United States District Court,
S.D. New York.

NOVO NORDISK A/S, Novo Nordisk of North America, Inc. and Novo Nordisk Pharmaceuticals Inc,
Plaintiffs.
v.
BECTON DICKINSON AND COMPANY,
Defendant.

No. 96 CIV. 9506(BSJ)

March 12, 1998.

In action alleging infringement of patents for a pen-type insulin injection system and a 30-gauge needle for use therewith. On the patentee's motion for preliminary injunction, the District Court, Jones, J., held that the alleged infringer raised a substantial question whether the patents were invalid as obvious.

Motion denied.

A patent claim is anticipated and therefore invalid when a single prior art reference discloses each and every limitation of the claim. 35 U.S.C.A. s. 103(a).

John Paul Reiner, Robert B. Smith, Edward V. Filardi, White & Case, New York, NY, for Plaintiffs.

Douglas Sharrott, John A. Krause, Fitzpatrick Cella Harper & Scinto, New York, NY, for Defendant.

OPINION & ORDER

JONES**, District Judge.**

This case involves a patent dispute between pharmaceutical companies competing for control of the diabetes treatment market in the United States. At issue, are patents held by plaintiffs Novo Nordisk A/S, Novo Nordisk of North America, Inc., and Novo Nordisk Pharmaceuticals Inc. (collectively "Novo") for (1) a pen-type insulin injection system and (2) a G30 FN1 (or "thirty-gauge") disposable insulin pen needle.

FN1. "G" merely refers to the outer diameter or gauge of the needle; the higher the gauge number, the smaller the diameter.

Novo's pen-type insulin injection system, issued as United States Patent No. 5,462,535 (" '535 patent") on October 31, 1995,FN2 consists of three components: (1) a pen-type insulin delivery device, (2) a G30 needle, and (3) a cartridge "containing only insulin types that may flow freely through a G30 needle. " '535

Patent, Becton Ex. 1. Novo's G30 needle patent, issued United States Patent No. 5,599,323 (" '323 patent") on February 4, 1997, consists of a G30 needle positioned on a hub and fitted for use with a pen-type insulin delivery system.FN3

FN2. The '535 patent issued from (1) Application Number 08/323,401, filed on October 14, 1994, as a continuation-in-part of (2) Application Number 08/167,831, filed on December 16, 1993, which was the United States filing and continuation of (3) PCT Application Number PCT/DK92/00212, filed July 2, 1992, for which priority was claimed under 35 U.S.C. s. 119 to (4) Denmark Patent Application 1346/91, filed July 12, 1991.

FN3. The '323 patent issued from a continuation of the '535 patent.

Novo alleges that defendant Becton Dickinson and Company ("Becton") directly and contributorily infringes, as well as induces infringement of, these two patents by marketing its own pen-type insulin injection device and a disposable G30 needle that fits both Novo's and Becton's insulin pens. Claiming a violation of Section 271 of the Patent Act, 35 U.S.C. s. 271, Novo brings this motion seeking a preliminary injunction barring further infringement.

In defense, Becton claims, among other things, that Novo's patents are invalid because Claim 1 in each patent is obvious in view of, if not anticipated by, prior art.

On June 23 and June 25, 1997, the Court conducted a hearing. Having analyzed the evidence presented, the Court finds that Becton has raised a substantial question as to the validity of the patents and therefore denies Novo's motion for a preliminary injunction.

BACKGROUND

I. ***The Development of the Pen-Type*** Insulin Injection ***System***

Of the approximately 8 million Americans that have been diagnosed with diabetes, 3.5 million require daily insulin injections. The most commonly used insulin delivery system in the United States is the conventional syringe and vial, which currently is used by over 90% of insulin users. Recognizing the various limitations of the syringe and vial system, including dosage accuracy, convenience and privacy, and patient compliance, Novo began developing technology for the pen-type insulin injection system in 1980.

In 1985, Novo produced the world's first pen-type insulin injection system, the NovoPen, which, like the system covered by the '535 patent, was comprised of a pen-type insulin injection device, a disposable needle, and an insulin cartridge. Because of its pen-like shape, this system was both easier to carry and could be used more discreetly than the syringe and vial system. In 1989, Novo introduced a more sophisticated version of the NovoPen, the NovolinPen, which had the same three components, but also included a "dial-a-dose" FN4 mechanism. The NovoPen and NovolinPen employed G27, G28, or G29 disposable needles.FN5

FN4. The dial-a-dose mechanism is a feature that allows the pen user to set the appropriate insulin dosage to be injected without actually having to measure the insulin manually.

