

United States Court of Appeals for the Federal Circuit

03-1013

GLAXO WELLCOME, INC.,

Plaintiff-Appellant,

v.

IMPAX LABORATORIES, INC.,

Defendant-Appellee.

Stephen B. Judlowe, Morgan Lewis & Bockius LLP, of New York, New York, argued for plaintiff-appellant. With him on the brief were Dennis J. Mondolino, Jason A. Lief, and Timothy P. Heaton.

Steven J. Lee, Kenyon & Kenyon, of New York, New York, argued for defendant-appellee.

Appealed from: The United States District Court for the Northern District of California

Chief Judge Marilyn Hall Patel

United States Court of Appeals for the Federal Circuit

03-1013

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Plaintiff-Appellant,

v.

IMPAX LABORATORIES, INC.,

Defendant-Appellee.

DECIDED: January 29, 2004

Before RADER, Circuit Judge, PLAGER, Senior Circuit Judge, and GAJARSA, Circuit Judge.

RADER, Circuit Judge.

Glaxo Wellcome, Inc. (Glaxo) appeals the summary judgment finding of non infringement of its patent claims relating to a controlled sustained release formulation of bupropion hydrochloride. Glaxo Wellcome, Inc. v. Impax Labs., Inc., 220 F. Supp. 2d 1089 (N.D. Cal. 2002). Because Glaxo cannot prove infringement literally or under the doctrine of equivalents, this court affirms the United States District Court for the Northern District of California.

I.

Glaxo owns U.S. Patent No. 5,427,798 (the '798 patent) directed to controlled sustained release tablets containing bupropion hydrochloride. Pharmacologically, bupropion (m-chloro- α -t-butylaminopropiophenone) is a monocyclic aminoketone antidepressant. See U.S. Patent No. 4,393,078

(issued July 12, 1983) (the '078 patent). These compounds treat depression and inebriation. In addition, they facilitate the cessation of smoking by producing neural stimulation in mammalian systems. See '798 patent, col. 1, ll. 5-10; '078 patent, col. 1, ll. 29-39; U.S. Patent No. 3,819,706 (issued June 23, 1974). Due to this action as a stimulant, a spike in bupropion concentrations can have the side effect of causing seizures. '798 patent, col. 1, ll. 15-25.

To avoid the need for multiple dosages with the attendant fluctuations in plasma bupropion concentrations, Glaxo invented a sustained release formulation of the compound. While bupropion hydrochloride itself was separately patented, Glaxo obtained the '798 patent to protect its sustained release formulation of the drug. Glaxo markets this patented sustained release formulation as Wellbutrin[®]SR for treatment of depression and as Zyban[®] for smoking cessation. The key ingredient for achieving sustained release in this invention is hydroxypropyl methylcellulose (HPMC), which is a partly *O*-methylated and *O*-(2-hydroxypropylated) cellulose. In oral preparations, HPMC extends drug release by transforming into a gel that swells upon ingestion. The hydrogel state of HPMC releases bupropion hydrochloride from an ingested tablet over a period of time.

The '798 patent claims a sustained release tablet containing an admixture of bupropion hydrochloride and HPMC. However, many of the claims as originally filed did not recite HPMC as a limitation. During prosecution on the merits in the United States Patent and Trademark Office (Patent Office), the examiner rejected the claims that did not recite HPMC for lack of enablement under 35 U.S.C. § 112, ¶ 1. Glaxo amended those claims to overcome the rejection. The exemplary independent claims[1] of the '798 patent state:

1. A controlled release tablet comprising 25 to 500 mg of bupropion hydrochloride and hydroxypropyl methylcellulose, the amount of hydroxypropyl methylcellulose to one part bupropion hydrochloride being 0.19 to 1.1 and said tablet having a surface to volume ratio of 3:1 to 25:1 cm⁻¹ and said tablet having a shelf life of at least one year at 59° to 77° F. and 35 to 60% relative humidity, said tablet releasing between about 20 and 60 percent of bupropion hydrochloride in water in 1 hour, between about 50 and 90 percent in 4 hours and not less than about 75 percent less in 8 hours.

