United States District Court,
N.D. Illinois, Eastern Division.

APOTEX CORP,
Plaintiff.
v.
MERCK & CO., INC,
Defendant.

Jan. 25, 2000.

MEMORANDUM OPINION AND ORDER

KENNELLY**, District J.**

In this patent infringement suit, Apotex Corporation accuses Merck & Co. of infringing two patents held by Apotex, U.S. Patent No. 5,573,780 and U.S. Patent No. 5,690,962. The parties filed cross motions for summary judgment on the infringement issue, and in addition, Merck has filed a motion for summary judgment that the patents are invalid. We address each motion below.

FACTUAL BACKGROUND

The Patent and Trademark Office issued Patent No. 5,573,780 (the '780 Patent), entitled "Stable Solid Formulation of Enalapril Salt and Process for Preparation," to Dr. Bernard Sherman on November 12, 1996. The PTO issued Patent No. 5,690,962 (the '962 Patent), which is a continuation of the '780 Patent and therefore shares the same title, on November 25, 1997. Sherman assigned his rights in both patents to Apotex. The patents cover a process for making a pharmaceutical compound for use in the treatment of high blood pressure. In the simplest of terms, the patented process involves mixing the active ingredient, enalapril maleate, with an alkaline sodium compound and at least one other inactive ingredient or "excipient," FN1 adding water to the mix, drying the mix and processing the dried mix into tablets. The claimed novelty of the invention was that it produced a stable compound "without requiring the steps of suspending the enalapril maleate in water, adding the alkaline sodium compound and mixing until the reaction is complete and a clear solution is formed." U.S. Patent No. 5,573,780, col. 1, line 65-col. 2, line 4; U.S. Patent No. 5,690,962, col. 1, line 65-col. 2, line 4. In this lawsuit, Apotex accuses Merck of infringing all of the claims of its two patents.

FN1. An excipient is an inert substance added to a mixture to give it bulk or some other desirable characteristic.

Before we turn to the merits of the parties' summary judgment motions, a bit of history is in order. This is not the first time these parties have sparred over their respective rights to patents involving the drug enalapril maleate. In 1991, Merck and its Canadian subsidiary, Merck Frosst Canada, Inc., sued Apotex's

Canadian affiliate, Apotex Canada, for infringement of Merck Frosst's patent that claims the drug substance enalapril. The record does not permit the Court to determine whether the Canadian patent Merck sought to enforce in the Canadian litigation covers the same process Apotex attacks in this lawsuit. Nor is it clear what process or product of Apotex's Merck was accusing of infringement in that litigation, though it clearly was not the process covered in the '780 and '962 Patents because Sherman had not yet conceived of that process. But Merck's process for making VASOTEC-the accused process here-was definitely at issue in the Canadian litigation because as part of its case, Merck played a videotape of one of its employees demonstrating the process, and Merck's then vice president of marketing, Brian McLeod, took the stand to narrate the tape and to give a play-by-play of the process.

The outcome of the Canadian litigation is not important for our purposes. However, the trial is relevant here because it set the stage for this lawsuit: Sherman apparently conceived of the patented process within days after McLeod testified about Merck's process.

DISCUSSION

1. *Applicable Legal Standard*

The Federal Circuit has stated that summary judgment is as appropriate in a patent case as it is in any other case. *See, e.g.,* Avia Group International, Inc. v. L.A. Gear California, Inc., 853 F.2d 1557, 1561 (Fed.Cir.1988). Thus, summary judgment is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c). In determining whether there is a genuine issue of fact, we view the evidence and draw all reasonable inferences in favor of the party opposing the motion. *See* Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986); Becton Dickerson & Co. v. C.R. Bard, Inc., 922 F.2d 792, 795 (Fed.Cir.1990). Where cross motions are filed, we apply the same standard, adopting a dual perspective. *See* Stimsonite Corp. v. Nightline Markers, Inc ., 33 F.Supp.2d 703, 705 (N.D.Ill.1999).

