff,	:	Civil Action No. 15-6701 (CCC) (MF)
	:	
v.	:	
	:	
LIFENET HEALTH,	:	JURY TRIAL DEMANDED
	:	
Defendant.	:	
	:	

FIRST AMENDED COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff LifeCell Corporation (“LifeCell”), for its First Amended Complaint against Defendant LifeNet Health (“LifeNet”), hereby alleges as follows:

NATURE OF THE ACTION

1. Pursuant to the Declaratory Judgment Act §§ 2201-02 and the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, this is an action for declaratory judgment of non-infringement of U.S. Patent No. 9,125,971, entitled “Plasticized Bone and Soft Tissue Grafts and Methods of Making and Using Same.”

PARTIES

LifeCell Corporation

2. LifeCell is a regenerative medicine company based in New Jersey. LifeCell's manufacturing facility and technical operations center is located at 1 Millennium Way, Branchburg, New Jersey 08876. LifeCell's corporate offices and research and development laboratories are located at 95 Corporate Drive, Bridgewater, New Jersey 08807.

3. The vast majority of LifeCell's employees are residents of New Jersey. At its manufacturing, technical operations, and distribution facilities in Branchburg, LifeCell employs 395 people. At its corporate offices and research and development laboratories in Bridgewater, LifeCell employs an additional 174 people.

4. LifeCell was founded in 1986 with the goal of revolutionizing the field of regenerative medicine. LifeCell has accomplished that goal over its nearly 30 years of operation by developing innovative soft tissue grafts that help thousands of patients each year.

5. LifeCell's soft tissue grafts include AlloDerm® Regenerative Tissue Matrix RTU ("AlloDerm"), Strattice™ Reconstructive Tissue Matrix ("Strattice"), and Conexa™ Reconstructive Tissue Matrix ("Conexa"). Those soft tissue grafts are currently sold and used in reconstructive surgery, such as breast reconstruction following a mastectomy or hernia repair.

6. AlloDerm, Strattice, and Conexa are manufactured in and shipped from Branchburg, New Jersey.

7. LifeCell's sales and marketing team is based in Bridgewater, New Jersey.

8. LifeCell's R&D team is based in Bridgewater, New Jersey.

9. The allegedly infringing products—AlloDerm, Strattice, and Conexa—were designed in New Jersey and are made in, sold from, and shipped from New Jersey.

LifeNet Health

10. Defendant LifeNet Health (“LifeNet”) is a Virginia corporation with its principal place of business located at 1864 Concert Drive, Virginia Beach, Virginia 23453.

11. LifeNet is the assignee of U.S. Patent Nos. 6,569,200 (the “’200 patent”) and 9,125,971 (the “’971 patent”).

JURISDICTION AND VENUE

12. This action arises under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, and under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

13. This Court has subject matter jurisdiction over these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and the patent laws of the United States 35 U.S.C. § 1 *et seq.*

14. This Court has personal jurisdiction over LifeNet by virtue of its sufficient minimum contacts with this forum at least because LifeNet conducts regular business in New Jersey.

15. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) at least because LifeNet conducts regular business in this District and is subject to personal jurisdiction in this District.

EXISTENCE OF AN ACTUAL CONTROVERSY

The ’200 Patent

16. The ’200 patent, entitled “Plasticized Soft Tissue Grafts, and Methods of Making and Using Same,” claims priority to U.S. Patent Application No. 09/107,459, which was filed on June 30, 1998 and is now issued as U.S. Patent No. 6,293,970. The ’200 patent is attached as Exhibit 1 and U.S. Patent No. 6,293,970 is attached as Exhibit 2.

17. Lloyd Wolfinbarger, Jr., Robert K. O’Leary, and Billy G. Anderson are the named inventors on the ’200 patent.

18. LifeNet is the assignee of the '200 patent.

19. The '200 patent is generally directed to preserving soft tissue grafts with chemical "plasticizers," including glycerol.

