

UNITED STATES DISTRICT COURT  
FOR THE  
DISTRICT OF COLUMBIA

GYLCOBIOSCIENCES INC.	)	
	)	
Plaintiff	)	
	)	
v.	)	Civil Action No. 1:14-CV-01281-TSC
	)	
DARA BioSciences, Inc.	)	
	)	
and	)	
	)	
HELSINN Healthcare SA	)	
	)	
Defendants,	)	

**AMENDED COMPLAINT**

Plaintiff, by and through counsel, files this Amended Complaint as a matter of right since no answer has been filed. This Amended Complaint corrects a typographical error in paragraphs 5 and 12. Plaintiff complains of Defendants and alleges as follows:

**FACTS COMMON TO AND APPLICABLE TO ALL COUNTS**

1. Plaintiff Glycobiosciences, Inc., is a corporation duly organized and existing under the laws of the Province of Ontario, Canada, and having a principal place of business at 7 Timber Court, Georgetown, Ontario L7G 4S4 Canada.

2. Plaintiff is the developer of numerous pain relief products used in the treatment of damaged skin, wounds, ulcers, sores and pain management, as well as several other diseases and conditions utilizing the Plaintiff's proprietary and patented Ionic Polymer Matrix (IPM) delivery system.

3. Plaintiff is the owner of various United States patents including U.S. Patent No. 6,335,035 which was duly and legally issued on January 2, 2002. A True and Correct Copy of U.S. Patent No. 6,335,035 is attached as Exhibit A. A True and Correct Copy of the documents evidencing title in the name of Plaintiff is attached as Exhibit B.

4. Defendant DARA Biosciences, Inc., (DARA) upon information and belief, is a corporation organized and existing under the

laws of the State of North Carolina and has a principal place of business at 8601 Six Forks Road, Raleigh, North Carolina.

5. Defendant HELSINN Healthcare SA (HELSINN) upon information and belief a Swiss “Societe Anonyme” having a principal place of business at Via Pian Scairolo 9, 6912 Lugano/Pazzollo, Switzerland.

***Jurisdiction and Venue***

6. This is a suit for infringement of United States Patent No. 6,335,035.

7. This Court has exclusive subject matter jurisdiction pursuant to 28 U.S.C. §1400(b) because this suit is brought under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

8. Each Defendant, upon information and belief, does business in the United States and within the District of Columbia.

9. Specifically, and without limiting the foregoing DARA markets and sells within the United States and within the District of Columbia a product known as Gelclair which is manufactured by HELSINN.

10. Venue is proper in this District at least pursuant to 28 U.S.C. § 1391 (b,d).

11. Gelclair is identified by one or both of the Defendants as a bioadherent oral rinse gel for management of mucositis, and symptoms associated with mucositis by adhering to the mucosal surface of the mouth, coating the same, and thus providing relief from mucositis and the symptoms of mucositis, for an extended time interval. In fact, Defendants infer that Gelclair has at least a 30 to 60 minute extended release interval by instructing patients not to eat or drink for at least 30-60 minutes following an oral rinse treatment.

12. Should either or both defendants deny that Gelclair functions with an extended release interval, Plaintiff reserves the right to amend this Complaint to allege false and misleading advertising and other violations of 15 U.S.C. §1125(a).

13. Without limiting any other allegation in this Complaint, the ingredients of Gelclair include sodium hyaluronate and hydroxyethylcellulose and water.

14. The ingredients of Gelclair including hyaluronic acid.

15. Hyaluronic acid falls within the definition of a mucopolysaccharide.

16. Hyaluronic acid (at least in solution) falls within the definition of a negatively charged polymer.

17. Hydroxyethylcellulose falls within the definition of a nonionic polymer.

18. The Gelclair product as manufactured and sold by Defendants has a molar ratio of negatively charged polymer to nonionic polymer of approximately 1:1.8, and hyaluronic acid is present in an amount of approximately 1.67%.

## **COUNT I**

### **DIRECT PATENT INFRINGEMENT AGAINST DARA**

19. Plaintiff realleges paragraphs 1 – 18 as fully and completely as if set forth herein verbatim.

20. Within the six years immediately preceding the filing of this Complaint, DARA has directly infringed U.S. Patent No. 6,335,035 by importing, offering for sale and/or selling a Gelclair product falling within the claims of said patent without authority, license or permission from Plaintiff.

