Keywords: **enablement, enablement of an anticipating reference, interferences**

Summary: **A prior art reference under 35 U.S.C. §102 need not demonstrate utility in order to serve as an anticipating reference.**

Rasmusson v. SmithKline Beecham Corp.
75 U.S.P.Q.2d 1297
Decided June 27, 2005

I. Facts

At issue were claims from an application filed on June 2, 1995 by Gary Rasmusson and Glenn Reynolds ("the Rasmusson application"). The Rasmusson application claimed a method of treating prostate cancer in humans by administering a therapeutically effective amount of the compound finasteride, a known selective 5–α–reductase ("5αR") 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 claimed 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 disclosed a method of treating prostate cancer by using finasteride as a selective 5αR 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 5αR inhibitor. Therefore, these earlier applications failed to satisfy the written description and enablement requirements of 35 U.S.C. §112.

The Board also held that SmithKline's patents were not anticipated by a European patent application, EP No. 285383 ("EP '383") because the EP '383 application was not an enabling reference.

II. Issues

1. Was the Rasmusson application entitled to an earlier priority date?

2. Were SmithKline's patents anticipated by the EP '383 reference?

III. Discussion

1. No. The Court found that the Rasmusson application was properly denied priority to the earlier-filed applications as these applications were not enabling. The Court 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.

Surprisingly, while one of the earlier-filed Rasmusson applications lacked enablement, an identical continuation of this application was found to be enabled. Furthermore, enablement was established not by whether one of ordinary skill in the art could have made and used the claimed invention without undue experimentation, but whether one of ordinary skill in the art would have believed they could have made and used the invention. The court stated,

> [W]here there is no indication that one skilled in the art would accept without question statements as to the effects of the claimed drug products and no evidence has been presented to demonstrate that the claimed products do have those effects, an applicant has failed to demonstrate sufficient utility and therefore cannot establish enablement.

The fact that Rasmusson was not entitled to the priority of the eighth application because the application was non-enabled but was entitled to the benefit of the ninth application filing date may suggest that one cannot establish enablement of claims and therefore cannot satisfy the §112 requirements by submitting evidence of utility (*e.g.*, a Rule 132 Declaration) after an application is filed where one of ordinary skill in the art would not have accepted the asserted utility at the time of filing.

Finally, the Court declined to address the issue of whether or not the early-filed Rasmusson applications lacked adequate written description, as they had already established that these applications were not enabled.

2. Yes. 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. 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."

   Consequently, the Court 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. The Rasmusson application and EP '383 share the same disclosure, but the EP '383 was published more than one year before the priority date assigned to the Smithkline patents.

   The Court remanded the question of anticipation of the SmithKline patents by EP '383 to the Board for further consideration.

IV. Conclusion

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.