

United States Court of Appeals for the Federal Circuit

01-1095, -1114

NOVO NORDISK A/S, NOVO NORDISK OF NORTH AMERICA, INC.,
and NOVO NORDISK PHARMACEUTICALS, INC.,

Plaintiffs-Appellants,

v.

BECTON DICKINSON AND COMPANY,

Defendant-Cross Appellant.

Edward V. Filardi, Skadden, Arps, Slate, Meagher & Flom LLP, of New York, New York, argued for plaintiffs-appellants. With him on the brief were Robert B. Smith and Desiree M. Garbar.

John A. Krause, Fitzpatrick, Cella, Harper & Scinto, of New York, New York, argued for defendant-cross appellant. With him on the brief were Ronald A. Clayton and Douglas Sharrott. Of counsel was Lee A. Goldberg.

Appealed from: United States District Court for the Southern District of New York

Judge Barbara S. Jones

United States Court of Appeals for the Federal Circuit

01-1095, 1114

NOVO NORDISK A/S, NOVO NORDISK OF NORTH AMERICA, INC.,
and NOVO NORDISK PHARMACEUTICALS, INC.,

Plaintiffs-Appellants,

v.

BECTON DICKINSON AND COMPANY,

Defendant-Cross Appellant.

DECIDED: September 19, 2002

Before NEWMAN, SCHALL, and BRYSON, Circuit Judges.

NEWMAN, Circuit Judge.

The Novo Nordisk companies (collectively "Novo") appeal the judgment of the United States District Court for the Southern District of New York, entered pursuant to jury verdict, that all of the claims of U.S. Patents No. 5,462,535 (the '535 patent) and No. 5,999,323 (the '323 patent) are invalid on the ground of obviousness, and that U.S. Patent No. 5,984,906 (the '906 patent) is invalid based on same-invention double patenting and

obviousness. Becton Dickinson and Company (Becton) conditionally cross-appeals the district court's denial of its pre-trial motion for summary judgment on the ground of anticipation. We affirm the district court's judgment,¹ and dismiss the cross-appeal.

DISCUSSION

The '535, '323, and '906 patents are directed to a pen-shaped insulin delivery system for use by diabetic patients. The system comprises a pen-shaped syringe having an insulin-containing cartridge, and is designed to inject a measured amount of insulin through a needle. The invalidity issues turn on the diameter of the needle. Needle diameter is important to insulin injection systems, for crystallization and other aspects of insulin solutions limit their ability to flow through very narrow needles. Conversely, the pain associated with injection increases with the size of the needle.

The claims of the '535 and '323 patents are specific to injection pens having needles of 30 gauge (G-30)². Claim 1 of the '535 patent is representative:

1. An insulin injection system comprising a pen shaped syringe comprising a cartridge with insulin and an injection needle, wherein the needle is a G30 needle and the cartridge contains an insulin type which may freely flow through the G30 needle.

The '906 patent defines the needle as "thinner than G-29," as illustrated in claim 1:

¹ Novo Nordisk A/S v. Becton Dickinson & Co., 96 Civ. 9506 (S.D.N.Y. October 23, 2000) (judgment); 96 F. Supp.2d 309 (S.D.N.Y. 2001) (denial of summary judgment); 185 F.3d 884, 52 USPQ2d 1795 (Fed. Cir. 1999) (denial of preliminary injunction).

² The higher the gauge, the thinner the outer diameter of the needle.

1. An insulin system comprising a pen shaped syringe comprising a cartridge with insulin and an injection needle, wherein the needle is thinner than a G-29 needle and the cartridge contains an insulin type which may freely flow through a needle thinner than a G-29 needle.

The court construed the "thinner than G-29" limitation of the '906 claims to mean "thinner than 29 gauge, but not thinner than 30 gauge." Becton stipulated to infringement if the patents were valid, and Novo agrees that there is double patenting if the court's construction of the '906 claims is correct.