FN5. As pen needles have progressed from G27 to G30, the needles have become both shorter and thinner. It is only the diameters of the needles, both internal and external, that are relevant to this case. A G27 needle has an external diameter of 0.40 mm, and an internal diameter of 0.21 mm; a G28 has an external diameter of 0.36 mm, and an internal diameter of 0.16 mm; a G29 has an external diameter of 0.33 mm and-like the G28 needle-an internal diameter of 0.16 mm; and, a G30 has an external diameter of 0.30 mm, and an internal diameter of 0.15 mm.In determining the internal diameters of these needles, the Court relies on Novo's expert, Dr. Wayman Wendell Cheatham. *See* Preliminary Injunction Hearing Transcript at 47. The Court notes, however, that both the '535 and '323 patents list the G27 needle as having an internal diameter of 0.25 mm, that is, 0.04 mm larger than the diameter indicated by Dr. Cheatham.

In June 1996, Novo launched its NovoPen 1.5 insulin delivery system nationwide in the United States.FN6 The NovoPen 1.5 embodies the principles of the '535 and '323 patents and consists of three components: (1) the NovoPen 1.5 insulin pen device featuring a "dial-a-dose" mechanism, (2) the NovoFine 30 disposable needle-a G30 needle, and (3) the Novolin PenFill insulin cartridge.

FN6. The NovoPen 1.5 was released outside the United States in 1993. The NovoPen 1.5's precursor models-the NovoPen and NovolinPen-are no longer marketed in the United States.

Beginning in or about September 1996, Becton began marketing in the United States its own pen-type insulin delivery device called the B-D Pen, and a G30 needle called the Ultra-Fine II that Becton markets for use with both the B-D Pen and the NovoPen 1.5.FN7 Novo asserts that both the B-D Pen and Ultra-Fine II infringe Novo's '323 and '535 patents.

FN7. Becton also began marketing the Ultra-Fine needle, a G29 needle, in or about September 1996. Novo, however, admits that this needle does not infringe either the '323 or '535 patents, and Novo does not seek to enjoin sales of this needle.

To assemble the pen-type insulin delivery system, a patient loads an insulin cartridge into the pen and threads a needle onto the front end of the pen. After the insulin is injected, the needle is removed and discarded. The insulin cartridge, on the other hand, contains sufficient insulin for multiple doses, and thus may last several days before replacement is necessary. Currently, the NovoPen 1.5 and the B-D Pen account for more than 95% of the United States insulin pen market. Insulin in cartridges is manufactured only by Novo and Eli Lilly and Company ("Lilly"). FN8 Novo's NovoFine 30 and Becton's Ultra-Fine II currently are the only thirty-gauge needles marketed for use with the Novo and Becton pen devices. FN9

FN8. In a separate action before the Court, Novo claims that Lilly's insulin cartridges manufactured for use in pen-type insulin injection systems also infringe Novo's '535 patent.

FN9. In a cross action that is the subject of a companion opinion issued by the Court, Becton claims that certain promotional materials distributed by Novo in connection with the NovoPen 1.5 and NovoFine 30 needle constitute false advertising.

Insulin for use with pen-type insulin injection systems comes in two forms: insulin suspensions and insulin solutions. An insulin suspension is an insulin embodying crystalline particles. An insulin solution, in contrast, contains no particles.

II. ***Novo's Infringement Claims and Becton's Defenses***

First, Novo claims that Becton's Ultra-Fine II thirty-gauge needle directly infringes Novo's '323 patent covering the G30 needle assembly in violation of Section 271(a) of the Patent Act. Specifically, Novo claims that Becton's Ultra-Fine II directly infringes the '323 patent because, like Novo's G30 needle, it is comprised of a needle hub and G30 needle.

Second, Novo claims that Becton induces infringement of and contributorily infringes Novo's '535 patent on the pen-type insulin injection system, in violation of Sections 271(b) and 271(c) of the Patent Act, respectively. FN10 Specifically, Novo argues that Becton's marketing of its Ultra-Fine II needle induces consumers to infringe Novo's '535 patent by encouraging them to combine the Becton G30 needle with a pen-type insulin delivery device manufactured by either Novo or Becton. Novo also argues that Becton's marketing of the B-D Pen induces consumers to infringe by encouraging them to combine the B-D Pen with an Ultra-Fine II needle and a Novo or Lilly insulin cartridge.FN11

FN10. There is no claim of direct infringement of the '535 patent because Becton sells only two of the '535 patent's three components, namely, an insulin pen device and G30 disposable needle. The insulin user must buy the insulin cartridge from Novo or Lilly to assemble the combination.

