United States Court of Appeals for the Federal Circuit

02-1439

GENEVA PHARMACEUTICALS, INC.,

Plaintiff/Counterclaim Defendant-Appellee,

and

NOVARTIS AG and BIOCHEMIE GmbH,

Counterclaim Defendants,

and

RANBAXY PHARMACEUTICALS, INC. and RANBAXY LABORATORIES LIMITED,

Plaintiffs/Counterclaim Defendants- Appelle

and

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff/Counterclaim Defendant-Appellee,

v.

GLAXOSMITHKLINE PLC,
SMITHKLINE BEECHAM CORPORATION (doing business as GlaxoSmithKline Inc.),
SMITHKLINE BEECHAM PLC, and BEECHAM GROUP PLC,

Defendants/Counterclaimants-Appellants.

Dimitrios T. Drivas, White & Case, of New York, New York, argued for plaintiff-counterclaim defendants-appellees Geneva Pharmaceuticals, Inc. Of counsel was Leslie Morioka.

Joseph F. Jennings, Knobbe, Martens, Olson & Bear, of Irvine, California, for plaintiff/counterclaim defendants-appellees. Ranbaxy Pharmaceuticals, Inc. and Ranxbaxy Laboratories Limited. Ranbaxy relied on the brief and the argument of Teva Pharmaceuticals USA, Inc. Of counsel were William R. Zimmerman, Christy L. Green, and Darrell L. Olson.

2

Thomas J. Meloro, Jr., Kenyon & Kenyon, of New York, New York, argued for

plaintiffs/counterclaim defendants-appellees Teva Pharmaceuticals USA, Inc. With him on the brief were Steven J. Lee, Larissa A. Soccoli, and Robert V. Cerwinski. Of counsel on the brief was C. Kyle Musgrove, Kenyon & Kenyon, of Washington, DC.

Donald R. Dunner, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, argued for defendants/counterclaimants-appellants. With him on the brief were Kelly A. Casey and Michael J. McCabe II, Finnegan, Henderson, etc., of Atlanta, Georgia.

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

Judge Henry C. Morgan, Jr.

United States Court of Appeals for the Federal Circuit

02-1439

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GLAXOSMITHKLINE PLC,
SMITHKLINE BEECHAM CORPORATION (doing business as GlaxoSmithKline Inc.),
SMITHKLINE BEECHAM PLC, and BEECHAM GROUP PLC,

Defendants/Counterclaimants-Appellants.

DECIDED: November 21, 2003

Before MAYER, Chief Judge, RADER, and BRYSON, Circuit Judges.

RADER, Circuit Judge.

The United States District Court for the Eastern District of Virginia granted summary judgment invalidating the claims of several patents for nonstatutory double patenting. Geneva Pharms., Inc. v. GlaxoSmithKline, PLC, 189 F. Supp. 2d 377 (E.D. Va. 2002) (Geneva I); 213 F. Supp. 2d 597 (E.D. Va. 2002) (Geneva II); No. 2:01cv391 (E.D. Va. July 19, 2002) (Geneva III). Because the district court correctly found that these patents are invalid, this court affirms.

I.

The invalidated patents all originated in U.S. Patent Application No. 05/569,007 (the '007 application, now abandoned) filed almost thirty years ago on April 17, 1975. The United States Patent and Trademark Office (PTO) issued a restriction requirement in the '007 application, asking the applicants to choose from one of eight distinct inventions that the PTO identified by groups of claims. This action separated the applications into two branches – one leading to patents granted in 1985, the other to patents granted in 2000/01, as shown by the table below. The record shows no terminal disclaimers in any of the patents. The appendix contains a diagram of the relationships amongst the patents and their parent applications.

1985 Patents[*]	2000/01 Patents
4,525,352 ('352 patent)	6,031,093 ('093 patent)
4,529,720 ('720 patent)	6,048,977 ('977 patent)
4,560,552 ('552 patent)	6,051,703 ('703 patent)
	6,218,380 ('380 patent)

[a*] "1985" and "2000/01" refer to the patents' issue dates.

GlaxoSmithKline, PLC, SmithKline Beecham Corporation, SmithKline Beecham PLC, and Beecham

Group PLC (collectively GSK) own the 1985 and 2000/01 patents, which relate to the antibiotic clavulanic acid and its salts. One of these salts, potassium clavulanate, is an active component of a commercially successful antibiotic that GSK markets as Augmentin®. Augmentin® contains a second active component, the antibiotic amoxycillin. Amoxycillin is the primary antibiotic in Augmentin®.

Some bacteria produce ß-lactamase, a compound that deactivates some antibiotics and makes them less effective against the bacteria. While potassium clavulanate has some antibiotic activity, its main function in Augmentin® is to inhibit ß-lactamase. By inhibiting ß-lactamase, potassium clavulanate prevents deactivation of amoxycillin in patients with bacteria producing ß-lactamase. Thus, amoxycillin and potassium clavulanate act synergistically against these bacteria to generate greater antibiotic activity.

