

Keywords: inequitable conduct; indefiniteness

General: Summary judgment holding of inequitable conduct reversed due to a lack of showing of deceptive intent, and cumulative nature of the art negated materiality.

Star Scientific Inc v. R.J. Reynolds Tobacco Co.
88 U.S.P.Q.2d 1001 (Fed. Cir. 2008)
Decided August 25, 2008

I. Facts

Star Scientific filed a provisional patent application, and a later non-provisional application for a method for preventing formation of tobacco specific nitrosamines (TSNAs) in the curing of tobacco. TSNAs may be carcinogenic, and appear to result from forced curing by exposure of green or yellow tobacco to combustion exhaust gases (which are typically oxygen depleted). The application claimed control of curing conditions in a curing barn environment free of combustion exhaust, and with an airflow sufficient to substantially prevent an anaerobic condition around the leaves. While there were some changes made in the non-provisional application, both acknowledged certain known prior art in which indirect heating was used, resulting in reduced levels of TSNAs. The inventor and a researcher the company hired were aware of studies showing significantly reduced levels of TSNAs both in the U.S. and abroad, where curing was performed without exposure to exhaust gases.

After the filing of the non-provisional application, Star changed prosecution counsel, coordinating the file transfer through a third firm. Neither the previous firm nor the successor disclosed letters summarizing the additional known prior art (the successor firm appeared to be unaware of it). The patent issued in 2001. Prior to its issue, Star filed a continuation application, but again did not cite to the PTO at least one of the letters summarizing the additional research findings. Although the present suit had been filed in 2001, and in 2002 the litigation counsel thought it advisable to cite all known art, the prosecution counsel did not do so, believing the material, of which they only then became aware, was cumulative.

Star sued on the first patent, and when the second issued, added it to the complaint. The district court interpreted certain claim terms in a Markman hearing, and then granted summary judgment in favor of Reynolds, holding the patents were unenforceable for inequitable conduct and invalid for indefiniteness. The inequitable conduct claim was based on the failure to cite the additional research findings, and on a theory that Star's change of law firms was intended to "quarantine" the successor firm and thereby avoid problems with citing the additional art.

Star appealed both holdings.

II. Issues

- A. Was summary judgment of unenforceability for inequitable conduct proper?
- B. Was summary judgment of invalidity for indefiniteness proper?

III. Discussion

- A. No. The court reviewed recent decisions on the issue and standards of inequitable conduct, as well as the standards for review of inequitable conduct holdings. In general, inequitable conduct requires that an accused infringer present evidence that the applicant (1) made an

affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information; and (2) intended to deceive the PTO. Regarding the actual proof of intent, while recent cases have seemed to blur the line between proof of materiality and proof of intent (in a “balance of equities”), the court recognized that intent can be inferred from indirect and circumstantial evidence. The court stressed, however, that such evidence must still be clear and convincing, and inferences drawn from lesser evidence cannot satisfy the deceptive intent requirement. Further, the inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.

Regarding the materiality prong, the court held that information is material when a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. Consistent with established precedent, the court reiterated that information is not material if it is cumulative of other information already disclosed to the PTO.

Regarding the standard of review, the court indicated that the underlying factual determinations are reviewed for clear error, and the ultimate decision as to inequitable conduct is reviewed for abuse of discretion.

In this case, Star had disclosed prior art, and admitted in passages of the application, that others had obtained reduced levels of TSNAs with curing techniques that did not expose the leaves to combustion exhausts, and that therefore created an environment less depleted in oxygen. With regards to the first patent, the court primarily focused on Reynolds’ “quarantine” theory, and found that there was no evidence that the change in firms was motivated by an intent to deceive the patent office (it seems to have been motivated, rather by the death of a key attorney). Given the paucity of evidence, the court found that no inference of intent was warranted.

Regarding the second patent, the court focused more on the materiality prong. That is, because the law suit was ongoing during its prosecution, interrogatory responses and other litigation-related materials were apparently submitted to the PTO. These were deemed to be at least as relevant as the omitted materials, making the uncited materials cumulative, and therefore not material. This finding was consistent with the evaluation by the firm that prosecuted the continuation application.

- B. No. Despite the district court’s ability to interpret the term “anaerobic condition”, the court still held that the claims were indefinite. While the appeals court recognized that claim terms that are susceptible to interpretation can nevertheless be indefinite, it based its reversal on a distinction made in the 2005 case of *Invitrogen v. Biocrest Manufacturing*. There the court held that the test for indefiniteness does not depend on a potential infringer’s ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention.

This test seems difficult to apply in practice, and draws a line that many may find on the margin of other caselaw. That is, it is generally considered that claims must be sufficiently clear to place potential infringers on notice of what they may not do. In this case, however, the court seemed to indicate essentially that an “anaerobic condition” in the sense of the claims is an anaerobic condition that accomplishes the goal of the invention (which was basically what the Markman interpretation had already found).

In one practice note, the court repeated that when a word of degree is used, the patent specification must provide some standard for measuring that degree to be definite. This mitigated in favor of at least some definition of such terms in the patent specification.

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