14. A controlled sustained release tablet comprising an admixture of 100 mg of bupropion hydrochloride and hydroxypropyl methylcellulose which after oral administration of a single one of said tablets in adult men produces plasma levels of bupropion as free base ranging between the minimum and maximum levels as shown in Fig. 5 over twenty four hours.

18. A sustained release tablet containing a mixture of (a) 100 mg of bupropion hydrochloride and (b) means for releasing between about 25 and 45% of bupropion hydrochloride in one hour, between 60 and 85% in 4 hours and not less than 80% in eight hours in distilled water said means comprising hydroxypropyl methylcellulose.

'798 patent, col. 11, l. 40 – col. 12, l. 60 (emphases added).

Impax Laboratories, Inc. (Impax), a manufacturer of generic pharmaceuticals, filed two Abbreviated New Drug Applications (ANDAs) with the United States Food and Drug Administration (FDA), one proposing a generic substitute for Wellbutrin[®]SR, and the other proposing a generic substitute for Zyban[®]. In both ANDAs, Impax made a paragraph IV certification that its generic sustained release bupropion hydrochloride tablets do not infringe Glaxo's '798 patent. The sustained release agent in Impax's proposed composition is hydroxypropyl cellulose (HPC), a hydrogel-forming compound. Glaxo, upon receiving notice of Impax's ANDA filings, commenced infringement actions in California, alleging infringement of claims 1, 14-15, and 18-19 of the '798 patent and seeking an injunction to enjoin further infringing actions.

During litigation, Impax moved for summary judgment of noninfringement on the basis of prosecution history estoppel. Glaxo opposed and filed its own motion for summary judgment. The district judge found that "[t]he amendments indisputably narrowed the patent with respect to sustained release." Glaxo, 220 F. Supp. 2d at 1094. The trial court further noted: "At the time of the disputed amendments, anyone skilled in the art would have known that HPC and HPMC were substantially equivalent. Neither party appears to challenge this equivalency." Id. Therefore, the district court granted Impax's motion for summary judgment of noninfringement.

Glaxo timely appealed to this court. Glaxo argues the district court erred in granting summary judgment because HPC is an infringing equivalent of HPMC. Glaxo further contends that it did not surrender HPMC equivalents during prosecution of the '798 claims. This court has exclusive jurisdiction under 28 U.S.C. § 1295(a)(1).

II.

This court reviews summary judgment without deference, drawing all reasonable factual

inferences in favor of the nonmoving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986); Johns Hopkins Univ. v. Cellpro, Inc., 152 F.3d 1342, 1353 (Fed. Cir. 1998). This court reviews infringement, either literal or by equivalents, as a question of fact. RF Del., Inc. v. Pac. Keystone Techs., Inc., 326 F.3d 1255, 1266 (Fed. Cir. 2003). Prosecution history estoppel as a limit on the doctrine of equivalents presents a question of law. Wang Labs., Inc. v. Mitsubishi Elecs. Am., Inc., 103 F.3d 1571, 1578 (Fed. Cir. 1997). Thus, Impax is entitled to summary judgment only if the facts and inferences, when viewed in the light most favorable to Glaxo, would not persuade a reasonable jury to return a verdict for Glaxo, the nonmoving party. Anderson, 477 U.S. at 255.

A. Narrowing Amendment

Impax does not literally infringe the '798 patent because HPMC, a recited claim limitation, is not present in its sustained release bupropion formulation. Instead, Glaxo seeks a judgment of infringement under the doctrine of equivalents. Therefore, infringement depends on whether the prosecution history of the '798 patent forecloses Glaxo's reliance on the doctrine of equivalents. Specifically this court must examine whether Glaxo narrowed claims 14-15 and 18-19 of the '798 patent during prosecution, thereby presumptively surrendering the territory that embraces Impax's sustained release agent.

According to the Supreme Court in Festo, "a narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 736 (2002) (Festo VIII). Such a narrowing amendment, whether made to avoid prior art or to comply with § 112, creates a presumption that the patentee surrendered the territory between the original claims and the amended claims. Id. at 741. The patentee may rebut that presumption by showing that the alleged equivalent could not reasonably have been described at the time the amendment was made, or that the alleged equivalent was tangential to the purpose of the amendment, or that the equivalent was not foreseeable (and thus not claimable) at the time of the amendment. Id. at 740-41. This court has recently acknowledged and applied these rebutting criteria. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 344 F.3d 1359 (Fed. Cir. 2003) (Festo IX).

