United States Court of Appeals for the Federal Circuit

04-1522

SMITHKLINE BEECHAM CORPORATION
and SMITHKLINE BEECHAM, P.L.C.,

Plaintiffs/Counterclaim Defendants-Appellants,

and

GLAXOSMITHKLINE, P.L.C.,

Plaintiff/Counterclaim Defendant,

and

BEECHAM GROUP, P.L.C.,

Plaintiff,

v.

APOTEX CORPORATION, APOTEX, INC.,
and TORPHARM, INC.,

Defendants/Counterclaimants-Appellees.

Ford F. Farabow, Jr., Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, argued for plaintiffs/counterclaim defendants-appellants. With him on the brief were Robert D. Bajefsky, Howard W. Levine, Sanya Sukduang, and Jennifer S. Swan.

Hugh L. Moore, Lord, Bissell & Brook LLP, of Chicago, Illinois, argued for defendants/counterclaimants-appellees. With him on the brief were Scott B. Feder, Hugh S. Balsam, and Kevin M. Nelson. Of counsel were Keith D. Parr and Sara A. Lufrano.

Appealed from: United States District Court for the Eastern District of Pennsylvania

Judge R. Barclay Surrick

United States Court of Appeals for the Federal Circuit

04-1522

SMITHKLINE BEECHAM CORPORATION,
SMITHKLINE BEECHAM, P.L.C.,

Plaintiffs/Counterclaim Defendants-Appellants,

and

GLAXOSMITHKLINE, P.L.C.,

Plaintiff/Counterclaim Defendant,

and

BEECHAM GROUP, P.L.C.,

Plaintiff,

v.

APOTEX CORPORATION, APOTEX INC.,
and TORPHARM, INC.

Defendants/Counterclaimants-Appellees.

DECIDED: February 24, 2006

Before NEWMAN, SCHALL, and DYK, Circuit Judges.

Opinion for the court filed by Circuit Judge DYK. Dissenting opinion filed by Circuit Judge NEWMAN.

DYK, Circuit Judge.

SmithKline Beecham Corporation and SmithKline Beecham, P.L.C. (collectively "SmithKline") brought suit against Apotex Corporation, Apotex Inc., and Torpharm, Inc. (collectively "Apotex") for infringement of SmithKline's patent, U.S. Patent No. 6,113,944

("'944 patent"). Apotex moved for summary judgment, arguing that the '944 patent was invalid. The district court granted summary judgment to Apotex. We agree that the claims of the '944 patent are invalid and thus affirm.

BACKGROUND

This case presents the question whether SmithKline's product patent for paroxetine, U.S. Patent No. 4,721,723 (filed Oct. 23, 1986) ("'723 patent"), anticipated its '944 product-by-process patent claiming paroxetine made by an allegedly novel process. SmithKline's '723 patent claimed a pharmaceutical product aimed at treating depression. In SmithKline's own words, the "'723 patent disclose[d] a pharmaceutical composition in tablet form containing paroxetine."[1] J.A. 63. The '723 patent also disclosed that the product is "usually presented as a unit dose composition containing from 1 to 200 mg, more usually from 5 to 100 mg, for example 10 to 50 mg such as 12.5, 15, 20, 25 or 30 mg." '723 patent, col. 5, ll. 53-56.

In 1992, SmithKline obtained approval from the Food and Drug Administration ("FDA") to market crystalline paroxetine hydrochloride, which it began to sell under the trade name Paxil®. SmithKline then filed various other related patent applications, including application No. PCT/EP94/04164, on December 14, 1994, which eventually matured into the '944 patent. The '944 patent contained the following two product-by-process claims:

[1] The '723 patent claimed, among other things, an "anti-depressant pharmaceutical composition comprising an effective anti-depressant amount of crystalline paroxetine hydrochloride hemihydrate and a pharmaceutically acceptable carrier." '723 patent, col. 10, ll. 39-43.

> Claim 1. A pharmaceutical composition in tablet form containing paroxetine, produced on a commercial scale by a process which comprises the steps of:
> a) dry admixing paroxetine and excipients in a mixer to form a mixture; or
> b) dry admixing paroxetine and excipients, compressing the resulting combination into a slug material or roller compacting the resulting combination into a strand material, and milling the prepared material into a free flowing mixture; and
> c) compressing the mixture into tablets.
>
> Claim 2. A pharmaceutical composition in tablet form according to claim 1 containing an amount of paroxetine selected from 10 mg, 20 mg, 30 mg, 40 mg and 50 mg, wherein the amount of paroxetine is expressed as the free base, produced on a commercial scale by a process which comprises the steps of:
> a) dry admixing paroxetine and excipients in a mixer to form a mixture; or
> b) dry admixing paroxetine and excipients, compressing the resulting combination into a slug material or roller compacting the resulting combination into a strand material, and milling the prepared material into a free flowing mixture; and
> c) compressing the mixture into tablets using a single punch or rotary tablet machine.