20. On September 6, 2013, LifeNet brought a patent infringement suit against LifeCell in a case captioned *LifeNet Health v. LifeCell Corp.*, C.A. No: 2:13-cv-486-HCM-DEM (E.D. Va.) (the "2013 Litigation"), which accused LifeCell of infringing the '200 patent by making and selling soft tissue grafts, including AlloDerm and Strattice. The complaint in the 2013 Litigation is attached as Exhibit 3.

21. During the 2013 Litigation, LifeNet argued that AlloDerm, Strattice, and Conexa infringed the '200 patent because they were cleaned soft tissue grafts treated with a proprietary preservation solution, Solution E, which contains glycerol.

22. A jury returned a verdict in the 2013 Litigation that LifeCell directly infringed the '200 Patent and granted a lump-sum award of approximately \$34.7 million. Final judgment has been entered in the 2013 Litigation and that case is currently on appeal before the United States Court of Appeals for the Federal Circuit.

The '971 Patent

23. On September 8, 2015, the United States Patent Office issued the '971 patent, entitled "Plasticized Bone and Soft Tissue Grafts, and Methods of Making and Using Same." The '971 patent is attached as Exhibit 4.

24. The '971 patent also claims priority to U.S. Patent Application No. 09/107,459, which was filed on June 30, 1998.

25. Lloyd Wolfinbarger, Jr., Robert K. O'Leary, and Billy G. Anderson are also the named inventors on the '971 patent.

26. LifeNet is also the assignee of the '971 patent.

27. The '971 patent is also generally directed to preserving soft tissue grafts with chemical "plasticizers," including glycerol.

28. As recorded in the public prosecution history file for the '971 patent, the United States Patent Office rejected all of the claims in the '971 patent because they are "unpatentable over claims 1-15 of U.S. Patent No. 6,569,200." As explained by the Patent Office: "Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are substantially minor changes in the phraseology and arrangement of claim limitations."

29. To overcome that rejection, LifeNet filed a terminal disclaimer for the '971 patent in view of the related '200 patent.

30. In light of the 2013 Litigation, the relationship between the '971 patent and the previously-litigated '200 patent, and the overlap in parties, technologies, and products, issuance of the '971 patent on September 8, 2015 placed a cloud of uncertainty over LifeCell's manufacture and sale of AlloDerm, Strattice, and Conexa, which gives rise to an immediate controversy between LifeCell and LifeNet concerning LifeCell's rights regarding the '971 patent.

In The 2013 Litigation, LifeNet Sought To Assert Claims In Its Pending Patent Applications And Sought Discovery From LifeCell Concerning LifeNet's Pending Patent Applications, Including The Application That Issued As The '971 Patent

31. During the 2013 Litigation, LifeNet had at least two patent applications pending: (1) U.S. Patent App. No. 13/836,803 (the "'803 application), which issued as the '971 patent at issue in this declaratory judgment action and (2) U.S. Patent App. No. 12/701,634 (the "'634 application"). The '634 application is attached as Exhibit 5.

32. Like the '200 patent and the '971 patent, the '634 application: (1) claims priority to U.S. Patent Application No. 09/107,459, which was filed on June 30, 1998; (2) lists Lloyd Wolfinbarger, Jr., Robert K. O'Leary, and Billy G. Anderson as the inventors; (3) lists LifeNet as the assignee; and (4) is generally directed to preserving soft tissue grafts with chemical "plasticizers," including glycerol. The '971 patent, '200 patent, and '634 application are therefore all "related" and based on the same "parent" application.

33. LifeNet sought to assert claims from the '634 application against LifeCell in the now-concluded 2013 Litigation, despite the fact that no patent had issued (and still has not issued). LifeNet even prepared infringement contentions against LifeCell's Strattice and AlloDerm grafts based on the claims in the pending '634 application.

