

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DESTON THERAPEUTICS, L.L.C. and)	
UNIGEN PHARMACEUTICALS, INC.,)	
)	
)	
Plaintiffs,)	C.A. No. _____
)	
v.)	
)	
TRIGEN LABORATORIES, INC.)	DEMAND FOR JURY TRIAL
and IRISYS, INC.,)	
)	
Defendants.)	

COMPLAINT

Plaintiffs Deston Therapeutics, LLC (“Deston”) and Unigen Pharmaceuticals, Inc. (“Unigen”) file this Complaint against Defendants TriGen Laboratories, Inc. (“TriGen”) and Irisys, Inc. (“Irisys”) (collectively, “Defendants”) and allege as follows:

1. This is an action for a permanent injunction and for further relief based on patent infringement under 35 U.S.C. § 271, false advertising and unfair competition under Section 43(a) of the Lanham Act, deceptive trade practices under 6 Del C. § 2532, and/or common law unfair competition.

PARTIES

2. Plaintiff Unigen is a corporation organized under the laws of Delaware. Unigen’s headquarters are in Lacey, Washington. Among other patents, Unigen owns United States Patent Nos. 6,683,116 and 7,034,060 by assignment. Unigen supplies its patented polycosanol composition to AURALGAN’s manufacturer for use as an active ingredient in AURALGAN.

3. Plaintiff Deston is a limited liability company organized under the laws of North Carolina. Deston is headquartered in Chapel Hill, North Carolina. Deston markets prescription AURALGAN® Otic Solution (“AURALGAN”) to doctors and other health care practitioners throughout the United States. Deston holds an exclusive license from Unigen under United States Patent Nos. 6,683,116 and 7,034,060 to use Unigen’s patented polycosanol composition in the prescription otic market.

4. Defendant TriGen is a corporation organized under the laws of New Jersey and having its principal place of business at 2400 Main Street Extension, Suite 6, Sayreville, New Jersey 08872. Defendant TriGen markets, promotes, advertises, offers for sale, sells and/or distributes a prescription product known as Treagan® Otic Solution (“Treagan”) to customers including wholesalers, retailers, chains, distributors, mail order houses, independent pharmacies, managed care organizations and/or others throughout the United States, including in the District of Delaware. Defendant TriGen may be served with process through its Registered Agent, Mike Hudy, at 104 Union Avenue (Rt 71), Manasquan, New Jersey 08736.

5. Defendant Irisys is a corporation organized under the laws of California and having its principal place of business at 8810 Rehco Rd., Suite F, San Diego, California, 92121. Upon information and belief, Irisys manufactures Treagan for TriGen. Irisys may be served with process by serving a copy of the Complaint on its Registered Agent, Gina M. Stack, at 8810 Rehco Rd., Suite F, San Diego, California, 92121.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, 35 U.S.C. § 271 et seq. Accordingly, the Court has jurisdiction over this matter under 28 U.S.C. §§ 1331 and 1338(a). In the alternative, this Court has subject matter jurisdiction pursuant to 28 U.S.C.

§§ 1331, 1332, 1338, and 1367, and 15 U.S.C. §§ 1116 and 1121, as this case arises under the Lanham Act. Additionally, the amount in controversy exceeds \$75,000 and involves citizens of different states.

7. The exercise of personal jurisdiction in Delaware is proper because acts giving rise to Plaintiffs' causes of action have occurred in the State of Delaware. More specifically, Defendants market, promote, advertise, offer for sale, sell and/or distribute Treagan to customers including wholesalers, retailers, chains, distributors, mail order houses, independent pharmacies, managed care organizations and/or others throughout the United States, including in the District of Delaware. Defendants have purposefully and voluntarily placed Treagan into the stream of commerce with the expectation that it will be purchased by consumers in the District of Delaware.

8. Venue is proper in the District of Delaware under 28 U.S.C. § 1391 (b) and (c) and § 1400 (b).

BACKGROUND

The U-Polycosanol 410 Patents

9. Policosanol (or polyicosanol) is the general term for a mixture of high molecular weight, primary aliphatic alcohols that may be extracted and/or derived from the waxes of plants such as sugar cane, rice bran, wheat germ and yams, or certain insects (e.g., beeswax).

10. Plaintiff Unigen develops, manufactures and markets a range of botanical and marine-derived therapeutic compounds that address consumer health needs and improve quality of life. In 2002, Unigen's Chief Scientific Officer invented a novel policosanol composition and a method of making the composition from the wax secreted by the insect

Ericerus pela, a soft scale insect indigenous to southern China. In 2003, Plaintiff applied for patents on this policosanol composition, its method of manufacture, and its use in the treatment of certain medical conditions.