J.A. 483-84 (Certificate of Correction).

On March 31, 1998, Apotex, a generic drug manufacturer and defendant here, submitted an Abbreviated New Drug Application ("ANDA") to the FDA, seeking approval to market a generic version of Paxil®. In connection with its ANDA, Apotex filed a so-called "paragraph IV certification," which is a statement by the applicant that designated patents claiming either the drug or a use of the drug at issue are invalid or will not be infringed by the applicant. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000). Apotex's paragraph IV certification claimed that the '944 patent was invalid. Pursuant to 35 U.S.C. § 271(e)(2), which makes submitting an ANDA an act of infringement, SmithKline brought suit against Apotex, alleging infringement of the '944 patent. Apotex counterclaimed that the '944 patent was invalid and in due course moved for summary judgment of invalidity.

In its decision, the district court held the '944 patent anticipated and thus invalid. The district court appeared to view the question of anticipation as turning on the scope of the '944 patent, namely whether the patent should be viewed as claiming paroxetine without regard to the process by which it was made or whether the process steps were to be treated as claim limitations. The district court perceived a conflict in this respect between our decisions in Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991) (which the district court viewed as holding that the process steps were not claim limitations) and Atlantic Thermoplastics Co., Inc. v. Faytex Corp., 970 F.2d 834 (Fed. Cir. 1992) (which the district court viewed as holding that the process steps were claim limitations). The district court concluded that it was bound to follow the earlier Scripps decision, finding that Scripps required it to "evaluate the validity of the ['944 patent's] claims by reference to the products claimed therein, without the process limitations of those claims." J.A. 61. Because the '723 patent disclosed tablets containing paroxetine, including in the dosages specified in claim 2 of the '944 patent, the court determined that the '723 patent anticipated the '944 patent.

In holding the '944 patent anticipated, the district court found that the product claimed by the '944 patent was the same product disclosed by the '723 patent, despite SmithKline's arguments that the paroxetine tablets claimed by the '944 patent were different because they lacked a pink hue, did not contain spherical granules, and had a different content uniformity. The court stated that these characteristics were "not required by the patent claims or specification" and that the "product characteristics now cited by SmithKline are insufficient to distinguish the product of the '944 Patent from the products claimed in the '723 Patent." J.A. 64-65. The court therefore granted Apotex's

summary judgment motion. Pursuant to Fed. R. Civ. P. 54(b), the court entered a separate judgment with respect to the invalidity of the '944 patent. SmithKline timely appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

On appeal, SmithKline argues that the district court improperly "ignored the process limitations of the two product-by-process claims in the '944 patent" when it determined validity. SmithKline's Br. at 17, 23-24, 27. In other words, if the district court had treated the process steps recited in the '944 patent as claim limitations, it would have found that the '723 patent did not anticipate the '944 patent, or that there was a genuine issue of fact over whether the '723 patent disclosed those process limitations.

SmithKline misunderstands the nature of anticipation. As set forth below, once a product is fully disclosed in the art, future claims to that same product are precluded, even if that product is claimed as made by a new process.

I

A product-by-process claim is "one in which the product is defined at least in part in terms of the method or process by which it is made." Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 158 n. (1989) (quoting D. Chisum, Patents § 8.05, at 8-67 (1988)). While the patent statute does not provide for product-by-process claims, the courts have long recognized the appropriateness of such claims. See, e.g., In re Thorpe, 777 F.2d 695, 697 (Fed. Cir. 1985); In re Brown, 459 F.2d 531, 535 (C.C.P.A. 1972); In re Steppan, 394 F.2d 1013, 1018 (C.C.P.A. 1967). The purpose of product-by-process claims is to allow inventors to claim "an otherwise patentable product that

resists definition by other than the process by which it is made." In re Thorpe, 777 F.2d at 697. Thus, an inventor will not be foreclosed from the benefits of the patent system simply because a product is difficult to describe in words, or its structure is insufficiently understood. Today, however, product-by-process claims are used by inventors even if the invention could have been described independent of the process.[2]

This court has previously considered the scope of product-by-process claims. In Scripps, we held that the product-by-process claims at issue were not limited by the process steps within those claims. 927 F.2d at 1583. There, the patent concerned a protein, Factor VIII:C, essential to blood clotting. Id. at 1568. The patent contained product-by-process claims directed at the product made in accordance with a particular process, also claimed in the patent. Id. at 1570. The court found that Factor VIII:C that was produced by a different process would nonetheless infringe the product-by-process claims because:

> In determining patentability we construe the product as not limited by the process stated in the claims. Since claims must be construed the same way for validity and for infringement, the correct reading of the product-by-process claims is that they are not limited to product prepared by the process set forth in the claims.