The following are representative claims of the 1985 and 2000/01 patents:

The ’352 patent (issued June 25, 1985):

1. A pharmaceutical composition useful for treating bacterial infections in humans and animals which comprises a synergistically effective amount of clavulanic acid and an antibacterially effective amount of amoxycillin, in combination with a pharmaceutically acceptable carrier.

The ’720 patent (issued July 16, 1985):

1. A method of effecting ß-lactamase inhibition in a human or animal in need thereof arising from a ß-lactamase producing bacteria which comprises administering to said human or animal a ß-lactamase inhibitory amount of clavulanic acid or a pharmaceutically acceptable salt thereof.

The ’552 patent (issued Dec. 24, 1985):

1. A pharmaceutical composition for treating bacterial infections in humans and animals which comprises a synergistically effective amount of clavulanic acid, or a pharmaceutically acceptable salt thereof, and an antibacterially effective amount of a penicillin, or a pharmaceutically acceptable salt or ester thereof.

The ’093 patent (issued Feb. 29, 2000):

1. A solid pharmaceutically acceptable salt of clavulanic acid.

The ’977 patent (issued Apr. 11, 2000):

1. Clavulanic acid free of penicillin N,7-(5-amino-5-carboxyvaleramido)-3-carbamoyloxymethyl-3-cephem-4-carboxylic acid and 7-(5-amino-5-carboxyvaleramido)-3-carbamoyloxymethyl-7-methoxy-3-cephem-4-carboxylic acid.

The ’703 patent (issued Apr. 18, 2000):

1. Purified clavulanic acid.

7. A ß-lactamase inhibitor comprising purified clavulanic acid or a pharmaceutically acceptable salt thereof.

The ’380 patent (issued Apr. 17, 2001):

1. A pharmaceutical composition useful for effecting ß-lactamase inhibition in humans and animals which comprises ß-lactamase inhibitory amount of a pharmaceutically acceptable salt of clavulanic acid, in combination with a pharmaceutically acceptable carrier.

The appellees (collectively Geneva) are generic drug makers seeking to market generic versions of Augmentin®. Geneva applied for regulatory approval to market this compound from the Food and Drug Administration (FDA). See 21 U.S.C. § 355 (2000). That application for FDA approval constitutes infringement. See 35 U.S.C. § 271(e)(2) (2000). Thus the generic pharmaceutical companies initiated three separate lawsuits, later consolidated into this case, seeking a declaratory judgment that the 1985 and 2000/01 patents are invalid.

On February 22, 2002, a magistrate judge limited discovery in the consolidated case to the contents of Geneva’s Abbreviated New Drug Applications (ANDAs). In Geneva I, the district court granted GSK’s motion for partial summary judgment that the ’552 patent is not invalid for nonstatutory double patenting over the ’352 patent, and granted Geneva’s motion for partial summary judgment that the ’380 patent is invalid for nonstatutory double patenting over the ’720 patent. In reaching this result, the district court found that a 1979 examiner interview (1979 interview) in the ’007 application did not show that the PTO issued a restriction requirement. Therefore, 35 U.S.C. § 121 would not shield the

’380 patent against invalidity over the ’720 patent.

In Geneva II, the district court granted Geneva’s motion for partial summary judgment that the ’093, ’977, and ’703 patents are invalid for nonstatutory double patenting over the ’720 patent. The district court concluded that the 1979 interview summary did not require the applicant to file separate patents for the relevant claims. Because the applicant could have avoided the multiple filings, the district court applied the one-way obviousness test. Accordingly, the district court ruled that the ’093, ’977, and ’703 patents’ claims are not patentably distinct from the ’720 patent’s claims and are thus invalid for nonstatutory double patenting.

In Geneva III, the district court ruled that the ’552 and ’352 patents are invalid for nonstatutory double patenting over U.S. Patent No. 4,441,609 (Crowley patent), and that the ’720 patent is invalid for nonstatutory double patenting over U.S. Patent No. 4,367,175 (Fleming patent). GSK owns the Crowley and Fleming patents because GSK has merged with the original assignees of those patents, Beecham Group, Ltd. and Glaxo Laboratories, Inc. The district court heard testimony from three experts, Drs. Sanders and Benet for Geneva, and Dr. Schofield for GSK. In reaching its obviousness ruling, the district court found that Geneva’s experts were more credible than GSK’s expert.

GSK timely appealed the discovery order and the three decisions to this court, which has jurisdiction under 28 U.S.C. § 1295(a)(1) (2000). On appeal, GSK contends that the district court erred in Geneva I and Geneva II because 35 U.S.C. § 121 should shield the 2000/01 patents against nonstatutory double patenting over the ’720 patent. GSK contends that the district court erred in Geneva III because application of double patenting in light of the Crowley and Fleming patents should not render the ’352, ’552, and ’720 patents invalid. GSK also contends that the district court abused its discretion by limiting discovery to the ANDAs.

II.

