3. The Vasotec Process Qualifies as Prior Art Because it Occurred in the United States Prior to the Invention Date of the Claims of the '450 Patent.

In order to qualify as prior art under 35 U.S.C. § 102(g)(2), the prior invention must not only meet all the limitations of the claim, but must also have occurred in the United States prior to the invention date of that claim. The evidence proves that the Vasotec Process meets these additional requirements.

Before being retained as a Warner-Lambert expert witness in this case, Dr. Gerald S. Brenner worked on Vasotec throughout the second half of his 33-year tenure at Merck. PTX 239, Brenner 590:5-10. On November 12, 1999, Dr. Brenner filed a sworn declaration on behalf of Merck in the *Merck v. Apotex* U.S. litigation describing that work. Paragraph 6 of that declaration states:

> The process that Merck has used and uses to make its VASOTEC® brand enalapril maleate tablets in the United States involves mixing enalapril maleate (the active ingredient), lactose (a carrier), starch (a disintegrant/binder) and sodium bicarbonate (the stabilizer) in a wet granulation process to create a damp mass. The damp mass is then dried and blended with magnesium stearate (a lubricant) and is tableted. ***Thus, with respect to the manufacturing steps and the ingredients used, Merck's process has remained virtually the same since Merck developed it in the early 1980's in its West Point[, Pennsylvania] facility.***

DTX 301, at A1107-08 (emphasis added). Dr. Brenner reaffirmed this declaration at trial (Brenner 137:3-6) and also agreed that the statement accurately reflected the process described in Merck's NDA for Vasotec. Brenner 642:9-14.

As confirmed by Dr. Brenner's 1999 declaration and trial testimony, Vasotec was manufactured and sold in the United States, no later than January 1986 (Brenner 136:18-137:2; 140:14-141:11), and the commercial manufacture of the Vasotec tablets could not have been accomplished without utilizing the Vasotec Process. Schwartz 269:5-12. This date is prior to the earliest possible invention date of the '450 patent.[12] The Vasotec Process thus satisfies the additional requirements of § 102(g)(2).

4. Merck Did Not Abandon, Suppress, or Conceal the Vasotec Process.

A prior invention's status as prior art that is otherwise eligible under § 102(g)(2) may be negated under certain circumstances if the inventor is found to have abandoned, suppressed, or concealed the invention. Abandonment, suppression, and concealment occurs if the inventor, within a reasonable time after first making the invention, fails to: (1) file a patent application; (2) describe the invention in a published document; or (3) use the invention publicly. *Dow Chem.*, 267 F.3d at 1342.

[12] It is not apparent from the trial testimony and admitted evidence exactly when in the second half of 1986 Warner-Lambert believes the process recited in claims 16 and 17 of the '450 patent was invented. Nonetheless, it is undisputed that this alleged invention took place ***after*** Merck's introduction of Vasotec in the U.S. in January 1986 and therefore after the Vasotec Process was practiced in the U.S.

a. Six Merck-Related References Disclose Every Limitation of Claims 16 and 17 of the '450 Patent.

To the extent that the Court finds Merck ever abandoned, suppressed, or concealed the knowledge of the Vasotec Process from the public — and Teva asserts that Merck did not do so — Merck rectified that action by the publication of six Merck-related references in 1985 and 1986. These references are: (1) two 1985 non-U.S. references disclosing the starting ingredients of Vasotec; (2) a 1985 article published by a Merck scientist in *Analytica Chimica Acta* discussing the cyclization of enalapril; (3) the publicly-available package insert accompanying Vasotec in the U.S.; and (4) two 1986 articles published by Merck scientists in *Drug Development & Industrial Pharmacy*.

- ***Dictionnaire Vidal* and *Pharmaceutisch Weekblad***

In 1985, Merck disclosed in the French publication, *Dictionnaire Vidal*, and the Dutch publication, *Pharmaceutisch Weekblad* that Renitec (Merck's name for the European version of Vasotec, Brenner 131:15-19)[13] contained the excipients lactose and sodium bicarbonate. DTX 256; DTX 255; Schwartz 222:25-225:3.