21. The importing, offering for sale and/or selling the Gelclair product literally infringes each of claims 6, 7, 8 and 10 of U.S. Patent No. U.S. Patent No. 6,335,035.

22. The activities of DARA as set forth in this Count I are in violation of 35 U.S.C. § 271(a).

23. If and to the extent that the activities complained of in this Count I do not constitute literal infringement of one or more of claims 6-8 and 10 of U.S. Patent No. 6,335,035, then in that event the activities complained of in this Count I constitute infringement of claims 6, 7, 8 and 10 of U.S. Patent No. U.S. Patent No. 6,335,035 under the doctrine of equivalents.

24. Discovery will indicate which, if any additional claims of U.S. Patent No. 6,335,035 are infringed (and whether any other U.S. Patent owned by Plaintiff is infringed).

25. The infringement referred to in this Count I has been to the injury and detriment to Plaintiff in an amount to be determined at trial.

## **COUNT II**

### **INDIRECT PATENT INFRINGEMENT AGAINST HELSINN**

26. Plaintiff realleges paragraphs 1 – 18 as fully and completely as if set forth herein verbatim.

27. Within the six years immediately preceding the filing of this Complaint, HELSINN has indirectly infringed U.S. Patent No. 6,335,035 by manufacturing for sale and selling to DARA for subsequent offering for sale and/or selling a product falling within the claims of said patent without authority, license or permission from Plaintiff.

28. The offering for sale and selling of the Gelclair product by DARA as described above literally infringes each of claims 6, 7, 8 and 10 of U.S. Patent No. U.S. Patent No. 6,335,035.

29. The manufacture of Gelclair by HELSINN for DARA actively induces DARA to literally infringe each of claims 6, 7, 8 and 10 of U.S. Patent No. U.S. Patent No. 6,335,035 and HELSINN is liable for actively inducing infringement in violation of 35 U.S.C. §271(b).

30. If and to the extent the activities complained of in this Count II do not constitute literal infringement by DARA and active inducement by HELSINN of one or more of claims 6-8 and 10 of U.S. Patent No. 6,335,035, then the offering for sale and selling of the Gelclair product by DARA as described above infringes each of claims 6, 7, 8 and 10 of U.S. Patent No. U.S. Patent No. 6,335,035 under the doctrine of equivalents and the manufacture of Gelclair by HELSINN for DARA actively induces DARA to infringe each of claims 6, 7, 8 and 10 of U.S. Patent No. U.S. Patent No. 6,335,035 under the doctrine of equivalents, and HELSINN is liable for actively inducing infringement in violation of 35 U.S.C. §271(b).

31. Discovery will indicate which, if any additional claims of U.S. Patent No. 6,335,035 are infringed (and whether any other U.S. Patent owned by Plaintiff is infringed).

32. The infringement referred to in this Count II has been to the injury and detriment to Plaintiff in an amount to be determined at trial.

**WHEREFORE, PLAINTIFF PRAYS AS FOLLOWS:**



1. For judgment that claims 6-8 and 10 of U.S. Patent No. 6,335,035 remains valid;
2. For judgment that claims 6-8 and 10 of U.S. Patent No. 6,335,035 have been directly infringed by DARA either literally or under the doctrine of equivalents;
3. For judgment that the infringement of claims 6-8 and 10 of U.S. Patent No. 6,335,035 by DARA has been actively induced by HELSINN and thus indirectly infringed by HELSINN;
4. For an accounting and an award of damages to Plaintiff against Defendants, jointly and severally, in an amount to be determined at trial but in no even less than a reasonable royalty;
5. For an injunction against further infringement;
6. For an award of taxable costs Plaintiff against Defendants, jointly and severally; and
7. For such other and further relief as to the Court appears just and proper.

September 9, 2014

Respectfully submitted,

/s/ Jerold I. Schneider

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Counsel for Plaintiff

## CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 9<sup>th</sup> day of September 2014 I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system. I also certify that the foregoing document is being served this day on all counsel of record or *pro se* parties identified on the Service List below in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to received Notices of Electronic filing electronically.

/s/ Jerold I. Schneider

Jerold I. Schneider  
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