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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NYCOMED US INC. and JAGOTEC AG, Plaintiffs, v. TOLMAR, INC., Defendant.	§	Civil Action No. _____ **COMPLAINT FOR DECLARATORY JUDGMENT AND PATENT INFRINGEMENT**

Plaintiffs Nycomed US Inc. ("Nycomed" or "Plaintiff") and Jagotec AG ("Jagotec") (collectively, "Plaintiffs") for their Complaint against TOLMAR, Inc. ("TOLMAR" or "Defendant") for declaratory judgment and, in the alternative, for patent infringement, upon information and belief allege as follows:

Nature Of The Action

1. In this action, Plaintiffs seek declaratory judgment relief against TOLMAR's improper triggering of the litigation process that Congress has carefully constructed for resolving patent disputes when a drug company seeks approval to market a generic version of a branded drug by filing an Abbreviated New Drug Application ("ANDA"), as described in more detail below.

2. This action relates to ANDA No. 20-936 submitted by TOLMAR to the United States Food and Drug Administration (the "FDA") for approval of an ANDA with respect to Nycomed's SOLARAZE® Gel product (the "TOLMAR ANDA"). With that ANDA, TOLMAR seeks to engage in the commercial manufacture, use, and/or sale of TOLMAR's gel containing 3% diclofenac sodium (the "TOLMAR Gel").

3. At least as of May 20, 2010, TOLMAR does not have an ANDA that has been accepted by the FDA as sufficiently complete to begin substantive review. The acceptance for filing of an ANDA by the FDA is a prerequisite that must be satisfied for TOLMAR to send Plaintiffs proper notification of the ANDA and "Paragraph IV certification" (the "Paragraph IV Notice"). Such a notice letter, if it were valid, would start a time period within which Plaintiffs must sue for patent infringement in order to obtain a 30-month statutory delay during which the FDA cannot approve TOLMAR's ANDA. However, since the FDA has rescinded its acknowledgement of acceptance for filing by TOLMAR of a sufficiently complete ANDA, TOLMAR's notice letter to Plaintiffs is not valid, and therefore it cannot trigger Plaintiffs' statutory right to sue for infringement or commence the 30-month stay.

4. Nevertheless, despite the FDA rescission, TOLMAR refused to withdraw its purported "Paragraph IV Notice" to Plaintiffs.

5. Since the FDA has rescinded its acknowledgement of acceptance for filing by TOLMAR of a sufficiently complete ANDA, there is no sufficiently complete ANDA under substantive review and thus the service of this purported Paragraph IV Notice is not lawful and cannot trigger Plaintiffs' rights or obligations to sue TOLMAR or begin the 30-month stay of ANDA approval under 21 U.S.C. § 355(j)(5)(B)(iii) and 21 C.F.R. § 314.107(b)(3).

6. Since TOLMAR's now improper attempt to trigger the ANDA patent litigation process is in violation of federal law, this Court should declare TOLMAR's Paragraph IV Notice and attempts to trigger the ANDA litigation process improper and without legal effect.

7. Plaintiffs also seek alternative relief. TOLMAR's proposed generic products would infringe Plaintiffs' patents claiming SOLARAZE® Gel and the use of SOLARAZE® Gel if a TOLMAR ANDA directed to the proposed generic products was accepted for filing by the FDA. In that instance, the filing of such an ANDA would be an act of infringement under 35 U.S.C. § 271(e)(2).

8. Accordingly, in the alternative, if the purported Paragraph IV Notice received by Plaintiffs is deemed sufficient by the court to trigger the deadline for Plaintiffs to sue TOLMAR under 21 U.S.C. § 355(j)(5)(B)(iii) and 21 C.F.R. § 314.107(b)(3), then Plaintiffs seek all available relief under the patent laws of the United States, 35 U.S.C. § 100 et. seq., and other applicable laws for TOLMAR's infringement of their patents.

The Parties

9. Plaintiff Nycomed US Inc. is a company organized and existing under the laws of the State of New York, having its principal place of business at 60 Baylis Road, Melville, NY 11747-0103.

