NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

ASTRAZENECA LP AND ASTRAZENECA AB,
Plaintiffs-Appellants,

v.

BREATH LIMITED,
Defendant-Appellee,

AND

APOTEX, INC. AND APOTEX CORP.,
Defendants-Cross Appellants,

AND

SANDOZ INC.,
Defendant-Appellee,

AND

WATSON LABORATORIES, INC.,
Defendant-Appellee.

2013-1312, -1352

Appeals from the United States District Court for the District of New Jersey in No. 11-CV-3626, Judge Renee Marie Bumb.

Decided: October 30, 2013

CHRISTOPHER N. SIPES, Covington & Burling LLP, of Washington, DC, argued for plaintiffs-appellants. With him on the brief were RODERICK R. MCKELVIE and ALI MOJIBI. Of counsel on the brief were JEFFREY M. DAVIDSON and DANIELLE L. GOLDSTEIN, of San Francisco, California. Of counsel were DANIELLE LUCE GOLDSTEIN, Covington & Burling LLP, of San Francisco, California; PABLO D. HENDLER and BRIAN KAO, Ropes & Gray, LLP, of New York, New York; and RICHARD T. MCCAULLEY, JR. and JON M. SPANBAUER, Ropes & Gray LLP, Chicago, Illinois.

RICHARD J. BASILE, St. Onge Steward Johnston & Reens, LLC, of Stamford, Connecticut, argued for defendants-cross appellants. With him on the brief were DAVID W. ALDRICH, BENJAMIN J. LEHBERGER and ALYSON J. DILENA.

WILLIAM A. RAKOCZY, Rakoczy, Molino Massochi Siwik LLP, of Chicago, Illinois, argued for all defendants-appellees. With him on the brief was AMY D. BRODY for defendants-appellees Watson Laboratories, Inc. and Breath Limited. Of counsel on the brief were MEREDITH MARTIN ADDY, TARAS A. GRACEY and MARK H. REMUS, Steptoe & Johnson LLP, of Chicago, Illinois for defendant-appellee Sandoz, Inc.

Before RADER, *Chief Judge,* BRYSON, and LINN, *Circuit Judges.*

LINN, *Circuit Judge.*

AstraZeneca LP and AstraZeneca AB ("AstraZeneca") appeal the district court's judgment following a bench trial, holding that the asserted claims of AstraZeneca's U.S. Patent No. 7,524,834 ("'834 Patent") were not infringed and that the asserted claims of U.S. Patent No. 6,598,603 ("'603 Patent") were invalid as anticipated and obvious, thus ruling in favor of the defendants Breath Limited ("Breath"); Apotex, Inc. and Apotex Corp. ("Apotex"); Sandoz, Inc. ("Sandoz"); and Watson Laboratories, Inc. ("Watson") (collectively "Appellees"). Opinion, *AstraZeneca LP v. Breath Ltd.*, No. 08-1512, 2013 WL 1385224 (D.N.J. Apr. 3, 2013) ("*Opinion*") *amended*, Opinion, No. 08-1512, 2013 WL 2404167 (D.N.J. May 31, 2013) ("*Amendment*"). Apotex cross-appeals the district court's dismissal of its counterclaim of invalidity of certain claims of the '603 Patent, *Amendment*, and the district court's decisions to limit Apotex's recovery with respect to the bond amount, Trial Transcript, *AstraZeneca LP v. Breath Ltd.*, No. 08-1512 (D.N.J. Nov. 8, 2012), *in* J.A. 37304–16. This court reverses and remands on the '834 Patent based on the district court's incorrect claim construction. This court affirms the district court with respect to the finding of obviousness of the asserted claims of the '603 Patent, the dismissal of Apotex's invalidity counterclaim as to other claims, and the decisions regarding the bond amount.

I. BACKGROUND

A. The '834 Patent

The '834 Patent covers a sterile, pharmaceutically effective budesonide product, which is used to treat asthma in children. Claim 1 states:

> 1. A pharmaceutically acceptable *micronized powder composition* at least 98.5% by weight of which is pure budesonide or an ester, acetal or salt thereof, wherein the composition meets the criteria of sterility according to the US Pharmacopoeia [sic] 23/NF18, 1995, pages 1686-1690 and 1963-1975.

