HOW CLOSE IS CLOSE ENOUGH?[1]

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and

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Introduction

This is a companion to Gholz & Englehart, How Good is Good Enough?, 17 Intellectual Property Today No. 4 at page 12 (April 2010). That article dealt with situations in which the inventor(s) (or, more commonly, the assignee of the inventor(s)) had a specific, numerically quantifiable goal, but the alleged actual reduction to practice ("ARP") fell short of that goal. This article deals with situations in which the inventor(s) or the assignee of the inventor(s) intend to use the invention in a specific environment, but the alleged ARP did not take place in that environment. Examples of such situations are (a) medical inventions which are intended for use on human beings, but the alleged ARP took place on a laboratory animal, and (b) inventions which are intended for use in outer space, but the alleged ARP took place in an earthbound laboratory.

What the Federal Circuit Did in Scott v. Finney

Scott v. Finney, 34 F.3d 1058, 32 USPQ2d 1115 (Fed. Cir. 1994), is far from the most important opinion in this genre, but it is the funniest. Accordingly, it makes a good teaching tool.

The subject matter in dispute in Scott was a penile implant designed to permit the implantee to simulate an erection by manipulation of the implanted device through his skin. That

is, the intended environment consisted of the implantee's causing his own penis to simulate an erection.

The alleged ARP was the implantation of a prototype of the device into an anesthetized patient and the manipulation of the implanted prototype by a surgeon while the implantee remained anesthetized. (The opinion does not indicate whether the surgeon was male or female.) After the surgeon had successfully tested the prototype (in the sense that he or she had caused the penis of the anesthetized patient to become erect), he or she removed the prototype and implanted a prior art, externally pumped, penile implant.

The board had held that the testing of the prototype did not constitute an ARP because the test "had not shown utility, i.e., that the device would successfully operate under actual use conditions for a reasonable length of time."[4]

The court reversed, saying that "the Board imposed an overly strict requirement for testing to show reduction to practice…."[5]

Two facts were key to the reversal.

First, "The issue of reduction to practice is a question of law which…[the Federal Circuit] reviews *de novo*."[6]

Second, the invention was a minor improvement in a crowded art. As the court put it:

> Only the hydraulics of a fully self-contained internal prosthesis remained to be tested for workability. [The test on the anesthetized patient]…adequately showed the workability of these features.[7]

Comments on Scott v. Finney

If only the hydraulics of the fully self-contained internal prosthesis had to be tested, why was it necessary to put the prototype in the patient at all? It seems to us that the hydraulics could

have been tested for workability just as well by manipulating the prototype externally of a patient—on a laboratory bench, for example.

Moreover, it seems to us that the board's requirement for "testing of an implantable medical device under actual use conditions or testing under conditions that closely simulate actual use conditions for an appropriate period of time"[8] is far closer to the spirit (or, in view of the subject matter involved, should I say "the thrust"?) of the prior opinions on the subject of the adequacy of simulations than the court's acceptance of such an unrealistic "testing" of the prototype prosthetic. After all, the whole point of the requirement for testing is that a thing that looks like it will work frequently does not work in practice—or works for far less than the period of time for which it will have to work in practice or does not work anywhere near as well as it will have to work in practice.

Besides being entertaining, we think that Scott v. Finney is exemplary of the fact that, in recent years, the court's standards for an ARP have been far lower than the board's standards.

Pre-Scott v. Finney Opinions Involving Test Animals

The question of how close the testing environment must be to the environment of intended use has been raised repeatedly over the years in cases involving test animals. In particular, courts have often been presented with situations in which an applicant or patentee is attempting to rely on animal testing to demonstrate the utility of a pharmaceutical invention intended for use in human beings for purposes of showing that that invention had been actually reduced to practice as of the date of the animal testing. See, e.g., Blicke v. Treves, 241 F.2d 718, 112 USPQ 472 (CCPA 1957); Engelhardt v. Judd, 369 F.2d 408, 151 USPQ 732 (CCPA 1966); Ray-Bellet v. Engelhardt, 493 F.2d 1380, 181 USPQ 453 (CCPA 1974); and Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881 (CCPA 1980).

A composition of matter cannot be a patentable invention unless it has utility. 35 USC 101; Blicke, 241 F.2d at 720, 112 USPQ at 475. This in turn means that a composition of matter cannot be considered to have been reduced to practice until a utility (not necessarily the contemplated commercial utility, but a utility) has been established. Ray-Bellet, 493 F.2d at 1382-83, 181 USPQ at 454. Thus, the question of how close is close enough in these cases resolves into whether the tests in a given testing environment are sufficient to show that the claimed invention is useful.