This court reviews a grant of summary judgment without deference. Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1327 (Fed. Cir. 2001). A court considering summary judgment

must draw all reasonable inferences in favor of the nonmovant. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1985). This court gives due weight to a patent's presumed validity under 35 U.S.C. § 282 (2000), and an accused infringer must show by clear and convincing evidence that a patent is invalid. Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc., 98 F.3d 1563, 1569 (Fed. Cir. 1996).

This court reviews both claim construction and double patenting without deference. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998); Texas Instruments Inc. v. United States Int'l Trade Comm'n, 988 F.2d 1165, 1179 (Fed. Cir. 1993) (citing Gen. Foods Corp. v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 1277 (Fed. Cir. 1992)).

A.

Turning first to the district court's Geneva I and Geneva II decisions, this court examines the holding that the 2000/01 patents are invalid for nonstatutory double patenting over the '720 patent (a 1985 patent). This question, in turn, leads to an examination of the district court's ruling that 35 U.S.C. § 121 does not shield the 2000/01 patents against double patenting.

In § 101, title 35 precludes more than one patent on the same invention. See 35 U.S.C. § 101 (2000). Accordingly, an applicant may obtain "a patent" for an invention. In re Lonardo, 119 F.3d 960, 965 (Fed. Cir. 1997). Section 101, however, only prohibits a second patent on subject matter identical to an earlier patent. Id. Thus, applicants can evade this statutory requirement by drafting claims that vary slightly from the earlier patent.

This court's predecessor, the United States Court of Customs and Patent Appeals, recognized this problem and fashioned a doctrine of nonstatutory double patenting (also known as "obviousness-type" double patenting[1]) to prevent issuance of a patent on claims that are nearly identical to claims in an earlier patent. This doctrine prevents an applicant from extending patent protection for an invention beyond the statutory term by claiming a slight variant. See id. With nonstatutory double patenting, a terminal disclaimer may restrict the slight variation to the term of the original patent and cure the double

patenting rejection. In re Longi, 759 F.2d 887, 892 (Fed. Cir. 1985).

This case asks this court to examine whether 35 U.S.C. § 121 shields the 2000/01 patents from double patenting rejections in light of the '720 patent because the latter resulted from a divisional of a common parent, the '007 application. The '720 patent claims priority to U.S. Patent Application No. 05/964,035 ('035 application). If the '035 application is a divisional of the '007 application, then § 121 would prevent the '720 patent from erecting a nonstatutory double patenting bar against the 2000/01 patents. Section 121 states: "A patent issuing on an application with respect to which a requirement for restriction under this section has been made . . . shall not be used as a reference either in the [PTO] or in the courts against a divisional application or against the original application or any patent issued on either of them." 35 U.S.C. § 121 (2000). Thus, if the 2000/01 patents and the '720 patent trace their lineage back to a common parent which was subject to a restriction requirement, then § 121 intervenes to prevent a nonstatutory double patenting rejection.

During reexamination proceedings for the '093, '977, and '703 patents over the '720 patent, the PTO detected a common ancestry and a restriction requirement. The PTO concluded that § 121 shielded the '093, '977, and '703 patents. The district court examined the record and disagreed, finding no restriction requirement that enables § 121 to act as a shield against the '720 patent.

In this case, GSK faces two hurdles to reach § 121 protection. First, the original '007 application (the parent to the 2000/01 patents and the '720 patent) did not contain the "method of use claims" that later appeared in the '720 patent. Second, the examiner did not issue a formal restriction requirement relating to the claims at issue in any document in the record.

When the PTO requires an applicant to withdraw claims to a patentably distinct invention (a restriction requirement), § 121 shields those withdrawn claims in a later divisional application against rejection over a patent that issues from the original application. The PTO Manual of Patent Examining Procedure (M.P.E.P.) warns examiners to apply restriction requirements carefully to avoid issuing two patents to the same (i.e., patentably indistinct) invention:

> Since requirements for restriction under 35 U.S.C. 121 are discretionary with the Commissioner, it becomes very important that the practice under this section be carefully administered. Notwithstanding the fact that this section of the statute apparently protects the applicant against the dangers that previously might have resulted from compliance with an improper requirement for restriction, IT STILL REMAINS IMPORTANT FROM THE STANDPOINT OF THE PUBLIC INTEREST THAT NO REQUIREMENTS BE MADE WHICH MIGHT RESULT IN THE ISSUANCE OF TWO PATENTS FOR THE SAME INVENTION.

M.P.E.P. § 803.01 (8th ed. Aug. 2001). This passage recognizes that if an examiner issues a restriction requirement between patentably indistinct claims, two patents may issue and prolong patent protection beyond the statutory term on obvious variants of the same invention. This prolongation would occur because § 121 would immunize the restricted application against nonstatutory double patenting rejections.

At the outset, GSK argues that § 121 does not require that the claims later sought to be shielded must appear in an application before restriction. Section 121 indicates otherwise. The first clause states: "If two or more independent and distinct inventions are claimed in one application . . . ." 35 U.S.C. § 121 (emphasis added). This clause notes that the restriction requirement applies to a single application that formally claims two or more distinct inventions. This indicates that the earlier application must contain formally entered claims that are restricted and removed, and that claims to the second invention reappear in a separate divisional application after the restriction. The text of § 121 does not suggest that the original application merely needs to provide some support for claims that are first entered formally in the later divisional application.