2. *The Parties' Cross Motions on Infringement*

Patent infringement occurs if a person makes, uses, offers to sell or sells a patented invention within the United States during the term of the patent. 35 U.S.C. s. 271(a). Infringement exists if every limitation of the patent claims asserted to be infringed (in this case, all of the claims) is found in the accused process. SmithKline Diagnostics, Inc. v. Helena Laboratories Corp., 859 F .2d 878, 889 (Fed.Cir.1988). To determine whether infringement has occurred, we must first define as a matter of law the meaning and scope of each patent claim at issue; then we compare the accused process against the properly construed claims to see whether the claim limitations are met either literally or by a substantial equivalent. *See* Markman v. Westview Instruments, Inc., 517 U.S. 370, 387-91 (1996); Stimsonite, 33 F.Supp.2d at 706-07 (citing Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1247-48 (Fed.Cir.1998)). To determine the meaning and scope of the patent claims, we look first to the intrinsic evidence-namely, the claims, the specification or written description, and the prosecution history. Vitronics Corp. v. Conceptronic, Inc., 90 F .3d 1576, 1582 (Fed.Cir.1996). If one of ordinary skill in the art can interpret the intrinsic evidence unambiguously, the court looks no further. Id. at 1583.

The principal dispute about claim interpretation in this case is whether Apotex's process requires a "complete" reaction of the active ingredient, enalapril maleate; in other words, whether the patents are limited to those processes in which all of the enalapril maleate is converted to enalapril sodium. Merck argues that the patents require a complete reaction; Apotex argues that they do not. To resolve the dispute,

we look first to the claims themselves. *See* Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed.Cir.1999) (claim construction begins with the language of the claims). The '780 Patent claims:

1. A process of manufacture of a pharmaceutical solid composition comprising enalapril sodium, which process comprises the steps of:

(i)(a) mixing enalapril maleate with an alkaline sodium compound and at least one other excipient, adding water sufficient to moisten, and mixing to achieve a wet mass, or

(b) mixing enalapril maleate with at least one excipient other than an alkaline sodium compound, adding a solution of alkaline sodium compound in water, sufficient to moisten and mixing to achieve a wet mass; thereby to achieve a reaction without converting the enalapril maleate to a clear solution of enalapril sodium and maleic acid sodium salt in water.

(ii) drying the wet mass, and

(iii) further processing the dried material into tablets.

2. A process as in claim 1 wherein the alkaline sodium compound is selected from the group consisting of sodium hydroxide, sodium carbonate and sodium bicarbonate.

3. A process as in claim 1 or 2 wherein the excipient is lactose.

4. A process as in any of claims 1 to 3 which further comprises addition of a lubricant.

5. A process as in claim 4 wherein the lubricant is a metal stearate.

6. A process as in claim 5 wherein the metal stearate is magnesium stearate.

7. A process as in any of claims 1 to 6 which further comprises the addition of a disintegrant.

8. A process as in claim 7 wherein the disintegrant is starch.

9. A pharmaceutical solid composition comprising enalapril sodium salt when made by a process according to any of claims 1 to 8. U.S. Patent No. 5,573,780 at col. 5, line 34-col. 6, line 34.

The '962 Patent's claims are identical in all respects relevant to this lawsuit. *See* U.S. Patent No. 5,690,962, col. 5, line 22-col. 6, line 27.

Nothing in the claim language calls for a complete reaction. Claim 1(i)(b)-the only claim to specifically mention the reaction-states that the goal of the patented process is "to achieve a reaction without converting the enalapril maleate to a clear solution of enalapril sodium and maleic acid sodium salt in water." U.S. Patent No. 5,573,780, col. 6, lines 10-12. *See also* U.S. Patent No. 5,690,962, col. 6, lines 5-7 ("to achieve a reaction without converting the enalapril maleate to a clear solution of enalapril sodium and maleic acid in water."). Neither this claim nor any of the other claims speak in terms of a "complete" reaction of the enalapril maleate. Similarly, the specification emphasizes that the reaction is designed to produce stability. *See* U.S. Patent No. 5,573,780, col. 1, lines 23-67; U .S. Patent No. 5,690,962, col. 1, 24-col. 2, line 4. If a

process that otherwise reads on the claims achieves stability with a reaction that is less than complete, that process would infringe the patents.

