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)

Oct. 30, 2001.

Fitzpatrick, Cella, Harper & Scinto, New York, By Thomas H. Beck, Esq., Counsel for Plaintiff.

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

OPINION AND ORDER

PATTERSON**, D.J.**

Defendants Rhone-Poulenc Rorer, Inc., Centre National De La Recherche Scientifique, and Rhone-Poulenc Rorer, S.A. (collectively, "RPR") move, pursuant to Rule 59 of the Federal Rules of Civil Procedure and Local Civil Rule 6.3, for reconsideration of this Court's Order dated August 1, 2001 (the "8/1/01 Order"), adopting the Special Master's Report and Recommendation (the "Report") covering construction of claims of U .S. Patent No. Re. 34,277 (the " '277 patent"). RPR suggests that (1) the Court did not conduct the required *de novo* review of the Report, and (2) "the Court overlooked controlling decisions or factual matters put before it on the underlying motion." (RPR's Memorandum in Support of Motion for Reconsideration ("RPR Reconsideration Mem.") at 1.)

The Court did conduct a *de novo* review of the entire proceeding in preparing its 8/1/01 Order. As stated in that Order, the Court reviewed the Special Master's Report, RPR's Objections to the Report ("RPR's Objs."), Bristol-Myers Squibb Company's ("Bristol") Response to RPR's Objections, and RPR's reply. The Court had also previously attended the entire Markman Hearing held on March 26 and 27, 2001, and had reviewed the underlying briefs submitted to the Special Master, as well as the '277 patent. The Court reviewed all of these materials in conducting its *de novo* review.

RPR presented only two objections to the Special Master's Report: (1) that the Special Master clearly erred by concluding that claims 1 and 16 of the '277 patent must yield taxol in "more than trace amounts"; and (2) that the Special Master clearly erred by failing to find that the term "replaced by hydrogen" limits the term "hydroxy protecting group" encompassed within claims 1 and 16 of the '277 patent. (RPR's Objs. at p. ii.) In

the 8/1/01 order, the Court ruled on both of RPR's objections and gave concise reasons for its rulings.

It is well recognized that, as a general matter, "[c]laims must be read in view of the specification of which they are a part." Markman v. Westview Instruments, Inc., 52 F.3d 967, 979-80 (Fed.Cir.1995), *aff'd,* 517 U.S. 370 (1996); *see also* Netword LLC v.. Centraal Corp., 242 F.3d 1347, 1352 (Fed.Cir.2001) (claims are always construed in the light of the specification of which they are a part); Scimed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc., 242 F.3d 1337, 1340-41 (Fed.Cir.2001) (scope of claims' interpretation turns entirely on specification).

The invention specification of the '277 patent clearly asserts the process claimed is for preparing semi-synthetic taxol "in good yield," in contrast to the process for preparing natural taxol or the process relating to preparing semi-synthetic taxol controlled by two European patents. The specification states (1) that the invention is a "process for preparing taxol from a derivative of 10-deacetylbaccatine III [("10-DAB")] or baccatine" (col.1, ll.11-13); (2) that taxol in vitro is an especially important anti-leukemic and anti-tumor agent, whereas 10-DAB and baccatine III do not manifest these activities (col.1, ll.40-46); (3) that taxol and baccatine III are extracted with difficulty and " *in generally low yields* " from trunk barks of different Taxus species (col.1, ll.47-51) (emphasis added); (4) that baccatine III is found in larger amounts in the wood of the different Taxus species (col.1, ll.52-53); (5) that 10-DAB is extracted much more readily and " *in better yields* " from yew leaves (col.1, ll.54-57) (emphasis added); (6) that a process enabling taxol to be prepared from 10-DAB is especially advantageous because of its ready accessibility and because it does not necessitate the destruction of the plant species (col.1, ll.58-64); (7) that European patent applications, EP Nos. 253738 and 253739, describe the preparation of taxol from 10-DAB and baccatine III, but do not allow " *all the* baccatine III or 10-deacetylbaccatine III introduced *to yield* taxol having the appropriate configuration" (col. 1, l. 65; col. 2, l. 20) (emphasis added); and (8) that the present invention provides a process for preparing taxol that "may be used to produce taxol in *good yields* from a starting material that is easily obtained in quantity" (col.2, ll.64-66) (emphasis added). FN1

FN1. Further, the example of the process given in the specification stresses the "good yields" afforded by the process by noting that the yield upon esterification is 40% and the yield upon deprotection is 91%. (col.4, l.67, col.5, l.61).