'834 Patent col. 11 ll. 48–52 (emphasis added). Claim 50 is similar, but is directed to a suspension including a powder:

> 50. A pharmaceutically acceptable suspension consisting of a *micronized powder composition* at least 98.5% by weight of which is pure budesonide or an ester, acetal or salt thereof suspended in an aqueous solution, wherein the suspension meets the criteria of sterility according to the US Pharmacopoeia [sic] 23/NFl8, 1995, pages 1686-1690 and 1963-1975.

Id. at col. 13 ll. 55–60 (emphasis added). Claims 2 and 51 depend from claims 1 and 50, respectively, and limit the claimed drug to budesonide.

B. The '603 Patent

The '603 Patent is directed to a once-daily treatment of patients with budesonide administered by nebulizer. Claim 1 is the only asserted independent claim at issue:

> 1. A method of treating a patient suffering from a respiratory disease, the method comprising administering to the patient a nebulized dose of a budesonide composition in a continuing regimen at a frequency of not more than once per day.

'603 Patent col. 10 ll. 18–22. Dependent claims 12, 14, and 16 respectively limit the age range of the patient to "one day to fifteen years old," "one month to eight years old," and "six months to five years old." *Id.* at col. 10 ll. 44–53. Dependent claims 13, 15 and 17 respectively limit claims 12, 14, and 16 to budesonide compositions in which budesonide is the only active ingredient. *Id.* at col. 10 ll. 46–55. Dependent claims 24–28 add limitations to claim 1 regarding the amount of budesonide in the budesonide composition. *See id.* at col. 11 ll. 5 to col. 12 ll. 2.

AstraZeneca markets its "once-daily nebulized budesonide suspension used to treat asthma in children" under the name Pulmicort Respules®. *Opinion*, at *1.

C. The Parties and Previous Proceedings

The Appellees are generic drug manufacturers who have filed ANDAs seeking authorization to market generic versions of AstraZeneca's Pulmicort Respules® drug. AstraZeneca sued the Appellees for induced infringement, and the Appellees counterclaimed seeking declaratory judgments of invalidity and noninfringement. With respect to Apotex, AstraZeneca requested, and the district court on May 22, 2009 granted, a preliminary injunction predicated on the '603 Patent, preventing the launch of Apotex's generic drug, subject to the posting of a bond by AstraZeneca.

During the bench trial, the district court considered a motion by Apotex to increase the amount of bond associated with the preliminary injunction. The district court

noted on November 8, 2012 that the bond had not been modified since June 2, 2009 and that the parties, at the time the bond amount originally was set, had assumed a more rapid resolution of the case than actually occurred. The district court then increased the bond amount to cover future damages but refused to increase the bond amount to cover past damages. The district court made clear that the increased bond amount only applied to damages going forward from September 1, 2012, the day after Apotex filed its motion for increase.

Following the bench trial, the district court found, based on its construction of the term "micronized powder composition," that claims 50 and 51 of the '834 Patent were not infringed by Apotex and Sandoz, and that claims 1, 2, 50, and 51 of the '834 Patent were not infringed by Breath and Watson.

The district court also found that Appellees' labels induce infringement of asserted claims 1–3, 7, 8, 12–17, and 24–28 of the '603 Patent but that those claims were both anticipated and obvious based on a number of references and thus were invalid.

The district court treated as conceded and, thus, dismissed with prejudice AstraZeneca's infringement contentions with respect to claims 6, 11, 18, and 21–23 ("dismissed claims") of the '603 Patent because AstraZeneca presented no evidence at trial that those claims were infringed. *Opinion* at *4 n.11. The district court then declined to exercise jurisdiction over Apotex's invalidity counterclaims directed to the dismissed claims and dismissed them without prejudice, concluding that the noninfringement judgment resolved the case and Apotex showed no additional benefit to be gained from an invalidity decision. *Amendment*, at *7.

II. DISCUSSION

A. Standards of Review

"We review claim construction *de novo*." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). "Obviousness is a question of law, reviewed *de novo,* based upon underlying factual questions which are reviewed for clear error following a bench trial." *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006). "Under the clear error standard, a reversal is permitted only when this court is left with a definite and firm conviction that the district court was in error." *Id.* "Our review of a district court's decision to decline jurisdiction [under the Declaratory Judgment Act] is reviewed under a deferential abuse of discretion standard." *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271, 1288 (Fed. Cir. 2007).