Glaxo amended claims 14-15 and 18-19 of the '798 patent to recite HPMC. Glaxo's application

did not disclose any other sustained release mechanism. Therefore, Glaxo's disclosure of HPMC alone could not support a broad generic claim to other sustained release mechanisms. Nonetheless Glaxo contends that this amendment did not surrender other hydrogels equivalent to HPMC. Rather, Glaxo contends that it only added HPMC to the claims to distinguish the sustained release agent in its invention from other disclosed excipients in the application.

The examiner rejected originally filed claims 14-15 and 18-19 of the '798 patent for lack of enablement. The application claimed controlled sustained release tablets with particular plasma concentration profiles over twenty-four hours and specific bupropion release rates. The application, however, did not recite the release mechanism responsible for these profiles. The disclosed rate of release, according to the examiner, distinguished the claimed "unique tablet" from instant release tablets known in the art. The examiner stated that bupropion's rate of release is "directly related to the release retarding affect [sic] of hydroxypropylmethylcellulose." Thus, the examiner considered the recitation of HPMC "critical" for the controlled or sustained release aspect of the claims. The examiner also noted that the application's disclosure of a single species (HPMC) does not support claims to a "generic concept."

The examiner did not require the recitation of HPMC to distinguish the claims from other disclosed excipients. Those excipients had no bearing on the patentability of the claimed sustained release tablets over conventional instant release tablets. Rather, the examiner required Glaxo to restrict the claims to a particular controlled drug release agent, i.e., HPMC. The claims as originally written embraced all controlled sustained release tablets comprising bupropion hydrochloride. The application did not enable any sustained release agents other than HPMC, however, because it only disclosed HPMC's time release and plasma profiles. Indeed the original claims recited those profiles. The examiner expressly stated that only HPMC enabled claims with these profiles. The application did not enable one of skill in the art to make and use a broader genus of sustained release agents. Thus, the examiner's enablement argument, which Glaxo did not rebut, shows that Glaxo surrendered other controlled sustained release agents known to act as equivalents of HPMC. Festo, 535 U.S. at 734 ("A rejection indicates that the patent examiner does not believe the original claim could be patented. While

the patentee has the right to appeal, his decision to forgo an appeal and submit an amended claim is taken as a concession that the invention as patented does not reach as far as the original claim.”).

Glaxo also contends that claims 14-15 were not narrowed upon amendment because the amendment consisted of removing the originally recited “shelf life” limitation and replacing it with the sustained release HPMC limitation. Glaxo, relying on Lockheed, states that while the “overall scope” of these claims was “surely narrowed,” the HPMC limitation itself was never narrowed by amendment because it was added while a completely unrelated limitation was deleted. See Lockheed Martin Corp. v. Space Sys./Loral Inc., 249 F.3d 1314, 1327 (Fed. Cir. 2001) (affirming the district court’s finding that prosecution history estoppel barred the application of the doctrine of equivalents), vacated by 535 U.S. 1109 (2002), remanded to 324 F.3d 1308, 1321 (Fed. Cir. 2003).

To the contrary, the examiner explained that the original claims broadly embraced a genus of sustained release compounds. Because the claims did not enable use of that broader genus, the examiner required an amendment. The “sustained release tablet” phrase recited in the preamble gives life and meaning to the claims, because sustained release is an essential feature of the invention. Generally, “a preamble limits the [claimed] invention if it recites essential structure or steps, or if it is ‘necessary to give life, meaning, and vitality’ to the claim.” Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002). Thus, the amendment did not simply replace the shelf life limitation with an entirely new HPMC limitation. Rather, the amendment limited the sustained release feature to HPMC, thereby narrowing the claims. The elimination of the shelf life limitation did not affect the question of equivalents and the question of whether the claims embrace sustained release agents beyond HPMC.