11. On January 27, 2004, United States Patent No. 6,683,116 (the “‘116 Patent”) entitled “Polycosanols from *Ericerus Pela Wax*” was duly and legally issued. A copy of the ‘116 Patent is attached hereto as Exhibit A and incorporated herein. It has a total of 47 claims covering compositions and methods.

12. On April 25, 2006, United States Patent No. 7,034,060 (the “‘060 Patent”) entitled “Polycosanols from *Ericerus Pela Wax*” was duly and legally issued. A copy of the ‘060 Patent is attached hereto as Exhibit B and incorporated herein. It has 5 claims total, all of which are composition claims.

13. Collectively, the above-mentioned patents are the “u-polycosanol 410 patents.” Plaintiff Unigen owns the u-polycosanol 410 patents by assignment.¹

14. Unigen manufactures and markets a commercial embodiment of the u-polycosanol 410 patents, described as “u-polycosanol 410.”² U-polycosanol 410 is composed of the following aliphatic alcohols: Hexacosanol 44-46%, Octacosanol 35-40%, Triacontanol 4-8%, Tetracosanol 3-5%, Nonacosanol Trace, Dotriacontanol Trace.

¹ Unigen also owns by assignment two additional patents concerning polycosanol: United States Patent No. 6,822,004 B2 entitled, “Polycosanols from *Ericerus Pela Wax*” and United States Patent No. 6,984,666 B2 entitled, “Polycosanols from *Ericerus Pela Wax*.” These two additional patents claim methods of using the polycosanol composition described in the ‘116 and ‘060 patents for treating certain medical conditions and are not at issue in this suit.

² The name u-polycosanol 410 reflects the manufacturer of the product (Unigen) and the product’s molecular weight (410).

Deston Selects U-Polycosanol 410 for Use in AURALGAN Otic Solution

15. Otic (ear) disorders are believed to rank second only to the common cold as the most frequent illness among children in the United States. Most otic disorders are responses to inflammation from infections, allergic reactions or trauma to the ear. A particularly common otic disorder is otitis media, a painful inflammation of the middle ear that is often accompanied by fever, swelling, inflammation of the tympanic membrane and considerable pain. Nearly 70% of children develop otitis media by age 2. Otitis media accounts for over 35% of all visits to pediatricians each year, represents more than \$5 billion in U.S. health care costs annually, and may be the most common cause of hearing loss in the U.S. Another common otic disorder, otitis externa, is an inflammation of the external ear canal that occurs in hot, humid weather, and after swimming, and is commonly known as “swimmer’s ear.”

16. In young children, the management of ear pain associated with otic disorders is often a major concern for parents. Although physicians commonly recommend acetaminophen (an orally ingested analgesic) for pain control, it has a slow onset of action and produces mixed results. Topically applied otic solutions (ear drops) containing analgesic agents and local anesthetics may assist in reducing the pain and inflammation that accompany otic disorders.

17. Founded in 2005, Deston is a pharmaceutical company focused on acquiring, marketing and developing therapies for acute and chronic inflammatory diseases. Since 2007, Deston has marketed AURALGAN, a leading prescription otic solution used to relieve the pain, swelling and congestion that often accompany acute otitis media and otitis externa.

18. AURALGAN contains the following active ingredients: acetic acid (0.01%), antipyrine (5.4%), benzocaine (1.4%) and u-polycosanol 410 (0.01%). These

ingredients are listed on AURALGAN's label and package insert. A copy of AURALGAN's package insert is attached hereto as Exhibit C and incorporated herein.

19. U-polycosanol 410 was selected for use in AURALGAN to provide astringent qualities, *i.e.*, the ability to shrink or constrict inflamed tissues by drawing excess water out of the cells lining the ear canal, while avoiding the excessive drying and irritation effects sometimes associated with other types of alcohols (*e.g.*, isopropyl alcohol). Deston holds an exclusive license from Unigen for the use of u-polycosanol 410 for otic (ear) indications and in otic applications. Consequently, AURALGAN is the only otic solution in North America authorized by Unigen to contain u-polycosanol 410 as an ingredient.

20. AURALGAN has become a leading prescription product for the treatment of otic disorders, and annual sales of AURALGAN have grown to more than 3.3 million units.