[13] Also in 1985, Heinrich Koch published an article discussing Merck's enalapril product, relying on published Merck references, indicating that it is marked under the trade names "Renitec," "Reniten," and "Vasotec." The Koch article provides information about the properties of the active ingredient in Vasotec. DTX 253.

- **Kato**

Also in 1985, Toshihiro Kato of Nippon Merck-Banyu Co. in Japan published an article that in its first paragraph discloses that enalapril is susceptible to cyclization. DTX 261; Schwartz 227:24-229:3.

- **Vasotec package insert**

The FDA approved Vasotec in December 1985, and Merck launched Vasotec in the U.S. in January 1986. DTX 134, at MCK 16023; Brenner 134:4-25. On January 20, 1986, a copy of Merck's package insert for Vasotec in the U.S. was distributed to Warner-Lambert's quinapril team. DTX 117. The package insert, which was distributed with Vasotec prescribed to patients and was therefore publicly available, stated: "In addition to the active ingredient enalapril maleate, each tablet contains the following inactive ingredients: iron oxides, lactose, magnesium stearate, starch, and other ingredients." DTX 117, at WL 74412.

- **Bohidar et al. and Shiromani et al.**

In 1986, Merck scientists published two articles in *Drug Development & Industrial Pharmacy* discussing Merck's work on the formulation of Vasotec. The first article, Bohidar et al., disclosed that sodium bicarbonate can be used to prevent cyclization of a drug substance known to cyclize at low pH. DTX 259, at TP 50711. This article did not specify the drug that was being studied.

The second article, Shiromani et al., disclosed that enalapril is susceptible to cyclization. DTX 38, at WL 30576. Shiromani et al. further disclosed the optimum conditions for the storage of the tablets and the bulk material so as to minimize this cyclization. DTX 38, at WL 30582.

Because the two common authors of both articles are identified as working for Merck and the two articles discuss the same dosage strengths and wet granulation preparation methods, one of skill in the art would conclude that Bohidar et al. refers to enalapril maleate, Schwartz 263:7-264:23, as Dr. Murthy and his colleagues, all persons skilled in the art of pharmaceutical formulation, did conclude.

Taken together, the six Merck-related references disclose the following:

- That Vasotec includes lactose and sodium bicarbonate as starting ingredients (*Dictionnaire Vidal, Pharmaceutisch Weekblad*);
- That enalapril, the active ingredient in Vasotec, was susceptible to cyclization (Kato, Bohidar et al., Shiromani et al.);
- That enalapril, lactose, and sodium bicarbonate were mixed together to form Vasotec (*Dictionnaire Vidal, Pharmaceutisch Weekblad*, Vasotec package insert);
- That sodium bicarbonate in Vasotec serves to stabilize the formulation against cyclization (*Dictionnaire Vidal, Pharmaceutisch Weekblad;* Bohidar et al.); and

- That any cyclization in Vasotec was sufficiently inhibited so as to achieve FDA approval (Vasotec package insert and/or product).[14]

Accordingly, by the time the alleged invention of the '450 patent took place, Merck had already disclosed to the public each limitation of claims 16 and 17 of that patent.[15]

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[14] Even if the Court disagrees and determines that an earlier invention date disqualifies Bohidar et al. and Shiromani et al., the other four Merck publications — Kato, *Dictionnaire Vidal*, *Pharmaceutisch Weekblad*, and the Vasotec package insert — taken together reveal all limitations of claims 16 and 17 of the '450 patent. Thus, they establish that Merck did not abandon, suppress, or conceal the Vasotec Process.