PTO regulations at the time also limited restrictions to cases where the examiner enters claims to a separate invention:

> § 1.145 Subsequent presentation of claims for different invention.
>
> If, after an office action on an application, the applicant presents claims directed to an invention distinct from and independent of the invention previously claimed, the applicant will be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in §§ 1.143 and 1.144.

37 C.F.R. § 1.145 (1978) (emphasis added). Section 1.145 thus implies that there can be no restriction

unless the claims are presented and entered. Section 1.142 also requires that the claims must have been pending before any restriction requirement:

§ 1.142 Requirement for restriction.

(a) If two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant in his response to that action to elect that invention to which his claim shall be restricted, this official action being called a requirement for restriction (also known as a requirement for division).

. . . .

(b) Claims to the invention or inventions not elected, if not canceled, are nevertheless withdrawn from further consideration by the examiner by the election, subject however to reinstatement in the event the requirement for restriction is withdrawn or overruled.

37 C.F.R. § 1.142 (1978). By referring to the examiner's "action" as an "official action," the regulation instructs examiners to document restriction requirements. The regulation also plainly refers to claims that were entered in an application. Unless the relevant claims have been entered or are otherwise pending, there would be no need to cancel, withdraw, or reinstate the claims.

In the '007 application, the method of use claims were not entered. Therefore, those claims could not have been subject to a restriction requirement. If the applicants sought the benefit of § 121, the applicants should have requested entry of the claims so that the PTO could issue a formal restriction requirement under § 1.145.

Even if non-pending claims could be restricted, the prosecution history in this case does not document a restriction requirement. The examiner issued no document referring anywhere to "restriction." GSK relies on the 1979 interview summary, which states:

Agreed that "simple ß-lactamase inhibition" compositions are proper in this case, but that method of use claims will go in a (Goldberg) Divisional (964035).

The interview summary does not explain why the compositions were "proper" and the method of use claims were not. This brief text also does not describe the subject matter of the "method of use claims."

The PTO issued two formal restriction requirements in the '007 application (the ultimate parent

of the 1985 and 2000/01 patents). In April 1976, the examiner required restriction between four groups of claims as follows:

Group I: Claims 1-14 and 29-35 [clavulanic acid, its salts and esters, methods of use, and compositions thereof]

Group II: Claims 15-22 [methods of preparation of clavulanic acid from bacteria]

Group III: Claims 23-24 [methods of de-esterification of esters of clavulanic acid]

Group IV: Claims 25-28 [methods of esterification of clavulanic acid]

In June 1976, the applicants filed a response amending the claims. The response acknowledged a May 1976 examiner interview and noted that it was agreed at the interview to reorder the restriction requirement into eight groups. In a subsequent official action dated August 1976, the examiner issued another restriction requirement with the identical groups that appeared in the applicants' response:

Group I: Claims 1, 3-6, 8-10, 36, 39 and 42-69 [clavulanic acid, its salts and esters, methods of use, and compositions thereof]

Group II: Claims 15-22 [microbiological preparation of clavulanic acid and esters]

Group III: Claims 23 and 24 [methods of de-esterification of esters of clavulanic acid]

Group IV: Claims 25-28 [methods of esterification of clavulanic acid]

Group V: Claims 7, 35, 38 and 40 [clavulanic acid esters]

Group VI: Claim 37 [non-pharmaceutically acceptable salt of clavulanic acid]

Group VII: Claims 11-14 and 30-34 [compositions of clavulanic acid or its salts with penicillins or cephalosporins, and methods of use thereof]

Group VIII: Claim 41 [compositions of clavulanic acid or its salts with amino cephalosporins and other antibiotics]

At oral argument, GSK's counsel conceded that the 1979 interview summary does not refer to groups of claims set forth as separate inventions as required by an earlier PTO restriction requirement. Indeed, the record does not show that the 1979 interview summary refers to groups of claims that the examiner considered patentably distinct in the restriction requirements quoted above, or any other formally issued restriction requirement. The restriction requirements quoted above clearly set forth the subject matter and the specific claims that the PTO considered patentably distinct. Both restriction requirements group composition claims together with corresponding method of use claims, e.g., Groups I and VII. No separate groupings correspond to the "simple ß-lactamase inhibition compositions" and "method of use" – the subjects referred to in the 1979 interview summary. GSK contends that the 1979 interview summary refers to a restriction requirement made orally at the interview. The record does not support that contention.

Section 121 shields claims against a double patenting challenge if consonance exists between the divided groups of claims and an earlier restriction requirement. Symbol Techs., Inc. v. Opticon, Inc., 935 F.2d 1569, 1579 (Fed. Cir. 1991) ("Consonance requires that the line of demarcation between the 'independent and distinct inventions' that prompted the restriction requirement be maintained . . . . Where that line is crossed the prohibition of the third sentence of Section 121 does not apply.") (quoting Gerber Garment Tech., Inc. v. Lectra Sys., Inc., 916 F.2d 683, 688 (Fed. Cir. 1990)). If a restriction requirement does not clearly set forth the line of demarcation, then challenged claims could not satisfy the consonance requirement. Therefore restriction requirements must provide a clear demarcation between restricted subject matter to allow determination that claims in continuing applications are consonant and therefore deserving of § 121's protections.

