Patents

Numeric Values Not Needed Where Patent Is 'More of an Art Than a Science'

• **Case Summary:** Star Scientific's patents on tobacco curing are not invalid, as a lower court had found, but the Federal Circuit affirms that tobacco giant R.J. Reynolds did not infringe the patents because its farmers' methods do not meet the carcinogen-reducing levels described in the patents.

• **Key Takeaway:** A patent method claim is not necessarily indefinite by failing to provide numerical values for variables that can be manipulated in implementing the method when the value selections for those variables are "more of an art than a science."

For a tobacco curing technology that is "more of an art than a science," numerical values are not necessary to avoid a charge of patent claim indefiniteness, a 2-1 majority of the U.S. Court of Appeals for the Federal Circuit ruled Aug. 26 (Star Scientific Inc. v. R.J. Reynolds Tobacco Co., Fed. Cir., No. 10-1183, 8/26/11).

The majority, overturning a lower court's invalidity judgment, determined that one of ordinary skill in the art of tobacco curing would understand how to manipulate three variables to create the optimal "controlled environment" described in the asserted claims, depending on various conditions in the curing barn.

The dissent looked at the patent specifications and found references defending the inventiveness of the method specifically contrasting the controlled environments used in conventional curing. The patents claimed differences between the methods known to those skilled in the art and the invented method, but failed to explain the differences, thus rendering the claims indefinite under Section 112 of the Patent Act, 35 U.S.C. §112, para. 2, according to the dissent.

The court nevertheless affirmed a noninfringement decision in favor of tobacco giant and alleged infringer R.J. Reynolds Tobacco Co., largely because of RJR's own testimony that its farmers' curing methods did not reduce the levels of certain carcinogens to those claimed under Star Scientific Inc.'s patented method.

**Second Trip to Federal Circuit**

Star owns two "Williams" patents (6,202,649 and 6,425,401) relating to methods of curing tobacco to reduce the content of tobacco specific nitrosamines (TSNAs), which are known carcinogens. Inventor and Star employee Jonnie Williams submitted a provisional patent application Sept. 15, 1998, and a nonprovisional one year later. The company developed the "StarCure" process, acknowledged to be the best mode of practicing the claimed invention, in the interim.

Star had agreements with Brown & Williamson to use the Williams patented method, but RJR terminated the agreements after it acquired B&W. RJR instead developed the patented "Peele method" (6,805,134) of tobacco curing. Star sued RJR, alleging that the Peele method infringed the Williams patents.

Senior Judge Marvin J. Garbis of the U.S. District Court for the District of Maryland found the patents unenforceable due to inequitable conduct during prosecution and further ruled that the asserted patent claims were invalid for indefiniteness under Section 112. He also ruled that Star was entitled priority only to the 1999 nonprovisional application date.

On appeal in 2008, the Federal Circuit reversed the inequitable conduct and indefiniteness judgments, but did not rule on the priority date issue nor on an anticipation defense. 537 F.3d 1357, 88 USPQ2d 1001 (Fed. Cir. 2008) (175 PTD, 9/10/08).

In a 2009 trial on remand, the jury found the patents invalid for obviousness, indefiniteness, and failure to disclose the best mode (120 PTD, 6/25/09). The jury also concluded that the Peele method did not infringe the Williams patents.

Garbis upheld the verdict and denied Star's post-trial motions. Star appealed again.

**Priority Date in Star's Favor**
Chief Judge Randall R. Rader first made quick work of reversing the priority date finding, but that decision had a considerable impact on the outcome of the appeal.

The lower court had denied priority to 1998 because the provisional application cited a minimal air flow in the curing process that was higher than an example added to the nonprovisional. However, Rader said, the provisional also said that the minimum could vary dependent on the conditions in the curing barn, and that a person of ordinary skill would therefore know that the minimum could be lower in certain circumstances. Rader further noted that the Patent and Trademark Office, acting on an ex parte reexamination request by Star, also granted the earlier priority.