A bond amount is a procedural issue that is not unique to patent law, and so the law of the regional circuit applies. *Int'l Game Tech. v. WMS Gaming, Inc.*, 217 F.3d 850, 850 n.1 (Fed. Cir. 1999). The Third Circuit treats as "a question of law whether a district court may retroactively increase a bond amount . . ." subject to "plenary review." *Sprint Commc'ns Co. L.P. v. CAT Commc'ns Int'l, Inc.*, 335 F.3d 235, 239 (3d Cir. 2003).

B. '834 Patent Claim Construction

The district court construed "micronized powder composition" to mean "heat sterilized finely divided dry particles." After reviewing the patent's specification and prosecution history, expert testimony, and inventor testimony, the district court further explained that "heat sterilized" refers to "particles that have been sterilized through a process, consistent with heat sterilization, that allows them to essentially maintain the same pharmaco-

logical activity, physico-chemical properties, chemical purity, and physical form as the starting material." *Opinion* at *35–36.

AstraZeneca argues that the district court erred by importing limitations into the claims because the plain meaning of "micronized powder composition" has nothing to do with heat sterilization. For further support, AstraZeneca points to the claim's other language as well as language in the patent's other claims. The Appellees' disagree, contending that the district court's construction is correct and that the plain language and claim differentiation cannot control because the '834 Patent so limited the invention throughout the specification and prosecution history.

> The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history. There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution.

Thorner, 669 F.3d at 1365 (citation omitted). "The standard for disavowal of claim scope is . . . exacting." *Id.* at 1366. "The patentee may demonstrate intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Id.* at 1366 (internal quotation marks omitted). "To constitute disclaimer, there must be a clear and unmistakable disclaimer." *Id.* at 1366–67. "Mere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to

rise to the level of clear disavowal." *Id.* at 1366. "It is likewise not enough that the only embodiments, or all of the embodiments, contain a particular limitation." *Id.*

With respect to the ordinary, plain meaning of the term "micronized powder composition," none of the three words imposes, or even implies, any form of sterilization. Indeed, Appellees do not argue to the contrary, arguing instead that the court must look to other evidence to understand that the term is limited to dry heat sterilization. Def.-Appellees' Br. at 36; Apotex Br. at 42.

Appellees also argue that AstraZeneca waived argument based on the term's plain meaning because it was not argued to the district court, *id.*, but the issue of whether the term "imputes" a sterilization process into the claim clearly was raised to the district court. *See Opinion* at *36 ("the Court notes that the parties have disputed whether the term 'heat sterilized' imputes a process limitation into the claims.").

Appellees argue that the term's otherwise plain meaning is limited to heat sterilization because of the patent specification's disavowal of any other type of sterilized micronized powder compositions. Appellees point to statements within the patent that refer to "the invention" as associated with the particular form of dry heat sterilization described in the patent. They also note that the only acceptable form of sterilization described in the '834 Patent is heat sterilization. Lastly, they note that the patent disparages several forms of prior art sterilization. The flaw in this argument, however, is that the '834 Patent's specification discloses three separate concepts: a process ("a process for sterilization of a powerdered [sic] form of a glucocortico-steriod"), products ("sterile glucocorticosteroids" and "sterile formulations containing glucocorticosteroids"), and methods of use ("use [of the products] thereof in the treatment of an allergic and/or

inflammatory condition on the nose or lungs"). '834 Patent col. 1 ll. 17–21.

There is no dispute that the patent refers only to dry heat sterilization as the preferred method of achieving the claimed "micronized powder composition" and criticizes, often sharply, other forms of sterilization. Nonetheless, "[m]ere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal." *Thorner*, 669 F.3d at 1366. "It is likewise not enough that the only embodiments, or all of the embodiments, contain a particular limitation." *Id.* Moreover, statements with respect to "the invention" are ambiguous at best, given the three distinct types of inventions (processes, products, and methods of use) described in the specification. "To constitute disclaimer, there must be a clear and unmistakable disclaimer." *Id.* at 1366–67. At most, the specification is confusing with respect to whether it limits only the disclosed process to a specific form of sterilization or both the process and the disclosed product to a specific form of sterilization. However, that confusion leaves available an interpretation of the patent that the products, as opposed to the processes, are not limited to any particular form of sterilization. Accordingly, we cannot conclude that AstraZeneca disclaimed non-heat sterilized micronized powder compositions based on the specification.

