

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

GLYCOBIOSCIENCES, Inc.
7 Timber Court
Georgetown, Ontario
L7G 4S4 Ontario, Canada

and

The Estate of Alan Drizen
7 Timber Court
Georgetown, Ontario
L7G 4S4 Ontario, Canada

Plaintiffs

v.

Fougera Pharmaceuticals Inc
60 Baylis Road
Melville, New York 11747-0103

and

JAGOTEC AG
Eptingerstrasse 51
CH-4132 Muttenz, Switzerland

Defendants

Civil Action No.

12-cv-

**COMPLAINT FOR CORRECTION OF INVENTORSHIP
UNDER 35 U.S.C. § 256**

For its complaint, Plaintiffs GlycoBioSciences (“Glyco”) and The Estate of Alan Drizen allege as follows:

NATURE OF THE CASE

1. This is a civil action pursuant to 35 U.S.C. § 256 for correction of inventorship of

U.S. Patents Nos. 5,639,738, 5,792,753, 5,852,002, 5,914,322, 5,929,048, 5,985,850 all directed to gels containing Hyaluronic Acid or Dyclofenac which has been commercialized as "SOLARAZE" by Defendant Fougera. Copies of the six patents in dispute are attached as exhibits to the complaint.

2. This action arises out of the failure of the predecessors of defendant Fougera to name Dr. Alan Drizen as the inventor of the inventions claimed in the six SOLARAZE patents. Mr. Drizen was the founder, lead scientist and owner of Sterivet Laboratories which later became Hyal Pharmaceuticals, which subsequently became owned by Nycomed and is now known as Fougera,

THE PARTIES

3. Plaintiff, GlycoBioSciences, ("Glyco") is a corporation existing under the laws of Canada located at 7 Timber Court, Georgetown, Ontario, L7G 4S4, Ontario Canada and is the owner of a product for relief of Arthritic pain, developed by Dr. Alan Drizen, referred to as IPM Diclofenac Pain Gel. Glyco is the owner of United States Letters Patent 5,897,880 (the '880 patent) and 6,723,345 (the '345 patent) both entitled Topical Drug Preparations and naming Dr. Alan Drizen as the inventor. Glyco is a research pharmaceutical company which has developed IPM Diclofenac Pain Gel for Arthritic Pain and a wound healing gel as well as other formulations for the treatment of dermatological conditions and other indications. Glyco has invested significant resources in the development of IPM Diclofenac Pain Gel, has applied for FDA approval for use as an arthritic treatment and introduced the product into the market in 2011.

4. Plaintiff, The Estate of Alan Drizen, is a Canadian legal entity located in Ontario Canada. The executor of the estate is Kevin Drizen.

5. Defendant Nycomed US, Inc, upon information and belief, is a corporation organized and existing under the laws of the State of New York and has a principle place of business at: 60 Baylis Road, Melville, New York 11747-0103 and is the owner of NDA No. 21-005 and the FDA approved drug product called SOLARAZE[®] Gel. Nycomed is engaged in making, importing, using, offering for sale and/or selling the SOLARAZE[®] Gel pharmaceutical products which include the formulation as taught and claimed in the '880 and '345 patents in suit and is covered by Claims of the '880 and '345 patent. SOLARAZE is manufactured and sold under a license of the six SOLARAZE patents. Fougera is the exclusive licensee of the six SOLARZE patents. The products, which are covered under the claims of the '880 and '345 patents in suit, are being sold throughout the United States, including substantial sales in New York and in the Judicial District of the Eastern District of New York. Jurisdiction and Venue are proper in this District as to Defendant Nycomed, under 28 U.S.C. §1391(b), and §1400(b).