The earlier date meant that a prior art reference attributed to the Peele method inventor was no longer useful for obviousness purposes. Also, because the StarCure process was developed after the September 1998 provisional, its absence in the application did not constitute a failure to disclose the best mode. The court reversed the best mode judgment accordingly.

The appeals court then addressed Star's objections to evidentiary decisions by the lower court. Even though the court found one decision "troubling," as RJR appeared to restate inequitable conduct arguments in the context of its validity challenge, the court found no abuse of discretion by the district court.

'Controlled Environment' Not Indefinite

The claim indefiniteness issue in this second appeal differed from that in the first. Representative Claim 4 of the '649 patent described curing "in a controlled environment ... wherein said controlled environment is provided by controlling at least one of humidity, temperature, and airflow." RJR disputed whether a person of ordinary skill would know how to establish a controlled environment, especially since the claim identified no specific numerical boundaries for each variable.

Citing Star's argument that "the practice of tobacco curing is more of an art than a science, because curing conditions during any given cure must be adjusted to take into account" the variables, the court concluded that "specific numerical values are not needed for one skilled in the art to implement conventional curing."

Accordingly, the term "controlled environment" is not insolubly ambiguous, the court concluded, as required for an indefiniteness finding under Datamize LLC v. Plumtree Software Inc., 417 F.3d 1342, 1347, 75 USPQ2d 1801 (Fed. Cir. 2005) (153 PTD, 08/10/05).

Obviousness, Anticipation Judgments Faulted

The jury's obviousness judgment was based on two references: a literature survey that cited speculation on how TSNAs might be reduced, and a Japanese patent that taught the manipulation of the three controlled environment variables without mentioning TSNAs. The court found both lacking in terms of showing obviousness, even apart from the question of whether it would be reasonable to combine the two.

The Japanese patent described means of eliminating a "nasty odor," the court said, and did not link the associated gas levels with the elements of the Williams patents that are ultimately responsible for reducing TSNAs. And the literature survey, the court added, contained "speculative and tentative disclosure of what 'might' or 'may' lead to TSNA production [and therefore] does not sufficiently direct or instruct one of skill in the art."

The record further contained "many secondary considerations that support nonobviousness," the court continued, citing as one example a long-felt industry need with "decades of unsuccessful attempts at reducing TSNAs to the extent achieved by the Williams patents."

RJR also challenged validity on anticipation grounds under Section 102(b), citing its own public use more than one year before the priority date. However, the court ruled that each of three proffered examples of public use failed to meet the clear and convincing evidence standard.

However, Noninfringement Finding Upheld

Nevertheless, the court ultimately ruled in RJR's favor as to noninfringement.

RJR's expert's testimony, the court said, showed that its farmers "had not substantially prevented anaerobic conditions and ... that TSNA levels measured from the farmers' barns were above the levels claimed in the Williams patents."

The court thus affirmed the noninfringement judgment.

Judge Richard Linn joined the opinion.

Dissent Sees Contradiction in Specification
Judge Timothy B. Dyk dissented as to the majority’s indefiniteness reversal only.

He faulted the majority for its conclusion that the controlled conditions were within the realm of "conventional methods commonly and commercially used in the U.S.," when, he said, "that is the opposite of what the patents actually state."

Dyk particularly cited text from the ‘401 patent specification that, "far from equating the claimed ‘controlled environment’ to conventional curing, ... make clear that conventional curing is conducted ‘without’ the controlled conditions described herein.’”

He said in conclusion, "the patents describe the claimed ‘controlled environment’ as something different from conventional curing methods, but fail to explain those differences in a way that would permit a skilled artisan to determine the bounds of the claims."

Carter G. Phillips of Sidley Austin, Washington, D.C., represented Star. RJR was represented by Meredith Martin Addy of Brinks, Hoefer, Gilson & Lione, Chicago.

By Tony Dutra