

United States Court of Appeals for the Federal Circuit

03-1077

BRISTOL-MYERS SQUIBB COMPANY,

Plaintiff-Appellee,

and

RESEARCH CORPORATION TECHNOLOGIES, INC.,

Plaintiff-Appellee,

v.

PHARMACHEMIE B.V.,

Defendant-Appellant.

David T. Pritikin, Sidley Austin Brown & Wood, of Chicago, Illinois, argued for both plaintiffs-appellees. With him on the brief were Constantine L. Trela, Jr., Lisa A. Schneider, and Marc A. Cavan; and Eugenia S. Hansen, Sidley Austin Brown & Wood, of Dallas, Texas. On the brief for plaintiff-appellee Bristol-Myers Squibb Company, was Robert L. Baechtold, Fitzpatrick, Cella, Harper & Scinto, of New York, New York.

Francis C. Lynch, Palmer & Dodge, LLP of Boston, Massachusetts, argued for defendant-appellant. With him on the brief was Laurie S. Gill.

Appealed from: United States District Court for the District of New Jersey

Judge Mary L. Cooper

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Defendant-Appellant.

DECIDED: March 17, 2004

Before NEWMAN, MICHEL, and BRYSON, Circuit Judges.

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

BRYSON, Circuit Judge.

The question in this patent case is whether the patent in suit is invalid for double patenting. The district court held on summary judgment that an earlier patent, which stemmed from the same application as the patent in suit, could not be used as a reference against the patent in suit for double patenting purposes. Bristol-Myers Squibb Co. v. Pharmachemie, B.V., No. 01-3751 (MLC) (D.N.J. July 29, 2002). Because we

disagree with a key conclusion on which the district court's summary judgment was based, we vacate the district court's judgment and remand the case to the district court for further proceedings.

I
A

Research Corporation Technologies, Inc., is the owner of U.S. Patent No. 4,657,927 ("the '927 patent"), and Bristol-Myers Squibb Co. is the exclusive licensee under that patent. The patent claims (1) methods for treating malignant tumors with certain platinum coordination compounds and (2) compositions containing those compounds in amounts sufficient to cause regression of those tumors. Appellant Pharmachemie, B.V., filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration, seeking FDA approval to market a cancer-treating drug covered by the '927 patent. Research Corporation Technologies, Inc., and Bristol-Myers Squibb Co. (collectively "Bristol-Myers") brought suit charging Pharmachemie with patent infringement under 35 U.S.C. § 271(e)(2). As a defense, Pharmachemie asserted that the '927 patent was invalid for obviousness-type double patenting over U.S. Patent No. 4,140,707 ("the '707 patent"), which was issued in 1979 and expired in 1998.

B

The double patenting issue in this case turns on whether Bristol-Myers is entitled to invoke section 121 of the Patent Act, 35 U.S.C. § 121, as a defense against the claim of double patenting. That issue in turn depends on an interpretation of the prosecution history of the '707 and '927 patents.

The '927 patent can be traced to an application filed with the Patent and Trademark Office in 1972. That application, Serial No. 260,989 (“the '989 application”), disclosed and claimed compounds corresponding generally to the compounds that were ultimately claimed in the '707 patent. In addition, the '989 application claimed methods of treatment and compositions corresponding to the claims that were ultimately included in the '927 patent.

In the course of the prosecution of the '989 application, the examiners imposed two restriction requirements. The first, imposed in 1973, required that the applicants elect either the compound claims, classified in art class 260, or the method of treatment and composition claims, classified in art class 424. In addition, the 1973 restriction requirement directed the applicants to elect “a single disclosed species for examination on the merits.” As a result of the 1973 restriction requirement, the applicants elected the compound claims and withdrew the non-elected method of use and composition claims from further consideration at that time. The examiner then rejected the elected compound claims on the basis of lack of utility.

In 1974, a different examiner issued a second restriction requirement on the '989 application. That restriction requirement identified four different compound groups within the compounds claimed in the application as constituting independent and distinct inventions. The four groups were: (1) “Organometallic platinum compound[s] classified in class 260, subclass 429”; (2) “Platinum compounds containing ‘heterocyclic amines’ or [‘]heterocyclic substituents’ classified in class 260, subclass 270R and many various subclasses”; (3) “Compounds of the above type with 2-valent platinum and no L moiety”; and (4) “Compounds with 4-valent platinum containing various ‘anionic’ ligands.” In

addition, the examiner expressly stated that the 1973 restriction requirement segregating the compound claims from the method of use and composition claims was maintained. The applicants did not file a divisional application in response to either of the restriction requirements, but instead appealed the final rejection of the claims to the PTO Board of Appeals.