Importantly, courts have held that, if no specific utility is recited in the patent or application, utility can be established by showing that the claimed invention is useful for any purpose.[9] Accordingly, successful animal testing can constitute an ARP based only on the "production of the desired pharmacological effect" in the animal subject, as long as the patent or application does not recite the specific utility of human therapy.[10] In Blicke, the court noted that the Blicke application made no mention of human therapy, and merely stated that the claimed compounds "are useful in the form of their water-soluble non-toxic salts as antispasmodic agents."[11] Accordingly, animal testing that demonstrated the compounds' antispasmodic effects – on dogs – was held to be sufficient to establish an ARP of the claimed invention.[12]

However, in situations where human therapy is referenced in the application or patent, it becomes more difficult – though certainly not impossible – to show an ARP through animal testing. In Engelhardt v. Judd, the court noted that the applicant's specification contained references to dosing humans with the claimed antihistamine/antiserotonin compound.[13] Nevertheless, testing on guinea pigs and rats was held to be sufficient to constitute an ARP because the court found that "there is satisfactory evidence of the correlation between antihistamine and antiserotonin activity in [those] laboratory animals and in human beings."[14] In

other words, even though the specification contained a reference to human therapy – and therefore, unlike in Blicke, it was necessary to show usefulness specifically for human therapy to have an ARP – the court found that the testing on those specific laboratory animals constituted an ARP because there was "satisfactory evidence of the correlation" between the drug's effect on those animals and its effect on humans.

In contrast, in Rey-Bellet the court held that animal testing was insufficient to show an ARP of the claimed anti-depressant/tranquilizer compound because the animal testing in question did not show any utility for the claimed compound, either in animals tested or in humans.[15] The court acknowledged the existence of the two lines of cases on animal testing discussed above: (1) those like Engelhardt v. Judd, where "the tests, though carried out on animals, were considered to prove that the drug would be useful in human therapy;" and (2) those like Blicke v. Treves, where "the tests done on animals, even though they might have been designed to indicate a utility for human therapy, prove that the drug is useful for treating animals."[16] The court then found that the animal testing at issue was insufficient to show utility under either line of precedent. For example, in one of the cited animal tests (on mice), the applicant attempted to rely on the fact that the compound had caused the pupils of the mice to dilate to show anticholinergic activity.[17] However, the court found this insufficient because of testimony and other evidence showing that there was an inadequate correlation between pupil dilation and anticholinergic activity.[18] The court noted that "One of [the applicant's] own witnesses testified that drugs other than those having anticholinergic activity can cause pupil dilation. Therefore, the test cannot be regarded as being specific for this property."[19] Accordingly, the animal testing was insufficient to show that the claimed compound had a useful effect even in mice, let alone in humans.

Pre-Scott v. Finney Opinions Involving Inventions Intended for Use in Outer Space

Another interesting scenario where the issue of how close is close enough has come up involves the Earth-bound testing of inventions that are intended to be used in outer space. In Williams v. Administrator of Nat'l Aeronautics & Space Admin., 463 F.2d 1391, 175 USPQ 5 (CCPA 1972), the court needed to decide if the laboratory testing of an attitude control system that was ultimately intended to be used on an orbiting satellite was sufficient to establish an ARP. The board had noted (and the court did not disagree) that, since the applicant's specification specifically referred to the use of the invention with orbiting satellites, the testing needed to show utility for that specific purpose in order to be considered an ARP – utility for any purpose was insufficient in view of the specific references in the specification.[20] To resolve the question of whether the laboratory tests were sufficient in this instance, the court relied on the test from Larsen v. Marzall, 195 F.2d 200, 92 USPQ 306 (D.C. Cir. 1952), that the invention is considered to be actually reduced to practice if "the tests show that the invention will serve the purpose for which it is intended so conclusively that practical men, men skilled in the art,[21] would take the risk of putting it into commercial use."[22] The court then discussed – quite convincingly – NASA's and its partner's willingness to promptly adopt Williams's invention after seeing the results of the laboratory tests in question.[23] In view of these facts, NASA could not reasonably deny that Williams had reduced his invention to practice through these tests, because to do so would be to deny that NASA's own decision makers were "practical men!"

Post-Scott v. Finney Opinions of the Federal Circuit

The Federal Circuit does not deal with the question of how close is close enough very often, but there have been a couple of notable opinions out of the court in the years since Scott v. Finney.