The language on which Merck relies to support its claim construction appears in the specification: "It has been found that so long as the amount of water used is sufficient to render the mass very moist, the acid-base reaction will occur rapidly and will be complete or essentially complete before the drying of the mass in the subsequent drying process is completed." U.S. Patent No. 5,573,780, col. 3, lines 38-42; U.S. Patent No. 5,690,962, col. 3, lines 30-34 (emphasis added). Merck argues that "essentially complete" means "complete." This interpretation is unreasonable because it would require the Court to read "essentially complete" out of the equation. The more reasonable interpretation of that phrase is that it means "virtually complete," that is, "mostly complete but not entirely complete."

Having construed the pertinent claim language, we compare the patented process with the process accused of infringement. During the Canadian infringement litigation, Merck's witness Brian McLeod testified in detail about the process Merck uses to make VASOTEC. McLeod testified that the active ingredient, enalapril maleate, is mixed with "a carrier," "a stabilizer," "a binder" and a "disintegrant." Transcript of McLeod Testimony at 123, 125. Then that mixture is mixed in a "wet granulation" FN2 with water to get "a damp mass" or "a wet mass." Id. at 127. He clarified that by "damp" or "wet mass" he meant that the mixture was "damp but not gooey." Id. He stated that the mass is then spread thinly on trays and placed into a "drying oven" to remove the moisture. Id. at 128. He stated that after the mixture is dried, a lubricant is added-he specifically identified the lubricant as magnesium stearate. Id. He stated that the mixture is then formed into tablets. Id. at 128-29. Finally, he testified that the goal of the process was to make the tablets in a way that "ensure[d] that each tablet will deliver the exact amount of active ingredient." Id. at 125. Thus the only apparent difference between Merck's process, as described by McLeod, and Apotex's process, as described in the claims, is that Merck's process uses "a carrier," "a stabilizer," and "a binder" whereas Apotex's process uses "an alkaline sodium compound and at least one other excipient." If we dig a little deeper, we see that these are really different names for the same things. Interestingly, Apotex's specification uses one of these same words. *See* U.S. Patent No. 5,573,780, col. 1, 15-18; U.S. Patent No. 5,690,962, col. 1, lines 15-18 ("In order to manufacture pharmaceutical tablets, it is necessary to mix the active ingredient with inactive ingredients which may serve as binders ....") (emphasis added). And Merck's product monograph states that, in addition to the active ingredient enalapril maleate, the mix contains the following inactive ingredients or excipients: "lactose, magnesium stearate [the lubricant], sodium bicarbonate and starch [the disintegrant]." Product Monograph for VASOTEC and VASOTEC I.V., at 15 (Oct. 19, 1992). Claim 2 of the patents makes clear that sodium bicarbonate is "an alkaline sodium compound," and Claim 3 of the patents makes clear that lactose is an excipient. U.S. Patent No. 5,573,780, col. 6, lines 16-21; U.S. Patent No. 5,690,962, col. 6, lines 12-16. Thus, Merck's process reads on all of the claims of the '780 and '962 Patents.

FN2. "Wet granulation" is a term used to describe a processing method in pharmaceutical manufacturing in which a solvent (usually water) is used to wet, to the consistency of damp snow or brown sugar, the ingredient being mixed in making a medicinal tablet. Merck's Mem. in Support of Its Summary Judgment Motion on Invalidity, at 3-4.

Merck argues that its process does not infringe the patented process because its process "is not 'wet' enough to meet the 'wet mass' limitation" in Claim 1. Merck's Mem. at 12. The argument is undercut substantially by the fact that McLeod described Merck's "wet mass" the same way Sherman described Apotex's "wet mass."