10. PharmaDerm® is a wholly owned subsidiary of Nycomed US Inc. and it has a principal place of business at 210 Park Avenue, Florham Park, NJ 07932. PharmaDerm® markets and sells SOLARAZE® Gel in New Jersey and other states.

11. Plaintiff Jagotec AG is a company organized and existing under Swiss law, having a principal place of business at Eptingerstrasse 51, CH-4132 Muttenz, Switzerland.

12. Upon information and belief, Defendant TOLMAR, Inc. is a corporation incorporated under the laws of State of Delaware, having its principal place of business at 701 Centre Avenue, Fort Collins, Colorado 80526.

Jurisdiction And Venue

13. This action arises under the Federal Declaratory Judgment Act, the Patent laws of the United States, and the Food and Drug laws of the United States, Titles 28, 35, and 21, respectively, of the United States Code. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202 and 35 U.S.C. § 271.

14. Venue is proper in this Court under 28 U.S.C. § 1391(c) and § 1391(b).

The Drug Approval Process

15. Any person wishing to market a pioneering drug – that is, a new drug that has not previously been approved by the FDA – must first file a New Drug Application ("NDA") with the FDA demonstrating that the drug is safe and effective for its intended use under 21 U.S.C. § 355(b)(1). To secure approval of an NDA, the NDA applicant must, among other things, collect and submit to the FDA extensive animal and human clinical trial data at a substantial cost of time and money.

16. A company seeking to market a generic version of a previously approved drug is not required to submit a full NDA. Instead, it may file an ANDA. *See* 21 U.S.C. § 355(j). The generic drug approval process is considered "abbreviated" because the generic manufacturer may

piggyback on and take advantage of the innovator company's data and the FDA's prior finding of safety and efficacy by demonstrating, among other things, that the generic product is bioequivalent to the previously approved drug (the "listed drug" or "branded drug").

17. In conjunction with this "abbreviated" application process, Congress has put in place a process for resolving patent disputes relating to generic drugs, pursuant to which an ANDA filer must provide certifications addressing each of the patents listed in the Orange Book for the branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12). An ANDA filer may certify that it believes a patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(l2)(i)(A)(4). This certification is known as a so-called "Paragraph IV Certification."

18. When an applicant submits an ANDA to the FDA, the FDA has 60 days to preliminarily review the application to ensure that it is sufficiently complete to permit substantive review. 21 C.F.R. § 314.101(a)(1). Only after FDA notifies the applicant that its ANDA is sufficiently complete is the ANDA deemed to have been "received" or "filed" by the FDA. 21 C.F.R. § 314.101(a)(2).

19. The sponsor of an ANDA which is accepted for review by the FDA that contains a Paragraph IV Certification must provide notice to both the holder of the NDA and the owner of the listed patent for the reference listed drug. This "Paragraph IV Notice" must include a detailed statement of the factual and legal bases for the applicant's belief that the challenged patent is invalid, unenforceable, or not infringed by the proposed generic product. 21 U.S.C. § 355(j)(2)(B)(iv)(II); 21 C.F.R. § 314.95(c)(6). The federal regulations specifically govern the timing of such Paragraph IV Notifications, by directing that the sending of such notices should

occur after FDA has officially received the ANDA as "sufficiently complete" for substantive review. 21 U.S.C. § 355(j)(2)(B)(ii); 21 C.F.R. § 314.95(b).

20. If the NDA holder and/or patentee file(s) a patent infringement action within 45 days after the date of receipt of a Paragraph IV Notice from an ANDA filer, final approval of the ANDA is generally subject to a 30-month stay. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3). The 30-month stay is important to innovator companies, such as Nycomed and Jagotec, because it protects them from the severe financial harm that could otherwise ensue from the FDA granting approval to a potentially infringing product without first providing an opportunity for the infringement case to be resolved. The innovator company is thus assured of a 30-month period during which it may try to enforce its intellectual property rights and resolve any patent dispute before the generic product enters the market. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3).