Appellees' argument with respect to the prosecution history similarly is flawed. Critically, much of the prosecution history relied on by Appellees concerns two different categories of claims: product claims (then-pending claims 65–83) and product-by-process claims (then-pending claims 84–157). For example, claim 65 recites a "sterile" powder, while claim 84 recites a "sterilized" powder. AstraZeneca explained that a powder can be "sterile" without ever having been "sterilized," but that a "sterilized" powder must have undergone a sterilization

process. AstraZeneca further explained that claims directed to "sterilized" powders were product-by-process claims, rather than product claims. The asserted claims at issue here do not recite a "sterilized" powder. Rather, the claims recite a "micronized powder composition" that "meets the criteria of sterility" according to the US Pharmacopeia. *See, e.g.,* '834 Patent at Claim 1. Rather than invoking the "steriliz*ed*" product-by-process limitations, the asserted claims refer merely to a powder that is sterile, irrespective of how that sterility was achieved. Nothing in the prosecution history expresses an unmistakable disavowal of that scope.

"Courts must generally take care to avoid reading process limitations into an apparatus claim . . . because the process by which a product is made is irrelevant to the question of whether that product infringes a pure apparatus claim . . . ." *Baldwin Graphic Systems, Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1344 (Fed. Cir. 2008) (internal quotations omitted). In general, "[t]he method of manufacture, even when cited as advantageous, does not of itself convert product claims into claims limited to a particular process. . . . A novel product that meets the criteria of patentability is not limited to the process by which it was made." *Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372 (Fed. Cir. 2000). AstraZeneca, during prosecution, was careful to specify which claims were product-by-process claims, implicating the method by which the product is made, and which claims were not so limited.

The prosecution history is replete with examples of AstraZeneca noting that prior art sterilization methods resulted in compounds with a different structure than that claimed in the then-pending product-by-process claims 84–157, but these arguments never were made with respect to then-pending claims 65–83. It is true that a patent applicant may disclaim products created by other

processes during the prosecution history when the patent applicant overcomes a rejection against product and process claims by indicating that the process is necessary to produce the claimed product and the patent applicant does not limit the disclaimers to the process claims. *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384–85 (Fed. Cir. 2005). Here, however, we cannot conclude that this is the case where arguments were directed specifically only to the then-pending product-by-process claims 84–157.

With respect to then-pending claims 65–83, AstraZeneca's arguments were limited to statements that it would not have been obvious to achieve the claimed powder (at the time of the invention) because of certain flaws in the prior art sterilization techniques. This is conceptually distinct from disavowing sterile powders that could be produced by the prior art techniques.

Appellees further direct the court to aspects of the prosecution history discussing then-pending claims 3, 8, 10, 11, and 39, which specifically recite elements for sterilization by heat treatment or require that a dry powder be sterilized. Neither concept is present in the asserted claims, which in contrast do not specifically recite heat treatment and, though sterile, could either 1) never have been sterilized (if synthesized as sterile in the first instance, for example) or 2) have been sterilized and then dried. With these distinctions between the then-pending claims and the asserted claims, we cannot conclude that comments directed to the then-pending claims disavow scope regarding the asserted claims.

Concluding that the claim term's plain meaning does not impart sterilization to the composition and that nothing contained in the specification or the prosecution history limit the term to a specific type of sterilization or disavow other types of sterilization, we need not reach

AstraZeneca's arguments concerning claim differentiation and the other language in the claims.

For the foregoing reasons, we hold that the district court erred by adding the "heat sterilized" limitation into the claims at issue. The term "micronized powder composition" is construed more accurately as "finely divided dry particles."

Remand is necessary for all Appellees under the new claim construction. Though Sandoz and Apotex contend that remand is unnecessary under a new construction, the court disagrees. While AtraZeneca does not appear to dispute that the "micronized powder composition" must be "dry," remand still is necessary because asserted claim 50 does not claim, as Apotex contends, a sterile powder, but rather claims a sterile suspension consisting of that powder composition and an aqueous solution.

C. '603 Patent Claim Invalidity

The district court found the asserted claims of the '603 Patent invalid as obvious and as anticipated. As for obviousness, the district court concluded that the '603 patent's "essential teaching" is "once-daily dosing of nebulized budesonide" and that a person of ordinary skill in the art would have been motivated to arrive at this "obvious conclusion." *Opinion* at *19.

The obviousness analysis involves four factual inquiries: (1) "'the scope and content of the prior art,'" (2) the "'differences between the prior art and the claims at issue,'" (3) "'the level of ordinary skill in the pertinent art,'" and (4) "'secondary considerations'" of nonobviousness. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (quoting *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17–18 (1966)). "One of the ways in which a patent's subject matter can be proved obvious is by noting

that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims." *Id.* at 419–20. "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.* at 420. "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id.* at 421.