B. Rebutting the Presumption

In its Festo decision, the Supreme Court explained that not all narrowing amendments surrender subject matter that the doctrine of equivalents cannot later recapture. The Court noted:

The equivalent may have been unforeseeable at the time of the application; the rationale

underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question. In those cases the patentee can overcome the presumption that prosecution history estoppel bars a finding of equivalence.

Festo VIII, 535 U.S. at 740-41.

This court recently gave more guidance on factors influencing a finding of foreseeability:

This criterion presents an objective inquiry, asking whether the alleged equivalent would have been unforeseeable to one of ordinary skill in the art at the time of the amendment. Usually, if the alleged equivalent represents later-developed technology (e.g., transistors in relation to vacuum tubes, or Velcro[®] in relation to fasteners) or technology that was not known in the relevant art, then it would not have been foreseeable. In contrast, old technology, while not always foreseeable, would more likely have been foreseeable. Indeed, if the alleged equivalent were known in the prior art in the field of the invention, it certainly should have been foreseeable at the time of the amendment. By its very nature, objective unforeseeability depends on underlying factual issues relating to, for example, the state of the art and the understanding of a hypothetical person of ordinary skill in the art at the time of the amendment. Therefore, in determining whether an alleged equivalent would have been unforeseeable, a district court may hear expert testimony and consider other extrinsic evidence relating to the relevant factual inquiries.

Festo IX, 344 F.3d at 1369 (citation omitted).

In this case, Glaxo could not have added HPC as an amendment in 1994 without drawing a new matter rejection; Glaxo had not recited in its application any reference to HPC or other sustained release agents beyond HPMC. Glaxo also notes that the Supreme Court emphasized an applicant's ability to claim an alleged equivalent as a hallmark of the unforeseeability excuse: "The patentee must show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." Festo VIII, 535 U.S. at 741. Because it could not have added HPC to its claims at the time of amendment (without drawing a new matter rejection), Glaxo contends that it has on that basis alone sufficiently rebutted the Festo presumption and justified its invocation of the doctrine of equivalents. For several reasons, Glaxo is incorrect.

In the first place, new matter prohibitions are not directly germane to the doctrine of equivalents or the patentee's proof to overcome the Festo presumption. The new matter doctrine prevents an

applicant from adding new subject matter to the claims unless the specification shows that the inventor had support for the addition at the time of the original filing. See Kolmes v. World Fibers Corp., 107 F.3d 1534, 1539 (Fed. Cir. 1997). Thus, the new matter doctrine ensures the temporal integrity of the amendment process in the Patent Office and does not apply to nontextual infringement. See 35 U.S.C. § 132 (2000); TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co., 264 F.3d 1111, 1118 (Fed. Cir. 2001). In fact, the quintessential example of an enforceable equivalent, after-arising technology, would always be unclaimable new matter. In that sense, the doctrine of equivalents compensates for the patentee's inability to claim unforeseeable new matter.

Glaxo also removes the Supreme Court's passage in Festo VIII from its proper context. The Supreme Court ties foreseeability to whether the applicant would have been expected to know of, and thus properly claim, the proposed equivalent at the time of amendment. The Supreme Court's passage addresses the time of amendment only and does not address the instance where the applicant could not properly claim a known equivalent because it had purposely left that known substitute out of its disclosure at the time of filing. In such an instance, the applicant should have foreseen and included the proposed equivalent in its claims at the time of filing. The Supreme Court states clearly in Festo: "The patentee, as the author of the claim language, may be expected to draft claims encompassing readily known equivalents." 535 U.S. at 740. The Supreme Court excuses an applicant from failure to claim a proposed equivalent in the event "[t]he equivalent may have been unforeseeable at the time of application," id., or, as this court has explained, at the time of the amendment. Festo IX, 344 F.3d at 1365 n.2 ("[T]he time when the narrowing amendment was made . . . is the relevant time for evaluating unforeseeability, for that is when the patentee presumptively surrendered the subject matter in question and it is at that time that foreseeability is relevant."). In any event, read in context, the Supreme Court in Festo neither excuses an applicant from failing to claim "readily known equivalents" at the time of application nor allows a patentee to rebut the Festo presumption by invoking its own failure to include a known equivalent in its original disclosure. Instead, the critical inquiry is whether Glaxo could have foreseen sustained release agents for bupropion other than HPMC at the time of filing or amendment.[2]