But it fails for another reason as well. The claim language is silent as to how much water goes into the mix; the claims do not specify how much water is "sufficient to moisten" or how much water is necessary to "achieve a wet mass." The specification does, however, includes 3 examples of how to achieve the intended result. *See* U.S. Patent No. 5,573,780, col. 3, line 65-col. 5, line 32; U.S. Patent No. 5,690,962, col. 3, line 57-col. 5, line 20. In the first example, the desired "wet mass" was achieved by dissolving 12.2g of sodium hydroxide (an alkaline sodium compound) in 400g of water and then adding that solution to a mixture containing 50g of enalapril maleate and 1660g of lactose monohydrate powder (the other excipient). Id. at col. 4, lines 5-31. In the second example, the desired "wet mass" was achieved by dissolving 32.3g of sodium carbonate in 400g of water and then adding that solution to a mixture containing 100g of enalapril maleate, 1600g of lactose monohydrate powder and 5g of a colouring agent. Id. at col. 4, lines 35-67. In the third example, the desired "wet mass" was achieved by adding 400g of water to a mixture containing 50g of enalapril maleate, 25.6g of sodium bicarbonate and 1650g of lactose monohydrate powder. Id. at col. 5, lines 1-32. Merck's process uses a much lower proportion of water to the enalapril maleate compound than is specified in the specification's examples. The wet granulation in Merck's process is generated by mixing about 12% water by weight as compared with the dry ingredients, whereas, according to Merck, if we did the math in the above examples, we would find that Apotex's process uses at least 23% water by weight. Based on this fact, Merck argues that its process cannot literally infringe the patents. We disagree.

Merck's noninfringement argument would require the Court to read a limitation from the written description into the claims, something we are not permitted to do under the law. *See* Vitronics, 90 F.3d at 1582. It is true that if a particular term in need of definition is used but not defined in the claims, we may look to the specification for such a definition. *See* Renishaw, 158 F.3d at 1248. But even if we were to find that the terms "sufficient to moisten" and "wet mass"-used but not defined in Claim 1-open the door for us to look at the specification for elucidation of those phrases, the specification clearly states that it is not intended to confine the patents' scope. Certainly the examples given clarify what amount of water *may* be "sufficient to moisten" and what combination of ingredients *may* create a "wet mass." The specification expressly states, however, that the examples disclosed are "intended to be illustrative but not limiting of the invention." U.S. Patent No. 5,573,780, col. 3, lines 65-67; U.S. Patent No. 5,690,962, col. 3, lines 54-56. The examples are just that-examples; they do not foreclose the possibility that other proportions would also achieve the intended result. Thus, the fact that Merck uses different amounts of water or different amounts of enalapril maleate or different amounts of any of the other ingredients is of little consequence.

There are no material issues of fact on the infringement issue; the parties' respective processes are what they are. Based on the facts, as described above, the Court finds that Merck's process literally infringes Apotex's patents, that Apotex is entitled to judgment as a matter of law and that Merck is not. Of course, invalidity is a defense to infringement. *See* 35 U.S.C. s. 282 (alleged infringer who can show that the patent asserted against him or her is invalid cannot be liable for infringement); Ever-Wear, Inc. v. Wieboldt Stores, Inc., 427 F.2d 373, 376 (7th Cir.1970) (only valid patents may be infringed). So we must still consider Merck's motion for summary judgment that the patents are invalid.

2. *Merck's Motion for Summary Judgment that Apotex's Patents are Invalid*

This is not the first time Merck has asked the Court to hold Apotex's patents invalid. Merck previously sought summary judgment on the same issue, though on different grounds. In its earlier motion, Merck argued that it was entitled to summary judgment under 35 U.S.C. s. 102(f) because Sherman derived the subject matter of the patents in suit from Merck's process (in other words, Sherman was not the original inventor; Merck was). Subsection (f) provides that a person shall be entitled to a patent unless "he did not