[15] This finding is further bolstered when the references are combined with the knowledge of one of ordinary skill in the art. A person of ordinary skill with a list of ingredients (*e.g, Dictionnaire Vidal, Pharmaceutisch Weekblad*) and the Vasotec tablet would know, by the presence of starch in the formulation, that a wet granulation was suggested. Schwartz 268:20-25. That person could easily ascertain the proper amount of sodium bicarbonate to use during manufacture by measuring the pH of a slurry of a Vasotec tablet in water ("target pH"). Schwartz 246:21-248:2. Armed with knowledge of this target pH and the dosage strength of the tablet (*i.e.*, 5 mg), it would have been a simple exercise to add increasing amounts of sodium bicarbonate to a wet granulation containing the relevant dosage strength of enalapril until the target pH for that dosage strength was achieved. Schwartz 248:12-250:3. The '450 patent does not suggest that knowledge of precise amounts of any of the starting ingredients is necessary to achieve a stable formulation. However, to the extent a person of skill in the art required these amounts, they would have been readily ascertained by reverse engineering the commercial Vasotec tablet. Schwartz 268:12-15. A formulation having the target pH and prepared from a wet mixture containing the proper ratio of sodium bicarbonate to enalapril would necessarily be stable. Schwartz 248:12-250:3; 269:1-4.

b. All Six Merck References Should be Considered to Demonstrate that Merck Did Not Abandon, Suppress, or Conceal the Vasotec Process.

Where the patent challenger (*i.e.*, Teva) proves "resumed activity" of the prior inventor (*i.e.*, Merck) before the ***invention date*** of the patent at issue, the prior inventor cannot be deemed to have abandoned, suppressed, or concealed the invention within the meaning of § 102(g)(2). *Paulik v. Rizkalla*, 760 F.2d 1270, 1275-76 (Fed. Cir. 1985). Accordingly, if the Court finds that the invention date of claims 16 and 17 occurred prior to September 1986, then Bohidar et al. and Shiromani et al. — which were published after September 1986 — may not be considered when determining whether Merck abandoned, suppressed, or concealed the Vasotec Process under § 102(g)(2). However, Warner-Lambert failed to prove the earlier invention date.

The invention date of patent claim is presumed to be the filing date of the patent application — in this case, February 24, 1987. *See Mahurkar v. C.R. Bard Inc.*, 79 F.3d 1572, 1576-77 (Fed. Cir. 1996). A patentee relying on an earlier date of invention must show earlier conception before that filing date. *See id.* at 1577. The showing must include independent corroboration of the alleged prior conception. *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1371 (Fed. Cir. 1998). The patentee bears the burden of production on this issue. *Innovative Scuba Concepts, Inc. v. Feder Industries, Inc.*, 26 F.3d 1112, 1115 (Fed. Cir. 1994). Warner-Lambert failed to meet that burden.

Conception requires that an invention must be sufficiently complete to enable one of ordinary skill in the art to reduce the invention to practice without undue experimentation. *Slip Track Sys. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1262-63 (Fed. Cir. 2002). This Court determined in its claim construction that a drug product must be stable in accordance with generally understood guidelines in existence in 1987 that would meet the requirements for FDA approval. Cl. Const. Order, at 1.[16] Although Dr. Harris recounted details about the development at Warner-Lambert that led to the filing of the '450 patent application, he never established that a stable formulation in accordance with these guidelines existed prior to the filing of that application. Nor did Warner-Lambert present any corroboration of Dr. Harris' testimony. To establish an invention date earlier than the filing date, inventor testimony alone is not enough. *Woodland*, 148 F.3d at 1371. Warner-Lambert's failure to meet its burden of production to establish an earlier conception of its alleged invention means that the invention date for the '450 patent is its filing date — February 24, 1987.

c. Dr. Brenner's Testimony Does Not Negate a Finding that Merck Did Not Abandon, Suppress, or Conceal the Vasotec Process.

