IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG, NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD., and LTS LOHMANN THERAPIE-SYSTEME AG, Plaintiffs, v. PAR PHARMACEUTICAL, INC., Defendant.	Civil Action No. 11-1077-RGA (Consolidated)
NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG, NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD., and LTS LOHMANN THERAPIE-SYSTEME AG, Plaintiffs, v. WATSON LABORATORIES, INC., WATSON PHARMA, INC., and ACTAVIS, INC., Defendants.	Civil Action No. 11-1112-RGA

TRIAL OPINION

Michael P. Kelly, Esq., McCARTER & ENGLISH, LLP, Wilmington, DE; Nicholas N. Kallas, Esq., FITZPATRICK, CELLA, HARPER & SCINTO, New York, NY; Filko Prugo, Esq., FITZPATRICK, CELLA, HARPER & SCINTO, New York, NY.

Attorneys for Plaintiffs Novartis Pharmaceuticals Corporation, *et al.*

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Attorneys for Defendants Watson Laboratories, Inc., *et al.*

June 18, 2014

Richard G. Andrews

ANDREWS, U.S. DISTRICT JUDGE:

Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd., and LTS Lohmann Therapie-Systeme AG (collectively, "Novartis" or "Plaintiff") brought this suit against Watson Laboratories, Inc., Watson Pharma, Inc., Watson Pharmaceuticals, Inc. (collectively "Watson" or "Defendant"), and Par Pharmaceutical, Inc.[1] alleging infringement of U.S. Patent Nos. 6,335,031 ("the '031 patent") and 6,316,023 ("the '023 patent") (collectively, "the patents in suit"). Both patents share the same specification.[2] The '031 and '023 patents claim pharmaceutical compositions, transdermal devices, and methods of stabilizing compositions comprising the drug rivastigmine, which is an acetylcholinesterase inhibitor, and an antioxidant. (D.I. 310, p. 1). Novartis sells an Exelon® transdermal patch for the treatment of Alzheimer's disease that contains rivastigmine. Novartis listed the '031 and '023 patents in the Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations," frequently referred to as the "Orange Book," as covering the Exelon® patches. Watson's Abbreviated New Drug Application 202,119 ("ANDA") seeks approval to engage in the commercial manufacture, importation, use, or sale of a transdermal patch containing rivastigmine and an antioxidant prior to the expiration of the patents in suit.

Watson's ANDA product is a transdermal patch that contains a backing film, an adhesive bilayer comprised of a 905A adhesive and a 900A adhesive, and a protective release liner, a schematic of which is shown below:

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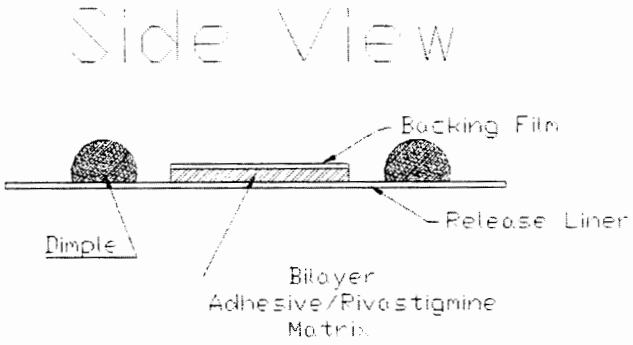
[1] Both the Par and Watson defendants were scheduled for trial beginning on August 26, 2013. Par and Novartis informed the Court on the morning of the first day of trial that a settlement had been reached. Relying on this representation, the Court entered an order staying the action with respect to Par for forty-five days and dismissed Par from the trial. (D.I. 293). The settlement later fell through, and a trial for Par and Novartis took place on May 1, 2014.

[2] Unless otherwise noted, all citations to the specification refer to the '031 patent.



(JTX 56, p. 1822-23). The process for manufacturing Watson's ANDA product can be summarized as follows: 1) the 905A adhesive and rivastigmine, the active ingredient, are mixed to form the 905A casting solution; 2) the 905A casting solution is applied to a polyester release liner, which is subsequently passed through a drying oven; 3) the 900A adhesive is applied to a polyester release liner and passed through a drying oven; 4) the release liner for the 905A layer is removed and the exposed 905A layer is laminated onto the 900A layer, thereby forming the adhesive bilayer; 5) the adhesive bilayer is then cut to size, packaged, and heat sealed into pouches. (*Id.*, pp. 1832-34). Watson's ANDA product is available in 5 and 10 square centimeter sizes. (*Id.*).

Novartis asserts that Watson's ANDA products infringe claims 3, 7, 13, 16, and 18 of the '031 patent and claims 2 and 7 of the '023 patent. Watson counters that the asserted claims are obvious under 35 U.S.C. § 103(a) and not infringed. The Court held a four day bench trial from August 26-29, 2013. (D.I. 306, 307, 308 & 309). As explained below, Novartis proved that Watson's ANDA products infringe by a preponderance of the evidence, and Watson did not prove by clear and convincing evidence that the asserted claims were invalid as obvious.

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