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Federal Circuit Patent Bulletin: *Storer v. Clark*

June 22, 2017

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On June 21, 2017, in *Storer v. Clark*, the U.S. Court of Appeals for the Federal Circuit (Prost, Newman,* Dyk) affirmed the U.S. Patent and Trademark Office Patent Trial and Appeal Board interference decision that awarded priority of invention to U.S. patent application Serial No. 11/854,218 (Clark), assigned to Gilead Pharmasset LLC, over U.S. Patent No. 7,608,600 (Storer), assigned to Idenix Pharmaceuticals LLC. The interfering technology related to treating hepatitis C by administering compounds having a specific chemical and stereochemical structure, based on a specific foundation formula of a five-membered ring with a fluorine substituent in the 2'(down) position. The Federal Circuit stated:

Enablement is relevant for validity and to the issue of whether the provisional application is a constructive reduction to practice. "Constructive reduction to practice means a described and enabled anticipation under 35 U.S.C. 102(g)(1), in a patent application of the subject matter of a count." "When a party to an interference seeks the benefit of an earlier-filed United States patent application, the earlier application must meet the requirements of 35 U.S.C. § 120 and 35 U.S.C. §112 ¶ 1 for the subject matter of the count." [W]hen the issue is priority based on the content of the specification, "[t]he earlier application must contain a written description of the subject matter of the interference count, and must meet the enablement requirement." . . . "The enablement requirement is met where one skilled in the art, having read the specification, could practice the invention without 'undue experimentation.'" "Whether undue experimentation is required 'is not a single, simple factual

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determination, but rather is a conclusion reached by weighing many factual considerations.'" [R]elevant factors may "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." . . . The boundary between a teaching sufficient to enable a person of ordinary skill in the field, and the need for undue experimentation, varies with the complexity of the science. Knowledge of the prior art is presumed, as well as skill in the field of the invention. The specification need not recite textbook science, but it must be more than an invitation for further research. . . .

The Storer provisional specification does not describe synthesis of the 2'F(down) target compounds. The question devolves to the adequacy of the disclosure in the provisional of general schemes for synthesizing these general classes of modified nucleosides, taken with the knowledge of the art. The S1 provisional discloses two general approaches. Provisional schemes 3 and 8 modify the sugar portion of the target compound and then add the base portion, as the provisional application calls the "Glycosylation of the nucleobase with an appropriately modified sugar."

Provisional scheme 4 shows modifying a compound with the base already attached, to achieve the desired structure. The provisional calls this "Modification of a preformed nucleoside." The Board observed that none of the approaches in the provisional proceeds through a compound like Matsuda Compound 17, or suggests how Matsuda 17 may be converted into the target 2'F(down) compounds. The Board found that the Storer provisional does not exemplify such a reaction, or lead a person of ordinary skill to perform it. The Board also observed that the S1 provisional schemes produce compounds with opposite spatial arrangement from Matsuda Compound 17. On review, we conclude that substantial evidence supports the Board's findings that the synthetic schemes in Storer's provisional application do not teach or suggest conversion of any precursor into the 2'F(down) structure, and that the Matsuda synthesis of a corresponding 2'methyl (down), 2'-hydroxyl (up) structure does not enable a person of ordinary skill to produce the target compounds without undue experimentation. . . .

Even on Storer's position that a person skilled in this science would have started with Matsuda Compound 17, Storer has not shown that the critical stereochemical result would predictably ensue, although the reaction had never been performed. The Board received evidence of side reactions and the skepticism of experts. The Board received evidence that Storer and his team had difficulty and failures in synthesizing the target compound, as well as evidence that Clark and his team were more readily successful using apparently the same method. The Board's finding that the chemistry was unpredictable is in accord with the evidence. . . .

The Board found, on consideration of the entire record, that a person of ordinary skill, with the disclosure in the provisional application and knowledge of the prior art, would not have been led to make the target compound, and could not do so without undue experimentation. The Board received evidence that successful fluorination reactions of the desired stereochemistry had not been reported for structurally similar compounds. We conclude that substantial evidence supports the Board's finding that "a high amount of experimentation is necessary to synthesize" the target compound. The record before the Board showed sufficient variability and unpredictability to support the Board's conclusion that Storer's provisional application did not enable the

interference subject matter.