Warner-Lambert may attempt to support a finding of abandonment, suppression or concealment by way of Dr. Brenner's testimony that Merck

[16] Indeed, this is the claim construction that Warner-Lambert urged.

intended to keep the details about Vasotec a trade secret and did not file for a patent application on the Vasotec Process. Brenner 157:12-158:20. Nonetheless, the fact that the prior inventors intended to keep their invention a secret "does not necessarily mean [that the court] must conclude that the work is concealed or suppressed." *Oak Indus. v. Zenith Elecs.*, 726 F. Supp. 1525, 1535 (N.D. Ill. 1989) (*citing E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1436 n.5 (Fed. Cir. 1988)). Nor is it necessary for a prior inventor to file a patent application on an invention for that invention to retain its status as prior art under § 102(g)(2). *See Checkpoint Sys. v. United States Int'l Trade Comm'n*, 54 F.3d 756, 763 (Fed. Cir. 1993).

Dr. Brenner's testimony does not support the proposition that Merck abandoned or suppressed Warner-Lambert's ***claimed invention***. Dr. Brenner described Merck's attempt to protect the confidentiality of proprietary "know-how" concerning the way Merck solved a number of difficulties encountered in its commercialization of Vasotec — the type of mixing equipment, the duration of mixing, the temperature of mixing, the holding time of the mixer before drying of the wet granulation, and the particle size of the sodium bicarbonate. Brenner 617:8-16.

But this "know-how" is not the invention. ***Not one*** of the factors discussed by Dr. Brenner is even mentioned, much less claimed in the '450 patent. DTX 1;

Brenner 637:23-648:17. Indeed, claims 16 and 17 do not recite ***any*** particular method of stabilization against cyclization beyond the mixing of sodium bicarbonate, lactose, and enalapril.[17]

Thus, even if the Court credits Dr. Brenner's testimony that Merck kept certain ***manufacturing details*** about Vasotec a trade secret for many years, it should find based on the uncontested evidence that Merck disclosed the ***basic mechanism*** of the Vasotec Process — all that is claimed in the '450 patent — through at least Kato, *Dictionnaire Vidal*, *Pharmaceutisch Weekblad*, and the Vasotec package insert. Merck published enough information to disclose the process claimed in the '450 patent. Merck did not abandon, suppress, or conceal the Vasotec Process by 1986.[18] The Vasotec Process anticipates claims 16 and 17 of the '450 patent under 35 U.S.C. § 102(g).

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[17] Warner-Lambert cannot have it both ways. If all of the details discussed by Dr. Brenner are vital to claims 16 and 17 of the '450 patent — none of which are in the patent — those claims are invalid under 35 U.S.C. § 112, ¶ 1, which requires the patent to "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same."

[18] In a similar, but not identical case, the Federal Circuit found that a combination of disclosures similar to what Teva relies upon in this case was sufficient to rebut a finding of abandonment, suppression and concealment. *Apotex v. Merck*, 253 F.3d 1031, 1040 (Fed. Cir. 2001).

B. Claims 16 and 17 Are Invalid Because They Are Obvious in View of the Prior Art

An invention is invalid if "the difference between the new thing and what was known before is not considered sufficiently great to warrant a patent." *Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966). This requirement is codified in 35 U.S.C. § 103, which provides that an invention is not patentable if it "would have been obvious at the time the invention was made to a person having ordinary skill in the art." To the extent that the Court finds any deficiency in the prior-art Vasotec Process for anticipation under 35 U.S.C. § 102(g)(2), then a ruling of obviousness is appropriate here. Any difference between the claimed invention and the prior art is so limited that it cannot be an "invention."

To determine whether a claimed invention is merely an obvious variation of what was already known, the Court must determine what was known at the time the patent holder filed his patent application ("the scope and content of the prior art"), and must assess the difference between the patented invention and this prior knowledge. *See Graham*, 383 U.S. at 17; *In re Huang*, 100 F.3d 135, 138 (Fed. Cir. 1996).