GSK does not meet its burden to show that the record provides a clear demarcation of the allegedly restricted subject matter. In the first place, the record makes the substance of the documented interview uncertain. For example, the interview summary does not state what specific subject matter the allegedly restricted claims cover. The interview summary description refers generally to "simple ß-lactamase inhibition compositions" and "method of use claims." While the 1979 interview summary refers to "method of use claims" in the plural, GSK entered only one claim in the '035 application. This record provides no clear line of demarcation.

The term "restriction" does not appear in the July 9, 1979, response that the applicants filed to Examiner Berch after the interview in the '007 application. That response essentially parrots the 1979 interview summary:

> [I]t was agreed that "simple ß-lactamase inhibition" composition claims, i.e., new claims 97 through 112, are proper in the present case but that method of use claims, that is a method of effecting ß-lactamase inhibition in humans and animals would not be proper in the present case and therefore an appropriate set of method of use claims corresponding to new claims 97 to 112 will be presented in Divisional Application, Serial No. 964,035.

The quoted passage does not state that the examiner required restriction between those two sets of claims. Moreover, the passage does not state that any claims are patentably distinct. The passage refers to composition claims 97-112, but provides no further details about the method of use claims other than that they would "correspond to" claims 97-112.

As to the '035 application, the applicants filed an amendment on April 12, 1979, adding a single method of use claim 106. The '035 application was under examination by a different examiner (Examiner Goldberg). In the amendment, the applicants state for the first time that the Examiner Berch considered the added claim separate and distinct from the claims of the '007 application:

> [T]he Examiner in [569,007] held that the instant method-of-use claim was separate and patentably distinct from the compound, simple compositions and methods employing clavulanic acid . . . and indicated that the claim should be submitted in the instant divisional application.

Examiner Goldberg was not at the interview and therefore could not personally corroborate that statement. The record shows no examiner response to the statement. Thus, applicants' uncorroborated

and self-serving statement does not adequately document with sufficient clarity that the PTO required restriction.

This court notes that the PTO reexamined three of the 2000/01 patents (the '093, '977, and '703 patents) in light of the '720 application and concluded that § 121 shielded the patents against the '720 application. But in confirming the claims under reexamination, the examiner relied on flawed reasoning expressed in the corresponding Notices of Intent to Issue Reexamination Certificate (NIRC). In each reexamination, the examiner relied on the ambiguous 1979 interview summary to substantiate the alleged restriction requirement. The reexamination examiner stated that the "present series of application [sic] has been consistent with the patentable distinction of compounds (and simple compositions thereof) and their methods of use." That statement is plainly inaccurate. As explained above, the issued restriction requirements in this case grouped compounds, compositions, and methods of use together.

GSK took about a quarter-century to prosecute the 1985 and 2000/01 patents to issue. This record does not explain that delay. In any event, the effect of that delay could potentially extend patent protection for the invention in the original '007 application. For that reason as well, this thin and insufficient record simply does not operate to shield these patents under § 121 against double patenting rejections. Section 121 can extend the patent term for inventions that are not patentably distinct, as apparently would be the case here. Given the potential windfall such patent term extension could provide to a patentee,[2] this court applies a strict test for application of § 121. Specifically, § 121 only applies to a restriction requirement that is documented by the PTO in enough clarity and detail to show consonance. The restriction documentation must identify the scope of the distinct inventions that the PTO has restricted, and must do so with sufficient clarity to show that a particular claim falls within the scope of the distinct inventions. In other words, § 121 requires a record that shows a discernable consonance.

This record is deficient. Accordingly, § 121 does not shield the 2000/01 patents against the '720 patent. Without a patentable distinction, the 2000/01 patents are invalid for nonstatutory double patenting. Thus, the district court correctly discerned that the allegedly restricted claims were not

pending at the time and that the alleged restriction requirement was not sufficiently memorialized to show consonance.

B.

In Geneva III, the district court held that the claims of the '352 and '552 patents are invalid for nonstatutory double patenting over the Crowley patent. The table below shows claim 1 of the Crowley, '352, and '552 patents (paragraphing added).

Crowley (U.S. 4,441,609)	'352 Patent	'552 Patent
1. A packaged pharmaceutical composition of enhanced storage stability which comprises a closed container containing one or more unit-dose compositions suitable for oral administration each dosage unit of which comprises 20 mg to 1500 mg of amoxycillin trihydrate, 20 mg to 500 mg of potassium clavulanate and a pharmaceutically acceptable carrier with the proviso that the weight ratio of amoxycillin trihydrate to	1. A pharmaceutical composition useful for treating bacterial infections in humans and animals which comprises a synergistically effective amount of clavulanic acid and an antibacterially effective amount of amoxycillin, in combination with a pharmaceutically acceptable carrier.	1. A pharmaceutical composition for treating bacterial infections in humans and animals which comprises a synergistically effective amount of clavulanic acid, or a pharmaceutically acceptable salt thereof, and an antibacterially effective amount of a penicillin, or a pharmaceutically

potassium clavulanate is from 6:1 to 1:1 and a desiccant.		acceptable salt or ester thereof.