Obviousness - The '535 and '323 Patents

The jury concluded that the '535 and '323 patents are invalid on the ground of obviousness, in view of several references offered by Becton. These references are of two general categories. The first category describes pen-style insulin injection systems, but either does not state the needle size, or shows needles of 27 and 28 gauge. For example, U.S. Patent No. 4,973,318 (the Holm patent) describes a pen-shaped insulin injection system substantially the same as that shown in the Novo patents, except that it does not state the needle gauge.

The second category of references shows 30 gauge needles for insulin injection, but not in insulin pens. For example, U.S. Patent No. 4,552,561 (the Eckenhoff patent) shows a 30 gauge needle in a rotary syringe for insulin injection, and U.S. Patent No. 4,894,054 (the Miskinyar patent) describes syringes for insulin injection with needle diameters in the range of 23 to 30 gauge.

At the trial there were no significant disputes as to the facts of the scope and content of the prior art, the level of ordinary skill, and the nature of the claimed invention.

See Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). The only question, argued to the jury, was that of motivation to combine the teachings of the references in order to produce the claimed device. Novo argues that Becton failed to establish a motivation, supported by prior art, whereby a person of ordinary skill in this field would have been motivated to combine the teachings of these references to produce the insulin pen of the '535 and '323 patents.

Becton's experts, Dr. Snyderman and Dr. Sherwin, testified that it was well known that thinner needles reduced the pain associated with self-administered insulin injections, and that this knowledge provided motivation to reduce the needle size. Novo's expert, Dr. Charles, testified similarly, stating that the "trick" was to get the needle size down in order to reduce the pain associated with insulin needle injections. Novo stresses its evidence of commercial success and copying. Although Novo points to the absence of documentary evidence of motivation and criticizes the presentation of "conclusory" testimony by Becton's witnesses, these are matters of weight and credibility.

There was substantial evidence whereby a reasonable jury could have found that the known pain reduction provided the requisite motivation to narrow the needle. See In re Beattie, 974 F.2d 1309, 1311, 24 USPQ2d 1040, 1041-42 (Fed. Cir. 1992) (motivation to combine references to achieve the claimed invention is a question of fact). The jury verdict of obviousness is not vulnerable on this ground.

The Requested New Trial

Novo seeks a new trial based on the district court's refusal to include a jury instruction that "obvious to try" is not the correct legal standard for determination of obviousness. Novo argues that Becton's motivation evidence was no more than "obvious to try" testimony, citing Dr. Sherwin's testimony:

So one would try to use the smallest needle because patients have to stick themselves with insulin and - I mean, I think good companies are going to try to do their best to reduce patient pain. So it would be obvious to me to try to do that.

Becton states that there was no prejudicial error in the district court's six pages of careful and correct instructions on the law of obviousness. Novo had requested the following additional instruction:

The evidence might indicate to you that what the inventor did was obvious to try. If so, this does not indicate the patent is invalid for obviousness. Obvious to try is not the standard. Or put differently, the question is not whether the invention could be made, rather, the test is whether the invention as a whole would have been obvious to those of ordinary skill in the inventor's field at the time he or she made the invention.

The district court declined to add this text, stating that the parties were free to characterize Dr. Sherwin's testimony during the argument: "You'll interpret Dr. Sherwin's testimony your way, whether or not, under what I tell them obviousness is."

We do not discern prejudicial error in the court's decision to leave it to the parties to argue the weight and significance of this evidence. While "obvious to try" is not a correct obviousness standard, there was extensive argument on the issue. We do not discern a "miscarriage of justice," U.S. Surgical Corp. v. Ethicon Inc., 103 F.3d 1559, 1566, 41 USPQ2d 1225, 1234 (Fed. Cir. 1997), in the jury instructions that were given and in the trial procedure. Taken as a whole, there was substantial evidence to support the jury verdict.

Prejudicial Arguments

Novo states that Becton presented unduly prejudicial arguments, referring during its opening statement to patents as "monopolies" that raise the price to the public. Becton also told the jury that patent examiners are prone to error because they are overworked and inexperienced, and presented testimony to this effect. Novo states that these prejudicial statements require a new trial. Becton responds that Novo failed to object to these arguments during the trial, did not present neutralizing testimony, and did not request a curative instruction from the judge. In addition, the district court instructed the jury that Novo's patents carried a presumption of validity, and that clear and convincing evidence of invalidity was needed to overcome that presumption.