The controlling case law of the Federal Circuit sets forth the test for determining obviousness under 35 U.S.C. § 103. A claimed invention is obvious if there is something in the prior art as a whole to suggest making the claimed combination to one of ordinary skill in the art. *See Merck & Co. v. Biocraft Labs.*,

874 F.2d 804, 809 (Fed. Cir. 1989). Even an implied suggestion to make the claimed invention invalidates the patent. *See In re GPAC Inc.*, 57 F.3d 1573, 1581-82 (Fed. Cir. 1995).

The prior art rarely contains an explicit suggestion to make the claimed invention. In the few cases in which it does, the conclusion of obviousness is virtually unavoidable. *See, e.g., In re Larson*, 340 F.2d 965, 969 (C.C.P.A. 1965). This is such a case. Numerous references ***expressly*** teach, illustrate and suggest the alleged invention recited in claims 16 and 17 of the '450 patent.

1. The Prior Art Includes *Dictionnaire Vidal*, *Pharmaceutisch Weekblad*, Kato, the Vasotec Package Insert, Bohidar et al., and Shiromani et al.

The Supreme Court has set forth four factors that are relevant to the conclusion of obviousness: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) other secondary considerations. *Graham*, 383 U.S. at 17-18.

The first *Graham* factor to be considered is the scope and content of the prior art. *Graham*, 383 U.S. at 17. References to be considered in an obviousness inquiry include art under 35 U.S.C. § 102(a), which provides that "the invention was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the

applicant for patent." 35 U.S.C. § 102(a). The relevant public to whom § 102(a) prior knowledge or use must be accessible is comprised of those persons concerned with the art to which the prior knowledge relates. *Cooper Cameron Corp. v. Kvaerner Oilfield Prods.*, 291 F.3d 1317, 1324 (Fed. Cir. 2002).

Here, the earliest four of the six prior art references — *Dictionnaire Vidal*, *Pharmaceutisch Weekblad*, Kato, and the Vasotec package insert — were publicly available even before the earliest invention date that Warner-Lambert has advocated for the '450 patent. These four references are indisputably prior art because they were "described in a printed publication in this or a foreign country" prior to the earliest possible invention date of the '450 patent. *See* 35 U.S.C. § 102(a). And if, as Teva argues above, Warner-Lambert cannot demonstrate that the invention date of the '450 patent was before the filing date of the '450 patent, Bohidar et al. and Shiromani et al. are also prior art because these references were published before the filing date of the '450 patent.[19]

2. The Prior Art Expressly Urges Persons Skilled in the Art to Make and Use the Combination that Warner-Lambert Later Claimed as an Invention.

The second *Graham* factor focuses on the differences between the claimed invention and the prior art. *Graham*, 383 U.S. at 17. To do so, the decision-maker

[19] These six references are the same six references discussed above regarding abandonment, suppression, and concealment.

must first construe the patent claims at issue. *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1355 (Fed. Cir. 2000). The claimed subject matter as a whole is then compared with the prior art. *Id.*

As demonstrated in the chart below, the prior art references disclose each and every limitation of the features recited in claims 16 and 17 of the '450 patent.

Claim Terms of the '450 Patent	Claim Construction	Disclosure in the Prior Art
16. A process for stabilizing an ACE inhibitor drug against cyclization which comprises the step of contacting the drug with:	"a process for stabilizing . . . means a method of making a pharmaceutical dosage form of an ACE inhibitor in which cyclization has been inhibited." Cl. Const. Order, at 2. "to inhibit cyclization . . . means reducing cyclization . . . to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval." Cl. Const. Order, at 1. "the step of contacting the drug" means "mixing the components with one another." Cl. Const. Stip., at 4.	Kato discloses that enalapril is subject to cyclization. The Vasotec package insert discloses the existence of an FDA-approved, stable ACE inhibitor formulation that was manufactured by the mixing of enalapril maleate and excipients. Schwartz 268:3-6. These references can be combined by one skilled in the art to disclose this limitation. Schwartz 269:13-17; 269:5-12.