In light of the specification's description of the invention, the Special Master concluded that a person of ordinary skill in the art of organic chemistry (a "POSA") "would understand the inventors to be saying that the process being described and claimed as the 'present invention' is for a process that produces taxol in 'good' yields." (Report at 23.) FN2 The '277 patent does not, however, define what constitutes a "good yield." Neither the patent history nor the available extrinsic evidence assists in this endeavor. All parties agree, however, that production of a trace amount of taxol does not constitute a good yield. Accordingly, the Special Master determined that the processes described in claims 1 and 16 of the '277 patent require production of taxol in more than a trace amount. The Court finds this conclusion is sound and well-reasoned and imposes a minimum burden on the patent holder. Accordingly, the Court adopts the Special Master's recommendation that claims 1 and 16 must yield taxol in "more than trace amounts."

FN2. The Court notes that the JACS article, which is the sole piece of extrinsic evidence bearing on the subject, is consistent with this conclusion. The JACS article describes the process as a "highly efficient, practical approach" to the production of taxol. (Dec. of Maurice Ross, Ex.A.)

The Court also adopts the Special Master's finding that the claims do not limit the term "hydroxy protecting group," and should not be read, as urged by RPR, as those "hydroxy protecting groups that are successfully 'replaced by hydrogen' (deprotected) to obtain some amount of taxol." (RPR's Objs. at 17.) The Court reaches this conclusion based in large part on the testimony of RPR's own expert, Dr. Martin, who testified that there are no restrictions on the R_2 and R_3 hydroxy-protecting groups that are attached, respectively, to the (2R, 3S) 3 phenylisoserine derivative of formula (III) and the taxan derivative of formula (IV) in claim 1. (Transcript of Markman Hearing, March 26-27, 2001 ("Tr.") at 98.) Dr. Martin's testimony was consistent with the language of claim 1 of the '277 patent, where both R_2 and R_3 are defined as " *a* hydroxy-protecting group" without any limitation (col. 9, l. 67; col. 10, l. 14) and with the same definition of R_2 and R_3 contained in the specification (col. 2, l. 46; col. 2, l. 61).FN3

FN3. Dr. Martin also testified that the hydroxy-protecting group's replacement with hydrogen was *the final step* in the process that first included esterification of the derivative of formula (III) and the derivative of formula (IV). (Tr. at 33-35, 96-97) (emphasis added). Again, this testimony is consistent with the language of Claims 1 and 16 of the '277 patent that states "[T]he protecting groups R_2 and R_3 are *then* both replaced by hydrogen" and "replacing both of the protecting groups R_2 and R_3 by hydrogen." (col.10, ll.14-16, col.14, ll.2-3) (emphasis added).

The Court also notes that, in its post-hearing memorandum, RPR took the position that "[t]here is nothing about the term 'hydroxy protecting group' which requires interpretation." (RPR Post-Hearing Mem. at 15.) RPR argued that:

The "R" group can be varied in accordance with, and to the degree recited, in the claims. For example, in Claim 1, both "R_2" and "R_3" are defined generally as "hydroxy protecting groups." Thus, each "derivative" referred to in claim 1 can result from the use of *any* hydroxy-protecting group.

(RPR Post-Hearing Memorandum dated 5/3/01 at 14) (emphasis added.) Accordingly, RPR's current position that R_2 and R_3 should be construed as "hydroxy protecting groups that are successfully 'replaced by hydrogen' (deprotected) to obtain some amount of taxol" is a new position and at variance with both its previously stated position on the interpretation of the term "hydroxy protection group" and its general position that all claims should be read broadly.

