

banner pharmacaps dutasteride

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Select at least one primary interest: With regard to the written description requirement, defendants argue that the specification offers only conclusory statements that do not adequately describe all three solvates. There was no evidence to suggest that Glaxo had those same issues when it sought to make a safe solvate with therapeutic effects. Additionally, any difficulties associated with the development of soft gel capsules and tablet formulation relates to the finished drug product, which need not be enabled by the patent. Finally, steroids were routinely ground up and dissolved in solutions to make solvates. Sign up now for free access to this content. Your email address will not be published. Password at least 6 characters required. Because solvation has long been known in the art, steroids are prone to solvation, and methods of creating and testing solvates have also long been known, this factor weights slightly in favor of an enablement finding. Relying on Federal Circuit precedent, the Court found that results from animal tests or in vitro experiments may be sufficient to satisfy the utility requirement. Further, the evidence indicates that Merck itself associated dutasteride, in one way or another, with [Glaxo]. Emails are serviced by Constant Contact. Patent Number 5, covers dutasteride, Androgens are a class of hormones; testosterone is the major circulating androgen. In a short opinion dated February 24, App. In some target tissues, including prostate and skin tissue, testosterone produces certain effects by first being converted to dihydrotestosterone. Here, the written description described the same class by identifying a particular structure obtained by particular processes. Id. Defendants argued that the specification would have to independently describe a sufficiently wide range of crystalline, precipitated, and reacted solvates in order to support claims broadly directed to dutasteride solvates. GlaxoSmithKline LLC v. Banner Pharmacaps, Inc., No. CV, WL at *5 (D. Del. GlaxoSmithKline LLC (GSK) is the holder of the ' patent, which includes claims directed to the chemical compound dutasteride or a pharmaceutically acceptable solvate thereof. Slip op. at 3 (citation omitted). GSK markets Avodart and Jalyn, which contain dutasteride. Banner Pharmacaps, Inc., Impax Laboratories. Dutasteride is useful in the treatment of androgen responsive diseases. Androgens are a class of hormones; testosterone is the major circulating androgen. Androgens are implicated in diseases including benign prostatic hyperplasia, prostate cancer, acne, male pattern baldness and hirsutism. In some target tissues. Mar 3, - 5,, to dutasteride or a pharmaceutically acceptable solvate thereof on the basis that the term [dutasteride] solvate failed to meet the written description requirement (WDR). The district court construed a solvate of this steroidal drug to mean a complex formed by dutasteride in which dutasteride. Case Name: GlaxoSmithKline LLC v. Banner Pharmacaps, Inc., Civ. No. 11RGA, U.S. Dist. LEXIS (D. Del. Aug. 9,) (Andrews, J.) Drug Product and Patent(s)-in-Suit: Avodart (dutasteride); U.S. Patent No. 5,, (the ' patent). Nature of the Case and Issue(s) Presented: The ' patent is. Feb 26, - The lawsuit involved the drug dutasteride, sold by GSK under the brand names Avodart and Jalyn for the treatment of "androgen responsive diseases," and GSK brought suit under the provisions of 35 U.S.C. (e)(2) following ANDA filings by defendants Banner Pharmacaps, Inc., Impax Laboratories. May 30, - your manufacture, use, or sale of Dutasteride Capsules, mg, under this ANDA. You have notified the agency that Banner. Pharmacaps, Inc. (Banner) complied with the requirements of section (j)(2)(B) of the Act, and that litigation was initiated against Banner for infringement of these patents within the. Feb 24, - BANNER PHARMACAPS, INC. and Impax Laboratories, Inc., Defendants Appellants, Roxane Laboratories, Inc., Defendant Appellant, Mylan Inc. and Mylan Pharmaceuticals Inc., The parties agree that dutasteride is the molecule identified before or a pharmaceutically acceptable solvate thereof. May 5, - Banner Pharmacaps, Inc., Nos. . . . , U.S. App. LEXIS (Fed. Cir. Feb. 24,) (Circuit Judges Taranto, O'Malley, and Wallach presiding; Opinion by Taranto, J.) (Appeal from D. Del., Andrews, J.) Drug Product and Patent(s)-in-Suit: Avodart and Jalyn (dutasteride);. Mar 12, - Are claims that recite a solvate of a chemical compound invalid for lack of written description if the patent does not describe any specific solvates? In GlaxoSmithKline LLC v. Banner Pharmacaps, Inc., the Federal Circuit said No, and upheld the district court's determination that the defendants had not.