Claim Terms of the '450 Patent	Claim Construction	Disclosure in the Prior Art
(a) a suitable amount of an alkali or alkaline earth-metal carbonate and,	"a suitable amount" means "an amount sufficient to inhibit cyclization." Cl. Const. Stip., at 4. "an alkali or alkaline earth metal carbonate" means the salt of an alkali metal or alkaline earth metal cation, and a carbonate $(CO_3)^{-2}$ anion or a bicarbonate $(HCO_3)^{-1}$ anion. Fed. Cir. Op., at 11.	Because the Vasotec package insert discloses the existence of an FDA-approved stable enalapril maleate formulation, cyclization was inhibited. *Dictionnaire Vidal* and *Pharmaceutisch Weekblad* both disclose the presence of sodium bicarbonate — an alkali metal carbonate — in the European version of Vasotec. Once the ingredients of the Vasotec formulation are known, a person of ordinary skill would understand that sodium bicarbonate is the stabilizer of the formulation. Schwartz 230:24-233:15; 269:1-4. These references can be combined by one skilled in the art to disclose this limitation. Schwartz 269:21-25. Also, although the references are not necessary to support a finding of obviousness, Bohidar et al. and Shiromani et al. disclose that sodium bicarbonate inhibits cyclization in the Vasotec formulation.

Claim Terms of the '450 Patent	Claim Construction	Disclosure in the Prior Art
(b) one or more saccharides.	"one or more saccharides . . . means a saccharide or saccharides which are a component of a dosage form of an ACE inhibitor in which cyclization has been inhibited." Cl. Const. Order., at 2.	*Dictionnaire Vidal*, *Pharmaceutisch Weekblad*, and the Vasotec package insert all disclose that Vasotec includes lactose, a saccharide. Schwartz 270:1-4. These references can be combined by one skilled in the art to disclose this limitation. Schwartz 269:5-12; 270:10-14.
17. The process of claim 16 wherein the drug is selected from the group consisting of quinapril, enalapril, and indolapril, or a pharmaceutically acceptable acid addition salt thereof.	No additional terms construed.	The Vasotec package insert discloses that enalapril maleate, a pharmaceutically acceptable acid addition salt of enalapril, is an ACE inhibitor. These references can be combined by one skilled in the art to disclose this limitation. Schwartz 270:10-14.

3. A Person of Ordinary Skill in the Art Would Have Had Access to All Cited Prior Art References.

The third *Graham* factor is the level of skill in the art of a person who would have worked in this area at the time of the invention. *Graham*, 383 U.S. at 17. The level of skill in the art is relevant because the ultimate test of obviousness is whether a person "having ordinary skill in the art" would have considered the

claimed invention to be obvious. 35 U.S.C. § 103. This Court has already defined the level of ordinary skill as:

> a pharmaceutical formulator, that is a person having a working knowledge of drug development and formulation, who has either an advanced degree in pharmaceutics, chemistry or related science with one or more years of industry experience or a bachelor's degree in pharmaceutics, chemistry or a related science and at least five or more years of industry experience or the equivalent.

PTX 235, at 24. Dr. Schwartz adopted this definition in his analysis. Schwartz 207:20-208:7. Dr. Brenner never testified about the level of ordinary skill in the art.

"[A]ll prior art references in the field of the invention are available to this hypothetical skilled artisan." *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). And here, all six prior art references — *Dictionnaire Vidal*, *Pharmaceutisch Weekblad*, Kato, the Vasotec package insert, Bohidar et al., and Shiromani et al. — deal with enalapril explicitly or would be understood as dealing with enalapril. Schwartz 271:13-272:3. Thus, the disclosure of all limitations of claims 16 and 17 in these references render the claims not valid for obviousness. Schwartz 270:18-271:12.[20]

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[20] Dr. Brenner's testimony to the contrary is not credible. He never discussed how the disclosure of Kato would factor into his analysis, leaving Dr. Schwartz's testimony about Kato unrebutted. *Cf. Novo Nordisk A/S v. Becton Dickinson & Co.*, 304 F.3d 1216, 1219 (Fed. Cir. 2002) (crediting unrebutted expert testimony in an obviousness analysis); *Minton v. Nat'l Assoc. of Securities Dealers, Inc.*, 226 F. Supp. 2d 845, 879 (E.D. Tex. 2002) (same).