Id. at 1583.

A year later this court decided Atlantic Thermoplastics. There, we held that the process steps in a product-by-process claim do serve as claim limitations. 970 F.2d at 846-47. The patent in Atlantic Thermoplastics concerned shock absorbing shoe

[2] See 3 Chisum on Patents § 8.05[2][c] (2003 ed.) (explaining that the Patent and Trademark Office ("PTO") has rejected the "necessity rule" which permitted product-by-process claims only in cases where the product was otherwise undefinable; instead, the PTO has opted to allow product-by-process claims so long as the definiteness requirement is met).

innersoles. Id. at 835. The patentee argued that the defendant had infringed its product-by-process claim. Id. at 836. Finding that the accused products were made by a different process than that claimed in the patent's product-by-process claim, the court determined that the patent did not extend to cover the product as made by any process. Id. at 846-47. This court stated that "[i]n light of Supreme Court caselaw and the history of product-by-process claims, this court acknowledges that infringement analysis proceeds with reference to the patent claims. Thus, process terms in product-by-process claims serve as limitations in determining infringement." Id.

A sharply divided court denied rehearing en banc of Atlantic Thermoplastics, with four judges dissenting in four separate opinions. See 970 F.2d 834, rehearing en banc denied, 974 F.2d 1299 (concurring opinion), 974 F.2d 1279 (dissenting opinions). Judge Newman, joined by Judges Rich and Lourie, urged that the panel in Atlantic Thermoplastics had incorrectly adopted a blanket rule that the process steps of a product-by-process claim should be automatically treated as claim limitations. 974 F.2d at 1282-83. In their view, the process steps should sometimes be treated as claim limitations and sometimes not, depending on the "class of claim" at issue. Id. at 1284.

Some commentators, like the district court here, have perceived a conflict between Scripps, where the court construed the product-by-process claims without reference to the process steps, and Atlantic Thermosplastics, where the court read the process steps as claim limitations.[3] We need not address this controversy here. The

[3] See Trs. of Columbia Univ. v. Roche Diagnostics GMBH, 126 F. Supp. 2d 16, 31 (D. Mass. 2000) (noting that after Scripps and Atlantic Thermoplastics, the district court is left in the unenviable position of choosing the better rule); DeKalb Genetics Corp. v. Northrup King Co., No. 96 C 50169, 1997 WL 587492, *2 (N.D. Ill. Aug. 14, 1997) (finding that Scripps and Atlantic Thermoplastics are "in seeming conflict");

issue here does not turn on how broadly or narrowly we construe the '944 patent's claims, for it is undisputed that the product that is the subject of the patent's claims is paroxetine. Rather the issue is whether the '723 patent anticipated the '944 product-by-process patent, when the '723 patent broadly claimed paroxetine without regard to the process by which it was made.[4] Thus, the ultimate issue is simply whether the prior art disclosure of a product precludes a future claim to that same product when it is made by an allegedly novel process.[5]

II

Regardless of how broadly or narrowly one construes a product-by-process claim, it is clear that such claims are always to a product, not a process. It has long been established that one cannot avoid anticipation by an earlier product disclosure by claiming the same product more narrowly, that is, by claiming the product as produced by a particular process. This was the exact issue in In re Thorpe. There, the patent concerned a composition that was used in carbonless copy paper systems. 777 F.2d at

---

Tropix, Inc. v. Lumigen, Inc., 825 F. Supp. 7, 8 (D. Mass. 1993) (noting the "disagreement" between Scripps and Atlantic Thermoplastics); see also 3 Chisum on Patents § 8.05[1][b] ("Federal Circuit panel decisions in 1991 and 1992 differed over whether a product-by-process claim can be infringed by a product not made by a specified process."); Conflicts in Federal Circuit Patent Law Decisions, 11 Fed. Cir. B.J. 723, 765 (2002) (describing controversy).

[4] The '723 patent also contained a separate process claim for the preparation of the paroxetine; however, this claim has not been implicated here. See '723 patent, col. 10, ll. 36-38.

[5] Although we have previously held the '723 patent invalid, SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1346 (Fed. Cir. 2005), it can still, of course, anticipate a later product patent. By virtue of publication, the '723 patent has become prior art. 1 Chisum on Patents § 3.06 (2003 ed.) ("A United States patent is published on the date it is issued and thereby becomes a printed publication within the meaning of Section 102(a) as well as a patent.").