FN11. Novo, however, seeks only to enjoin the manufacture and sale of Becton's Ultra-Fine II needle. With respect to the B-D Pen, Novo proposes a limited injunction requiring the B-D Pen's packaging, product literature, marketing materials, and advertisements to state that the B-D Pen is not for use with Novo's G30 needle or any other G30 needle.

Regarding contributory infringement, Novo claims that Becton's Ultra-Fine II needle infringes a material part of the '535 patent because it is sold specifically for use in an infringing pen-type insulin delivery system. FN12

FN12. Novo also contends that Becton is inducing infringement of and contributorily infringing the '535 patent abroad in violation of Sections 271(f)(1) and (2) of the Patent Act.

In response to Novo's claims, Becton argues that Novo's patents are invalid.FN13 Specifically,Becton contends that Claim 1 in the '323 and '535 patents is anticipated by or obvious in view of prior art, including three insulin injection devices and a Novo publication.

FN13. In addition to challenging the validity of Novo's patents, Becton claims that it has not infringed the patents because its Ultra-Fine II needle has a substantial noninfringing use relating to the injection of human growth hormones, and that the patents are not enforceable because Novo engaged in inequitable conduct by failing to disclose material information to the Patent Examiner. Because the Court finds that Becton has raised a substantial question as to the validity of the patents, the Court does not address these other

challenges.

A. ***Prior Art***

Before turning directly to the prior art, the Court notes that Novo admits that insulin injection pens, insulin cartridges, and G30 needles each were known prior to the issuance of the '323 and '535 patents. Novo further admits that before its inventions, G30 needles were marketed for use with nonpen-type insulin delivery systems employing insulin solutions. Prior to Novo's release of the NovoPen 1.5, however, the only needles available for use with pen-type insulin delivery systems, which accommodated both suspension and solution insulins, were G27, G28, and G29 needles.

Novo claims that prior to the release of the NovoPen 1.5, G30 needles never were used in combination with pen-type insulin delivery systems because they were believed to be too small to be used safely with insulin suspensions. According to Novo, because insulin suspensions contain crystalline particles, they present a clogging or sieving FN14 danger when used with certain needles. Novo claims that after "years of extensive research and development," it developed the NovoPen 1.5 insulin injection system, eliminating any danger of needle clogging. Memorandum of Law in Support of Plaintiffs' Motion for a Preliminary Injunction at 6. As Novo states in each patent, the "invention is based on the surprising recognition that needles thinner than G29 may be used for injecting insulin. " '535 Patent, Col 2., Lns. 6-8; '323 Patent, Col. 2, Lns. 9-11.

FN14. Sieving distorts the concentration of the insulin flowing through the needle and occurs when insulin crystals align themselves across the inside of the needle, blocking the delivery of insulin crystals while allowing the suspension fluid to pass.

In support of its contention that insulin suspensions cause needle clogging, Novo relies on, and cited in its patents, a 1976 article in Diabetes *Forecast* entitled "How to Avoid Clogging of Insulin Syringes." That article concluded that "with poor injection techniques all insulin suspensions produced" clogging in G25, G26, and G27 needles.FN15 Becton Ex. 19. The article also noted, however, that needle clogging did not occur when insulin solutions were injected through these needles.

FN15. The internal diameters of the G25 and G26 needles tested in the article were 0.20 mm, and the internal diameter of the G27 needles was 0.16 mm.

Turning to the prior art, Becton argues that Claim 1 in both the '323 and '535 patents-the only independent claim in each of the patents-describes inventions that "accept" ('323 patent) or "contain" ('535 patent) cartridges containing either insulin solutions or insulin suspensions which may flow freely through a G30 needle. Accordingly, because, as Novo admits, insulin solutions have always been known to flow freely through G30 needles, Becton argues that Claim 1 in each patent is obvious, rendering both patents invalid.FN16

FN16. Alternatively, Becton argues that Claim 1 in the patents should be construed to apply only to insulin suspensions. Under this interpretation, Becton contends that because "insulin solutions are sold in cartridges and are used with Becton pens and needles, because such use is not covered by Novo's claims, and because Becton has no control over whether a diabetic uses its pens and needles with insulin suspensions or

solutions, Becton does not infringe any Novo claims even if they were held to be valid." Defendant's Memorandum of Law in Opposition to Plaintiffs' Motion for a Preliminary Injunction at 32. Although the Court rejects this interpretation of Claim 1 infra pages 17-19, the Court notes that if Becton's interpretation was correct, then this argument would have substantial merit.