21. There are powerful incentives for generic companies to obtain the earliest possible filing date by submitting incomplete ANDA filings. The earliest ANDA filer may be entitled to 180 days of market exclusivity, during which time no other ANDA filer may come to market with a competing generic product. 21 U.S.C. § 355(j)(5)(B)(iv). By filing prematurely or notifying the NDA holder and patent owner prematurely, the first ANDA filer may also be able to manipulate the rules surrounding the 30-month stay to its advantage and reach the market sooner than would otherwise be permitted.

22. Accordingly, one of the important protections built into the ANDA process is that a generic applicant may not send a Paragraph IV Notice until it has received "from the FDA an acknowledgment letter stating that its abbreviated new drug application is sufficiently complete to permit a substantive review." 21 C.F.R. § 314.95(b).

23. This safeguard makes simple common sense. Incomplete ANDAs risk burdening the judicial system and the public with premature, and perhaps entirely unnecessary, patent infringement litigations. If the incomplete ANDA is never completed, forcing the parties and the courts to conduct infringement litigation will be unnecessary and generate unnecessary litigation costs. Even if the incomplete ANDA is eventually completed, the premature filing would prejudice not only the innovator company but also other ANDA filers. Accordingly, the ANDA applicant may not trigger the litigation process by serving a Paragraph IV Notice unless and until it has an ANDA on file that the FDA has accepted for substantive review.

The Approved SOLARAZE® Gel And Related Patents

24. Nycomed is the holder of NDA No. 21-005, which is approved by the FDA pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(b). This NDA is directed to a pharmaceutical product that is sold in the United States under the trade name SOLARAZE®.

25. The active ingredient in SOLARAZE® is diclofenac sodium. The dosage form of SOLARAZE® is a gel, and the route of administration is topical.

26. United States Patent Nos. 5,639,738 (the "'738 Patent"), 5,792,753 (the "'753 Patent"), 5,852,002 (the "'002 Patent"), 5,914,322 (the "'322 Patent"), 5,929,048 (the "'048 Patent"), and 5,985,850 (the "'850 Patent") (collectively "the Patents-in-Suit") are owned by Jagotec. The Patents-in-Suit are exclusively licensed to Nycomed.

27. The Patents-in-Suit are valid, enforceable, and have not expired.

28. The FDA has listed the '738 Patent, the '753 Patent, the '002 Patent, the '322 Patent, the '048 Patent, and the '850 Patent in its *Approved Drug Products with Therapeutic Equivalence Evaluations* publication, commonly known as the "Orange Book," in connection

with NDA No. 21-005 and SOLARAZE® Gel. The FDA also maintains an electronic version of the Orange Book at www.fda.gov/cder/ob/.

29. United States Patent No. 5,639,738, entitled "Treatment of basal cell carcinoma and actinic keratosis employing hyaluronic acid and NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on June 17, 1997 to inventors Falk et al.

30. A copy of the '738 Patent is attached hereto as **Exhibit A**.

31. United States Patent No. 5,792,753, entitled "Compositions comprising hyaluronic acid and prostaglandin-synthesis-inhibiting drugs," was duly and legally issued by the United States Patent and Trademark Office on August 11, 1998 to inventors Falk et al.

32. A copy of the '753 Patent is attached hereto as **Exhibit B**.

33. United States Patent No. 5,852,002, entitled "Treatment of conditions and disease," was duly and legally issued by the United States Patent and Trademark Office on December 22, 1998 to inventors Falk et al.

34. A copy of the '002 Patent is attached hereto as **Exhibit C**.

35. United States Patent No. 5,914,322, entitled "Treatment of disease and conditions," was duly and legally issued by the United States Patent and Trademark Office on June 22, 1999 to inventors Falk et al.

36. A copy of the '322 Patent is attached hereto as **Exhibit D**.

37. United States Patent No. 5,929,048, entitled "Treatment of conditions and disease," was duly and legally issued by the United States Patent and Trademark Office on July 27, 1999 to inventors Falk et al.

38. A copy of the '048 Patent is attached hereto as **Exhibit E**.

39. United States Patent No. 5,985,850, entitled "Compositions comprising hyaluronic acid and drugs," was duly and legally issued by the United States Patent and Trademark Office on November 16, 1999 to inventors Falk et al.