696. The composition was known in the prior art, but was previously made using zinc dibenzoate. In a product-by-process claim, Thorpe claimed the same composition made by a process that used zinc oxide and benzoic acid, rather than zinc dibenzoate. The court upheld the PTO's rejection of the claim. Id. at 698. It held that "[i]f the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." Id. at 697. In re Thorpe has never been overruled and has been followed for many years by the PTO.[6] The current MPEP states:

> [Even] though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

MPEP § 2113 (8th ed., Rev. 2, May 2004) (quoting In re Thorpe, 777 F.2d at 698).

At the time of In re Thorpe, the rule as articulated was hardly new. Long before In re Thorpe, our predecessor court, the Court of Customs and Patent Appeals, consistently held that product-by-process claims could not validly claim products already known in the art. See In re Fessmann, 489 F.2d 742, 744-45 (C.C.P.A. 1975); In re Johnson, 394 F.2d 591, 594-95 (C.C.P.A. 1968); In re Stephens, 345 F.2d 1020, 1023

---

[6] The 1987 revision of the PTO's Manual of Patent Examining Procedure ("MPEP") stated the rule for product-by-process claims as follows: "When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection . . . is appropriate." Atlantic Thermoplastics Co., Inc., 974 F.2d at 1288 (denial of rehearing en banc) (quoting MPEP § 706.03(e) (5th ed., Rev. 6, Oct. 1987)) (Newman, J., dissenting). Later revisions of the MPEP contain the identical quote. See, e.g., MPEP § 2113 (6th ed., Rev. 3, July 1997); MPEP § 2113 (7th ed., Rev. 1, Feb. 2000); MPEP § 2113 (8th ed., Rev. 1, Feb. 2003).

(C.C.P.A. 1965) ("We think it well settled that the presence of process limitations in product claims, which product does not otherwise patentably distinguish over the prior art, cannot impart patentability to that product."); In re Dilnot 300 F.2d 945, 950 (C.C.P.A. 1962) ("The addition of a method step in a product claim, which product is not patentably distinguishable from the prior art, cannot impart patentability to the old product."); In re Moeller, 117 F.2d 565, 567 (C.C.P.A. 1941) ("[T]he article itself must be inventive and patentably distinct from such articles disclosed in the prior art."); In re Ewert, 77 F.2d 498, 499 (C.C.P.A. 1935); In re Brawn, 77 F.2d 362, 363 (C.C.P.A. 1935); In re Harvey, 71 F.2d 200, 201 (C.C.P.A. 1934).

This rule is also supported by earlier Supreme Court cases. For example, in Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293 (1884) ("BASF"), natural alizarine was already known in the art. Id. at 311. However, BASF obtained a patent covering artificial alizarine, as produced by a bromine reaction process. Id. at 296. The accused infringer, Cochrane, then sold artificial alizarine made by a different, sulfuric acid reaction process. Id. at 309. The Court reasoned that if the BASF patent were construed to cover the product itself, it would be invalid because the product was old. Id. at 311-12. The Court stated that "[w]hile a new process for producing it was patentable, the product itself could not be patented, even though it was a product made artificially for the first time. . . ." Id. at 311. As the Atlantic Thermoplastics panel recognized, the BASF court thus held that "a patent applicant could not obtain exclusive rights to a product in the prior art by adding a process limitation to the product claim." Atlantic Thermoplastics, 970 F.2d at 841 (citing BASF, 111 U.S. at 311); see also Tri-Wall Containers, Inc. v. United States, 408 F.2d 748, 750-51 (Ct. Cl. 1969), cert. denied,

396 U.S. 828 (1969) (following BASF, and stating that "the addition of a method step in a product claim, which product is not patentably distinguishable from the prior art, cannot impart patentability to the old product"). This understanding of BASF has been recognized by leading commentators. See, e.g., 3 Chisum on Patents § 8.05[3] (2003 ed.) (citing BASF for the proposition that "[e]ven through a product may be claimed in terms of the process of making it, the product still must be new in structural terms in order to meet the novelty requirement."). Other Supreme Court cases have reached the same conclusion. See Gen. Elec. Co. v. Wabash Appliance Corp., 304 U.S. 364, 373 (1938) ("Although in some instances a claim may validly describe a new product with some reference to the method of production, a patentee who does not distinguish his product from what is old except by reference, express or constructive, to the process by which he produced it, cannot secure a monopoly on the product by whatever means produced."); Wood-Paper Patent, 90 U.S. 566, 596 (1874).