Second, Becton argues that even without Novo's admission that insulin solutions always have been known to flow freely through a G30 needle, the prior art demonstrates this fact, and therefore Claim 1 in each patent is obvious. Becton contends that the invention covered by Novo's '323 patent is invalid because it is obvious in view of U.S. Patent No. 4,552,561 ("Eckenhoff" or the "Eckenhoff patent"), issued on November 12, 1985, which teaches the use of an insulin pump that injects insulin solution through a G30 needle. Becton argues that it would have been obvious to one skilled in the insulin syringe art to combine the teachings of the Eckenhoff patent with other prior art, including the G27, G28, and G29 pen needles referred to in the '323 patent, to produce the claimed G30 pen needle.

As for the pen-type insulin injection system covered by Novo's '535 patent, Becton claims that it is invalid because it is obvious in view of U.S. Patent No. 4,973,318 ("Holm" or the "Holm patent"), issued on November 27, 1990, and assigned to Novo. The Holm patent discloses all of the claimed elements of the '323 and '535 patents, that is, a pen-type insulin injection device, an insulin cartridge, and a disposable pen needle, except that it does not identify the gauge of the pen needle. When Holm is viewed together with Eckenhoff, Becton argues that Novo's pen-type insulin injection system, insofar as insulin solutions are concerned, is obvious.FN17

FN17. Neither the Holm nor the Eckenhoff patents were disclosed to the Patent Examiner in connection with the '323 and '535 patent applications.

Third, even insofar as insulin suspensions are concerned, Becton claims that Novo's patents are invalid because the inventions they cover are obvious in view of a G29 syringe-type insulin needle manufactured by Terumo ("Terumo needle"),FN18 which was on the market in 1989 and accommodated not only insulin solutions, but also insulin suspensions.FN19 An internal Novo report discloses that in 1989, Novo purchased Terumo needles to test whether insulin suspensions caused clogging or sieving when injected through them. The "results of the test with the [Terumo needles] surprisingly showed no sieving effect." Kimer Decl. para. 8.

FN18. Terumo is based in the United States and has no affiliation with Novo.

FN19. A photocopy of packaging for the Terumo needle indicates that it was for use with U-100 insulin, an insulin suspension. *See* Becton Ex. 23.

Significantly, this report also indicates that the internal diameters of the Terumo needles tested with insulin suspensions ranged from 0.13 to 0.15 mm. *See* Kimer Decl. Ex. C. Thus, although labeled a G29 needle, the Terumo needle's internal diameter was in fact the same size as, if not smaller than, the internal diameter of Novo's G30 needle, which measures 0.15 mm. Accordingly, Becton argues that because Terumo needles were available for purchase in 1989 they constitute prior art, and because insulin suspensions passed through

the Terumo needle without causing clogging, it was obvious that insulin suspensions would also pass through Novo's G30 needle without causing clogging.

Finally, Becton claims that the inventions covered by Novo's patents are invalid because they are obvious in view of, if not anticipated by, a June 1991 article written by Novo research associate Lene Lytzen (the "Lytzen Article" or "MedView Article"), entitled "Hypodermic, Disposable Needles: Mechanical Properties and Pain Perception as a Function of Needle Diameter." The Lytzen Article, published in Novo's company magazine, MedView, and disseminated to affiliates, acknowledged that "[i]n-house laboratory tests have shown that reduction of the diameter of the needles to 0.30 mm (G30) does not cause alterations of insulin concentration, precipitation or needle clogging." Lytzen Article at 13, Becton Ex. 4. Since these G30 needles were tested in combination with pen-type insulin injection systems, Becton contends that Claim 1 in each of the patents is obvious in view of, if not anticipated by, the Lytzen Article, and therefore invalid.

DISCUSSION

[1] Because substantive matters unique to patent law are involved in this case, the law of the Federal Circuit controls. *See* Hybritech, Inc. v. Abbott Lab., 849 F.2d 1446, 1451 n. 12 (Fed.Cir.1988). Under the law of the Federal Circuit, in order to obtain a preliminary injunction, Novo must establish a right thereto in light of four factors: (1) reasonable likelihood of success on the merits, (2) irreparable harm, (3) the balance of the hardships tipping in its favor, and (4) the impact of the injunction on the public interest. *See id*. Irrespective of how the Court resolves the third and fourth factors, the Court may deny the motion based upon Novo's failure to establish either of the first two factors. *See* Reebok Int'l Ltd. v. J. Baker, Inc., 32 F.3d 1552, 1556 (Fed.Cir.1994).