40. A copy of the '850 Patent is attached hereto as **Exhibit F**.

41. The '738 Patent qualifies for listing in the Orange Book in connection with NDA No. 21-005 because it claims, inter alia, methods of treatment that are the subject of the approved NDA.

42. The '753 Patent qualifies for listing in the Orange Book in connection with NDA No. 21-005 because it claims, inter alia, pharmaceutical compositions that are the subject of the approved NDA.

43. The '002 Patent qualifies for listing in the Orange Book in connection with NDA No. 21-005 because it claims, inter alia, pharmaceutical compositions and methods of treatment that are the subject of the approved NDA.

44. The '322 Patent qualifies for listing in the Orange Book in connection with NDA No. 21-005 because it claims, inter alia, pharmaceutical compositions that are the subject of the approved NDA.

45. The '048 Patent qualifies for listing in the Orange Book in connection with NDA No. 21-005 because it claims, inter alia, pharmaceutical compositions and methods of treatment that are the subject of the approved NDA.

46. The '850 Patent qualifies for listing in the Orange Book in connection with NDA No. 21-005 because it claims, inter alia, pharmaceutical compositions that are the subject of the approved NDA.

The TOLMAR ANDA And Notice Letter

47. Upon information and belief, TOLMAR submitted ANDA No. 20-936, the TOLMAR ANDA, to the FDA, seeking approval to engage in the commercial manufacture, use, and/or sale of TOLMAR Gel.

48. TOLMAR sent a patent certification notice letter, TOLMAR's Paragraph IV Notice, dated April 8, 2010, addressed to Plaintiffs. The Paragraph IV Notice represented that TOLMAR had submitted to the FDA the TOLMAR ANDA and purported certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Paragraph IV certifications"). The purpose of the TOLMAR ANDA and purported Paragraph IV certifications was to obtain FDA approval to engage in the commercial manufacture, use, and/or sale of TOLMAR Gel, before the expiration of the '738, '753, '002, '322, '048 and '850 Patents listed in the Orange Book for NDA No. 21-005.

49. Upon information and belief, the FDA has rescinded its acknowledgement of acceptance for filing by TOLMAR of a sufficiently complete ANDA. TOLMAR has refused to provide Plaintiffs with a copy of the FDA's rescission under reasonable or timely terms.

50. Plaintiffs have requested that TOLMAR withdraw its ineffective Paragraph IV Notice, but TOLMAR has refused.

51. Plaintiffs have requested that TOLMAR acknowledge and stipulate that its Paragraph IV Notice is invalid, improper, null and void, but TOLMAR has refused.

52. Plaintiffs have requested that TOLMAR acknowledge and stipulate that the 45-day period for Plaintiffs to bring a patent infringement action against TOLMAR under 21 U.S.C. § 355(j)(5)(B)(iii) has not started, but TOLMAR has refused.

53. Plaintiffs have requested that TOLMAR acknowledge and stipulate that its Paragraph IV Notice cannot operate to trigger a 30-month stay of approval of TOLMAR's ANDA, but TOLMAR has refused.

54. Upon information and belief, if the TOLMAR ANDA is accepted for filing and approved by the FDA, TOLMAR will manufacture, offer for sale, and/or sell within the United States, and/or import into the United States, the product for which approval is sought in ANDA No. 20-936.

55. Upon information and belief, if the TOLMAR ANDA is approved by the FDA, TOLMAR will induce or contribute to the manufacture, use, offer for sale, and/or sale within the United States, and/or the importation into the United States, of the product for which approval is sought in ANDA No. 20-936.

56. TOLMAR's Paragraph IV Notice also included an offer for confidential access to purportedly relevant sections of the TOLMAR ANDA (the "TOLMAR Offer"). A copy of the Offer for Confidential Access is attached as **Exhibit G.**

