

**RASMUSSEN V. SMITHKLINE BEECHAM CORP.:**  
**ENABLEMENT UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

In an important pharmaceutical related case looking at the enablement requirement under 35 U.S.C. §112, first paragraph, the United States Court of Appeals for the Federal Circuit (“CAFC”) in *Rasmusson v. SmithKline Beecham Corp.*, 04-1191 (Interference No. 104,646), held that a patent specification must disclose as a matter of fact a practical utility for an invention. The court found that without efficacy data to support the claimed invention and “where there is ‘no indication that one skilled in the art would accept without question statements as to the effects of the claimed drug products’ an applicant has failed to demonstrate sufficient utility and therefore cannot establish enablement” under 35 U.S.C. §112, first paragraph.

The patent application (“the Rasmusson application”) at issue was filed on June 2, 1995. The Rasmusson application claims a method of treating prostate cancer in humans by administering a therapeutically effective amount of the compound finasteride, a known selective 5- $\alpha$ -reductase (“5 $\alpha$ R”) inhibitor. Finasteride inhibits production of dihydrotestosterone (“DHT”), which is associated with prostate cancer.

The United States Patent Office (“USPTO”) declared an interference between the Rasmusson application and two patents to SmithKline Beecham (“the SmithKline patents”). The SmithKline patents also claim a method of treating human prostate cancer with finasteride and were accorded the date of June 27, 1990. In an attempt to antedate the SmithKline patents, Rasmusson sought the priority date of three pre-June 27, 1990, patent applications. These earlier applications also disclose a method of treating prostate cancer by using finasteride as a selective 5 $\alpha$ R inhibitor. However, the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office (“the Board”) found that the Rasmusson application was not entitled to the priority of these applications as there was “a complete lack of data [in these applications] supporting the statements which set forth the desired results of the claimed invention.” As there was no evidence to demonstrate the claimed effects, the Board “found that a person of ordinary skill in the art would not have believed that finasteride was effective in treating prostate cancer simply because finasteride was a known selective 5 $\alpha$ R inhibitor. Therefore, these earlier applications failed to satisfy the written description and enablement requirements of 35 U.S.C. §112.

It was argued that the Rasmusson application should be granted priority based on the filing date of Rasmusson’s earlier filed applications because the applications were enabling as efficacy is irrelevant to enablement. However, the CAFC affirmed the Board’s ruling that the Rasmusson application was not entitled to priority based on the filing dates of the earlier applications.

The CAFC explained that an applicant must disclose the practical utility of an invention in order to satisfy the enablement requirements of 35 U.S.C §112. An applicant’s failure to disclose adequate data regarding the utility of an invention may be proper grounds for a rejection under 35 U.S.C. §112, paragraph 1, for lack of enablement,

or under 35 U.S.C. §101 for lack of utility. The court further explained that reliance on articles suggesting that various multi-active 5αR inhibitors were effective in treating prostate cancer did not necessarily mean that 5αR was responsible for anti-tumor effects. The anti-tumor effects could be attributable to contaminating activities having no relation to 5αR inhibition.

However, the court noted that “the standard of what constitutes proper enablement of a prior art reference for purposes of anticipation under section 102, however, differs from the enablement standard under section 112.” The court held that proof of efficacy is not required for a reference to be enabled for anticipation purposes under 35 U.S.C. §102. Consequently, the CAFC reversed the Board’s ruling that European Patent Application No. 285383 (“EP ‘383”) is not an enabling reference for purposes of anticipating the SmithKline patents. EP ‘383 was published more than one year before the priority date assigned to the Smithkline patents. The Rasmusson application and EP ‘383 share the same disclosure. The CAFC remanded the question of anticipation of the SmithKline patents by EP ‘383 to the Board.

In light of this ruling, constructive reduction to practice without providing evidence to support the utility of the claimed invention may prove inadequate to establish sufficient utility in “unpredictable” areas of art such as the pharmaceutical and biotechnology arts. Therefore, any data showing the practical utility of a drug or human therapeutic should be included in a patent application to satisfy the enablement requirement under 35 U.S.C. §112, first paragraph, and to demonstrate practical utility under 35 U.S.C. §101.

**Disclaimer:**

**This case alert is not legal advice. Do not act upon it without professional advice. You are welcome to forward this case alert to others if you attribute it to McCracken & Frank LLP and include the original without alteration.**