6. Defendant Jagotec AG, upon information and belief, is a company existing under Swiss law having a principle place of business at: 51, CH-4132 Muttenz, Switzerland. Jagotec is the owner and licensor of patents 5,639,738; 5,792,753; 5,852,002; 5,914,322; 5,929,048; and 5,985,850 (the Solaraze patents). The Solarze patents are listed in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* on connection with NDA No. 21-005 and the SOLARAZE[®] Gel pharmaceutical products. Upon information and belief, the Solaraze patents are exclusively licensed by Jagotec to Fougera for its production and sales of SOLARAZE[®] Gel. Upon information and belief, Jagotec receives income from the sale of SOLARAZE[®] Gel pharmaceutical products by Defendants Nycomed and PharmaDerm. The products, which are covered under the claims of the '880 and '345 patents in suit, are being sold throughout the United States, including substantial sales in New York and in the Judicial District

of the Eastern District of New York. Jurisdiction and Venue are proper in this District as to Defendant Jagotec, under 28 U.S.C. §1391(d), and §1400(b).

7. On their face, the six SOLARAZE patent list Rudolf Edgar Falk and Samuel Simon Asculai as inventors and list the company founded by Mr. Drizen, Hyal Pharmaceuticals, as the assignee.

8. This action requests naming Mr. Alan Drizen as sole inventor of the six SOLARAZE patents and restoring Mr. Drizen's financial interest in the commercialization of these patents and granting compensation to Plaintiff's for Defendants' improper use of the intellectual property assets in dispute, the six SOLARAZE patents.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, 35 U.S.C. § 101 *et seq.*, and specifically under 35 U.S.C. § 256. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338.

10. Upon information and belief, Defendant Fougera is located in this district and thus also subject to jurisdiction in this District. Defendant Jagotec is a foreign corporation and thus also subject to jurisdiction in this District. In addition, both parties derive revenue from this district, conduct, have transacted and continues to transact substantial business within the Eastern District of New York, and Jagotec is the owner of the intellectual property which is situated in this district by virtue of its issuance as United States Patents which are subject to the jurisdiction of this Court and by virtue of the exclusive license to Defendant Fougera and thus all defendant are subject to personal jurisdiction in this District.

11. In addition, the SOLARAZE products marketed and sold and licensed under the

patents in dispute are sold within this District.

12. Venue is proper in this District under 28 U.S.C. §§ 1391(b) (c) and (d) and §1400.

FACTUAL BACKGROUND

13. Based on information and belief, Glyco and the Estate of Mr. Alan Drizen assert an ownership interest in the Solaraze technology, and claim inventorship of and an ownership interest in the Solaraze patents (5,639,738, 5,792,753, 5,852,002, 5,914,322, 5,929,048, 5,985,850).

14. Mr. Alan Drizen founded Sterivet Laboratories which later became Hyal Pharmaceuticals and developed the original technology of the company including the technology which later became used in the Solaraze products.

15. Mr. Drizen is the sole inventor of the subject matter described in Canadian Publication No. CA 2,009,730, filed on February 9, 1990, a copy of which is attached to the Complaint. The products and invention covered by CA '730 were developed and owned by Mr. Drizen and Sterivet. CA '730 was filed and owned by Sterivet which was owned by Mr. Alan Drizen.

16. The '730 Canadian publication described an invention which was commercialized by Sterivet and Hyal Pharmaceuticals as a product call "Visible Youth." Visible Youth was sold by Hyal between 1990 and 2002. Visible Youth, a cosmetic product included the Hyaluronic Acid (HA) formulation which forms the foundation of SOLARAZE.

17. The CA '730 disclosure covers the HA formulation utilized in the Solaraze product, the HA formulation serves as SOLARAZE's delivery. The Molecular Weight, amount of HA included, penetration of HA through the dermis which are key aspects of the Solaraze

patents and product are all taught by the '730 publication. Recent activity by the USPTO in the reexamination of the six SOLARZE patents has recognized that Mr. Drizen's inventions encompass the SOLARAZE patent claims.

18. In 1992 Mr. Drizen left Hyal Pharmaceuticals.

19. In 1999 Hyal Pharmaceuticals was sold to Skyepharma the parent company of Defendant Jagotec.

20. In 2000, SOLARAZE was launched by Hyal.

21. In 1995, Mr. Alan Drizen founded LAM Pharmecuticals.

22. In 2007, Mr. Alan Drizen passed away and The Estate of Alan Drizen was established.

23. In or around 2006, LAM Pharmaceuticals ceased doing business.

24. In 2008, Plaintiff, GlycoBioSciences purchased the assets of LAM Pharmecutical and launched the Hylases product, based upon the work of Mr. Alan Drizen, in 2012.