57. TOLMAR requested that Plaintiffs accept the TOLMAR Offer before receiving access to purportedly relevant sections of the TOLMAR ANDA. The TOLMAR Offer contained unreasonable restrictions, above and beyond those that would apply under a protective order, on the scope of disclosure and on who could view the purportedly relevant sections of the TOLMAR ANDA, which effectively eliminated Plaintiffs' ability to meaningfully access the TOLMAR ANDA and process the information contained therein. For example, the TOLMAR Offer restricted disclosure to unspecified sections of the TOLMAR ANDA that TOLMAR in its sole discretion would choose to make available to Plaintiffs at some point in the future. At most, TOLMAR was willing to provide approximately 10 pages of its ANDA, but always under

unreasonable conditions. The TOLMAR Offer also unreasonably restricted access to purportedly relevant sections of the TOLMAR ANDA to a very limited number of Plaintiffs' outside counsel and certain of their support staff. The TOLMAR Offer also unreasonably required prior identification of the outside counsel who may receive access to purportedly relevant sections of the TOLMAR ANDA. The TOLMAR Offer further unreasonably barred any of Plaintiffs' in-house counsel from receiving access to purportedly relevant sections of the TOLMAR ANDA. The TOLMAR Offer further required Plaintiffs to acknowledge that the violation of any provision of the TOLMAR Offers "will cause irreparable injury to TOLMAR, and that an adequate legal remedy does not exist," requiring the granting of significant and onerous relief, no matter how minor, insubstantial or accidental an alleged breach.

58. Under 21 U.S.C. § 355(j)(5)(C)(i)(III), an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

59. Since receiving the Paragraph IV Notice and the TOLMAR Offer, Plaintiffs have negotiated with TOLMAR to request access to the TOLMAR ANDA under restrictions "as would apply had a protective order been issued." These negotiations have been unsuccessful.

60. TOLMAR delayed the negotiations until the 45-day period defined by 21 U.S.C. § 355(j)(5)(B)(iii) was imminently lapsing.

61. Plaintiffs have repeatedly requested that TOLMAR provide them with samples of the TOLMAR Gel, but TOLMAR has refused.

62. TOLMAR has also refused to provide Plaintiffs with its entire ANDA under any conditions.

63. TOLMAR has also refused, under any conditions, to provide Plaintiffs with any sections of the ANDA that pertain to the proposed labeling (e.g., for purposes of analyzing inducement of infringement), the formulation development description, sections like the QOS ("Quality Overall Summary"), the descriptions of the identity, properties and function of all of the components of the formulation and the final formulation, any assertions of bioequivalence, manufacturing, and any clinical study results.

64. TOLMAR frustrated the Hatch-Waxman system by attaching unacceptable and unreasonable conditions to its offer of access, and delayed in negotiating a reasonable offer, thereby unilaterally withholding information about its accused product until the 45-day window for filing suit was imminently lapsing.

65. Other than the description of the TOLMAR Gel set forth in the Paragraph IV Notice, TOLMAR has kept the contents of its ANDA, samples of TOLMAR Gel and the description of TOLMAR Gel in secret and refuses to provide them to Plaintiffs.

66. TOLMAR has revealed in its Paragraph IV Notice that TOLMAR Gel contains "Diclofenac sodium (3 wt%), polyethylene glycol monomethyl ether, benzyl alcohol, PEG-60 hydrogenated castor oil, hydroxyethyl cellulose and purified water." This list of components is very similar to the components used in SOLARAZE® Gel (from the SOLARAZE® Gel package insert), as the chart below shows:

TOLMAR Gel (from Paragraph IV Notice)	**SOLARAZE® Gel (from package insert)**
Diclofenac sodium, 3%	Diclofenac sodium, 3%
PEG monomethyl ether	PEG monomethyl ether
Benzyl alcohol	Benzyl alcohol
PEG-60 hydrogenated castor oil	Sodium hyaluronate

Purified water	Purified water
Hydroxyethyl cellulose	

67. Based on the above, TOLMAR Gel appears to be a substantial copy of SOLARAZE® Gel.

68. Upon information and belief, TOLMAR contends by and in its ANDA that the TOLMAR Gel is an appropriate generic substitution for SOLARAZE® Gel. TOLMAR refused to provide portions of its ANDA relating to such substitution to Plaintiffs under any circumstances.

69. Upon information and belief, TOLMAR contends by and in its ANDA that the TOLMAR Gel is bioequivalent to SOLARAZE® Gel. TOLMAR refused to provide portions of its ANDA relating to bioequivalence to Plaintiffs under any circumstances.