34. During the 2013 Litigation, LifeNet also sought interrogatory and document discovery from LifeCell concerning "Related Patent Applications," which LifeNet defined broadly as "any patent application that led to, or stems from, the application that matured into Patent-in-Suit [the '200 patent], either directly or indirectly, including any continuation, continuation-in-part, or divisional application thereof, and any application relied upon for priority by such applications." That definition encompasses the '803 application that became the '971 patent at issue in this declaratory judgment action. (*See* Exhibit 6, Definitions 3, 4, and 6 and Interrogatory Nos. 7, 11, and 14; Exhibit 7, Definitions 3 and 5 and Request For Production Nos. 12-14.)

35. For example, Request For Production No. 14 requested:

All documents, electronically stored information, and things concerning any decision by LifeCell to proceed with manufacturing, using, selling, or offering to sell in the United States, or importing into the United States, any LifeCell Ready to Use Soft Tissue Product after LifeCell became aware of or knew of the '200 Patent, any Related Patent, or any Related Application. (Exhibit 7 (emphasis added).)

36. As an additional example, Interrogatory No. 14 requested:

If this lawsuit or the possibility thereof, or the subject matter of this lawsuit including the '200 Patent, any Related Patent, and/or any Related Application, has ever been discussed by any person presently, or at any time prior, associated with LifeCell, whether such discussion was internal to LifeCell or involved any third party, identify all persons present during such discussion and the date and circumstances thereof. (Exhibit 6 (emphasis added).)

37. In discovery correspondence related to LifeNet's Interrogatories and Requests For Production in the 2013 Litigation, LifeNet continued to press its requests for documents and information concerning "Related Patent Applications," which included the '803 application that became the '971 patent at issue in this declaratory judgment action.

38. During the 2013 Litigation, LifeNet's discovery requests, correspondence, and infringement contentions made clear LifeNet's intention to assert against LifeCell's soft tissue grafts, including AlloDerm and Strattice, any LifeNet patents that issued from Related Patent Applications—including the '634 application and the '803 application that became the '971 patent at issue in this declaratory judgment action.

39. In light of LifeNet's discovery requests, correspondence, and infringement contentions made during the 2013 Litigation, issuance of the '971 patent on September 8, 2015 placed a further cloud of uncertainty over LifeCell's manufacture and sale of AlloDerm, Strattice, and Conexa, which gives rise to an immediate controversy between LifeCell and LifeNet concerning LifeCell's rights regarding the '971 patent.

COUNT ONE

Declaratory Judgment Of Non-Infringement Of The '971 Patent

40. LifeCell incorporates by reference the allegations set forth in paragraphs 1 through 16 as though fully set forth herein.

41. LifeNet claims to own all rights, title, and interest in the '971 patent.

42. An immediate, actual, substantial, and justiciable controversy exists between LifeCell and LifeNet as to whether LifeCell infringes the claims of the '971 patent by making and selling soft tissue grafts that are treated with LifeCell's own proprietary preservation solution, including AlloDerm, Strattice, and Conexa. A judicial declaration is necessary and appropriate so that LifeCell may ascertain its rights regarding the '971 patent.

43. There is an actual controversy within the jurisdiction of this Court under 28 U.S.C. §§ 2201 and 2202.

44. LifeCell does not infringe and has not infringed any claim of the '971 patent.

45. Based on the foregoing, LifeCell hereby requests a declaration from the Court that LifeCell does not infringe the claims of the '971 patent.

PRAYER FOR RELIEF

WHEREFORE, LifeCell respectfully requests that judgment be entered in its favor and prays that the Court grant the following relief:

- A. A declaration that LifeCell does not infringe any claim of the '971 patent.
- B. A declaration that this case is exceptional case under 35 U.S.C. § 285;
- C. An award to LifeCell of its costs and attorneys' fees; and
- D. Such other relief as this Court or a jury may deem just and proper.

JURY DEMAND

In accordance with Federal Rule of Civil Procedure 38, LifeCell respectfully demands a jury trial of all issues triable to a jury in this action.

CERTIFICATION PURSUANT TO L.CIV.R. 11.2

Plaintiff, by its undersigned counsel, hereby certifies pursuant to Local Civil Rule 11.2 that the matters in controversy are not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: November 12, 2015

Respectfully submitted,

/s/ Thomas R. Curtin

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