TriGen Develops and Markets Treagan to Exploit AURALGAN's Success.

21. Defendant TriGen is a New Jersey-based pharmaceutical company that distributes "generic" versions of brand name prescription drugs. Upon information and belief, TriGen does not employ a sales force to market its prescription products to doctors. Upon information and belief, TriGen's sales result when pharmacists substitute TriGen's allegedly generic products for "branded" drugs prescribed by doctors. Upon information and belief, sometime in 2009, TriGen saw an opportunity to exploit the reputation and success of AURALGAN by creating a knock-off otic solution.

22. Upon information and belief, TriGen began marketing a knock-off product, called Treagan, in July 2009. Treagan's package insert indicates that Treagan is manufactured for TriGen. Upon information and belief, TriGen contracted with Irisys to manufacture this product.

23. According to its package insert, Treagan contains the following active ingredients: acetic acid (0.01%), antipyrine (5.4%), benzocaine (1.4%) and “u-polycosanol 410 (synthetic mixture)” (0.01%). A copy of Treagan’s package insert is attached hereto as Exhibit D and incorporated herein.

Treagan Cannot Lawfully be Substituted for AURALGAN

24. A pharmacist presented with a doctor’s prescription for a brand-name drug may fill that prescription by dispensing the drug prescribed, or may instead dispense an identical, “generic” version of the drug. The latter procedure is known as generic drug substitution.

25. For drug wholesalers, distributors, pharmacies and pharmacists, generic drugs must be both *pharmaceutically equivalent* – e.g. have the same active ingredients, strength and dosage form – and *bioequivalent* – deliver the active ingredients to the site of action in the body at the same rate and in the same amount.

26. For pharmacists and other medical professionals, these two requirements – pharmaceutical equivalence and bioequivalence – ensure that a generic drug substituted for the prescribed brand-name drug is truly interchangeable and will provide the patient with the treatment the doctor ordered. This is critical because the doctor – not the wholesaler, distributor or pharmacist – is responsible for making the appropriate treatment decisions and tracking the patient’s progress.

27. In the United States, drugs wholesalers, distributors, pharmacies and ultimately pharmacists rely on comprehensive drug information databases, most notably, First DataBank®, to provide them with vital information concerning prescription drug products. The information in these databases are integrated with other computerized information systems that drug buyers and pharmacists use to obtain information important to their drug purchasing and dispensing decisions, including the decision whether to purchase, stock and dispense a “generic”

drug product as a substitute for a prescribed brand. In turn, comprehensive drug information databases rely on drug manufacturers to provide them accurate information about the active ingredients, strength and dosage form of their marketed products.

28. Although other drug companies market prescription otic solutions containing acetic acid (0.01%), antipyrine (5.4%), benzocaine (1.4%) and “polycosanol” (0.01%), drug information databases recognize that different polycosanol compositions are not equivalent and may have different pharmacological effects and benefits. Because of the unique chemical composition of u-polycosanol 410, drug information databases distinguish AURALGAN from other otic solutions that list “polycosanol” as an active ingredient, *i.e.*, they do not link otic solutions that do not contain u-polycosanol 410 to AURALGAN as pharmaceutically equivalent products that may be generically substituted for AURALGAN.

29. Upon information and belief, Defendants seek to exploit pharmacists’ reliance on information contained in drug information databases and price systems by having Treagan linked to (*i.e.*, assigned the same formulation coding as) AURALGAN. Upon information and belief, Defendants list u-polycosanol 410 on Treagan’s label so that drug information databases, and consequently drug wholesalers, distributors and pharmacies, will “link” Treagan to AURALGAN as a pharmaceutically equivalent product that may be substituted for AURALGAN prescriptions.

30. Defendants’ efforts have had their intended effect. Because Treagan’s package insert describes Treagan as containing the same active ingredients, including “u-polycosanol 410,” in the same amounts as AURALGAN, comprehensive drug information databases including First DataBank and Medi-Span have linked Treagan to AURALGAN as a pharmaceutically equivalent and potentially substitutable product. As a result of the linkage,

sales of AURALGAN solution have eroded, as many drug wholesalers, distributors, pharmacies and pharmacists in the District of Delaware and across the country buy Treagan with the intent to dispense it as a generic substitute for AURALGAN prescriptions.

31. Neither TriGen nor Irisys obtained a license from Unigen for the manufacture or use of u-polycosanol 410, or any other policosanol composition covered by the claims of the '116 or '060 patents.

