United States District Court,
S.D. New York.

BRISTOL-MYERS SQUIBB COMPANY,
Plaintiff.
v.
RH'd4NE-POULENC RORER, INC., Centre National De La Recherche Scientifique, and Rh'f4ne-Poulenc Rorer, S.A,
Defendants.

No. 95 Civ. 8833(RPP)

Nov. 28, 2001.

Fitzpatrick, Cella, Harper & Scinto, New York, NY, By: Thomas H. Beck, for Plaintiff.

Clifford Chance Rogers & Wells LLP, New York, NY, By: Philip E. Roux, Gaynell C. Methvin, Dallas, TX, for Defendants.

OPINION AND ORDER

PATTERSON**, J.**

Bristol-Myers Squibb Company ("Bristol") has brought a Motion for Summary Judgment of Invalidity Under 35 U.S.C. s. 112 on the grounds of 1) lack of enablement and 2) failure to disclose the best mode. The motion was referred to the Special Master, who issued a Report and Recommendation dated August 9, 2001 (the "Report") recommending denial of Bristol's motion. Bristol objects to the Special Master's Report.

Standard of Review

The Court's review and consideration of the parties' briefs, exhibits, declarations, statements of material facts pursuant to Local Rule 56.1, relevant authorities, the Special Master's Report, the objections thereto, responsive papers, reply papers, and further filings by the parties is *de novo*.

Applicable Statute

35 U.S.C. s. 112 (1975) states, in relevant part:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Lack of Enablement

The first ground of invalidity raised by Bristol is lack of enablement. "[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation." ' *Genentech, Inc. v. Novo Nordisk A/S,* 108 F.2d 1361, 1365 (Fed.Cir.1997) (quoting In re Wright, 999 F.2d 1557, 1561 (Fed.Cir.1993)). Under In re Wands, 858 F.2d 731, 737 (Fed.Cir.1988), "factors to be considered in determining whether a disclosure would require undue experimentation ... include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." Bristol, as movant, bears the burden of proof of lack of enablement by clear and convincing evidence. Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1359 (Fed.Cir.1998).

Applying the *In re Wands* factors to this case, the Special Master determined that Bristol had failed to prove by clear and convincing evidence whether a person possessing ordinary skill in the art (POSA) can practice the claimed invention without undue experimentation. The Special Master's conclusion was based in large part on (1) the opinions of Rhone-Poulenc Rorer, Inc.'s ("RPR") experts, Stephen F. Martin, Ph.D., and Gunda I. Georg, Ph.D., that a POSA would be able to practice the inventions in Patent Re. No. 34,277 (the " '277") patent without undue experimentation ("Martin Declaration" and "Georg Declaration" dated April 5, 2001); FN1 (2) Bristol's failure to offer an opinion of an expert contradicting the opinions of RPR's experts; and (3) a declaration by Bristol's leading expert, Elias J. Corey, Ph.D., dated February 17, 2000 ("Corey Declaration") opining that the '277 patent was obvious, which RPR attached to its opposing papers. (Declaration of Joel Bock, dated April 5, 2001 ("Bock Declaration"), Ex. 53.)

FN1. Bristol correctly argued that Dr. Georg's Declaration is conclusory and, thus, of no weight, but it failed to offer an expert affidavit opinion with references that a POSA would not be able to make and use the full scope of the claimed invention without undue experimentation despite its burden of proof by clear and convincing evidence.

In paragraph four of his declaration on obviousness, Dr. Corey states without any limitation:

4. For reasons which I set forth herein, I have reached the conclusion that claims 1, 2, 6, 8-9, and 12-17 of the '277 patent are obvious because they claim either findings that had previously been disclosed in the scientific literature or findings that are so similar to previously known disclosures as to be non-inventive to a person of ordinary skill (see paragraph 5 for definition), working as a synthetic chemist in the field of medicinal synthesis (see paragraph 6 for definition of obvious).FN2

FN2. Paragraph 6 explains that "obvious" means that when presented with a problem, a POSA "would readily see a possible solution to the problem which had a reasonable chance of success because of the teachings of prior art." Although Bristol contends that Dr. Corey's statement should be understood only to mean that a POSA could find "a" solution to make the invention work (as opposed to a solution for each and every protecting group claimed), this lawyers' argument is not adequate to narrow the broad statements contained in paragraphs 4 and 28-32 of Dr. Corey's declaration that a POSA could practice the invention without undue explanation.

Report at 6.

The plain meaning of this paragraph is that those claims had either been previously disclosed in the scientific literature or were so similar to previously known disclosures as to be non-inventive to a POSA. Though Bristol tries to limit the scope of this broad statement by arguing that Dr. Corey testified at the Markman hearing held on March 26-27, 2001 that "TMS was known to be far less stable than TES," and "MOM was known to require 'much more forcing conditions" ' for removal (Bristol Reply Mem. at 5), nowhere in its motion papers does any expert state that a POSA would have known that TMS and MOM would not work without undue experimentation.

