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## Must Utility Be Unquestionable at the Time of Filing a Patent Application under the Enablement Requirement of §112?

### THE FEDERAL CIRCUIT SAYS YES IN RASMUSSEN V. SMITHKLINE BEECHAM CORP.

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The first paragraph of 35 U.S.C. §112 requires an applicant to describe the claimed invention sufficiently to enable one skilled in the art to make **and use** the invention. On June 27, 2005, the Federal Circuit raised the standard for satisfying the “use” prong of the enablement requirement under §112 in its decision in *Rasmusson v. SmithKline Beecham Corp.* (“*Rasmusson*”).<sup>2</sup>

At least according to the panel of the Federal Circuit that decided *Rasmusson*,<sup>3</sup> a description of utility in a patent application fails to satisfy the enablement requirement of §112 unless, at the time of filing the application, “. . . one skilled in [the] art would accept without question . . .” the asserted utility.<sup>4</sup> A lower standard is unacceptable according to the panel, because otherwise, “. . . the ‘inventor’ would be rewarded the spoils instead of the party who demonstrated that the method actually worked.”<sup>5</sup>

As will be demonstrated below, the decision is the result of a misunderstanding of cited precedents. Many applicants, especially in the pharmaceutical area, will be faced with a serious dilemma if future Federal Circuit panels follow the decision as binding precedent.

The *Rasmusson* decision resulted from an appeal of a decision of the PTO Board of Patent Appeals and Interferences (the Board) regarding an interference. The claims involved in the interference relate to a method of treating prostate cancer by administering a chemical compound called finasteride.<sup>6</sup>

Finasteride was known prior to the invention by both parties in the interference as a “selective” inhibitor of an enzyme known as 5- $\alpha$ -reductase (“5- $\alpha$ -R”). 5- $\alpha$ -R is responsible for converting the hormone testosterone to dihydrotestosterone (“DHT”). Selective inhibitors of 5- $\alpha$ -R have no relevant activities other than producing DHT.<sup>7</sup>

It was also known in the prior art that “multi-active” inhibitors of 5- $\alpha$ -R exhibit anti-tumor effects. Unlike “selective” inhibitors, multi-active inhibitors have activities in addition to producing DHT. Such additional activities include inhibiting testosterone receptor binding.<sup>8</sup>

It was believed that high levels of either testosterone or DHT cause prostate cancer. It was not, however, known which was responsible.

Therefore, one could not be certain whether a selective 5- $\alpha$ -R inhibitor, such as finasteride, would be effective in treating prostate cancer. For example, if testosterone, and not DHT, is responsible for the disease, then a selective 5- $\alpha$ -R inhibitor would not be effective. This uncertainty regarding the utility of finasteride was crucial to the decision in *Rasmusson*, as we shall see below.

One party in the interference was Gary H. Rasmusson and Glenn F. Reynolds (collectively “Rasmusson”), who filed U.S. Patent Application Serial No. 08/460,296 (“the ‘296 application”) on June 2, 1995. The ‘296 application was the ninth in a series of continuing applications. The first application was filed April 3, 1987.<sup>9</sup>

The other party was SmithKline Beecham (“SmithKline”), which owned two patents, U.S. Patent Nos. 5,637,310 (“the ‘310 patent”) and 5,496,556 (“the ‘556 patent”), and reissue

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applications corresponding to each. The SmithKline patents and applications were all accorded an effective filing date of June 27, 1990. SmithKline's priority date falls between the filing dates of the third and fourth applications filed by Rasmussen.

The interference was declared on January 22, 2001. In order to prevail over SmithKline, Rasmusson had to be granted priority on the basis of any of his first three applications.<sup>10</sup>

The PTO Board of Patent Appeals and Interferences ("the Board") granted SmithKline's motion to deny Rasmusson the benefit of all eight of his earlier applications. The Board found that Rasmusson was not entitled to priority based on any of these earlier filing dates because the earlier applications failed to satisfy the enablement requirement of 35 U.S.C. §112.<sup>11</sup>

According to the Board, a person of ordinary skill in the art world, until the ninth Rasmusson application, have had no basis for believing that finasteride can be used to treat prostate cancer without undue experimentation.<sup>12</sup> The Board also took into account Rasmusson's failure to provide evidence demonstrating the efficacy of finasteride against prostate cancer.<sup>13</sup>

On appeal to the Federal Circuit, Rasmusson asserted that the enablement requirement was satisfied because a person of ordinary skill in the art could perform the steps disclosed in the specification without the need for any experimentation. Rasmusson further argued that efficacy is not relevant to enablement, but pertains only to the issue of utility under 35 U.S.C. §101.