70. Based upon the TOLMAR Paragraph IV Notice, the TOLMAR Gel contains the same diclofenac sodium (3 wt%), benzyl alcohol, and purified water that are listed in the package insert for SOLARAZE® Gel.

71. The only differences between the components of TOLMAR Gel and SOLARAZE® Gel based upon the above information are the substitution of PEG-60 hydrogenated castor oil for sodium hyaluronate and the addition of hydroxyethyl cellulose.

72. Only the substitution of PEG-60 hydrogenated castor oil for sodium hyaluronate could impact the question of the infringement of the claims of the Patents-in-Suit. The addition of hydroxyethyl cellulose as a gelling agent or for other uses is not related to an element of the claims of the Patents-in-Suit, which are comprising-type, open-ended claims that permit the addition of such components.

73. Upon information and belief, the scientific literature reports that PEG-60 hydrogenated castor oil is a substance that can affect the absorption of drugs. Sodium hyaluronate is also a substance that can affect the absorption of drugs.

74. If the TOLMAR Gel is bioequivalent to SOLARAZE® Gel, then substitution of PEG-60 hydrogenated castor oil for sodium hyaluronate does not change the function, way or result sodium hyaluronate works and thus the two components are not substantially different and they are equivalents of one another.

75. Based upon the above, if the TOLMAR Gel is bioequivalent to SOLARAZE® Gel, then it infringes the claims of the Patents-in-Suit, which also cover SOLARAZE® Gel, because it has all of the components of SOLARAZE® Gel and the claims of the Patents-in-Suit or their equivalents.

76. On the other hand, if TOLMAR Gel is not bioequivalent to SOLARAZE® Gel, and if PEG-60 hydrogenated castor oil is not equivalent to sodium hyaluronate, then the TOLMAR ANDA is defective, the TOLMAR Gel is not an appropriate substitute for SOLARAZE® Gel, the TOLMAR Gel is not bioequivalent to SOLARAZE® Gel, and the TOLMAR ANDA should be withdrawn by TOLMAR and denied by the FDA.

77. Upon information and belief, the package insert and other labeling for TOLMAR Gel is required to be under FDA rules and regulations, and will be, a substantial copy of the package insert and other labeling for SOLARAZE® Gel. 21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. § 314.94(a)(8). TOLMAR has refused to provide its proposed package insert and other labeling for TOLMAR Gel to Plaintiffs under any conditions.

78. Based upon the above, TOLMAR will intentionally induce others to use TOLMAR Gel to topically treat actinic keratosis in human skin under certain conditions through its package insert and other labeling.

79. Based upon the above, TOLMAR will intentionally induce others to use TOLMAR Gel to block prostaglandin synthesis and topically treat diseased, infected, underperfused and pathological tissue through its package insert and other labeling.

80. Based upon the above, TOLMAR's marketing and sale of TOLMAR Gel will be direct infringement, contributory infringement and inducement of infringement of the pharmaceutical composition and method claims of the Patents-in-Suit.

81. In the absence of any additional information being provided to Plaintiffs, Plaintiffs rely upon information and belief, set forth above, and the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present to the Court evidence that the TOLMAR Gel falls within the scope of one or more claims of the Patents-in-Suit.

82. This suit is being filed within 45 days of Plaintiffs' receipt of TOLMAR's Paragraph IV Notice.

COUNT I
(Declaratory Judgment Of Ineffective Paragraph IV Notice)

83. Plaintiffs reallege paragraphs 1 through 82 above as fully set forth therein.

84. Once the FDA rescinded its acknowledgement of acceptance for filing by TOLMAR of a sufficiently complete ANDA, TOLMAR no longer has an ANDA for SOLARAZE® Gel that had been accepted by the FDA as sufficiently complete for substantive review. Absent an ANDA that has been accepted by the FDA as sufficiently complete to permit

substantive review, TOLMAR has no legitimate basis to trigger the ANDA patent litigation process.

85. As a consequence, TOLMAR's Paragraph IV Notice to Plaintiffs was invalid, improper, null, void, and without legal effect.