himself invent the subject matter sought to be patented." It is a derivation provision, which provides that one may not obtain a patent on that which is obtained-through public information or through communications with the prior inventor-from someone else whose possession of the subject matter is inherently "prior." *See* Oddzon Products, Inc. v. Just Toys, Inc., 122 F.3d 1396, 1401 (Fed.Cir.1997). According to Magistrate Judge Ashman, to whom the case had been referred, both parties agreed "that Merck was the first to conceive the subject matter claimed in the '780 Patent" and that the only question for him to decide was whether Merck's conception was communicated to Dr. Sherman "in a manner that would enable one of ordinary skill in the art to make stable enalapril tablets." Report and Recommendation at 9. Judge Ashman recommended that the Court deny summary judgment because he found an issue of fact as to whether Dr. Sherman concluded on his own that Merck used a wet granulation process to make its tablets (as Sherman claimed) or whether Sherman learned about the process through some communication from Merck (as Merck claimed). Id. at 11. The parties did not object to Judge Ashman's recommendation, and Judge Marovich, to whom this case was previously assigned, accepted it and denied summary judgment. This time around, Merck is attempting to avoid the fact issues identified by Judge Ashman by arguing that it is entitled to summary judgment under 35 U.S.C. s. 102(g), which does not require that the second inventor actually know about the prior invention. *See* E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1437 (Fed.Cir.), *cert. denied,* 488 U.S. 986 (1988).

Before deciding whether Apotex's patents are invalid under 35 U.S . C. s. 102(g), we must quickly address Apotex's argument that this section "requires acts in the United States" and does not apply because Merck's public disclosure of its process took place in Canada. Section 102(g) provides as follows:

[a] person shall be entitled to a patent unless ... before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it.

By its plain language, the statute requires only that the process is invented in the United States, not that the process be employed or disclosed in the United States after being invented. *See also* Paulik v. Rizkalla, 760 F.2d 1270, 1278 (Fed.Cir.1985) (Rich, J., concurring). Judge Rich, who was intimately involved in drafting s. 102(g), explained that one of the earlier versions of the statute required more of the inventor's activities to occur in the United States; specifically, it required that the prior invention be "made in this country by another who had not abandoned it and who was using reasonable diligence in this country in reducing it to practice ...." Paulik, 760 F.2d at 1278 (Rich, J., concurring). That language was taken out in favor of the current version, which requires only that the invention be made in this country and not abandoned, suppressed or concealed-in any country. *Id*. The undisputed record evidence shows that Merck's scientists invented the accused process and reduced it to practice at Merck's lab in West Point, Pennsylvania. In short, section 102(g) does apply, and we now consider the consequences of that application.

A patent is presumed to be valid. 35 U.S.C. s. 282. The party challenging the patent's validity must show, by clear and convincing evidence, that the patent is invalid. Checkpoint Systems, Inc. v. United States International Trade Commission, 54 F.3d 756, 761 (Fed.Cir.1995); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1375 (Fed.Cir.1986), *cert. denied,* 480 U.S. 947 (1987). Thus, Merck must prove by clear and convincing evidence that Apotex's patents are invalid. Because it is asserting invalidity under 35 U.S.C. s. 102(g), Merck must prove by clear and convincing evidence that: (1) Merck invented its process within the United States before Sherman invented his process; and (2) Merck neither abandoned, suppressed nor concealed its invention.

The parties agree that Merck invented the allegedly infringing process long before Sherman conceived of the

idea. Apotex admits that Merck's scientists developed the process at its West Point, Pennsylvania facility in the early 1980s. Apotex further admits that Sherman conceived of the idea for the patented process some time after March 30, 1994 and before April 19, 1994 and that his invention was first reduced to practice on April 19 or within a few days thereafter. Thus the first element of Merck's defense is satisfied. Moreover, the evidence does not suggest, and Apotex does not contend, that Merck abandoned the process; indeed, the evidence establishes that Merck has been using its process continuously since at least 1983. Thus, under 35 U.S.C. s. 102(g), the only question for the Court is whether Merck suppressed or concealed its invention at the time Sherman allegedly conceived of the process.