On this point, the record shows that at the time the amendments were made, no known hydrogels

other than HPMC had been tested with bupropion hydrochloride to achieve sustained release. Thus, with respect to bupropion alone, a portion of the record might suggest that HPC was not a known sustained release agent at the time of the amendment. The record, however, contains considerable evidence that suggests Glaxo could have described the sustained release compound HPC at the time the '798 patent claims were amended, if not earlier. In this regard, the record shows that both HPMC and HPC were known as sustained release hydrogel-forming polymers in the art of pharmaceutical formulation. For example, a 1994 pharmaceutical handbook teaches that both HPC and HPMC may serve as "an extended release tablet matrix." Handbook of Pharmaceutical Excipients 229 (Ainley Wade & Paul J. Weller eds., 2d ed. 1994). A 1962 patent claimed HPMC as a sustained release agent. U.S. Patent No. 3,065,143 (Nov. 20, 1962). Similarly a 1987 patent claimed HPC as a sustained release agent for a formulation using a solid tablet. U.S. Patent No. 4,704,285 (Nov. 3, 1987).

The record also shows that Glaxo submitted references to the Patent Office in an Information Disclosure Statement that describe HPC, HPMC, and numerous other polymeric compounds as extended release drug formulations. A search result disclosed a prior art reference describing a "controlled release drug delivery device consist[ing] of a matrix core containing the drug and a polymeric material which swells in contact with aqueous fluids such as gastrointestinal juice," wherein the core polymeric material includes, *inter alia*, "hydroxypropyl methyl cellulose, methyl cellulose, polyvinyl alcohol, acrylic copolymers, polyvinyl pyrrolidone, anionic and cationic hydrogels." European Patent 250,374 (dated Dec. 23, 1987). Another cited reference teaches "a buoyant controlled release pharmaceutical formulation" capable of releasing a pharmaceutical "at a controlled rate" due to incorporation of a "hydrocolloid gelling agent," such as "hydroxypropylmethyl cellulose (HPMC), methyl cellulose and/or hydroxypropyl cellulose." U.S. Patent No. 5,169,638 (issued Oct. 23, 1991). Glaxo also submitted excerpts from a 1989 Dow Chemical catalogue that describes agents suitable for sustaining drug release rates, including HPMC and HPC. The catalogue noted HPMC was the preferred agent, as its tighter gel formation permits drug release to be sustained longer than with other cellulose.

These references suggest that Glaxo was aware of these potential hydrogel equivalents at the time of submitting the '798 patent claims and later amending those claims to recite only HPMC. This

court, therefore, discerns from this record that ordinarily skilled artisans at the time would have considered HPC a suitable sustained release agent for bupropion. Indeed this court has scoured the record in vain for any evidence of a verifiable scientific reason that Glaxo would not have considered HPC a suitable sustained release agent for bupropion. As the district court also observed, the record shows only that “anyone skilled in the art [at the relevant time] would have known that HPC and HPMC were substantially equivalent.” Glaxo, 220 F. Supp. 2d at 1094. Accordingly, Glaxo has not rebutted the presumption that prosecution history estoppel bars a finding of infringement under the doctrine of equivalents.

C. Infectious Estoppel

Claim 1 of the '798 patent originally recited HPMC as the sustained release agent for bupropion. Thus, the applicant did not amend the HPMC limitation of claim 1. Because the applicant did not narrow this claim, Glaxo contends that the Festo presumption does not operate to divest claim 1 of its equivalents armor. Thus, Glaxo asserts that the district court erred in removing the doctrine of equivalents from the equation used to evaluate infringement of this claim. According to Glaxo, claim 1 is plagued by “infectious estoppel,” an ailment Glaxo alleges the district court impermissibly imparted on the claim. Glaxo misdiagnoses the legal situation.