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

Id. at 421.

The district court found that the prior art included numerous studies, which "taught the safety and efficacy of once-daily inhaled budesonide" ("once-daily studies"), including once-daily treatment of children. *Id.* at *12. Further, the district court found that practitioners were taught to use a "stepwise" approach to dosing, wherein the practitioner would attempt to titrate the drug dose down to the lowest possible dose—a once-a-day dose. *Id.* at *22. Relatedly, the district court concluded that it was a known problem that the dosing frequency of young children with asthma created "issues of compliance and convenience." *Id.* at *20–21. AstraZeneca notes that none of the once-daily studies teaches use of a nebulizer to administer the drug. *Id.* Instead, the once-daily studies taught use of two other delivery devices: MDI and PDI. MDI devices use a canister filled with the drug, which when pressed by the user, propels the drug into a gaseous

solution inhaled by the patient. *Id.* MDIs are difficult for patients to use because proper inhalation of the gaseous solution requires considerable coordination. *Id.* DPI devices are similar, except that the user's own inhalation is used to propel the drug, which is a problem for small children. *Id.* Nebulizers create, without any effort from the patient, a fine mist of the drug. *Id.* The patient merely breaths and inhales the mist. Nebulizers are inefficient because much of the drug is lost to the air or ingested by the patient. *Id.*

The district court found that a publication by Brattsand & Selroos teaches that budesonide can be delivered via several different mechanisms, including nebulization, and though mistaken as to the correct mechanism, teaches that budesonide delivered to the lungs exhibits a "depot effect" where the drug continues to have an effect for a significant period after it is administered. *Id.* at *13–15. According to the district court, references such as Jackson and McCarthy further teach that the delivery method of budesonide does not impact its clinical effectiveness. *Id.* at *15–18. The district court also observed that the prior art also teaches that nebulizers were the "most practical delivery device for certain patients like young children." *Id.* at *20. The district court also made the following findings as to references by Jackson, McCarthy, and Möller. Though not in connection with once-daily dosing, Jackson specifically teaches use of nebulized budesonide on infants and children under three-years old. *Id.* McCarthy and Möller similarly teach use of inhaled budesonide once daily in the treatment of children of various age ranges, including 5 to 13, 7 to 13, as well as "small children" and "infants." *Id.* at 26. We can find no clear error with respect to these factual findings.

With respect to the differences between the prior art and the claimed invention, AstraZeneca contends that

the '603 Patent fills two gaps existing in the prior art, neither of which would have been obvious: (1) use of a once-daily nebulizer budesonide treatment and (2) a once-daily treatment of children.

The district court found that the once-daily studies demonstrate the safety and efficacy generally of once-daily inhaled budesonide. *Opinion* at *12, 15–16, 20. The district court also found that though Brattsand & Selroos incorrectly identify the location of the budesonide binding site, and thus incorrectly describe the budesonide depot mechanism, a person of ordinary skill in the art at the time of the invention nonetheless would have expected budesonide to exhibit the depot effect, which is an inherent property of the drug regardless of how it is delivered to the lung. *Opinion* at *15. This depot effect makes the drug attractive to once-daily dosing. Further, the district court found that Jackson and McCarthy teach that the delivery method of the budesonide does not impact its effectiveness. *Opinion* at *15–18. We agree with these findings and see no clear error by the district court. We also agree with the district court that the "compliance and convenience" factors, as well as the recognized stepwise approach to dosing suggest that once-daily dosing would have been preferred, especially with respect to young children.

Moreover, the evidence established a reasonable expectation of success for once-daily treatment of children. The district court found testimony of Appellees' expert, Dr. Barnes, credible with respect to the fact that "that a person of ordinary skill in the art would not have any concerns about using nebulized budesonide once daily in children under the age of five, because the principles for treating this patient group and for treating older children and adults are the same." *Opinion* at *26. We can find no clear error in this finding, particularly in light of the numerous studies—such as Jackson, Möller, and McCar-

thy—each teaching treatment of children (from infants to age 13) with inhaled budesonide. *Id.*[1]

Furthermore, the district court found, and the parties agreed, that a known problem existed at the time of the invention: "significant difficulty in the treatment of young children, including infants, who suffer from respiratory disease." *Opinion* at *12. Because children lack coordination and the ability to take strong breaths, which are required for MDI and PDI delivery but not for nebulizers, nebulizers would have been an obvious way to overcome the problem of finding an effective delivery mechanism to treat young patients. Moreover, the district court's factual findings establish a reasonable expectation of success for that treatment. The once-daily studies demonstrated the effectiveness of once-daily treatment with budesonide, including the treatment of young children. Use of nebulizers to administer budesonide was known, and based on the teachings of Jackson and McCarthy, those of skill in the art would not have expected differences in the budesonide delivery method to impact efficacy.