32. Defendants are liable to Plaintiffs for the damages caused to AURALGAN's sales by their conduct. If Treagan is found to contain u-polycosanol 410, Defendants are liable for infringing the claims of Unigen's u-polycosanol 410 patents. If Treagan is found not to contain u-polycosanol 410, it cannot be a generic substitute for AURALGAN since it does not contain the same active ingredients as AURALGAN and therefore cannot be pharmaceutically equivalent to AURALGAN.

COUNT ONE

(Literal Infringement, or under the Doctrine of Equivalence, of United States Patent Nos. 6,683,116 and 7,034,060)

33. Plaintiffs refer to and incorporate herein the allegations of Paragraphs 1-32.

34. The u-polycosanol 410 patents were duly and legally issued by the United States Patent and Trademark Office in 2004 and 2006. Unigen is the assignee of the u-polycosanol 410 patents.

35. Upon information and belief, Defendants have been and are now directly infringing, and/or actively inducing infringement by others, and/or contributing to the infringement by others of U.S. Patent No. 6,683,116 and U.S. Patent No. 7,034,060 in this

District, and elsewhere in the United States. The patents have been infringed literally and/or under the doctrine of equivalents.

36. Upon information and belief, Defendants have been (a) making, using, selling, offering to sell and/or having had made or used the composition that is the subject of the u-polycosanol 410 patents; and/or (b) making, using, offering for sale, selling and/or distributing an otic solution known as Treagan that contains a composition claimed in the u-polycosanol 410 patents.

37. Defendants have actively infringed, induced infringement and/or contributed to the infringement and are still actively infringing, inducing, and/or contributing to the infringement of the u-polycosanol 410 patents, and will continue to do so unless enjoined by the Court.

38. Plaintiffs have at all times complied with 35 U.S.C. § 287.

39. Plaintiffs have suffered and are suffering monetary damages from Defendants' unauthorized infringement that are compensable under 35 U.S.C. § 284 in an amount to be determined at trial or hearing.

40. Plaintiffs have been irreparably harmed by Defendants' acts of infringement of the u-polycosanol 410 patents and will continue to be harmed unless and until Defendants' acts of infringement are permanently enjoined and restrained by order of this Court.

41. Upon information and belief, Defendants' infringement of the u-polycosanol 410 patents has been and continues to be willful and deliberate, making this an exceptional case entitling Plaintiffs to recover additional damages and reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT TWO

(False Advertising – Lanham Act § 43(a), 15 U.S.C. § 1125(a))

42. To the extent not inconsistent with, or in the alternative, Plaintiffs refer to and incorporate herein the allegations of Paragraphs 1-41, the same as if set forth at length.

43. Defendants market Treagan to drug information databases and consequently to drug wholesalers, distributors, pharmacies and pharmacists, and others in interstate commerce as containing “u-polycosanol 410.” Defendants intend for drug information databases and pricing systems to link Treagan to AURALGAN as a pharmaceutically equivalent and potential substitute product for AURALGAN. Defendants intend for drug wholesalers, distributors, pharmacies and pharmacists to rely on this information and to form the belief that Defendants’ product is generically equivalent to and substitutable for AURALGAN, and on that basis to provide patients whose doctors have prescribed AURALGAN with Treagan instead.

44. To the extent “u-polycosanol 410 (synthetic mixture)” used in Treagan differs in chemical composition from Unigen’s u-polycosanol 410 and does not infringe Unigen’s u-polycosanol 410 patents, Defendants’ advertisements and promotional claims about Treagan are literally and/or impliedly false and misleading. Treagan is not pharmaceutically equivalent, generic to or substitutable for AURALGAN unless it contains the same active ingredients in the same amounts as AURALGAN. Defendants’ promotional claims violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), which provides in relevant part that “any person who, on or in connection with any goods or services, . . . uses in commerce any . . . false or misleading description of fact or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person’s goods, services, or commercial activities, shall be liable to a civil action by any person who believes that he or she is likely to be damaged by such act.”

45. By reason of Defendants' conduct, Plaintiffs have suffered and will continue to suffer, damage to their businesses, reputations and goodwill. Pursuant to 15 U.S.C. § 1117, Plaintiffs are entitled to damages for Defendants' Lanham Act violations, an accounting of profits made by Defendants on sales of Treagan and recovery of Plaintiffs' costs and reasonable attorneys' fees incurred in this action.

46. Defendants' acts are willful, wanton, and calculated to deceive, and are undertaken in bad faith, making this an exceptional case entitling Plaintiff to recover additional damages and reasonable attorneys' fees pursuant to 15 U.S.C. § 1117.