The purpose of our patent law is to "advanc[e] the useful arts" and "technological innovation"; "to encourage innovation and its fruits." Paulik, 760 F.2d at 1276. "As implemented by the patent statute, the grant of the right to exclude [others from making a particular product or using a particular process] carries the obligation to disclose the workings of the invention, thereby adding to the store of knowledge without diminishing the patent-supported incentive to innovate." Id. Section 102(g) fits into this scheme by encouraging "prompt public disclosure of an invention by penalizing unexcused delay or failure of a first inventor to share the 'benefit of the knowledge of [the] invention' with the public after the invention has been completed." Checkpoint Systems, 54 F.3d at 761 (quoting Paulik, 760 F.2d at 1280 (Rich, J., concurring)). Priority under this section goes to "the 'first' inventor in law, regardless of fact." Paulik, 760 F.2d at 1281 (Rich, J., concurring). To determine priority, we ask not only who first conceived of the invention, but also "whether the facts as to what was or was not done lead to the legal conclusion of 'suppressed, or concealed." ' Id. at 1280. *See also* Fujikawa v. Wattanasin, 93 F.3d 1559, 1567 (Fed.Cir.1996). Suppression or concealment may be intentional, as when the prior inventor "designedly, and with the view of applying it indefinitely and exclusively for his own profit, withholds his invention from the public." Paulik, 760 F.2d at 1273 (quoting Kendall v. Winsor, 62 U.S. (21 How.) 322, 328 (1858)). Or suppression or concealment may be inferred from the facts of the particular case, where for example, an inventor delays "too long" in filing a patent application. *Fujikawa,* 93 F.3d at 1556 (citing Paulik, 760 F.2d at 1273).

In *Paulik,* the Federal Circuit inventoried the decisions involving suppression or concealment under section 102(g). After briefly discussing the cases, the court summarized the law as follows:

The decisions applying section 102(g) balanced the law and policy favoring the first person to make an invention, against equitable considerations when more than one person had made the same invention: in each case where the court deprived the de facto first inventor of the right to the patent, the second inventor had entered the field during a period of either inactivity or deliberate concealment by the first inventor. 760 F.2d at 1275.

This case simply does not fit that mold. Certainly Apotex cannot accuse Merck of inactivity; by 1994, when Sherman conceived of the patented process, Merck had been continuously using its process to make VASOTEC tablets and it had been selling its product in the commercial markets for more than a decade. In 1993 alone Merck had more than $150 million in VASOTEC sales.

Nor do the facts of this case suggest that Merck deliberately suppressed or concealed its invention. The test for suppression or concealment under s. 102(g) is whether within a reasonable time after completion of the invention, the prior inventor took steps to make its invention publicly known. Levi Strauss & Co. v. Golden Trade, S.r.L., Nos. 92 Civ. 1667(RPP), 90 Civ. 6291(RPP), 90 Civ. 6292(RPP), 1995 WL 710822, at (S.D.N.Y. Dec. 1, 1995) (citing International Glass Co. v. United States, 408 F.2d 395, 403 (Ct.Cl.1969)).

See also Checkpoint Systems, 54 F.3d at 763 (no suppression or concealment if public promptly received the benefit of knowledge of first inventor's product). "Possible steps [to make the invention publicly known] include filing a patent application, describing the invention in a publicly disseminated document, and using the invention publicly." Levi Strauss, 1995 WL 710822, at *18. Merck prepared and distributed widely its product monograph, which describes its VASOTEC tablets and gives a list of the ingredients used to make the tablets, as well as the chemical name, the structural formula, the molecular weight and the composition. Merck distributed more than 30,000 copies of the monograph in 1993 alone. Merck also described its product in the *Dictionnaire Vidal,* a French language pharmaceutical dictionary, and it disclosed the process for making VASOTEC tablets at the Canadian infringement trial-significantly, without seeking any kind of a protective order or other means of limiting disclosure of the process to the general public. Merck also used its invention publicly, selling the fruits of the invention in mass quantities in the commercial markets. Taken together, these facts clearly and convincingly establish that Merck did not intentionally suppress or conceal its invention.

In opposition to Merck's motion, Apotex has argued that Merck suppressed and concealed its invention to keep others from breaking into the enalapril maleate tablet market. Yet, Apotex offers no evidence to back up this claim. Apotex can point only to the fact that Merck never filed a patent application, and this alone is not sufficient to support a finding of deliberate suppression or concealment. *See* E.I. du Pont, 849 F.2d at 1437 (failure to file patent application does not by itself constitute suppression or concealment).