25. In 1997 Hyal Pharmaceuticals stopped selling the Visible Youth product.

26. In 2007 Defendant Fougera then doing business as "Nycomed" became the sole licensee of the SOLRAZE patents. In 2012, Nycomed changed its name to Fougera.

27. SOLARAZE, in addition to the using the CA '370 formulation, also includes drug Diclofenac, a contribution from Alan Drizen, in the treatment of cancer. It is clear from the continued work, contemporaneous statements and sworn Declarations of Alan Drizen in the years after he left Hyal, that in addition to the HA formulation, Mr. Drizen also solely developed the inclusion of Diclofenac in the formulation as used in the Solaraze technology including the treatment of Actinic Keratosis.

28. Mr. Drizen's work, declarations and statements include reference to his work "in

the development of hyaluronic acid-based chemotherapeutic compounds for treatment of melanoma". The only technology that Hyal developed for the treatment of cancer or pre-cancerous tumors was the Alan Drizen Solaraze technology.

29. At no time did Mr. Drizen transfer his inventorship interest over to Hyal or any other entity and Mr. Drizen was not under any employment agreement to assign his technology.

30. The error in not listing Mr. Drizen as the sole inventor of the inventions claimed in the patents arose without any deceptive intent on Mr. Drizen's part.

31. Plaintiff The Estate of Mr. Drizen owns any and all personal interest in and to the SOLARAZE technology.

32. Plaintiff Glyco now own any and all interest in the Solaraze technology and all benefits that have flowed from it through Mr. Drizen's continued work at LAM Pharmaceutical, the assets for which are currently owned by Plaintiff Glyco.

33. Mr. Drizen's rights to this technology were fraudulently taken from him, and he was denied of the benefit that should have accrued to him.

COUNT I
(Correction of Inventorship of U.S. Patents Nos. 5,639,738;
5,792,753; 5,852,002; 5,914,322; 5,929,048;
5,985,850 Pursuant to 35 U.S.C. § 256)

34. All of the allegations of paragraphs 1-33 are incorporated herein by reference.

35. The inventorship of the six patents in dispute is incorrect because through omission, inadvertence and/or error, Alan Drizen is not listed as the inventor on the patents.

36. Mr. Drizen made all of the conceptual contributions and the reduction to practice of the inventions claimed in the six SOLARAZE patents in dispute.

37. The omission of Mr. Drizen as the inventor on the six SOLARAZE patents in

dispute, patent occurred without any deceptive intent on the part of Drizen, or Plaintiffs.

38. Plaintiffs have standing to request a correction of inventorship of the six SOLARAZE patents in dispute because they are successors in interest to the personal and business interests of Mr. Alan Drizen.

39. All parties concerned with the inventorship of the six SOLARAZE patents in dispute for which correction of inventorship is sought have been put on notice or will be put on notice pursuant to filing and service of this Complaint.

COUNT II
(conversion of property)

40. All of the allegations of paragraphs 1-33 are incorporated herein by reference.

41. Through the acts and actions described herein above, Defendants improperly appropriated the intellectual property of Plaintiffs.

42. Plaintiffs are entitled to the return of the intellectual property and an accounting for damages adequate to compensate for the use, in an amount at least equal to a reasonable royalty under 35 U.S.C. §284.

PRAYER FOR RELIEF

In view of the foregoing, Plaintiffs respectfully request that this Court grant relief as follows:

A. Judgment that Alan Drizen is the sole inventor of the six SOLARAZE patents in dispute;

B. Issuance of an order pursuant to 35 U.S.C. § 256, requiring the Director of the United States Patent and Trademark Office to correct inventorship of the six patents in dispute.

C. Restoration of Alan Drizen's ownership and economic interest in and to the six patents in dispute to Plaintiffs as the successors in interest to Mr. Alan Drizen.

D. An accounting for damages sufficient to compensate for the unauthorized and improper use by Defendants of the intellectual property protected by the six patents in dispute.

Respectfully submitted,

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