As this history of cases from the Supreme Court, our court, and our predecessor court make clear, anticipation by an earlier product patent cannot be avoided by claiming the same product more narrowly in a product-process claim. It makes no difference here whether the '944 patent's product-by-process claims are construed broadly to cover the product made by any process or narrowly to cover only the product made by a dry admixing process. Either way, anticipation by an earlier product disclosure (which disclosed the product itself) cannot be avoided. While the process set forth in the product-by-process claim may be new, that novelty can only be captured by obtaining a process claim. We agree with the district court's conclusion that the '723

patent disclosure anticipated the identical product claimed by the '944 patent even though that product was produced by an allegedly novel process.[7]

III

In the district court, the parties differed on a second issue, that is, whether the product produced by the process claimed in the '944 patent was, in fact, a different product than that disclosed in the '723 patent. If those product-by-process claims produced a different product than that disclosed by the '723 patent, there would be an argument that the '723 patent disclosure did not anticipate. In re Luck, 476 F.2d 650, 653 (C.C.P.A. 1973). On this appeal, in response to Apotex's argument that the issue had been waived by failure to include it in the opening brief, SmithKline did not point out in its reply brief where the issue had been presented in its opening brief. Questioned by this court at oral argument as to whether this second issue has been properly preserved on appeal, SmithKline urged that it had raised this issue on appeal and was challenging the district court's finding regarding the novelty of the product claimed by the '944 patent. We conclude that this issue has been waived for failure to brief it on appeal.

Our law is well established that arguments not raised in the opening brief are waived. See Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1320-21 n.3 (Fed. Cir. 2005). SmithKline's opening brief focused on the perceived conflict between Scripps and Atlantic Thermoplastics to the exclusion of arguments that the product produced by the allegedly novel process was novel. Indeed, SmithKline

[7] Contrary to the dissent's suggestion, the court does not hold that a claim to a product is never limited by process limitations. We simply hold that a prior art disclosure of a product precludes a future claim to that same product, even if it is made by an allegedly novel process. We take no position on whether a product-by-process claim is construed with reference to the process steps.

argued that "this Court should address only the issue that provided the basis for the district court—its incorrect interpretation of the product-by-process claims of the '944 patent." SmithKline's Br. at 30. SmithKline failed to include in the Argument section of its opening brief an argument that, contrary to the district court's finding, the product claimed in the '944 patent is itself different from that disclosed in the '723 patent. To be sure, there are various places in its opening brief where SmithKline alluded that the paroxetine tablets claimed in the '944 patent were different from tablets disclosed in the prior art and expressed its disagreement with the district court's determination that the product produced by the '944 patent was not new. In its Argument section, SmithKline stated "there were numerous factual disputes between the parties, including the scope and content of the prior art, and the unexpected improvement of the claimed invention over the prior art." SmithKline's Br. at 19. Similarly, on page 27 of its brief, SmithKline stated:

> Here, the district court held that "the product of the '944 Patent cannot be distinguished from the paroxetine tablets in the prior art . . . ." (A64.) Accordingly, although SB's disagrees with that determination, if the district court was determined to follow Scripps, it should have then considered the process limitations of the product-by-process claims of the '944 patent as essential limitations in determining validity.

SmithKline's Br. at 27 (emphasis added). [8] In a footnote to this sentence, SmithKline further noted that the '944 patent's tablets have a "significantly reduced tendency to pink, and have a different 'fingerprint' than tablets made by a [prior art] wet granulation process. The district court erroneously believed it did not need to consider such

[8] In various other places, SmithKline noted its disagreement with the district court's decision and stated in conclusory fashion that factual disputes "should have precluded the district court from entering summary judgment." See, e.g., SmithKline's Br. at 2, 13-14.

differences because they were not literally recited in the claim. This was an error of law." Id. at n.8. This footnote is the only statement that even approaches a substantive argument on novelty in the entire Argument section of SmithKline's opening brief.

We find that these mere statements of disagreement with the district court as to the existence of factual disputes do not amount to a developed argument. See, e.g., Anderson v. City of Boston, 375 F.3d 71, 91 (1st Cir. 2004) ("When a party includes no developed argumentation on a point . . . we treat the argument as waived under our well established rule."); Tolbert v. Queens Coll., 242 F.3d 58, 75 (2d Cir. 2001) ("It is a settled appellate rule that issues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived.") (internal quotation marks omitted); United States v. Elder, 90 F.3d 1110, 1118 (6th Cir. 1996) (same); Laborers' Int'l Union of N. Am. v. Foster Wheeler Corp., 26 F.3d 375, 398 (3d Cir. 1994), cert denied, 513 U.S. 946 (1994) ("An issue is waived unless a party raises it in its opening brief, and for those purposes 'a passing reference to an issue . . . will not suffice to bring that issue before this court.'") (quoting Simmons v. City of Philadelphia, 947 F.2d 1042, 1066 (3d Cir. 1991), cert. denied, 503 U.S. 985 (1992)); United States v. Dunkel, 927 F.2d 955, 956 (7th Cir. 1991) ("A skeletal 'argument', really nothing more than an assertion, does not preserve a claim. . . . Especially not when the brief presents a passel of other arguments . . . . Judges are not like pigs, hunting for truffles buried in briefs.").