[2] [3] [4] At the preliminary injunction stage, a patentee must establish a likelihood of success on the merits with respect to the patent's validity, enforceability, and infringement. *See* Nutrition 21 v. United States, 930 F.2d 867, 869 (Fed.Cir.1991). Patent infringement analysis involves two steps: first, the Court must construe the meaning of the patent's claims as a matter of law, and second, the Court must determine whether the accused product infringes the asserted claim as properly construed. *See* Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed.Cir.1995) (en banc), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). At the preliminary injunction stage, although the Court may in exercising its discretion decide to interpret the patent claims conclusively, it is under no obligation to do so. *See* Sofamor Danek Group, Inc. v. DePuy-Motech, Inc., 74 F.3d 1216, 1221 (Fed.Cir.1996). Here, the Court declines to construe the claims finally.

I. ***Claim Construction Under Markman***

A. ***General Principles***

[5] [6] To ascertain the meaning of a patent's claims, the Court examines the claims themselves, the specification, and the prosecution history. *See* Markman, 52 F.3d at 979. First, the Court looks to the words of the claim, both asserted and nonasserted, to define the scope of the patented invention. *See* Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). "The terms of a claim will be given their ordinary meaning, unless it appears that the inventor used them differently." ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d 1576, 1579 (Fed.Cir.1988); *see also* Hoganas AB v. Dresser Indus., 9 F.3d 948, 950 (Fed.Cir.1993).

[7] Second, the Court reviews the patent specification "to determine whether the inventor has used any

terms in a manner inconsistent with their ordinary meaning." *Id*. "The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Id*. "Thus, the specification is always highly relevant to the claim construction analysis," and usually "is the single best guide to the meaning of a disputed term." *Id*.

[8] Third, if a patent's prosecution history is in evidence, the Court may consider that history when construing the meaning of the patent's claims. *See id*. "This history contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims." *Id*.

B. *Claim 1 of the '323 and* '535 Patents

[9] Here, Becton and Novo disagree as to the proper construction of Claim 1 of the '323 and '535 patents.FN20 Claim 1 of the '323 patent states:

FN20. As previously indicated, Claim 1 is the only independent claim in both the '323 and '535 patents.

A needle assembly comprising:

(a) a needle hub having a base and a standard insulin needle fitting for removably mounting said needle assembly on a pen-type insulin syringe having a standard mounting and which accepts cartridges containing only insulin types that may flow freely through a G30 needle; and

(b) a G30 needle secured in said base and having first and second needle portions extending from said base in opposite directions.

'323 Patent, Becton Ex. 7.

Claim 1 of the '535 patent provides:

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.

'535 Patent, Becton Ex. 1.

At issue here is the meaning of the language "insulin types that may flow freely through a G30 needle" contained in the '323 patent, and the similar language "an insulin type which may freely flow through the G30 needle," contained in the '535 patent. Novo argues that this language applies to both insulin solutions and insulin suspensions. Becton counters that this language must be interpreted as applying only to insulin suspensions.

C. *Construing the Patents*

Having reviewed the specifications and prosecution histories of the patents, the Court agrees with Novo's reading of the claims. That is, for the limited purpose of ruling on Novo's motion for a preliminary injunction, the Court construes the language of Claim 1 of the '323 and '535 patents to apply to both insulin

suspensions and solutions.

Column 3, Line 10 of the '323 patent, and Column 3, Line 7 of the '535 patent explicitly refer to both insulin solutions and suspensions. Likewise, the Abstracts FN21 of both the '323 and '535 patents state in relevant part: "The needle is a G30 needle and *the* insulin *is a type which may freely flow through a G30 needle. When the insulin is the type comprising suspended crystals the maximum dimension of any crystal is 15 (mu)m*." FN22 '323 and '535 Patent Abstracts, Becton Exs. 1, 7 (emphasis added). The clear implication from these Abstracts is that insulin that may flow freely through a G30 needle can be insulin solutions or suspensions.

FN21. Patent Abstracts are relevant to claim construction. *See, e.g., Al-* Site Corp. v. Cable Car Sunglasses, 911 F.Supp. 410, 415 (N.D.Cal.1994).

FN22. The symbol (mu) represents microns. One micron is equal to 0.001 mm.