Under the law of this circuit, the Festo bar to the doctrine of equivalents applies to all of the '798 claims containing the “critical” HPMC limitation. This court has noted that subject matter surrendered via claim amendments during prosecution is also relinquished for other claims containing the same limitation. Builders Concrete, Inc. v. Bremerton Concrete Prods. Co., 757 F.2d 255, 260 (Fed. Cir. 1985). This court follows this rule to ensure consistent interpretation of the same claim terms in the same patent. In Builders Concrete, the patentee during prosecution surrendered claim scope by amending a claim that it later did not assert against the alleged infringer. Instead the patentee tried to recapture that same surrendered subject matter by asserting a claim that was not amended. This court estopped the patentee from interpreting the unamended claim to encompass the scope that was relinquished in the amended claim. Id. This court noted: “The fact that the ‘passage’ clause of patent claim 10 was not itself amended during prosecution does not mean that it can be extended by the

doctrine of equivalents to cover the precise subject matter that was relinquished in order to obtain allowance of claim 1.” Id. Thus, this court directs consistent interpretation of claim terms within a patent in view of the prosecution history. See also Allen Eng’g Corp. v. Bartell Indus. Inc., 299 F.3d 1336, 1350 (Fed. Cir. 2002). However, the quest for consistency in patent claims also has its limits. Claims that do not recite the amended term are not subject to an estoppel. Fiskars, Inc. v. Hunt Mfg. Co., 221 F.3d 1318, 1322-23 (Fed. Cir. 2000) (“The claims in suit were not amended to add the limitation of the spring in the rail. The district court correctly ruled that the claims in suit are not limited to a device wherein the spring is located in the rail, and that there is no estoppel against equivalency based on the location of the spring.”).

Builders Concrete involved a narrowing amendment and arguments made to overcome a prior art rejection, not a § 112-based rejection. The concept initiated by Builders Concrete, and confirmed by Allen Engineering, is that different claims of a single patent should not be afforded different ranges of equivalents for the same claim term, “absent an unmistakable indication to the contrary.” Am. Permehedge, Inc. v. Barcana, Inc., 105 F.3d 1441, 1446 (Fed. Cir. 1997).

Glaxo asserts that because the patentee did not argue that HPMC is critical to enablement of the ’798 claims, the principles of argument-based estoppel should not apply to any of its claims. Indeed the examiner initiated the arguments giving rise to the estoppel. Prosecution history estoppel, however, is not limited to the applicant’s own words, but may embrace as well the applicant’s responses to the examiner’s actions. If the patentee does not rebut an examiner’s comment or acquiesces to an examiner’s request, the patentee’s unambiguous acts or omissions can create an estoppel.

Here, the examiner rejected for lack of enablement the ’798 patent claims that did not recite HPMC. The applicant amended the claims to include the feature deemed critical to enablement, HPMC, thereby curing the defect. Claim 1 recited the HPMC term upon filing and needed no curing with respect to enablement. No record evidence indicates that the examiner viewed HPMC as less critical to the patentability of claim 1 than its amended counterparts. Because the examiner found this specific hydrogel critical to the enablement of the claimed sustained release bupropion tablets, a broader

construction via equivalents for one claim would create inconsistency within the patent. Therefore, following the logic of Builders Concrete and Allen Engineering, all of the '798 claims are held to the examiner's unrebutted characterization of HPMC as critical. This court affirms the district court on this issue.

D. Summary

Record evidence shows that Glaxo narrowed the scope of claims 14-15 and 18-19 by amendment during prosecution of the '798 patent to recite the critical term HPMC. The reason for making these narrowing amendments was to overcome a rejection for lack of enablement because the claims improperly embraced a genus of sustained release agents. On this record, this court determines there is ample evidence to find that HPC, the asserted equivalent, was a foreseeable sustained release agent for bupropion. Even though claim 1 was not amended to recite HPMC during prosecution, claim 1 will receive the same treatment as claims 14-15 and 18-19.

Glaxo's remaining arguments regarding tangentialness and the alleged retroactivity bar against applying Festo to the instant case have been considered, but are not found persuasive.

COSTS

Each party shall bear its own costs.

AFFIRMED

[1] Independent claims 15 and 19 mirror claims 14 and 18, respectively, but recite 150 mg of bupropion hydrochloride.

[2] Of course, if HPC were a foreseeable equivalent at the time of the amendment but not at the time of the application, Glaxo could have filed a continuation-in-part application to disclose and claim the additional subject matter.