In Fujikawa v. Wattanasin, 93 F.3d 1559, 1565, 39 USPQ2d 1895, 1900 (Fed. Cir. 1996)[24], the court held that *in vitro* activity that is "typically highly correlatable" to a desired pharmacological activity is sufficient to establish an ARP. This represents a refinement of the result in Engelhardt v. Judd, discussed above, where animal testing was held to be sufficient to show an ARP for purposes of human therapy because there was record evidence of a correlation between the relevant pharmacological activity in animals and in humans. In Fujikawa, the court held that *in vitro* activity could similarly be sufficient to show an ARP as long as there is sufficient evidence that the *in vitro* activity is "typically highly correlatable" to the alleged *in vivo* activity. See also Janssen Pharmaceutica N.V. v. Teva Pharms. USA, Inc., 583 F.3d 1317, 1324-35, 92 USPQ2d 1385, 1389-90 (Fed. Cir. 2009) (holding that "human trials are not required for a therapeutic invention to be patentable," but that, "[i]n this case[,]…neither in vitro test results nor animal test results involving the use of galantamine to treat Alzheimer's-like conditions were provided" and that, accordingly, the applicant had failed to show the necessary utility.)

Comments

The question of how close is close enough "is a question which must be decided on the basis of the facts of the particular case involved." Blicke, 241 F.2d at 720. A good way to approach the question is to apply the rule from Larsen v. Marzall (i.e., to look at whether "the tests show that the invention will serve the purpose for which it is intended so conclusively that practical men, men skilled in the art, would take the risk of putting it into commercial use." As discussed above, in Scott, testing under conditions of actual use was not necessary to show an ARP because only the hydraulics of the fully self-contained internal prosthesis had to be tested in order to convince "practical men, men skilled in the art" that the invention would work for its

intended purpose – the other elements of the invention could reasonably be expected to work without additional testing, based on what had already been shown to work in the relevant field. Similarly, in the animal testing and *in vitro* testing cases, the invention can be reduced to practice without human testing as long as the results of the animal and/or *in vitro* testing are "typically highly correlatable" with results in humans, based on what is already known in the relevant field. Accordingly, the issue is not whether the invention has been proved to work for its intended purpose, but only whether enough has been shown so that, in view of what is already known in the art, "practical men, men skilled in the art, would take the risk of putting [the invention] into commercial use."

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[4] Scott, 34 F.3d at 1060, 32 USPQ2d at 1117.

[5] 34 F.3d at 1059, 32 USPQ2d at 1116.

[6] 34 F.3d at 1061, 32 USPQ2d at 1117, citing Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376, 231 USPQ 81, 87 (Fed. Cir. 1986).

[7] 34 F.3d at 1063, 32 USPQ2d at 1120.

[8] 34 F.3d at 1060-61, 32 USPQ2d at 1117, quoting from the board's opinion.

[9] Blicke, 241 F.2d at 721, 112 USPQ at 475.

[10] 241 F.2d. at 722, 112 USPQ at 476.

[11] 241 F.2d. at 721, 112 USPQ at 476.

[12] 241 F.2d. at 722, 112 USPQ at 476.

[13] Engelhardt, 369 F.2d at 410, 151 USPQ at 734.

[14] 369 F.2d at 410-11, 151 USPQ at 734.

[15] Rey-Bellet, 493 F.2d at 1384, 181 USPQ at 455-56.

[16] 493 F.2d at 1384, 181 USPQ at 455-56. We wonder whether there is an implicit requirement in such cases that the animal being treated have some commercial utility. It is one thing to treat an ailment in a prize race horse or a family dog and something quite different to treat an ailment in an animal which, while in no danger of extinction, has no commercial utility.

[17] 493 F.2d at 1384, 181 USPQ at 455-56.

[18] 493 F.2d at 1384, 181 USPQ at 455-56.

[19] 493 F.2d at 1384, 181 USPQ at 455.

[20] Williams, 463 F.2d at 1398, 175 USPQ at 10.

[21] Sorry, ladies. It's an old opinion!

[22] 463 F.2d at 1399, 175 USPQ at 11. See also Goodrich v. Harmsen, 442 F.2d 377, 383, 169 USPQ 553, 558-59 (CCPA 1971) (Rich, J.) (approving of the test from Larsen).

[23] 463 F.2d at 1399, 175 USPQ at 11.

[24] Discussed in Gholz, A Critique of Recent Opinions of the Federal Circuit in Patent Interferences, 79 JPTOS 271, 280 (1997).