With respect to secondary considerations, AstraZeneca first points to alleged industry skepticism, noting inventor testimony that AstraZeneca did not believe once-daily dosing would be effective, as evidenced by AstraZeneca's decision to add not one, but two clinical studies

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[1] The rebuttal evidence cited by AstraZeneca merely established that for young children asthma is particularly dangerous and difficult to diagnose. The evidence does not show that a person of skill in the art would believe that the principles making once-daily budesonide treatment safe and effective for adults differ from those for young children.

with respect to once-daily dosing. In addition to a study concerning twice-daily dosing, AstraZeneca added studies for once-daily dosing and a study looking both at once-daily and twice-daily dosing. The district court found, and we agree, that this simply is evidence of corporate prudence based on AstraZeneca's own misgivings rather than industry skepticism.

AstraZeneca also argues long-felt, unmet need for once-daily dosing of budesonide via a nebulizer, noting that Pulmicort Respules® had been available for twice-daily dosing since 1990, but the efficacy of once-daily dosing of nebulized budesonide was not investigated prior to 1997. *See Opinion* at *11–12. That fact, alone, is inconclusive and insufficient in the circumstances of this case to support the argument of non-obviousness.

This court identifies no clear error in any underlying factual determinations of the district court, and finds that those facts establish by clear and convincing evidence that the asserted claims of the '603 Patent are obvious. This court, therefore, affirms the district court's obviousness finding. Given this court's conclusion on obviousness, we need not reach the issue of anticipation.

D. The Dismissed Claims

Apotex appeals the district court's decision to decline jurisdiction over Apotex's invalidity counterclaim with respect to the dismissed claims. AstraZeneca abandoned these claims at trial, and following trial the district court dismissed them with prejudice, "effectively represent[ing] a *final judgment* of non-infringement in favor of all of the defendants." *Amendment* at *6 (emphasis in the original). The district court then declined to exercise its jurisdiction over Apotex's declaratory judgment counterclaim of invalidity with respect to those claims. Apotex contends that in so doing, the district court abused its discretion

because that discretion is not absolute, arguing that there must be reasons for declining jurisdiction.

"If a district court's decision is consistent with the purposes of the Declaratory Judgment Act and considerations of wise judicial administration, it may exercise its discretion to dismiss (or stay) the case." *Sony*, 497 F.3d at 1288. On the other hand,

> [t]here must be well-founded reasons for declining to entertain a declaratory judgment action. Absent such reasons, precedent establishes that when there has been a direct charge of infringement by the patentee, and an actual controversy exists due to ongoing activity that has been accused of infringement, the accused infringer has the right to resolve the dispute.

Capo, Inc. v. Dioptics Med. Prods., Inc., 387 F.3d 1352, 1355 (Fed. Cir. 2004) (citation omitted).

Apotex argues that it should not be deprived of a final resolution as to all claims for which AstraZeneca asserted infringement, and that AstraZeneca's failure to submit proof of infringement should not foreclose Apotex from challenging validity. Apotex notes that the counterclaim was fully tried, that the district court already performed an analysis, and that the district court declared narrower claims than the dismissed claims invalid. Nonetheless, this court has indicated that a district court can dismiss an invalidity counterclaim when it finds noninfringement or dismisses an infringement claim with prejudice. *See Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 355 F.3d 1361, 1371 (Fed. Cir. 2004) ("A district court judge faced with an invalidity counterclaim challenging a patent that it concludes was not infringed may either hear the claim or dismiss it without prejudice, subject to review only for abuse of discretion."); *Nystrom v. TREX Co., Inc.*, 339 F.3d

1347, 1351 & n.* (Fed. Cir. 2003) ("[T]he district court could have dismissed the counterclaim without prejudice (either with or without a finding that the counterclaim was moot) following the grant of summary judgment of non-infringement."); *Phonometrics, Inc. v. N. Telecom Inc.*, 133 F.3d 1459, 1468 (Fed. Cir. 1998) ("We have previously held that a district court has discretion to dismiss a counterclaim alleging that a patent is invalid as moot where it finds no infringement.").