4. No Evidence of Secondary Considerations Can Overcome the Explicit Teaching of the Prior Art.

The prior art establishes a *prima facie* case that the alleged invention of claims 16 and 17 of the '450 patent was obvious. Warner-Lambert has the burden of presenting any evidence of "secondary considerations" — the fourth *Graham* factor — it believes shows that the claimed invention would not have been obvious to one skilled in the art. Warner-Lambert tried to argue that Accupril's commercial success resulted from the merits of the claimed invention. *See Graham*, 383 U.S. at 17-18.

For commercial success to have true relevance, however, that success must be shown to have been due to the claimed invention, as opposed to other economic and commercial factors unrelated to the patented characteristics of the successful product. Thus, a nexus is required between the merits of the claimed invention and the evidence offered of commercial success, if that evidence is to be given substantial weight. *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1370 (Fed. Cir. 2003). Such a nexus might be presumed where, as here, Warner-Lambert's commercial-success witness Dr. Harris testified that the '450 patent covers Accupril and that Accupril was commercially successful. Harris 78:7-79:23; *see also Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d. 1120, 1130 (Fed. Cir. 2000). But to the extent that the any such presumption arises, Teva clearly rebutted it.

At trial, Teva offered the testimony of Dr. Iain Cockburn, a Professor of Economics at Boston University. DTX 315. To reach his conclusions, Dr. Cockburn:

- designed an econometric model to analyze prescriptions of ACE inhibitors (Cockburn 552:25-556:13);
- reviewed ACE inhibitor product advertisements in the appropriate medical journals (Cockburn 557:6-561:19; DTX 195); and
- reviewed internal Warner-Lambert Accupril planning documents and training materials. Cockburn 561:20-562:23.

In sharp contrast, Dr. Harris — who has no personal experience in sales or marketing — did none of those things. Harris 118:8-23.

Dr. Cockburn concluded that the success of Accupril reflects standard factors such as pricing, promotion, and pharmacological characteristics of the active ingredient, the very factors that Warner-Lambert itself identified at its 30(b)(6) deposition. Cockburn 563:13-565:10. The invention described in the patent — which relates to the stability of Accupril — had no effect on the commercial success and sales of Accupril. Cockburn 550:14-21. The fact that Accupril was stable enough for FDA approval is a wash in the commercial success analysis because, without exception, all FDA-reviewed drugs must be that stable in order to be sold in the U.S. Cockburn 578:6-16. As Dr. Harris acknowledged, satisfying the FDA's stability requirements gave Accupril no competitive advantage whatsoever. Harris 118:24-119:15. Therefore the '450 patent has no

nexus with the commercial success of the product. The *sine qua non* of commercializing a product cannot be the ***cause*** of its commercial success — or, indeed, its failure.

Dr. Cockburn's essentially unrebutted conclusions negate any nexus between Accupril's commercial success and the '450 patent and confirm a finding that claims 16 and 17 of the '450 patent are obvious in view of the prior art.[21]

[21] Warner-Lambert offered no evidence at trial about copying, another secondary consideration for obviousness. In any event, a showing of copying is only equivocal evidence of obviousness in the absence of more compelling objective indicia of other secondary considerations. *In re GPAC*, 57 F.3d at 1580. Here, Teva did not copy the '450 patent. Instead, as this Court has found, Teva looked to the Accupril tablets themselves during its development work. S.J. Op., at 11. Teva's goal was to create a drug that was bioequivalent to Accupril, as required by the FDA's statutory scheme.

CONCLUSION

For the reasons stated above, this Court should find that: (1) the '450 patent is unenforceable due to Warner-Lambert's inequitable conduct before the PTO; and (2) claims 16 and 17 are invalid in view of the prior art.

Respectfully submitted,

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