The Federal Circuit disagreed and affirmed the Board's decision with regard to the priority date of Rasmusson's 296 application.<sup>14</sup> The court began its analysis by confirming that the enablement requirement under §112 overlaps the utility requirement under §101. According to the court, "the how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. §101 that the specification disclose as a matter of fact a practical utility for the invention."<sup>15</sup> The court further held that when there is a complete absence of data supporting the desired results of the claimed invention, an applicant's failure to disclose how to use an invention may support a rejection either under §112, first paragraph for lack of enablement or under §101 for lack of utility.<sup>16</sup>

The Federal Circuit then reviewed what is necessary to enable the stated utility under §112. The Federal Circuit relied on *In re Novak*, a 1962 case from its predecessor. The Court of Customs and Patent Appeals (CCPA).<sup>17</sup> Citing *Novak*, the Federal Circuit in *Rasmusson* held:

However, 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] 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.<sup>18</sup> (Original brackets. Emphasis added.)

Accordingly, the Federal Circuit reduced the issue in *Rasmusson* to whether a person of ordinary skill in the art would have believed, without question, before June 27, 1990 (the filing date accorded to SmithKline's patents and reissue applications) that finasteride would be effective in treating prostate cancer.<sup>19</sup> Relying on articles and testimony presented during the interference, the court concluded that it was not clear as of June 27, 1990 whether DHT or testosterone caused the prostate cancer. Therefore, the Federal Circuit agreed with the Board's conclusion that a person of ordinary skill in the art would not be certain as of June 27, 1990 whether or not a selective inhibitor of 5- $\alpha$ -R, such as finasteride, contributed to any anti-tumor effects.<sup>20</sup> See above. The court concluded that Rasmusson was not entitled to any of his early priority dates for failure to satisfy the enablement requirement of §112.<sup>21</sup>

The Federal Circuit also agreed with the Board's conclusion that a person of ordinary skill in the art would have been certain as of Rasmusson's ninth application, filed June 2, 1995, that finasteride was effective for its intended purpose. The court referred to a presentation made ten months earlier at the American Urological Association (AUA) by a doctor who reported that he had used finasteride successfully to treat prostate cancer.<sup>22</sup>

As a result of the AUA presentation, the court concluded that the utility stated in Rasmusson's ninth application finally satisfied §112 as of its filing date. It did not matter that the same utility had been asserted in Rasmusson's first eight applications.

Therefore, the Federal Circuit held that Rasmusson could not establish priority before the June 27, 1990 priority date of SmithKline's patents and reissue applications<sup>23</sup> and was, therefore, not entitled to a patent. As will be discussed below, this holding is based on a misconception of the CCPA's decision in *Novak*.

*Novak* reached the CCPA on appeal from the Board's decision affirming an examiner's rejection of claims based on "lack of utility." The issue in *Novak* was whether it was proper for the examiner to require further evidence from the applicant to demonstrate utility.<sup>24</sup>

The Board in *Novak* had affirmed the examiner's rejection for lack of utility absent "scientific evidence that the composition was safe and effective for the purposes set forth."<sup>25</sup> *Novak* relied on the information in the specification, and did not submit additional evidence.

On appeal, the CCPA in *Novak* affirmed the decision of the Board. The court reasoned:

[W]hen an applicant bases utility for a claimed invention on allegations of the sort made by appellants here [*i.e.*, safety and efficacy of a drug], unless one with ordinary skill in the art would accept those allegations as obviously valid and correct, **it is proper for the examiner to ask for evidence which substantiates them.**<sup>26</sup> (Emphasis added.)