Apotex argues that the way in which Merck disclosed its process was not sufficient to show a person of ordinary skill in the art how to duplicate the process. The Court disagrees. As described above, Brian McLeod's testimony and the accompanying videotape explained the process in detail. And to the extent McLeod failed to specifically name any of the ingredients used in the process, Merck's product monograph and the *Dictionnaire Vidal* were available to fill in any blanks. Apotex also argues that Merck's evidence of disclosure does not satisfy s. 102(g) because the disclosure was not made in a single written publication. But s. 102(g) does not require *disclosure* at all, let alone disclosure in a particular form. It requires, as we have already noted, that the invention not be abandoned, suppressed or concealed. Written public disclosure is just one possible way to demonstrate that an invention has neither been abandoned, suppressed or concealed.

Finally, Apotex argues that Merck lied to the Food & Drug Administration in its new drug application (NDA) for Tablets VASORIL (Enalapril Maleate, MSD) dated September 15, 1983. Apotex argues that in section 7 of the NDA, Merck listed the *starting* ingredients for these tablets when it should have listed the ingredients in the final composition of the tablets. Merck did this, according to Apotex, to hide the fact that a reaction occurs in the tableting process because, if Merck had disclosed the end product's ingredients, the FDA "would have been alerted to the fact that a chemical reaction had occurred and [the FDA reviewer] would have probed Merck as to the tableting process." Apotex's Mem. in Opposition to Merck's Summary Judgment Motion, p. 15. Even if we accept Apotex's allegations as true, we fail to see how this bears on the issue of suppression or concealment. To the extent Apotex is implying that in 1983 Merck was hiding the fact that its process involved reacting enalapril maleate to form a more stable enalapril sodium compound, that time frame is irrelevant. The relevant time frame for purposes of s. 102(g) is when the later inventor conceives of his invention-in this case, some time between March 30, 1994 and April 19, 1994. By that time, Merck had fully disclosed the ingredients and the process. Plus, even Apotex's witnesses agreed that any chemist who knew the ingredients and knew that the process involved adding water to the mix would automatically know that a reaction of the enalapril maleate occurred. Dr. Richard McKeag, a scientist who worked with Dr. Sherman at Apotex Canada, testified that "[i]t was so simple that it was obvious; any

chemist would know that, if you added bicarbonate or carbonate to a solution containing enalapril maleate, you would get the formation of the salt. You would get a chemical reaction to form a salt." McKeag Deposition Transcript, at 41. He also testified that "if you take sodium bicarbonate and put it into water and you have enalapril maleate in the same solution, it will react virtually spontaneously and irreversibly to form a new compound, to form enalapril sodium and disodium maleate." *Id*. at 46. Finally, he testified that "any chemist who looks at enalapril maleate would automatically assume its going to react with three moles of sodium bicarbonate ... if they are placed together in solution or in slurry or whatever, anything wet." *Id*. at 47. In short, what Apotex characterizes as "rank suppression and concealment" would not have fooled anyone-or at least anyone with a fundamental knowledge of chemistry.

Under the standards articulated above, Merck is both the first inventor in fact and the first inventor in law, and principles of equity, when viewed against the facts of this particular case, require the Court to give priority to Merck. Accordingly, the Court finds that Apotex's patents are invalid under 35 U.S.C. s. 102(g).

CONCLUSION

For the reasons explained above, the Court finds that Merck's process for making VASOTEC enalapril maleate tablets literally infringes U.S. Patent No. 5,573,780 and U.S. Patent No. 5,690,962. But the Court further finds that Merck has a defense to the literal infringement-namely invalidity under 35 U.S.C. s. 102(g)-because Merck invented its process for making VASOTEC in the United States before Sherman invented the process covered in the '780 and '962 Patents and neither abandoned, suppressed nor concealed that process. Accordingly, the Court denies Merck's motion for summary judgment of noninfringement, grants Apotex's motion for summary judgment of infringement and grants Merck's motion for summary judgment that the patents in suit are invalid. Judgment will enter in favor of Merck and against Apotex.

N.D.Ill.,2000.
Apotex Corp. v. Merck & Co., Inc.