As this table shows, the earlier Crowley claim is basically a species of the '352 and '552 compositions packaged in a closed container with a desiccant. Overall, the '352 and '552 claims recite limitations that are either broader than or obvious variants of corresponding limitations in the Crowley claim. The parties do not dispute that it would have been an obvious variation of the Crowley claim to omit the enhanced storage stability, the closed container, the packaged unit-dosages, the weight ratios, and the desiccant. Moreover, clavulanic acid would have been an obvious variant of Crowley's potassium clavulanate. Amoxycillin and penicillin are generic to Crowley's amoxycillin trihydrate.

Small differences in a few limitations prevent Crowley from being a pure species of the '352 and '552 claims. If the Crowley claims were purely a species of the broader genus claimed in the '352 and '552 claims, the latter would be anticipated outright. A claim cannot be patentably distinct over anticipatory subject matter. Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 970 (Fed. Cir. 2001); see also In re Goodman, 11 F.3d 1046, 1053 (Fed. Cir. 1993) (an earlier species claim anticipates and therefore is not patentably distinct from a later genus claim). With the Crowley claim so similar to the later claims, GSK focused its efforts to find a patentable distinction on a single limitation.

Thus, to escape the problem of substantially overlapping subject matter, GSK emphasized that the possible point of patentable distinction is the '352 and '552 claims' "synergistically effective amount" limitation. The corresponding limitation in Crowley is 20 mg to 500 mg of potassium clavulanate. The district court found the term "synergistically effective amount of clavulanic acid" ambiguous. Relying on a definition in the specification to resolve the ambiguity, the district court construed the term to mean 50 mg to 500 mg. The district court buttressed this conclusion with its finding that Geneva's two

experts, Drs. Sanders and Benet, were more credible than GSK's expert, Dr. Schofield. Based on that construction, the district court held that the '352 and '552 patents are invalid for nonstatutory double patenting over the Crowley patent.

Our predecessor court has stated that "effective amount" is a common and generally acceptable term for pharmaceutical claims and is not ambiguous or indefinite, provided that a person of ordinary skill in the art could determine the specific amounts without undue experimentation. In re Halleck, 422 F.2d 911, 914 (CCPA 1970). By its terms, a "synergistically effective amount" is a functional limitation. As explained in In re Swinehart, 439 F.2d 210, 213 (CCPA 1971), a functional limitation covers all embodiments performing the recited function. Thus, this claim term should not be limited to the disclosed dosage range of 50 mg to 500 mg but instead should encompass any dosage amount that can achieve therapeutic synergy.

This construction yields no patentable distinction if the covered amounts nearly or completely encompass Crowley's disclosed range of 20 mg to 500 mg. To avoid invalidity, GSK seeks to read more into these claim terms to make the dosage range depend on the particular antibiotic and bacteria. According to GSK, a formulation falls outside the scope of the claims if a given antibiotic, bacteria, and disease combination provides no synergy.

This reading of the claim is indefinite. A claim is indefinite if its legal scope is not clear enough that a person of ordinary skill in the art could determine whether a particular composition infringes or not. See 35 U.S.C. § 112 (2000). Here, "synergy" refers to activity against bacteria that the claims do not identify. By GSK's proposed construction, a formulation (including AUGMENTIN®) might infringe or not depending on its usage in changing circumstances. In other words, a given embodiment would simultaneously infringe and not infringe the claims, depending on the particular bacteria chosen for analysis. Thus, one of skill would not know from one bacterium to the next whether a particular composition standing alone is within the claim scope or not. That is the epitome of indefiniteness. This court therefore rejects this proposed construction.

The term "synergistically effective amount" must mean any amount that is synergistic against

any bacteria. The fact that the same dosage amount does not yield synergy under other circumstances is irrelevant; once a particular amount yields synergy under any circumstance, that amount is "synergistically effective." This construction is almost certainly broader than that of the district court and encompasses Crowley's corresponding "20 mg to 500 mg" limitation. There is no reason to believe that a bacterium providing synergy could not be found for any and all amounts within, and even outside, the range of 50 mg to 500 mg disclosed in the '352 and '552 patents and adopted by the district court.

This broader construction strengthens the district court's conclusion that the '352 and '552 claims are invalid for nonstatutory double patenting over the Crowley patent. The '352 and '552 patents claim subject matter that encompasses a substantial part of the subject matter of the Crowley claim. The '352 and '552 claims are thus generic to a substantial part of the scope of the Crowley claim. This genus-species relationship makes the claims patentably indistinct, because the earlier species within the Crowley claim anticipates the later genus of the '352 and '552 claims.