Moreover, the prosecution histories of both patents indicate that the patents apply to both insulin suspensions and solutions. *See* Declaration of Benjamin S. Lee, Ex. D at 3; '535 Patent Reexamination Request, Becton Ex. 14.

Accordingly, the Court concludes that the words "insulin types" and "insulin type" as used in Claim 1 of the '323 and '535 patents apply to both insulin solutions and insulin suspensions.

Having interpreted Claim 1 of Novo's patents, the Court now turns to whether the patents, as interpreted, are valid.

II. ***Validity of the Patents***

FN23. As a preliminary matter, the Court notes that Novo incorrectly asserts that the '323 and '535 patents are entitled to a presumption of validity. In fact, it is only at *trial* that the patentee is entitled to such a presumption. *See* Nutrition 21, 930 F.2d at 869 ("The presumption of validity of a patent is a procedural device that places the burden of going forward and the ultimate burden of persuasion *at trial* on the one attacking the validity of a patent." (emphasis added)); *see also* Edward V. Filardi & Scott Weingaertner, Injunctive Relief in Patent Infringement Cases, 492 PLI/Pat 227, 241 (1997) (In a preliminary injunction context, "the presumption [of patent validity] does not relieve the patentee of carrying the burden of demonstrating likelihood of success.").

A. ***Obviousness***

Here, Becton claims that it has raised a substantial question concerning the validity of Novo's patents. Specifically, Becton argues that Novo's patents are invalid because the inventions they describe are obvious in view of prior art, pursuant to Sections 103(a) of the Patent Act.FN24

FN24. Section 103(a) of the Patent Act provides:A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. s. 103(a).
[12] Whether a patent is obvious under Section 103 is a question of law requiring the examination of four factors: (1) the level of ordinary skill in the pertinent art; (2) the scope and content of the prior art; (3) the differences between the claims at issue and the prior art; and (4) secondary considerations, if any, of nonobviousness. *See* Graham v. John Deere Co., 383 U.S. 1, 17-18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966); B.F. Goodrich Co. v. Aircraft Braking Sys. Corp., 72 F.3d 1577, 1582 (Fed.Cir.1996).

1. ***Level of Ordinary Skill in the Pertinent Art***

Based upon the qualifications of various witnesses relied upon by the parties, the Court concludes that the pertinent art is medical supply manufacturing, and the level of ordinary skill is a bachelor's degree in pharmacy medicine, engineering, and possibly biology, with several years of experience.

2. ***The Scope and Content of the Prior Art*** FN25

FN25. Having considered the parties arguments regarding the critical prior art date, the Court agrees with Novo that the relevant date is July 2, 1992-the filing date of the PCT Application-pursuant to 35 U.S.C. s. 365(a). Accordingly, the Court rejects Becton's argument that Claim 1 in each of the patents is anticipated by a May 1993 brochure for Novo's NovoFine G30 needle.

[13] "The scope of the prior art has been defined as that reasonably pertinent to the particular problem with which the inventor was involved." Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1535 (Fed.Cir.1983) (internal quotations and citation omitted). The problem allegedly facing Novo was preventing needle clogging when insulin suspensions were used in pen-type insulin injection systems employing G30 needles. The prior art includes the 1976 Diabetes *Forecast* article, the Holm and Eckenhoff patents, and the Terumo needle-none of which were disclosed in the '323 and '535 patent applications-and the Lytzen Article, disclosed for the first time in connection with Novo's '535 patent Reexamination Request. Each of these items pertains to insulin injections.

Specifically, the 1976 Diabetes *Forecast* article addressed needle clogging caused by insulin suspensions when poor injection techniques were employed. Holm disclosed a pen-type insulin injection system and Eckenhoff taught the injection of insulin solutions through a G30 needle used with an insulin pump. Novo's own measurement of the Terumo needle in 1989 indicated that its internal diameter was the same size if not smaller than Novo's G30 needle, and Novo's own tests demonstrated that the Terumo needle safely accommodated insulin suspensions. Finally, the Lytzen Article disclosed that clogging did not occur when insulin suspensions were injected through a G30 needle.