The court then found that one skilled in the art would not accept "without question" the statements made in *Novak*'s specification. Therefore, the court held that the examiner had the right to request further evidence.<sup>27</sup>

Because *Novak* did not submit any such evidence, the CCPA agreed with the Board that *Novak* failed to establish utility. Therefore, the rejection of *Novak*'s application was affirmed.<sup>28</sup>

It is important to note that the CCPA in *Novak* never stated that the priority date of a patent application is irretrievably lost if, on the filing date, one skilled in the art would not accept the stated utility without question, and no evidence is presented to demonstrate the utility. The Federal Circuit in *Rasmusson* misstated the holding of the CCPA in *Novak* when it asserted otherwise.

As mentioned above, the CCPA in *Novak* merely stated that, if one with ordinary skill in the art would not accept the utility alleged in the specification without question, the examiner may properly request additional evidence of

utility. The CCPA further held that if the applicant refuses to come forward with such additional evidence, an enablement rejection of the claims will be upheld.

In *Rasmusson*, the Federal Circuit has added a new requirement to the utility prong of §112. The new requirement is that those skilled in the art “accept without question” the utility stated in the application as of the filing date.

If the new requirement is not met, the application, according to the Federal Circuit in *Rasmusson*, is not entitled to a filing date, even if evidence that establishes the stated utility is presented later. This requirement is not found in *Novak*, or in any other authority the authors are aware of.

The court in *Rasmusson* has confused the difference between two different situations. In one situation, an applicant fails to disclose a credible utility in the specification (referred to below as the “no utility situation”). In the other situation, an applicant provides evidence to address doubts about a utility stated in the specification (referred to below as the “no evidence situation”). Each of these situations has a different consequence. The different consequences can be critical, especially in the context of an interference, as it was in *Rasmusson*.

With regard to the “no utility situation,” it is well settled that an application must disclose a utility as required in §101, and enable the utility as required in §112, as of the filing date.<sup>29,30</sup> If a utility is not disclosed and enabled in the application as filed, the application is in violation of §§101 and 112, and does not accord the benefit of its filing date to later continuing applications.<sup>31</sup>

With regard to the “no evidence” situation, it is equally well settled that an applicant may provide evidence after the filing date to further support a utility already set forth in the specification as filed, and still maintain the original filing date. As was stated by the Federal Circuit in *In re Brana*<sup>32</sup>, such evidence “does not render an insufficient disclosure enabling, but instead goes to prove that the disclosure was in fact enabling when filed (i.e., demonstrated utility).”<sup>33,34</sup>

The specification in *Rasmusson* clearly stated a utility of the invention, i.e., administering finasteride to treat prostate cancer. Evidence that demonstrated the stated utility, i.e., suc-

cessful results from treating prostate cancer with finasteride in the presentation at the American Urological Association, ultimately became available, *albeit* not before Rasmusson’s ninth application.<sup>35</sup>

However, even though the evidence presented by Rasmusson was clearly in support of a utility already set forth in the specification, the Federal Circuit only permitted Rasmusson to claim priority to the filing date of the ninth application. The court’s holding is contrary to the long-stated position of the Federal Circuit and the CCPA that evidence dated after the filing date, “such as the teachings in pertinent references, will be available to substantiate any doubts” of the utility prong of enablement under §112, first paragraph. *In re Marzocchi*.<sup>36</sup>

The court in *Rasmusson* relied on its misconception of *Novak* and of §112, first paragraph, to deny Rasmusson the ability to claim priority back to his earlier eight applications. As a result, Rasmusson could not defeat the priority date accorded to SmithKline’s patents and reissue applications.<sup>37</sup>

The Federal Circuit’s decision, in the opinion of the authors, was wrongly decided. The court cited no authority, other than *Novak*, for the proposition that a continuing application is only enabled if a person of ordinary skill in the art would “accept without question” the asserted utility as of the filing date. As stated above, *Novak* does not stand for such a proposition, and the authors are unaware of any authority that does.