86. Plaintiffs have asked TOLMAR to withdraw the improper Paragraph IV Notice, but TOLMAR has refused.

87. An actual, substantial and justiciable controversy exists between Plaintiffs, on the one hand, and Defendant TOLMAR, on the other hand, regarding whether TOLMAR's Paragraph IV Notice was invalid, improper, null, void, and without legal effect and, as a consequence, whether TOLMAR attempted to improperly triggered the ANDA litigation process.

88. The controversy concerning the validity and effectiveness of TOLMAR's Paragraph IV Notice will cause Plaintiffs to suffer substantial prejudice and unnecessary legal fees and costs unless the controversy and the surrounding cloud of uncertainty is resolved by the Court.

89. Accordingly, Plaintiffs are entitled to a declaration that: (1) TOLMAR's Paragraph IV Notice is invalid, improper, null, void, and without legal effect and that TOLMAR was not entitled to trigger the ANDA patent litigation process; (2) this Court has no jurisdiction over Plaintiffs' alternative claims regarding the Patents-in-Suit because TOLMAR's Paragraph IV Notice is invalid, improper, null, void, and without legal effect; (3) the Paragraph IV Notice served by TOLMAR did not commence the 45-day period within which to file a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii); (4) if and when the FDA accepts TOLMAR ANDA as filed, TOLMAR must serve new Paragraph IV Notices on Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B); and (5) the 30-month stay will not begin until TOLMAR

sends a valid Paragraph IV Notice to Plaintiffs following FDA's acceptance of the TOLMAR ANDA.

COUNT II
(Patent Infringement of the '738 Patent)

90. Plaintiffs reallege paragraphs 1 through 89 above as fully set forth therein.

91. Jagotec is the owner and Nycomed is the exclusive licensee of the '738 Patent.

92. The submission of the TOLMAR ANDA to the FDA with a Paragraph IV certification for the '738 Patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '738 Patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

93. The commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug product that is the subject of the TOLMAR ANDA by TOLMAR would infringe one or more claims of the '738 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. § 271(a).

94. The commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug product that is the subject of the TOLMAR ANDA by TOLMAR would actively induce and contribute to infringement of the '738 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

COUNT III
(Patent Infringement of the '753 Patent)

95. Plaintiffs reallege paragraphs 1 through 94 above as fully set forth therein.

96. Jagotec is the owner and Nycomed is the exclusive licensee of the '753 Patent.

97. The submission of the TOLMAR ANDA to the FDA with a Paragraph IV certification for the '753 Patent for the purpose of obtaining approval to engage in the

commercial manufacture, use, or sale of a drug product before the expiration of the '753 Patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

98. The commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug product that is the subject of the TOLMAR ANDA by TOLMAR would infringe one or more claims of the '753 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. § 271(a).

99. The commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug product that is the subject of the TOLMAR ANDA by TOLMAR would actively induce and contribute to infringement of the '753 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

COUNT IV
(Patent Infringement of the '002 Patent)

100. Plaintiffs reallege paragraphs 1 through 99 above as fully set forth therein.

101. Jagotec is the owner and Nycomed is the exclusive licensee of the '002 Patent.

102. The submission of the TOLMAR ANDA to the FDA with a Paragraph IV certification for the '002 Patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '002 Patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

103. The commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug product that is the subject of the TOLMAR ANDA by TOLMAR would infringe one or more claims of the '002 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. § 271(a).

104. The commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug product that is the subject of the TOLMAR ANDA by

TOLMAR would actively induce and contribute to infringement of the '002 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

COUNT V
(Patent Infringement of the '322 Patent)

105. Plaintiffs reallege paragraphs 1 through 104 above as fully set forth therein.

106. Jagotec is the owner and Nycomed is the exclusive licensee of the '322 Patent.

107. The submission of the TOLMAR ANDA to the FDA with a Paragraph IV certification for the '322 Patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '322 Patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

108. The commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug product that is the subject of the TOLMAR ANDA by TOLMAR would infringe one or more claims of the '322 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. § 271(a).