3. ***The Differences Between the Claimed Invention and the Prior Art***

As Novo admits, the pen-type insulin injection device, insulin cartridge, and G30 needle each were known prior to the filing of the '323 and '535 patent applications; only the employment of a G30 needle in a pen-type insulin injection system, instead of G29 or other larger diameter needle, was supposedly unknown. *See, e.g.,* Preliminary Injunction Hearing Transcript at 15. Taken alone, the fact that each of these individual

components was known does not render Novo's patents invalid. *See* Environmental Designs, Ltd. v. Union Oil Co. of Cal., 713 F.2d 693, 698 (Fed.Cir.1983) ("Virtually all inventions are combinations and virtually all are combinations of old elements."), *cert. denied,* 464 U.S. 1043, 104 S.Ct. 709, 79 L.Ed.2d 173 (1984). Nevertheless, Becton has raised a substantial question as to the validity of the patents when the inventions they describe are considered as a whole in light of prior art. *See* Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1462 (Fed.Cir.1984) ("The claimed invention must be considered as a whole, and the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination."); *see also* Gillette Co. v. S.C. Johnson & Son, Inc., 919 F.2d 720, 724 (Fed.Cir.1990); Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1448 (Fed.Cir.1984); Stratoflex, 713 F.2d at 1540.

First, Novo admits that insulin solutions always have been known to flow freely through a G30 needle without any potential for clogging or sieving. Nevertheless, Novo failed to limit Claim 1 in either patent to insulin suspensions. Accordingly, because Claim 1 in each patent covers insulin solutions, and because insulin solutions always have been known to flow freely through G30 needles, the Court finds substantial merit in Becton's argument that Claim 1 in each patent is obvious.FN26 *See,* Richdel, Inc. v. Sunspool Corp., 714 F.2d 1573, 1580 (Fed.Cir.1983) (where patent claim was so broad as to read on prior art, claim was obvious and therefore invalid); Philip v. Mayer, Rothkopf Indus., Inc., 635 F.2d 1056, 1060 (2d Cir.1980) ("a patent is invalid, no matter how useful and original the invention it protects, if the applicant for the patent claims the invention so broadly that it encompasses already established prior art"); Maclaren v. B-I-W Group Inc., 535 F.2d 1367, 1372-73 (2d Cir.) (same), *cert. denied,* 429 U.S. 1001, 97 S.Ct. 531, 50 L.Ed.2d 612 (1976); *see also* 35 U.S.C. s. 251 (patent reissue statute) (stating that where patent holder's patent is deemed invalid because patentee claimed more than he had a right to claim, patentee may apply for reissuance of patent).

FN26. Becton made this argument during the preliminary injunction hearing. *See* Preliminary Injunction Hearing Transcript at 33.

Second, even without Novo's admission that insulin solutions have always been known to flow freely through a G30 needle, the Court finds that Becton has raised a substantial question as to the validity of Claim 1 of the '323 and '535 patents in light of the Holm and Eckenhoff patents. The Holm patent is directed to a pen-type insulin injection system; the Eckenhoff patent teaches that insulin solutions flow freely through a G30 needle. As discussed above, Claim 1 of the '323 and '535 patents is not limited to insulin suspensions, but rather covers both insulin suspensions and insulin solutions. Therefore, taken together, the Holm and Eckenhoff patents clearly teach the combination of a pen-type insulin injection system with a G30 needle that will allow insulin solutions to flow freely.

Third, even insofar as insulin suspensions are concerned, Becton has raised a substantial question as to the validity of the patents in light of the G29 Terumo needle. Novo's purchase and testing of Terumo needles, a photocopy of packaging for the Terumo needle, *see* Becton Ex. 23, and the Nielsen report, *see* Becton Ex. 25, all demonstrate that Terumo needles were on the market in 1989 and constitute prior art. As indicated on the packaging for the Terumo needle, the needles were syringe-type needles for use with U-100 insulin, an insulin suspension. Likewise, Novo itself conducted a study in 1989 that indicated that no clogging problem existed when insulin suspensions were injected through these needles. Moreover, Novo's measurements of the Terumo needles indicated that the internal diameter of those needles ranged from 0.13 to 0.15 mm, which is as small, if not smaller than, Novo's then-future G30 needle. Therefore, the Court finds substantial

merit in Becton's argument that the Terumo needle renders Claim 1 in each of Novo's patents obvious, even as to insulin suspensions.