The district court properly held that the '352 and '552 patents are invalid.

C.

In Geneva III, the district court held that the '720 patent is invalid for nonstatutory double patenting over the Fleming patent. The claims at issue state:

Fleming (U.S. 4,367,175)[3]	'720 Patent
1. Potassium clavulanate of the formula _____[4] having a molar extinction coefficient as determined in 0.1 M aqueous potassium hydroxide using ultraviolet light of wavelength 258 nm of about 17000.	1. A method of effecting ß-lactamase inhibition in a human or animal in need thereof arising from a ß-lactamase producing bacteria which comprises administering to said human or animal a ß-lactamase inhibitory amount of clavulanic

	acid or a pharmaceutically acceptable salt thereof.

The Fleming patent discloses that the molar extinction coefficient limitation indicates purity suitable for pharmaceutical use. Fleming patent, col. 1, l. 67, to col. 2, l. 2. Potassium clavulanate is a salt of clavulanic acid. The patent emphasized the importance of purifying clavulanic acid. Indeed the applicants obtained the compound by fermenting a strain of *Streptomyces clavuligerus* and not by chemical synthesis. Id., col. 1, ll. 10-12, 18-29, and 51-54. So the '720 patent claim differs only as a method of inhibiting ß-lactamase and in specifying the amount of compound necessary to inhibit the ß-lactamase. The district court held that inhibiting ß-lactamase is an inherent property of potassium clavulanate, and therefore the Fleming claims anticipated the '720 claims.

To review the district court's judgment on this point, this court examines the disclosure of the Fleming claim. Nonetheless, this court does not consider the Fleming claim in a vacuum, as a simple compound, without considering the compound's disclosed utility. Because nonstatutory double patenting compares earlier and later claims, an earlier patent's disclosure is not available to show nonstatutory double patenting. See Gen. Foods Corp. v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 1281-82 (Fed. Cir. 1992). Of course, the earlier patent's disclosure may register on the patentability scale if that patent qualifies as prior art under 35 U.S.C. § 102, which is generally not the case. Id.

The challenge of a double patenting analysis, however, is to understand the scope of the compared claims. In this case, for instance, claim 1 of the '720 patent is drawn to a compound having a certain physical property. Standing alone, that claim does not adequately disclose the patentable bounds of the invention. Therefore, this court examines the specifications of both patents to ascertain any overlap in the claim scope for the double patenting comparison. See In re Avery, 518 F.2d 1228, 1232 (CCPA 1975); In re Zickendraht, 319 F.2d 225, 228 (CCPA 1963).

A person of ordinary skill in the art reviewing the disclosure of the Fleming patent would recognize a single use for potassium clavulanate, administration to patients to combat bacteria that produce ß-lactamase. The Fleming patent discloses that the claimed compound is "a novel antibiotic . . . for use in conjunction with ß-lactam antibiotics which show susceptibility to ß-lactamases." Fleming patent, col. 1, l. 8, and col. 2, ll. 42-45. The Fleming patent discloses no other use. The '720 patent simply claims that use as a method.

Our predecessor court recognized that a claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use:

> It would shock one's sense of justice if an inventor could receive a patent upon a composition of matter, setting out at length in the specification the useful purposes of such composition, manufacture and sell it to the public, and then prevent the public from making any beneficial use of such product by securing patents upon each of the uses to which it may be adapted.

In re Byck, 48 F.2d 665, 666 (CCPA 1931). In Christmann, our predecessor court affirmed the PTO's nonstatutory double patenting rejection of claims to an insecticidal composition over a prior patent claiming the composition's active component. In re Christmann, 128 F.2d 596 (CCPA 1942). Our predecessor court stated that the applicant could only have obtained a patent by disclosing the composition's utility, and "[s]uch disclosure of usefulness did not constitute separate inventions, but an essential part of a single invention." Id. at 600 (quoting Byck).

These cases apply as well to this court's review of the '720 patent and the earlier Fleming patent. The Fleming patent's claim describes a compound, and Fleming's written description discloses a single utility of that compound as administration to a human in amounts effective for inhibiting ß-lactamase. The '720 patent claims nothing more than Fleming's disclosed utility as a method of using the Fleming compound. Thus, the claims of the Fleming and '720 patents are not patentably distinct. This court affirms the district court's judgment that the '720 patent is invalid for nonstatutory double patenting over the Fleming patent.

D.

Finally, this court considers GSK's appeal of the district court's decision to deny GSK's motion to compel discovery. The district court stated that "it appears that under the parameters set forth by the Federal Circuit at this stage of these cases that the ANDA is the go-by that is needed to be examined, and I'm going to limit the discovery to that."

This court applies the law of the regional circuit, here the Fourth Circuit, to review orders refusing to compel discovery. Am. Standard Inc. v. Pfizer Inc., 828 F.2d 734, 739 (Fed. Cir. 1987). The Fourth Circuit reviews discovery rulings for abuse of discretion. Gutierrez de Martinez v. DEA, 111 F.3d 1148, 1155 (4th Cir. 1997). Because this court affirms that the patents at issue in this case are invalid, the discovery issue is moot.