47. Unless enjoined by this Court, Defendants' acts will irreparably injure Plaintiffs' goodwill and erode their market share. Pursuant to 15 U.S.C. § 1116, Plaintiffs are entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing acts.

COUNT THREE

(Unfair Competition – Lanham Act § 43(a), 15 U.S.C. § 1125(a))

48. To the extent not inconsistent with, or in the alternative, Plaintiffs refer to and incorporate herein the allegations of Paragraphs 1-47, the same as if set forth at length.

49. Deston has become uniquely associated with AURALGAN and the public identifies Deston as the source for AURALGAN.

50. Defendants have marketed and continue to market their knock-off product as an equivalent to and substitute for AURALGAN, and in doing so, have deceived, misled and confused drug wholesalers, distributors, pharmacies and pharmacists. This has enabled Defendants to trade-off of Deston's reputation and good will.

51. Defendants' acts constitute unfair competition in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

52. By reason of Defendants' conduct, Plaintiffs have suffered and will continue to suffer damage to their businesses, reputations and goodwill. Pursuant to 15 U.S.C. § 1117, Plaintiffs are entitled to damages for Defendants' Lanham Act violations, an accounting of profits made by Defendants on sales of Treagan and recovery of Plaintiffs' costs for this action.

53. Defendants' acts are willful, wanton and calculated to deceive, and are undertaken in bad faith, making this an exceptional case entitling Plaintiffs to recover additional damages and reasonable attorneys' fees pursuant to 15 U.S.C. § 1117.

54. Unless enjoined by this Court, Defendants' acts will continue to cause immediate and irreparable harm to Plaintiffs for which there is no adequate remedy at law. Pursuant to 15 U.S.C. § 1116, Plaintiffs are entitled to preliminary and permanent injunctive relief to prevent Defendants' continuing acts.

COUNT FOUR

(Violation of the Delaware Deceptive Trade Practices Act)

55. To the extent not inconsistent with, or in the alternative, Plaintiffs refer to and incorporate herein the allegations of Paragraphs 1-54, the same as if set forth at length.

56. 6 Del. C. § 2532 provides that:

(a) A person engages in a deceptive trade practice when, in the course of his business, vocation, or occupation, that person:

(1) passes off goods or services as those of another;

(2) causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;

(3) causes likelihood of confusion or of misunderstanding as to affiliation, connection, or association with, or certification by, another;

...

(5) represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he or she does not have;

...

(7) represents that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;

...

(12) Engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.

57. 6 Del C. § 2533 provides a private right of action to enforce the provisions of 6 Del C. § 2532.

58. In the course of their businesses, Defendants, by and through their false and misleading representations of fact and conduct concerning Treagan have engaged in and continue to engage in deceptive trade practices in violation of 6 Del C. § 2532.

59. Defendants have willfully engaged in their actions regarding Treagan knowing them to be deceptive.

60. By reason of Defendants' conduct, Plaintiffs have suffered and will continue to suffer damage to its business, reputation and goodwill.

61. Pursuant to 6 Del C. § 2533, Plaintiffs are entitled to enjoin Defendants' unlawful conduct as well as recover reasonable attorneys' fees.

COUNT FIVE

(Common Law Unfair Competition)

62. To the extent not inconsistent with, or in the alternative, Plaintiffs refer to and incorporate herein the allegations of Paragraphs 1-61, the same as if set forth at length.

63. With full knowledge of AURALGAN, Defendants have made false and misleading explicit and implicit representations to drug information databases and pricing systems that their product contains the same active ingredients in the same strength as AURALGAN and is equivalent to and substitutable for AURALGAN. Defendants intend that these false and misleading explicit and implicit representations will be passed to drug wholesalers, distributors, pharmacies and pharmacists, who will form the belief that Defendants' product is generic to and can be substituted for prescriptions for AURALGAN.

64. Defendants' selective and misleading comparisons of Treagan with AURALGAN, and omission of relevant facts, are likely to cause confusion, mistake or deception about the nature, characteristics and qualities of their knock-off otic solution in comparison, connection, or association with AURALGAN.

65. Defendants know, or in the exercise of reasonable discretion should know, that their marketing program encourages the sale and substitution of their otic solution for prescriptions of AURALGAN and is likely to result in the improper substitution of Treagan for AURALGAN, and the deception of drug wholesalers, distributors, pharmacies, pharmacists and others about the nature, characteristics and qualities of Treagan in comparison, connection or association with AURALGAN.