[14] [15] Finally, Becton has raised a substantial question as to the validity of Claim 1 in each patent based on the Lytzen Article. FN27 After all, Novo contends that its inventions were issued patents because they solved a clogging problem that could occur when insulin suspensions were used in combination with pen-type insulin injection systems. Yet, the Lytzen Article-an article printed over two years before the filing of the '535 patent and over three years before the filing of the '323 patent-acknowledged that "[i]n-house laboratory tests have shown that reduction of the diameter of the needles to 0.30 mm (G30) does not cause alterations of insulin concentration, precipitation or needle clogging." Lytzen Article at 13, Becton Ex. 4. Furthermore, it is clear to the Court, despite Novo's assertions to the contrary, that the G30 needles discussed in the Lytzen Article were tested in combination with a pen-type insulin injection system.FN28 Therefore, insofar as Claim 1 covers insulin suspensions, that claim is obvious in view of the Lytzen Article, if not anticipated by that article.FN29

FN27. For purposes of this motion, the Court rejects Novo's assertion that the Lytzen Article is not a printed publication within the meaning of the Patent Act. The record indicates that the Lytzen Article was disseminated to "affiliates" and that Novo took measures to recall the June 1991 MedView edition containing the Lytzen Article. Moreover, as Novo stated at the Preliminary Injunction Hearing, a central reason for putting the '535 patent into reexamination was Novo's inability to get "a satisfactory answer" to the question of whether the Lytzen Article constituted prior art. Preliminary Injunction Hearing Transcript at 115.The Court also rejects Novo's argument that the '535 patent is valid because the Patent and Trademark Office confirmed the patent after Novo voluntarily placed it into reexamination. Novo correctly asserts that confirmation of a patent pursuant to a reexamination proceeding is a factor that militates in favor of validity. *See, e.g.,* Custom Accessories, Inc. v. Jeffrey-Allan Indus., 807 F.2d 955, 961 (Fed.Cir.1986). The Court notes, however, that in requesting a reexamination, Novo misstated the diameters of the G28 and G29 needles, *see* Preliminary Injunction Hearing Transcript at 44, 80, and as a result, the patent examiner may have mistakenly believed that there was a larger difference between the diameters of the G29 and G30 needles than actually exists. Moreover, although the '323 and '535 patents themselves list the diameters of the G27 and G28 needles, neither patent gives any indication whatsoever as to the diameters of a G29 needle.

FN28. After concluding that insulin suspensions do not cause clogging in G30 needles, the Lytzen Article immediately states: "It is at the moment being investigated whether the higher pressure in the cartridge-when injection is performed through a G30 needle-will result in fracture of the cartridge or leakage of insulin." Lytzen Article at 13, Becton Ex. 4. Additionally, the Lytzen Article, discussing the objections to moving toward thinner needles, states: "The injection rate will be too slow. This might cause excess pressure in a Penfill cartridge leading to its fracture or more likely leakage of insulin out of the cartridge." Id. at 12, Becton Ex. 4.

FN29. A patent claim is anticipated and therefore invalid when a single prior art reference discloses each and every limitation of the claim. *See* Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1047 (Fed.Cir.), *cert. denied,* 516 U.S. 988, 116 S.Ct. 516, 133 L.Ed.2d 424 (1995).

4. ***Secondary Considerations***

Finally, the Court notes that Novo has not presented any evidence of secondary considerations. Accordingly, the Court cannot engage in a secondary considerations analysis. *See,* Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc., 45 F.3d 1550, 1555 (Fed.Cir.1995) (courts must only consider evidence of secondary considerations such as commercial success, long-felt need, failure of others to find a solution to the problem at hand, and copying, when such evidence is presented by patent holder); Stratoflex, 713 F.2d at 1538 (same).

5. ***Summary***

At this preliminary injunction stage, the Court "does not resolve the validity question but rather must ... make an assessment of the persuasiveness of the challenger's evidence, recognizing that it is doing so without all evidence that may come out at trial." New England Braiding, 970 F.2d at 882-83. The Court may deny a preliminary injunction "where the evidence presented in support of invalidity raises a substantial question, although the defense may not be entirely fleshed out." *Id*. at 883. Here, based on the fact that insulin solutions always have been known to flow freely through a G30 needle, as well as upon the Holm, Eckenhoff, Terumoneedle, and Lytzen prior art, it is clear that Becton has raised a substantial question about the validity of Claim 1 of the '323 and '535 patents. Because Novo has failed to carry its burden on the likelihood of success by failing to demonstrate that Becton's defenses lack substantial merit, the Court denies Novo's motion for a preliminary injunction. *See* Reebok, 32 F.3d at 1556 .FN30

FN30. Moreover, because Novo has not established a likelihood of success, the Court need not consider the remaining preliminary injunction factors, that is, irreparable harm, the balance of hardships, and the impact on the public interest. *See* Reebok, 32 F.3d at 1556.

CONCLUSION

For the foregoing reasons, Novo's motion for a preliminary injunction is denied.

SO ORDERED:

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