Under *Rasmusson*, a patent application fails to satisfy the enablement requirement of §112 if a person skilled in the art would, as of the filing date, question the utility stated in the application. The identical application might be enabled if filed the next day, however, because a publication somewhere in the world, even if unknown to the inventor, would lead a skilled person to believe the stated utility.<sup>38</sup>

The decision in *Rasmusson* is in direct conflict with at least two earlier panel decisions of the Federal Circuit, namely *In re Brana* and *In re Marzocchi*. See above.

The rule in the Federal Circuit regarding two conflicting panel decisions is clear. Prior decisions of a Federal Circuit panel constitute binding precedent on subsequent panels unless and until overturned *en banc*.<sup>39</sup> Consequently,

where there is direct conflict between two Federal Circuit panel decisions, the earlier, and not the later, decision constitutes the binding precedent.<sup>40,41,42</sup>

Therefore, the earlier *In re Brana* and *In re Marzocchi* decisions continue to constitute binding precedent. The later, and conflicting, *Rasmusson* decision does not.

It should be noted that SmithKline also may not be able to obtain a patent for its method of treating prostate cancer using finasteride. The Federal Circuit reversed the Board and held that a corresponding European application filed by Rasmusson, and published more than one year before the priority date assigned to the SmithKline patent, could be cited as a §102 reference against SmithKline’s patents.<sup>43</sup>

The Board had found that Rasmusson’s European patent application did not anticipate SmithKline’s claims because the European application lacked an enabling disclosure for the same reason the U.S. application lacked utility. See above.

The Federal Circuit disagreed. The court acknowledged that Rasmusson’s European application failed to satisfy the enablement requirement for the purpose of satisfying §112, but noted:

The standard for 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.<sup>44</sup>

The court further explained its decision by stating:

Since *Hafner*<sup>45</sup>, this court has continued to recognize that a prior art reference need not demonstrate utility in order to serve as an anticipating reference under section 102. (Citations, omitted).<sup>46</sup>

The Federal Circuit remanded the issue to the Board to “resolve the anticipation question in the first instance.”<sup>47</sup> In the end, it is quite possible, if not likely, that neither Rasmusson nor SmithKline will obtain a patent for treating prostate cancer using finasteride.

Accordingly, unless overturned *en banc* by the Federal Circuit or by the Supreme Court, *Rasmusson* has the potential to present patent applicants with a dilemma. The experience of SmithKline suggests that patent applications should be filed as early as possible, even if the asserted utility might be questioned. Otherwise,

the application might be anticipated by a publication irrespective of whether or not the publication enables the utility.

The experience of *Rasmusson* suggests that an early application with a questionable utility should be re-filed as a series of continuing applications as often as possible, because a publication somewhere in the world might convert the status of the application from being non-enabled to being enabled. The optimum strategy would be to file continuing applications daily in order to be guaranteed the earliest possible date of enablement.

As stated above, it is possible that neither *Rasmusson* nor *SmithKline*, will obtain a patent for using finasteride to treat prostate cancer. In view of the lack of patent protection and the expense of conducting clinical trials to obtain FDA approval, the *Rasmusson*, decision may make it less likely that finasteride will be brought to market.

This result seems to run counter to the constitutional purpose of the patent act, which is "to promote the progress of ... useful arts..."<sup>48</sup> There are few arts more useful and in need of promoting than the treatment of cancer.

Clearly, the holding in *Rasmusson* is not, has never been, and should never be, the law.