Though the preceding analysis should be sufficient to satisfy RPR that its motion for reconsideration should be denied, the Court will state its grounds for not accepting RPR's ten miscellaneous arguments ((i) through (x)) which RPR restated in support of its two objections. RPR's argument (i) is that the Report is "internally inconsistent because it (a) construes the claims as encompassing esterifications wherein no activating or condensing agents were used (resulting indisputably in poor or 'trace' amount yields) but (b) imposed a 'more than trace amount' yield requirement." (RPR Reconsideration Mem. at 3.) The evidence produced at the Markman hearing does not clearly indicate that when no activating or condensing agents are used, esterifications would result in "trace" amount yields. Dr. Martin's testimony about esterifications when no activating or condensing agents are used revealed only that he was "not sure how much yield you would get if the carbolic acid were mixed directly with the alcohol." (Tr. at 95-96.) He did not testify that no yield would occur nor did he testify that the yield would be "in trace amounts." The clear implication of his testimony was that some yield would occur.FN4 Thus, there is no demonstrated internal inconsistency

between this testimony of Dr. Martin, which the Special Master accepted, and the Special Master's finding that the patent requires a yield of taxol in more than trace amounts.FN5

FN4. Dr. Martin stated:
Q. You are not sure whether you would get ester or not?
A. That is not what I said. I said I am not sure how much ester you would get.

(Tr. at 96.)
FN5. The Court reminds the parties that it construed the claims based on the language of the claims and specification of the patent. The Court's analysis is consistent with the extrinsic evidence. If the Court's construction demonstrably indicated that claims contained within the '277 patent were invalid, it would only be appropriate for the Court to construe the claims so as to preserve validity if it could do so without redrafting the claims. Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed.Cir.1999).

RPR's argument (ii) is that "the Special Master improperly applied the legal doctrine that claims are to be construed to uphold their validity because that rule of claim interpretation only applies where (a) there is some ambiguity in claim language and (b) interpretation preserving validity can be made without redrafting the claims." (RPR Reconsideration Mem. at 3.) FN6 RPR argues that the Special Master should not have construed the claims so as to have preserved their validity. The Report does not construe the claims so as to preserve their validity. Rather, the Report construes the claims solely based upon their language and the description of the invention in the specification.

FN6. RPR did not cite to any part of the Report for this assertion.

RPR's arguments (iii) and (iv) are that the Special Master erred as a matter of law by concluding that processes which produce trace amounts of taxol could not satisfy the utility requirement of 35 U.S .C. s. 101 or the enablement requirement of 35 U.S.C. s. 112. (RPR Reconsideration Mem. at 3-4.) In footnote five of the Report, the Special Master states:

had RPR proposed language in claims 1 and 16 that made it clear that the process made taxol 'in any amount, yield or purity,' based on the specification, the Patent Office would have had a solid basis for rejecting the claims under 35 U.S.C. s. 101 ... Since there is nothing in the intrinsic or extrinsic record before this Court that supports RPR's position that the patented taxol process is designed and directed to producing only insignificant or trace amounts of taxol, RPR would have had no evidence to persuade the Patent Office that such a process was either properly enabled under 35 U.S.C. s. 112 or met the "useful" requirements of s. 101.

(Report at 22). The footnote does not conclude that processes which produce trace amounts cannot satisfy the utility requirement of Section 101 or the enablement requirement of Section 112, but concludes that a reasonable patent examiner would have had a basis for rejecting the claims for lack of utility or enablement if RPR's proposed language had been added to the claims. The Special Master's Report did not rely upon any of the statements made in this footnote for his conclusion that RPR's processes must produce taxol in more than trace amounts. This conclusion was based solely on the language of the claims and the invention specification.FN7

FN7. The Special Master's statements in this footnote are not considered to be the law of the case.

RPR's argument (v) is that the Special Master erred in using extrinsic evidence (the JACS article) to interpret claims 1 and 16. (RPR Reconsideration Mem. at 4.) The Report shows the Special Master did not use the JACS article to interpret the claims. The Special Master referred to the JACS article only after concluding that the intrinsic evidence did not support RPR's position and for the purpose of showing that the extrinsic evidence was consistent with his own analysis. *See* AFG Indus., Inc. v. Cardinal IG Co., Inc., 239 F.3d 1239, 1249 (Fed.Cir.2001) (appropriate to consult trustworthy extrinsic evidence to assure one's claim interpretation is not inconsistent with such evidence).