Further, arguments raised in footnotes are not preserved. See Cross Med. Prods., Inc., 424 F.3d at 1320-21 n.3 (holding that an argument raised in a footnote in an opening brief was waived as not properly raised); Fuji Photo Film Co. v. Jazz Photo

Corp., 394 F.3d 1368, 1375 n.4 (Fed. Cir. 2005) (finding that an argument raised in a footnote in an opening cross-appeal brief and then more fully in the reply brief, was not properly raised); Graphic Controls Corp. v. Utah Med. Prods., 149 F.3d 1382, 1385 (Fed. Cir. 1998) (finding that an argument raised in a footnote which in turn referenced the full argument in the appendix was not preserved) (citing Fed. R. of App. P. 28(a)(6) which then stated that "[t]he argument [in the appellant's brief] must contain the contentions of the appellant on the issues presented, and the reasons therefor, with citations to the authorities . . . and parts of the record relied on . . . .").[9]

Therefore, SmithKline has not established that the district court erred in its ultimate judgment holding the '944 patent anticipated by the '723 patent.

CONCLUSION

For the foregoing reasons, the decision below is affirmed.

AFFIRMED

COSTS

No costs.

[9] As we held in Becton Dickenson and Co. v. C.R. Bard, Inc., 922 F.2d 792, 800 (Fed. Cir. 1990), this court nonetheless has discretion to consider arguments that are not properly raised in the opening brief. But here, as in Becton, we see no reason to exercise that discretion.

United States Court of Appeals for the Federal Circuit

04-1522

SMITHKLINE BEECHAM CORPORATION,
SMITHKLINE BEECHAM, P.L.C.,

Plaintiffs/Counterclaim Defendants-Appellants,

and

GLAXOSMITHKLINE, P.L.C.,

Plaintiff/Counterclaim Defendant,

and

BEECHAM GROUP, P.L.C.,

Plaintiff,

v.

APOTEX CORPORATION, APOTEX INC.,
AND TORPHARM, INC.,

Defendants/Counterclaimants-Appellees.

NEWMAN, Circuit Judge, dissenting.

The law of "anticipation" does not change in the special situation where claims contain both product and process limitations. The panel majority perpetuates a confusing misunderstanding of precedent governing product-by-process claims, ignoring the opportunity and need for clarification.

In this case the district court found "anticipation" based on a claim construction that erased critical limitations of the claim. At issue are claims that require the use of a specified process for the commercial production of tablets of the known pharmaceutical product paroxetine (Paxil®). The claims are simple and straightforward, and state the processing steps that produce the stabilized tableted product, as follows:

> 1. A pharmaceutical composition in tablet form containing paroxetine, produced on a commercial scale by a process which comprises the steps of:
> a) dry admixing paroxetine and excipients in a mixer to form a mixture; or
> b) dry admixing paroxetine and excipients, compressing the resulting combination into a slug material or roller compacting the resulting combination into a strand material, and milling the prepared material into a free flowing mixture; and
> c) compressing the mixture into tablets.
>
> 2. A pharmaceutical composition in tablet form according to claim 1 containing an amount of paroxetine selected from 10 mg, 20 mg, 30 mg, 40 mg and 50 mg, wherein the amount of paroxetine is expressed as the free base, produced on a commercial scale by a process which comprises the steps of:
> a) dry admixing paroxetine and excipients in a mixer to form a mixture; or
> b) dry admixing paroxetine and excipients, compressing the resulting combination into a slug material or roller compacting the resulting combination into a strand material, and milling the prepared material into a free flowing mixture; and
> c) compressing the mixture into tablets using a single punch or rotary tablet machine.

The general rule of infringement is that every claim limitation or its equivalent must be represented in the accused activity. See Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29 (1997) ("Each element contained in a patent claim is deemed material in defining the scope of the patented invention.") That which infringes if later, anticipates if earlier. Peters v. Active Manufacturing Co., 129 U.S. 530, 537 (1889); Door-Master Corp. v. Yorktowne, Inc., 256 F.3d 1308, 1312 (Fed. Cir. 2001) ("'[t]hat which infringes, if later, would anticipate, if earlier'") (quoting Peters). These rules, like all rules, have generated

exceptions, but the exceptions in connection with "anticipation" of claim content are rare, and represent a pragmatic adjustment to the needs of science, not law.