CONCLUSION

The district court correctly granted summary judgment that the 1985 and 2000/01 patents are invalid for nonstatutory double patenting.

COSTS

Each party shall bear its own costs.

AFFIRMED

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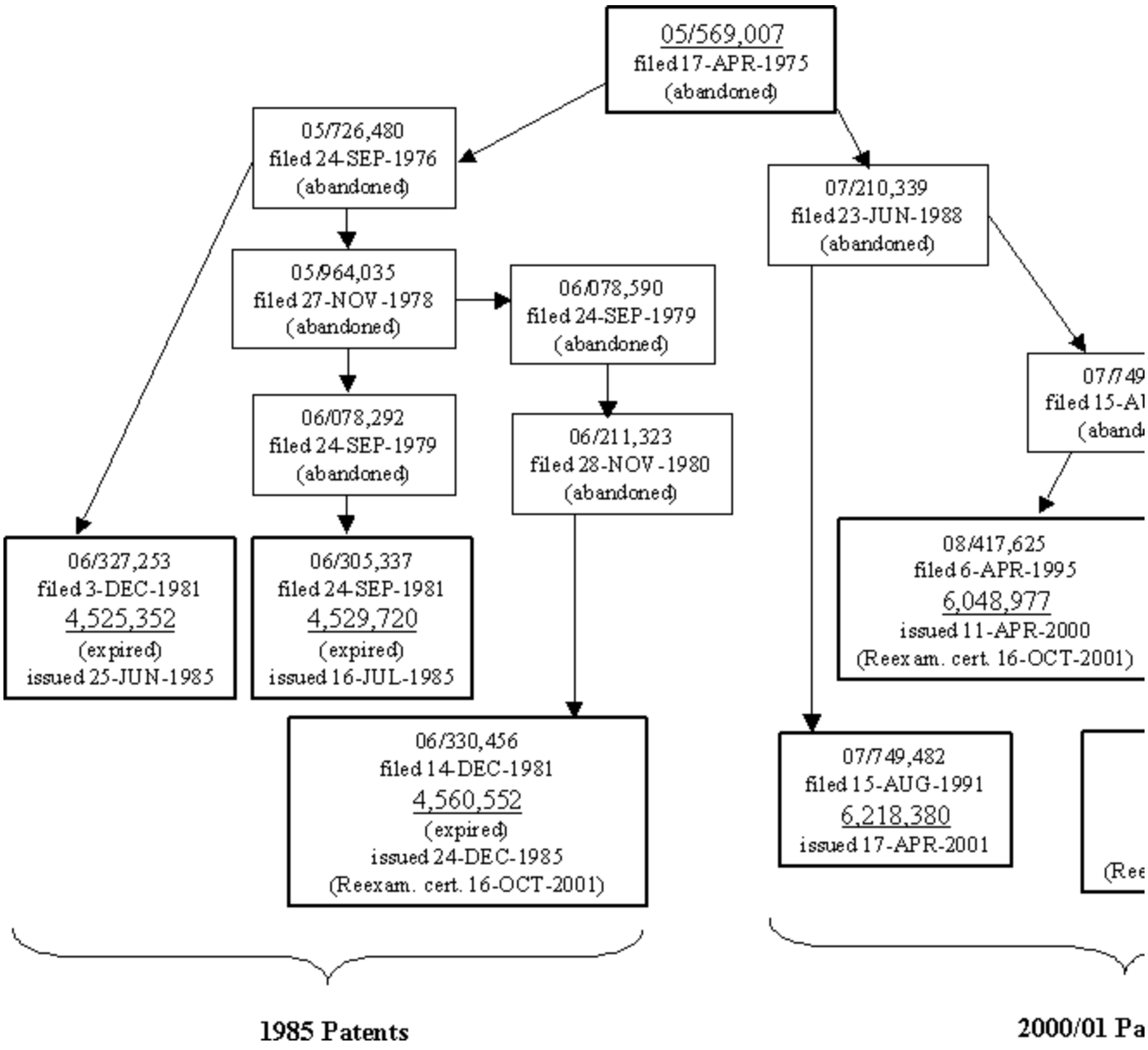

APPENDIX; GSK Patents

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[1] The distinctions between obviousness under 35 U.S.C. § 103 and nonstatutory double patenting include:

1. The objects of comparison are very different: Obviousness compares claimed subject matter to the prior art; nonstatutory double patenting compares claims in an earlier patent to claims in a later patent or application;

2. Obviousness requires inquiry into a motivation to modify the prior art; nonstatutory double patenting does not;

3. Obviousness requires inquiry into objective criteria suggesting non-obviousness; nonstatutory double patenting does not.

[2] One commentator has noted that § 121 can cause "extreme mischief." Martin J. Adelman, Patent Law Perspectives § 2.8[2] at 2-921 (2d ed. 1997).

[3] Claim 1 of two other Fleming patents replace potassium with lithium and sodium.

[4] The formula of the metal clavulanate is redundant to the recited chemical name.