Inflammatory insinuations and incorrect statements are improper, and their presentation to prejudice the jury is not condoned. See, e.g., Jamesbury Corp. v. Litton Industr. Prod., Inc., 756 F.2d 1556, 1558-59, 225 USPQ 253, 255 (Fed. Cir. 1985) ("[T]his court has disapproved of a challenger's characterization of a patentee by the term 'monopolist,' which is commonly regarded as pejorative.") The nature and context of prejudicial remarks warrant careful scrutiny. Becton's presentation of testimony on the subject of examiner qualifications was in contravention of the district court's statement that it did not "expect to hear . . . about overworked examiners or negligent examiners or anything else."

However, on balance, we conclude that a new trial is not warranted in the circumstances that here prevailed, for the issues of examiner competence and of "monopoly" were not raised by post-trial motion; this inaction by Novo suggests that in the overall context of the two-week trial, these aspects were less inflammatory than Novo now maintains. Novo failed to object to any of the statements at trial, failed to ask for corrective jury instructions, and failed to raise the issue in post-trial motions. Although appellate tribunals are not prohibited from taking remedial action when it is apparent that prejudice or unfairness entered the trial and the interest of justice requires, "counsel for the defense cannot as a rule remain silent, interpose no objections, and after a verdict has been returned seize for the first time on the point that the comments to the jury were prejudicial." United States v. Socony-Vacuum Oil Co., 310 U.S. 150, 238-39 (1940).

Viewed overall, we conclude that a new trial is not warranted on the grounds of prejudice.

The '906 Patent

Novo removed the '906 patent from the jury trial. The district court ruled that the '906 patent is invalid for same-invention type double patenting, following the jury verdict invalidating the '535 and '323 patents. On appeal, Novo states that the court incorrectly construed the term "thinner than a G-29" needle in the '906 claims, and thus erred in its conclusion. Claim 1 is representative:

1. An insulin injection system comprising a pen shaped syringe comprising a cartridge with insulin and an injection needle, wherein the needle is thinner than a G-29 needle and the cartridge contains an insulin type which may freely flow through a needle thinner than a G-29 needle.

The court ruled that "thinner than G-29" means "thinner than 29 gauge, but not thinner than 30 gauge." The court explained that it adopted this construction, despite the open-ended needle size in the claims, because "only one single value of this range, G30, has been consistently

defined." The court observed that the '906 patent specification mentions only the 30 gauge needle; there is no disclosure of any thinner needle.

Novo argues that this construction ignores the plain language of the claims and incorrectly imports limitations from the specification into the claims. Novo states that this construction violates the doctrine of claim differentiation, for the claims of the other patents are specific to 30 gauge. Novo also states that the district court erroneously premised its claim construction on principles of enablement, which is not at issue.

Novo conceded at oral argument that an affirmance of the jury verdicts of invalidity with respect to the '535 and '323 patents would in turn necessitate a finding that the '906 patent was also invalid. In light of that concession, it is unnecessary to determine which construction of the '906 patent is correct. Thus, the judgment of invalidity of the '906 patent is affirmed.

The Cross-Appeal

Becton cross-appeals the district court's denial of summary judgment on the question of whether a certain Novo publication is prior art within the meaning of 35 U.S.C. §102. Denials of summary judgment are not appealable. See *Glaros v. H.H. Robertson Co.*, 797 F.2d 1564, 1573, 230 USPQ 393, 399 (Fed. Cir. 1986) (denial of summary judgment is not reviewable on appeal from final judgment after trial on the issue).

Although Becton argues that it is entitled to appeal the denial of summary judgment because it relates to a "purely legal" question, the question was litigated and decided at trial. It appears that Becton made no motion for judgment as a matter of law on this issue. The decision of this question after trial and jury verdict cannot be circumvented through a pre-trial denial of a motion for summary judgment. None of Becton's purported authorities so holds.

The cross-appeal is dismissed.

Costs

No costs.

AFFIRMED, CROSS-APPEAL DISMISSED