For the same reasons set forth in the Special Master's Report, Bristol's motion is denied for failure to show by clear and convincing evidence that a POSA would be required to engage in undue experimentation to practice the full scope of the claimed invention. Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362 (Fed.Cir.1999); *Genentech,* 108 F.2d at 1365.

Failure to Set Forth the Best Mode

With regard to the issue of failure to set forth the best mode, the Court adopts the following findings by the Special Master:

(1) The '277 patent claims 1, 2, 8, 16 and 17 are process claims for the preparation of taxol, which include an estrification step using numerous reactants and reactant conditions;

(2) Although the '277 patent specification discloses only a 10-hour reaction time for the estrification step it makes no disclosure regarding the importance of the time aspect of the step;

(3) The inventors' patent disclosure on the subject states, "The colorless, homogenous solution obtained is allowed to react for 3 to 4 minutes at room temperature, then it is heated to 82-4C for 100 hours. Although the reaction is not complete, it is arrested." (Declaration of William E. Solander, dated February 28, 2001 ("Solander Declaration"), Ex. 9.);

(4) The JACS article states the reaction time required for the same estrification step disclosed in the patent was 100 hours;

(5) RPR admits that the 10-hour reaction time in the '277 patent was a mistake, "a mere typographical error"; (Solander Decl., Ex. 29.)

(6) If the reaction were to terminate at 10 hours, an ester would be produced in amounts less than the 40% claimed in the example in the '277 patent, according to Bristol's expert, Dr. Laird (Report of Trevor Laird, dated June 7, 2000 ("Laird Report"), p. 19, fn. 3), but according to RPR's expert, Dr. Ojima, the yield would be more than trace amounts (9.4%) and a POSA, monitoring the experiment, would carry out the experiment for a longer period. (Declaration of Iwao Ojima, dated April 5, 2001 ("Ojima Declaration") at para.para. 12, 13.)

A best mode inquiry has two components: one, did the inventor have a best mode of practicing his invention at the time he filed he application, and, two, whether his disclosure is adequate to enable to POSA to practice that best mode. Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1209 (Fed.Cir.1991).

Whether or not a specific disclosure is adequate for best mode purposes is determined by comparing the disclosure with the facts concerning the invention known to the inventor at the time the application was filed. Since "there is no objective standard by which to judge the adequacy of a best mode disclosure, ... only evidence of 'concealment', whether accidental or intentional, is considered.

Dana Corp. v. IPC Ltd. P'ship, 860 F.2d 415, 418 (Fed.Cir.1988) (internal citations omitted).

RPR argues that the inventors did not have a best mode of practicing their invention. This argument is rejected. In the JACS article, titled "A Highly Efficient Practical Approach to Natural Taxol," the inventors indicated that the preferred reaction time of the esterification step of the process was 100 hours. (Solander Decl. Ex. 2 at 5918.) RPR has acknowledged that the August 1998 JACS article's described methodology should be understood as the "best mode" or "preferred embodiment". (Solander Decl. Ex. 45 at 5; Solander Decl. Ex. 48 at 8.) The inventors point to no experiments in which they developed another preferred esterification reaction time. Accordingly, the record demonstrates that the inventors did have a best mode of 100 hours of esterification reaction time at the date of filing the '011 patent application.

Having determined that the inventors had a "best mode" at the time of filing the '011 patent, one must consider the second component of the best mode inquiry: whether the disclosure was adequate to enable a POSA to practice the best mode of the inventors. Applied to the facts of this case, the issue is whether the inventors' disclosure of an esterification reaction time of 10 hours is inadequate, *i.e.,* so poor as to effectively result in concealment. Matter of Application of Sherwood, 613 F.2d 809, 816 (C.C.PA.1980).

Dr. Ojima's Declaration states (1) that a POSA using the patent's disclosed reaction time would be able to practice the invention, *i .e.,* obtain a taxol yield of "more than trace amounts" (9.4% yield), and (2) that a POSA monitoring the experiment would then carry on the experiment. (Ojima Decl. at para.para. 12, 13.) Thus, there is testimony in the record that a POSA would increase the yield to the percentage stated in the patent without undue experimentation.

In addition, the JACS article was published in August 1988, well before the inventors applied for the '011 patent on April 3, 1989. Accordingly, a POSA would have had knowledge of the 100 hour best mode for the esterification reaction time and could have utilized it without engaging in undue experimentation.

Accordingly, a trier of fact could determine that the best mode of the invention was adequately disclosed in the patent and Bristol's motion for summary judgment under 35 U.S.C. s. 112 for failure to disclose the best mode is denied.

IT IS SO ORDERED.

S.D.N.Y.,2001.
Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.