66. Defendants' actions are willful and have been undertaken with the purpose of deceiving consumers.

67. As a result of such conduct, Defendants have caused, and unless enjoined by this Court, will continue to cause confusion as to the equivalence and interchangeability of their knock-off product with AURALGAN.

68. Plaintiffs are entitled to damages for Defendants' unfair competition, an accounting of profits made on sales of Treagan and recovery of Plaintiffs' costs of this action. In addition, Defendants knew or should have known that their conduct was reasonably likely to result in injury, damage or other harm, thus warranting the award of punitive damages.

69. As a result of Defendants' conduct, Plaintiffs have suffered, and unless such acts and practices are enjoined by this Court, will continue to suffer damage to their businesses, reputation and goodwill for which it is entitled to preliminary and permanent injunctive relief.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request that the Court enter judgment in their favor and against Defendants as follows:

A. A judgment that each Defendant has infringed U.S. Patent Nos. 6,683,116 and 7,034,060 as alleged herein;

B. A judgment and order that each Defendant, its agents, servants, employees, representatives, successors, and assigns, and those acting in privity or in concert with them, be preliminarily and permanently enjoined from further infringement of U.S. Patent Nos. 6,683,116 and 7,034,060;

C. A judgment and order that Defendants, their agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation with them, be preliminarily and permanently enjoined from directly or indirectly falsely advertising or promoting Treagan or inducing others to substitute Treagan for prescriptions of AURALGAN;

D. A judgment and order that Defendants, their agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation with them, be preliminarily and permanently enjoined from making or inducing others to make any false,

misleading or deceptive statement of fact, or representation of fact in connection with the promotion, advertisement, display, sale, offering for sale, manufacture, production, circulation or distribution of Treagan in such fashion as to suggest that this product is pharmaceutically equivalent to AURALGAN or can be freely interchanged with or substituted for prescriptions of AURALGAN;

E. A judgment and order that each Defendant, its agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation with them, be preliminarily and permanently enjoined from placing, and shall remove, information linking Treagan to AURALGAN in any drug information databases and/or pricing systems in the United States;

F. A judgment and order that Defendants include in any advertisement or promotion comparing Treagan with AURALGAN, whether oral or written, a notice in location and typeface as prominent as the comparison itself, that Treagan “is not pharmaceutically equivalent to AURALGAN otic solution. Therefore, the substitution of this product for AURALGAN may violate state law.”;

G. A judgment and order that Defendants take corrective action to correct any erroneous impression persons may have derived concerning the nature, characteristics or qualities of Treagan, including without limitation the placement of corrective advertising to prevent the inducement of others from substituting Treagan for prescriptions of AURALGAN;

H. A judgment and order granting Plaintiffs such other relief as the Court may deem appropriate to prevent the trade and public from deriving any erroneous impression concerning the nature, characteristics or qualities of Treagan or from inducing others to substitute Treagan for prescriptions of AURALGAN otic solution;

I. A judgment and order requiring Defendants to pay Plaintiffs damages under 35 U.S.C. § 284, including treble damages for willful infringement, and supplemental damages for any continuing post-verdict infringement up until entry of the final judgment with an accounting as needed;

J. A judgment and order requiring Defendants to pay Plaintiffs damages under 15 U.S.C. § 1117(a) in the amount of Plaintiffs' actual and consequential damages and any profits of Defendants resulting from their advertisements and marketing of Treagan;

K. A judgment and order requiring Defendants to pay Plaintiffs all of their reasonable attorneys' fees, costs and expenses, including those available under 35 U.S.C. § 284, 15 U.S.C. §1117(a) and any other applicable law;

L. A judgment and order finding that this is an exceptional case and requiring Defendants to pay Plaintiffs additional damages equal to three times the actual damages awarded Deston pursuant to 15 U.S.C. § 1117(a), 6 Del C. § 2533 and any other applicable law;

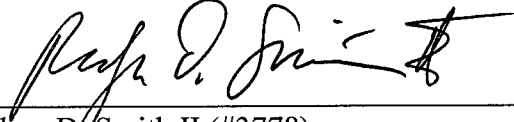
M. A judgment and order requiring Defendants to pay Plaintiffs' pre-judgment and post-judgment interest on the damages awarded and assessing all costs of this action against Defendants; and/or

N. A judgment and order providing such other and further relief as the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand that all issues so triable be determined by jury.

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