The decision whether to accept jurisdiction of a Declaratory Judgment counterclaim is quintessentially left to the discretion of the district court. Here, the district court stated that "the non-infringement judgment firmly and clearly resolves the case, and Apotex has not shown how a judgment of invalidity would provide any additional benefit." *Amendment* at *7. Consistent with this court's precedent, this is a sufficient reason to decline jurisdiction. Apotex raises an argument in its briefing with respect to how a judgment of invalidity might provide an additional benefit to it over and above the non-infringement judgment. However, AstraZeneca contends, and Apotex does not dispute, that this argument was not raised to the district court. Accordingly, we will not consider it here. *See Golden Bridge Tech., Inc. v. Nokia, Inc.,* 527 F.3d 1318, 1323 (Fed. Cir. 2008) (declining to consider a new argument the party could have raised before the district court).

We decline to say that the district court abused its discretion in dismissing without prejudice Apotex's inva-

lidity counterclaims as to claims 6, 11, 18, and 21–23 of the '603 Patent.[2]

E. Bond Amount

Apotex contends that the amount of the bond required when the preliminary injunction was granted is no longer sufficient, given the greater than anticipated time that transpired between the date of the injunction and trial. The district court issued the preliminary injunction on May 22, 2009 against Apotex predicated on the '603 patent. More than three years later, on August 31, 2012, Apotex filed a motion to increase the amount of bond posted by AstraZeneca. Apotex sought an increase in the amount of the bond both going forward and to cover the period between issuance and the time the motion was filed. The district court granted the motion with respect to the amount going forward but denied it with respect to the amount before the motion was filed. Apotex contends that this is reversible error.

Apotex concedes that, in the Third Circuit, there is a general prohibition on retroactive increases in the bond

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[2] Notwithstanding the fact that this court concludes that the district court did not abuse its discretion in declining jurisdiction, this court observes that broader claims are necessarily invalid where narrower claims have been found to be obvious. *See Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1319 (Fed. Cir. 2007) ("Because claims 10 and 17 were found to have been obvious, the broader claims 1 and 11 must also have been obvious."). Here, it is self-evident that each of the dismissed claims is broader than a claim the district court has already invalidated. *Compare* '603 Patent claims 6 to 7, 11 to 8, 18 and 22 to 24, *and* 21 and 23 to 25.

amount, *see Sprint Commc'n Co. v. Cat Commc'n Int'l*, 335 F.3d 235, 240–42 (3d Cir. 2003), but argues that this prohibition applies only after an injunction has been dissolved. The parties do not cite a Third Circuit decision directly addressing the present issue of whether a bond may be retroactively increased when it is still in effect. "Where the regional circuit court has not spoken, we need to predict how that regional circuit would have decided the issue in light of the decisions of that circuit's various district courts, public policy, etc." *Panduit Corp. v. All States Plastic Mfg. Co., Inc.*, 744 F.2d 1564, 1575 (Fed. Cir. 1984) *disapproved of on other grounds by Richardson-Merrell, Inc. v. Koller*, 472 U.S. 424 (1985).

Apotex does direct this court's attention to *Daiichi Pharma. Co., Ltd. v. Apotex, Inc.*, Civ. No. 03-937(WGB) (D.N.J. June 7, 2006), an unpublished decision in which a district court, during the pendency of a preliminary injunction, appears to have agreed to increase a bond amount to cover higher-than-expected losses by the accused infringer. The amount of the bond increase appears to apply to the period that already had passed. The district court in that case concluded that *Sprint* was distinguishable because, as argued by Apotex, the accused infringer had an opportunity to decide whether to accept the injunction, at least going forward. *Daiichi*, however, is a singular district court case, and the reasoning in *Sprint* and public policy caution against following it.

Based on *Sprint*, this court believes that the Third Circuit would consider improper an increase to cover past damages even in the present circumstances. "[T]he bond generally limits the liability of the applicant and informs the applicant of the price it can expect to pay if the injunction was wrongfully issued." *Sprint*, 335 F.3d at 240 (internal quotation marks and alteration marks omitted).

> When a court grants an applicant's request for a preliminary injunction, it will generally condition this grant on the applicant's posting a bond. The applicant then decides whether to accept the preliminary relief by posting the bond or to withdraw its request. The applicant may base its decision on whether it wants to expose itself to liability up to the bond amount.