Such an exception exists for inventions directed to a novel product that, although patentable as a product, cannot be adequately described other than by the way it was made; the process may or may not itself be novel, but that aspect is deemed irrelevant to the claim to the new product. This exception was created to accommodate the rare circumstances to which it has been applied, as illustrated in In re Thorpe, 777 F.2d 695 (Fed. Cir. 1985) and Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991). Yet the courts, including my colleagues on this panel, do not appear to have understood the role of the exception, as illustrated in the holding in this case. Thus my colleagues today adopt a one-rule-fits-all rule for claims with process limitations, a rule that is seriously flawed. Instead of taking this opportunity to clarify the confusion surrounding this issue, the court exacerbates it. I must, respectfully, dissent.

I

CLAIM CONSTRUCTION

The SmithKline inventors in the '944 patent describe the production of a stabilized paroxetine tablet by a specified process that reduces or eliminates the formation of a pink-colored catechol-based impurity. They claim the commercial paroxetine tablets produced by and limited to the specified process. That is their invention. They do not assert that the claims cover every form of paroxetine however it is produced, and they report that paroxetine is well known. The district court, citing the confusion of conflicting Federal Circuit precedent, held that the process steps in the '944 claims are not claim limitations, whereby the court held the claim invalid because paroxetine itself is a known compound.

It is not the law that process limitations in product claims are not claim limitations. It is not the law that process limitations are ignored in construing claims, whatever the nature of the invention. Claims state the invention for which a patent is sought. See 35 U.S.C. §112 ¶2 (claims state "the subject matter which the applicant regards as his invention"). All claims are construed in light of the specification: the observer looks to the specification to ascertain what has been invented, and understands the claim accordingly. See Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). This rule is not suspended when product and process limitations appear in the same claim. No precedent so requires, and no policy is served by this creative new rule.

Claim construction is a fact-dependent, invention-oriented exercise in logic and law. It requires judicial awareness that patent claims are directed to inventions which come in great variety. There is no need for judges to create one-type-fits-all pigeonholes for claims, even for claims containing process limitations.

When product and process limitation appear in the same claim it is generally because these limitations serve to define and distinguish the invention. Practitioners well understand the variety of types of claims that may contain both product and process limitations. As discussed by E.P. Mirabel, Product-by-Process Claims: A Practical Perspective, 68 J. Pat. & Trademark Off. Soc'y 3 (1986), the most prevalent types are (1) claims where the product is defined by the way it is made; (2) claims to a product that is limited by process steps, and (3) claims where a process limitation is a "structural" part of the product (e.g., a molded plastic). Failure to understand such distinctions led this court into debate at the time of Scripps Clinic, supra, and Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834 (Fed. Cir. 1992), a debate that remains of concern to practitioners and

courts, see notes 3 and 6 in the majority opinion. The panel majority, apparently itself misunderstanding the distinctions debated in those cases, both prolongs the confusion and misapplies the law to the facts of this case.

This court has sharpened the principles of claim construction, in fulfilling its assignment to bring national uniformity to patent principles. Thus the court reaffirmed *en banc* in Phillips that claims are construed in light of the specification, recognizing that the claims reflect the invention that is set forth in the specification. That is how we, our predecessor courts, and the Supreme Court, have always construed claims. For example, in Cochrane v. Badische Anilin & Soda Fabrik., 111 U.S. 293 (1884), the Court explained that claims to a new method of producing a known compound are limited to the new method, and do not cover the known compound however it is produced. In the case of General Electric Co. v. Wabash Appliance Corp., 304 U.S. 364, 373 (1938), the Court indicated that process limitations limit the claims to products produced by those processes unless the product itself is patentable, stating: "Although in some instances a claim may validly describe a new product with some reference to the method of production, a patentee who does not distinguish his product from what is old except by reference, express or constructive, to the process by which he produced it, cannot secure a monopoly on the product by whatever means produced." And in Merrill v. Yeomans, 94 U.S. 568 (1877), the Court explained that the principal consideration is whether the invention is the product itself, or the product made by a particular method. The Court recognized the diversity of situations in which product claims can contain process limitations, stating that:

> If the product is meant, the words "by treating them substantially as hereinbefore described" are useless. They are not only useless, but embarrassing; for, by the well-settled rules of construing all instruments,

> some importance must be attached to them; and, if they are to be regarded at all, they must either refer to the process of making the oils for which the applicant is claiming a patent, or they are intended to limit his claim for a patent for the product to that product only, when produced by treating the oils in the manner before described.