RPR's argument (vi) is that "the Special Master's recommended construction of the terms 'hydroxy-protecting group' and 'replaced by hydrogen' might render Claims 1 and 16 invalid for indefiniteness under 35 U.S.C. s. 112." (RPR Reconsideration Mem. at 4.) RPR cites to pages 12-13 of its Objections to the Special Master's Report for this argument. However, no such argument was made in RPR's Objections. RPR's objection at pages 12-13 was that construing claims 1 and 16 to require the production of taxol "in more than trace amounts" might make the claims invalid for indefiniteness. (RPR's Objs. at 12-13.) This argument presupposes that the parties and Court cannot reach a fair definition of "trace amounts" for the jury charge. The Court does not agree with this assumption.

RPR's argument (vii) is that the Special Master failed to follow legal precedent that every term or phrase in a patent claim must have some meaning by concluding that the term "replaced by hydrogen" does not modify the term "hydroxy protecting group." (RPR Reconsideration Mem. at 4.) The term "replaced by hydrogen" is not read out of the claims by the Special Master, as RPR asserts, but is construed merely as the next step in the process. This result is based on the plain language of claims 1 and 16, where the term "hydroxy protecting group" is not limited and where it is clearly indicated that replacement by hydrogen is the final step in the process, and the testimony of RPR's expert, Dr. Martin, who testified that the term "hydroxy protecting group" was not limited in any way and who described the replacement by hydrogen as the final step in the process (Tr. at 33-35). RPR does not cite any testimony from Dr. Martin or anyone else that the term "hydroxy-protecting group" would be understood by a POSA to mean only those hydroxy-protecting groups that work to produce taxol when replaced by hydrogen.

RPR's argument (viii) is that "the Special Master incorrectly asserted that chemical processes can only be defined in functional terms if written as 'means plus function' claims under 35 U.S.C. s. 112(6) because chemical process claims are commonly defined in functional terms without invoking the 'means plus function' format of 35 U.S.C. s. 112(6)." (RPR Reconsideration Mem. at 4.) The Court does not agree with RPR's construction of the Special Master's Report. The Court interprets the Special Master's allusions to Section 112 as consistent with his overall belief that the term "hydroxy protecting group" is not defined functionally in the claims.FN8 The plain language of the '277 is clear on this point. In claim 1, the patent states that "R_2 is a hydroxy-protecting group ... R_3 is a hydroxy group ... and the protecting groups R_2 and R_3 are then both replaced by hydrogen." In claim 16, replacement by hydrogen is described as step D of the process claimed. In addition, RPR's expert, Dr. Martin, described the term "replacement by hydrogen" as referring to the last step in the process, which he referred to as "deprotection," but not as limiting the term "hydroxy protecting group." He did not testify that a POSA would read that term as meaning only those hydroxy protecting groups that work to produce taxol when replaced by hydrogen.

FN8. The Court recognizes that "a patent applicant is free to recite features of an apparatus either structurally or functionally." In re Schreiber, 128 F.3d 1473, 1478 (Fed.Cir.1997).

RPR's argument (ix) is that "the Special Master incorrectly concluded that the general public is entitled to notice concerning precisely which protecting groups are encompassed within the claims when, in fact, there is no injustice or unfairness because the general process was fully disclosed and claimed in the patent." (RPR Reconsideration Mem. at 4.) RPR has failed to point to any place in the Report reflecting the Special Master's concern that the general public would have to have notice of which protecting groups are encompassed in the claims. (RPR's Objs. at 18.) Furthermore, the Report shows that the Special Master based his conclusions on reading the claims' language, not on lack of notice to the public.

RPR's argument (x) is that "the Special Master erred as a matter of law in concluding that the examiners did not consider the JACS Article when, in fact, as a matter of law the facts compel the conclusion that they considered the JACS Article thoroughly and nonetheless determined to allow the claims in the full breadth requrest by the applicant." (RPR Reconsideration Mem. at 4.) Once again, RPR does not cite any support for this position and the Report does not state that it is based on any such conclusion.

Conclusion

The Court adheres to (1) its conclusion that RPR's objections to the Special Master's detailed and well-reasoned claim construction recommendations are without merit, and (2) its conclusion in its decision of August 1, 2001 that the Special Master's Report and Recommendation is adopted in full.

Accordingly, the motion for reconsideration has been fully considered and it is denied.

IT IS SO ORDERED.

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