## ENDNOTES

- Hoffmann & Baron, LLP. The opinions expressed in this article are solely the current opinions of the authors, and not necessarily those of Hoffmann & Baron, LLP; any of its attorneys or agents; any of its clients; and not necessarily even the future opinions of the authors.
- Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 75 USPQ2d 1297 (Fed. Cir. 2005).
- Judges Bryson, Plager, and Prost.
- Rasmusson* at 1323, 1300.
- Id.* at 1324, 1301.
- Id.* at 1320, 1298.
- Id.*
- Id.* at 1324, 1301.
- Id.* at 1321, 1298.
- Id.* at 1322, 1299.
- Id.* at 1321 and 1322, 1298 and 1299.
- Id.* at 1322, 1299.
- Id.*
- Id.* at 1322, 1300.
- Id.* at 1323, citing *In re Cortright*, 165 F.3d 1353, 1356, 49 USPQ2d 1464 (Fed. Cir. 1999), quoting *In re Ziegler*, 1992 F.2d 1197, 1200, 26 USPQ2d 1600 (Fed. Cir. 1993); see also *In re Schoenwald*, 964 F.2d 1122, 1124, 22 USPQ2d 1671 (Fed. Cir. 1992).
- Rasmusson* at 1323, 1300.
- In re Novak*, 306 F.2d 924, 928, 134 USPQ 335, 337-338 (CCPA 1962).
- Rasmusson* at 1323, 1300, quoting *In re Novak* at 928, 337.
- The harsh standard of *Novak* ("no indication one skilled in the art would accept without question") has been replaced by the milder standard of *Brana* ("reason to doubt the objective truth")
- Rasmusson* at 1324, 1301.
- Id.*
- Id.*
- Rasmusson* at 1322-1323, 1299-1300.
- Novak* at 928, 337.
- Id.* at 927, 336.
- Id.* at 928, 337.
- Id.*
- Id.* at 928, 338.
- In re Glass*, 492 F.2d 1228, 1232, 181 USPQ 31, 34 (CCPA 1974).
- See, *Kawai v. Metlesics*, 480 F.2d 880, 178 USPQ 158 (CCPA 1973).
- Kawai* at 882-883, 160.
- In re Brana*, 51 F.3d 1560, 1567 fn 19, 34 USPQ2d 1436, 1441 fn 19 (Fed. Cir. 1995).
- Id.*
- See also, Utility Examination Guidelines, 66 Fed. Reg. 1092 (January 5, 2001), which state that after the examiner has established a *prima facie* case of no utility, the applicant can rebut the examiner's argument by, among other things, providing evidence in the form of a declaration under 37 CFR 1.132 or a printed publication. "Only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained." In other words, if the applicant submits evidence to show that the asserted utility is specific, substantial and credible, the rejection based on lack of utility is withdrawn, thereby permitting the application to issue with the same filing date.
- Rasmusson* at 1324, 1301.
- In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 370 (CCPA 1971).
- Rasmusson* at 1321, 1298-1299.
- The absurdity of such a rule is exacerbated by the issue of which time zone one uses to determine the day the application becomes enabled.
- UMC Elecs. V United States*, 816 F.2d 647, 652 n6, 2 USPQ2d 1465, 1468 n. 6 (errata) (Fed. Cir. 1987), cert. denied, 108 S. Ct. 748, 98 L.Ed.2d 761 (1988).
- Newell Companies v. Kenney Mfg.*, 864 F.2d 757 (Fed. Cir. 1988).
- Medimmune v. Centocor*, 409 F.3d 1376, 1380, 1381-82 (Fed. Cir. 2005).
- Tate Access Floors v. Interface*, 279 F.3d 1357, 1366 (Fed. Cir. 2002).
- Rasmusson* at 1326, 1302.
- Id.*
- In re Hafner*, 410 F.2d 1403, 161 USPQ 783 (CCPA 1969).
- Rasmusson* at 1326, 1302.
- Rasmusson* at 1326, 1303. The Federal Circuit also noted that its decision that *Rasmusson*'s European patent application is available to be cited under §102 "has significant ramifications" for the validity of *Rasmusson*'s ninth patent application ('296 application). As discussed above, the court decided that *Rasmusson* was not entitled to priority before the filing of his '296 application filed on June 2, 1995. This filing date is more than one year after the publication of *Rasmusson*'s European patent application. The court noted that *Rasmusson*'s European patent application and his '296 application appear to share the same disclosure. Nevertheless, the Federal Circuit remanded the case back to the Board to determine whether *Rasmusson*'s European patent application invalidates his '296 application. Thus, it is possible, under *Rasmusson*, for an otherwise allowable claim in a continuing application to be anticipated by its identical parent application, where the parent application, but not the continuing application, is held to be in violation of §112.
- U.S. Constitution, Article 1, Section 8.

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