109. The commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug product that is the subject of the TOLMAR ANDA by TOLMAR would actively induce and contribute to infringement of the '322 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

COUNT VI
(Patent Infringement of the '048 Patent)

110. Plaintiffs reallege paragraphs 1 through 109 above as fully set forth therein.

111. Jagotec is the owner and Nycomed is the exclusive licensee of the '048 Patent.

112. The submission of the TOLMAR ANDA to the FDA with a Paragraph IV certification for the '048 Patent for the purpose of obtaining approval to engage in the

commercial manufacture, use, or sale of a drug product before the expiration of the '048 Patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

113. The commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug product that is the subject of the TOLMAR ANDA by TOLMAR would infringe one or more claims of the '048 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. § 271(a).

114. The commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug product that is the subject of the TOLMAR ANDA by TOLMAR would actively induce and contribute to infringement of the '048 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

COUNT VII
(Patent Infringement of the '850 Patent)

115. Plaintiffs reallege paragraphs 1 through 114 above as fully set forth therein.

116. Jagotec is the owner and Nycomed is the exclusive licensee of the '850 Patent.

117. The submission of the TOLMAR ANDA to the FDA with a Paragraph IV certification for the '850 Patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '850 Patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

118. The commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug product that is the subject of the TOLMAR ANDA by TOLMAR would infringe one or more claims of the '850 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. § 271(a).

119. The commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug product that is the subject of the TOLMAR ANDA by

TOLMAR would actively induce and contribute to infringement of the '850 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

INJUNCTIVE RELIEF

120. Plaintiffs will be irreparably harmed by the Defendant TOLMAR's activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

EXCEPTIONAL CASE

121. This case is an exceptional one, and Plaintiffs are entitled to an award of its reasonable attorneys' fees, costs and expenses, under 35 U.S.C. § 285 and any other available statute or law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests the following relief:

A. Preliminarily and permanently enjoin Defendant (1) to withdraw their improper and ineffective Paragraph IV Notice, and (2) to refrain from sending any new Paragraph IV Notice to Plaintiffs unless and until the FDA has notified Defendant that its ANDA is sufficiently complete to be deemed received for review;

B. Enter a declaratory judgment that: (1) Defendant's Paragraph IV Notice is invalid, improper, null, void, and without legal effect and that Defendant was not entitled to trigger the ANDA patent litigation process; (2) this Court has no jurisdiction over Plaintiffs' alternative claims regarding the '738, '753, '002, '322, '048, and '850 Patents because Defendant's Paragraph IV Notice is invalid, improper, null, void, and without legal effect; (3) the Paragraph IV Notice served by Defendant did not commence the 45-day period within which to file a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii); (4) if and when the FDA accepts

Defendant's ANDA, Defendant must serve a new Paragraph IV Notice on Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B); and (5) the 30-month stay will not begin until Defendant sends a valid Paragraph IV Notice to Plaintiffs following FDA acceptance of Defendant's ANDA.

C. A judgment that TOLMAR has infringed the '738, '753, '002, '322, '048, and '850 Patents under 35 U.S.C. § 271(e)(2)(A);

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the TOLMAR ANDA be no earlier than the expiration of the '738, '753, '002, '322, '048 and '850 Patents, including any extensions or regulatory exclusivities appended thereto;

E. A judgment declaring that the making, using, offering to sell, selling within the United States, or importing into the United States, of the product for which approval is sought in the TOLMAR ANDA would constitute infringement of the '738, '753, '002, '322, '048, and '850 Patents, or inducing or contributing to such conduct, by TOLMAR pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

F. A judgment permanently enjoining TOLMAR and its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from making, using, selling, or offering to sell in the United States, or importing into the United States, the product for which approval is sought in the TOLMAR ANDA, or any product that infringes or induces or contributes to the infringement of the '738, '753, '002, '322, '048, and '850 Patents, until the expiration of those patents, including any extensions or regulatory exclusivities appended thereto;

G. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

H. Costs and expenses in this action; and

I. Such further and other relief as this Court determines to be just and proper.

Dated: May 21, 2010

Respectfully submitted,

By: */s/ Leda Dunn Wettre*

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