Id. at 240. "If a retroactive increase is permissible, the injunction bond is no longer cabined; the bond no longer fixes exposure nor caps liability. A retroactive increase subjects the successful applicant to an unexpected and unanticipated liability." *Id.* at 241.

Apotex argues that when, as here, the injunction is still in effect, the applicant for an injunction has notice and the opportunity to decline the additional bond amount or decline the continuation of the injunction. However, the Third Circuit focused in *Sprint* on the function of the bond in informing the applicant of its liability. AstraZeneca expected that its liability would be limited to the bond amount before Apotex's motion. AstraZeneca cannot be fairly informed after it obtained the benefit of the injunction that it must later pay more for the benefit it already obtained in order to obtain the benefit of a continued injunction. The bond would no longer serve to cabin or fix liability, and that would result in an unexpected liability, which *Sprint* sought to prohibit. It is immaterial whether the injunction has been dissolved, as in *Sprint*, or continues, as it does here. Either way: the party securing the injunction decided to accept the preliminary relief by posting the bond required at the time. Later requiring that party to post a higher bond for a period that already has passed results in a situation where that bond no longer fixes exposure or caps liability. The party no longer simply could withdraw its

request for an injunction over that period because that period already would have passed.

Apotex also argues that an exception to *Sprint*'s general prohibition on retroactive increases exists where the injunction holder always will choose to accept the injunction and pay a bond based on the accused infringer's damages. Apotex contends that here, because of the price structure of the drugs at issue, AstraZeneca always would stand to benefit from the injunction because its profits (in a market from which Apotex is excluded) will always exceed the damages to Apotex caused by a wrongful injunction. At the district court, Apotex did not raise this argument but instead argued that AstraZeneca would not be prejudiced by an increase to the bond because of its large profits. Because the argument was not raised at the district court, we decline to address it in the first instance. *Sage Prods., Inc. v. Devon Indus., Inc.,* 126 F.3d 1420, 1426 (Fed. Cir. 1997) ("[A]ppellate courts do not consider a party's new theories, lodged first on appeal . . . . In short, this court does not 'review' that which was not presented to the district court.").

Apotex also argues that it should be able to seek damages from AstraZeneca in excess of the bond amount because it would be inequitable to limit Apotex's recovery to that amount. Apotex points out that the Third Circuit has recognized that there are "rare exceptions" to the rule that "a defendant wrongfully enjoined has recourse only against the bond." *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 804 (3d Cir. 1989). However, Apotex does not argue that it fits into an exception previously recognized by the Third Circuit. Apotex cites only a case involving a finding of fraud. *See Hartford-Empire Co. v. Shawkee Mfg. Co.*, 163 F.2d 474, 477 (3d Cir. 1947).

Rather than alleging fraud, Apotex instead merely argues that it would be unjust to limit its recovery to the

bond because it will have suffered significantly more damages. However, Apotex identifies no circumstances that could have impeded it from moving well before August 31, 2012 to increase the amount of the bond. Though it appears undisputed that the trial occurred approximately two years after the parties anticipated it would occur, Apotex certainly was aware of the delay as it was happening. If this situation were considered an exception, the exception would swallow the rule. Any party that delays moving to increase a bond amount could move years later to recover damages in excess of the bond, defeating the intended purpose of the bond in the first instance. We decline to hold that the Third Circuit would invite such a result.

Lastly, Apotex argues that it should be able to use damages incurred from the earlier time period (*i.e.*, damages from the time between May 22, 2009 and August 31, 2012) to prove up the additional bond amount that AstraZeneca posted in response to Apotex's August 31, 2012 motion. This is essentially the same issue discussed above in connection with *Sprint*. AstraZeneca agreed to post the original bond amount, understanding that—absent "rare exceptions"—its liability during that time period would be limited to that amount. Allowing Apotex to use damages incurred during an earlier period to prove up to the bond amount in a later period still violates *Sprint*'s general prohibition against retroactive increases.

Accordingly, this court affirms the district court's conclusion on the bond amount.

III. CONCLUSION

For the forgoing reasons, this court affirms the district court's finding of obviousness for certain claims of the '603 Patent, dismissal of Apotex's invalidity counterclaims as to the dismissed claims, and decisions with

respect to the bond amount. This court, however, reverses the district court's noninfringement finding on the '834 Patent and remands for further proceedings.

AFFIRMED-IN-PART, REVERSED-IN-PART, AND REMANDED

IV. COSTS

Each party shall bear its own costs.