Merrill, 94 U.S. at 571.

These early cases nicely illustrate the fundamentals of modern-day claim construction in light of the specification; they are not a pronouncement that it is proper to ignore process limitations in product claims. To the contrary, all of these cases state the obverse of the panel majority's view. These long-standing rules of claim construction have had many iterations, such as summarized by our predecessor court in In re Luck, 476 F.2d 650, 653 (CCPA 1973), that "to the extent these process limitations distinguish the product over the prior art, they must be given the same consideration as traditional product characteristics." That is, the process limitations cannot be ignored.

While a patentee can choose how to claim his invention, the choice must be commensurate with the nature of the invention. Perhaps this is where the court lost its focus in the debate on Scripps and Atlantic Thermoplastics. When correctly viewed, these two decisions are not in conflict; they simply deal with different situations, as I have previously advised. See Id., 974 F.2d at 1282-84 (Newman, Rich and Lourie, JJ., dissenting from the denial of rehearing *en banc*). To the extent that these differences remain unclear, it is time for clarity.

In Scripps the invention was a novel protein (the blood clotting factor VIII:C) of unknown structure based on the science as it then existed. Applying precedent, this court held that the product claims characterized by the specific activity of the product were not limited to the method of production, and remanded for determination of infringement.

Although advances of science have diminished the reason for such claims, this recognition of the complexity of this important new science filled a pragmatic need. I will not reprise the old debate. What is important, now that the issue is again before us, is that it be correctly resolved.

The district court held that the process limitations in claims 1 and 2 do not limit the claims, such that the claims are simply directed to paroxetine, a known product, in the belief that Federal Circuit precedent so required. The court stated: "separated from the process limitations, claim 1 of the '944 Patent is a 'pharmaceutical composition in tablet form containing paroxetine,'" a product of the prior art, and held the claims invalid on the ground of anticipation. My colleagues repeat this error.

The fundamentals of claim analysis require that all of the claim limitations limit the claim. We have so held in myriad decisions. The panel majority's holding that a claim to a product is never limited by the process limitations in the claim is an extraordinarily mischievous holding, for there are thousands of patents with such claims. It is for the inventor, not the judge, to state what has been invented and to choose how to claim it. Our system of patents absorbs a glorious variety of human ingenuity, and each year well over a hundred thousand patents are granted, each claiming a different invention, each including claim limitations that the patentee is entitled to rely upon to distinguish the invention and avert "anticipation." Although my colleagues state that "[b]oth the district court and SmithKline misunderstand the nature of anticipation," maj. op. at 5, I fear that the misunderstanding is on the part of others.

The term "anticipation" in patent usage means that the invention was previously known to the public; that is, that it previously existed in the precise form in which it is

claimed, including all of the limitations in the claim. It is not correct that, as a rule of claim construction, a claim that contains product and process limitations is free of the process limitations, whatever the nature of the invention. The district court felt constrained to apply the holding in Scripps to the quite different facts of this case, a constraint for which this court must take responsibility by refusing to clarify the growing uncertainty. When the process limitations in a claim distinguish the invention as a whole from the prior art, when they are material to the invention as set forth by the inventor, the claim cannot be "anticipated" by prior art that does not have all of the limitations in the claim. Helifix Ltd. v. Blok-Lok, Ltd., 208 F.3d 1339, 1346 (Fed. Cir. 2000) (anticipating reference must disclose "each and every limitation of the claimed invention"); General Electric Co. v. Nintendo Co., 179 F.3d 1350, 1356-57 (Fed. Cir. 1999) ("To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter."). Applying the law correctly, the claims here at issue cannot be found on summary judgment to be anticipated.

II

RULE 54(B) AND SUMMARY JUDGMENT

The issue on this Rule 54(b) appeal of a summary judgment of anticipation related solely to the question of whether the process steps in the claims are limitations to the claims, for it is not disputed that if they are, the claims are not "anticipated." In such case, remand would be the next step, to consider other issues that were not part of the Rule 54(b) judgment. In their opinion, my colleagues volunteer that various issues not

mentioned in the summary judgment are deemed "waived," apparently because they were not fully briefed and argued on this appeal.

It is surely procedurally incorrect to require that issues not properly before us because not decided by the district court, must nonetheless be briefed and argued on appeal. According to the panel majority, when the appellant sticks to the issues on appeal he risks a waiver of the non-issues; and when he argues non-issues he risks a scolding. This appellant tried to satisfy both factions, and received both punishments. The reference to "pigs hunting for truffles buried in briefs," maj. op. at 14, is misdirected.