In 1977, while that appeal was pending, the applicants filed a continuation application, Serial No. 778,955 (“the ’955 application”), and abandoned the ’89 application. The ’955 application presented all of the original claims of the ’89 application for examination. A new examiner examined the ’955 application “for restriction only” and imposed a new restriction requirement. The 1977 restriction requirement differed from the 1973 and 1974 requirements that had been imposed in connection with the ’89 application. The 1977 restriction requirement mandated that the claims be separated into four groups, but unlike the 1973 restriction requirement, it did not segregate the compound claims from the method of use and composition claims. Instead, the first two of the four groups set forth in the restriction requirement referred to art groups that included methods of use and compositions as well as compounds. The first group consisted of “[o]rganometallic platinum compound[s] classified in class 260, subclass 429 [compounds] and class 424, subclass 287 [methods of use and compositions].” The second group consisted of “[p]latinum compounds containing ‘heterocyclic amines’ or [‘]heterocyclic substituents’ classified in Class 260, subclasses 270R and many various subclasses [compounds], and Class 424 subclass 245 [compositions and methods of use].” The third group set forth in the 1977 restriction requirement consisted of “[c]ompounds of the above type with 2-valent platinum and no

L moiety.” The fourth group consisted of “[c]ompounds with 4-valent platinum containing various ‘anionic’ ligands.”

The applicants responded to the 1977 restriction requirement by electing four claims, which corresponded to the claims that were ultimately included in the '707 patent that issued two years later. Before that patent issued, however, the applicants filed a divisional application, Serial No. 902,706 (“the '706 divisional application”). After a preliminary amendment, the '706 divisional application included 16 claims, denominated claims 5-20. Claims 5-13 were cancelled shortly thereafter. The remaining claims, in slightly rewritten form, claimed the non-elected compound groups and the methods of use and compositions originally claimed in both the '989 and the '955 applications. Following the filing of the '706 divisional application, the '707 patent issued, containing the four compound claims that had been elected from the '955 application.

The examiner issued a restriction requirement with respect to the '706 divisional application. The office action began with the statement “Restriction has been required . . . between the following inventions,” after which the examiner divided the claims into three groups: claim 14, “which is drawn to Platinum (II) complexes classified in Class 260, subclass 270R”; claim 15, “which is directed to platinum (IV) complexes classified in Class 260, subclass 429R”; and claims 16-20, “which are drafted to composition and method [sic] classified in Class 424, subclass 245, 287.” In the same office action, the examiner then set forth a second, four-way restriction requirement, which replicated the four-way restriction requirement that had earlier been imposed on the claims of the '955 application. The applicants responded to that office action by

asserting that the two restriction requirements seemed to be “somewhat in conflict” in that “any invention elected in accordance with the requirements [of the first] would necessarily involve election of one or more of the groups set forth [in the second].” In an effort to comply with the requirements, however, the applicants elected claim 14 of the '706 divisional application.

In 1983, after further unsuccessful appellate proceedings, the applicants filed another divisional application, which again consisted of the original 1972 application. In preliminary amendments, the applicants canceled the 13 original claims and added, as claims 14-19, the claims that had been claims 15-20 of the '706 divisional application. Another examiner was assigned to the application and another restriction requirement was issued. This time, the examiner divided the claims into two groups, one consisting of claim 14, “drawn to platinum IV complexes, classified in Class 260, subclass 239E,” and the other consisting of claims 15-19, “drawn to methods of use and compositions, classified in Class 424, subclass 245.” In 1987, that application matured into the '927 patent. The four claims of the '927 patent corresponded generally to four of the method of use and composition claims of the 1983 divisional application.

C

The district court noted that the question whether section 121 of the Patent Act is available to Bristol-Myers depends on whether the applicants were required by a restriction requirement to prosecute the claims that ultimately became part of the '927 patent separately from the claims that became part of the '707 patent. The court concluded that the statutory requirement was satisfied because “it is evident that the original 1973 restriction requirement remained in effect and required the applicants to

pursue their method of treatment and pharmaceutical composition claims in a divisional application. This restriction requirement was never cancelled, revoked, or withdrawn.”

Accordingly, the court concluded,

the divisional application pursuing method of treatment and pharmaceutical composition claims was filed as a result of the restriction requirement and was not a “voluntary” act; over the years, the applicants made repeated attempts to traverse the PTO’s restriction requirement but were not permitted to combine compound claims with method of treatment and composition claims.

Because the court concluded that section 121 barred the assertion of double patenting as a basis for Pharmachemie to assert the invalidity of the '927 patent, and because Pharmachemie abandoned any other defense against Bristol-Myers’ claim of infringement, the court entered final judgment of infringement. Pharmachemie appealed.

II

Section 121 of the Patent Act provides, in pertinent part, as follows:

If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 [of the Patent Act] it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

35 U.S.C. § 121.

As section 121 has been interpreted by this court, Bristol-Myers is entitled to invoke the statutory prohibition against the use of the '707 patent "as a reference" against the divisional application that resulted in the '927 patent only if the divisional application was filed as a result of a restriction requirement and is consonant with that restriction requirement. See Geneva Pharms., Inc. v. Glaxosmithkline PLC, 349 F.3d 1373, 1378, 1381 (Fed. Cir. 2003); Gerber Garment Tech., Inc. v. Lectra Sys., Inc., 916 F.2d 683, 687 (Fed. Cir. 1990). The district court held that the divisional application that led to the '927 patent was filed as a result of, and was consistent with, the restriction requirement issued in 1973. According to the court, that 1973 restriction requirement resulted in the 1978 divisional application that ultimately resulted in the '927 patent, because the 1973 restriction requirement "remained in effect and required the applicants to pursue their method of treatment and pharmaceutical composition claims in a divisional application." Although the 1973 restriction requirement was issued against the '989 application, and not against the '955 application, from which the 1978 divisional was filed, the court ruled that the 1973 restriction requirement applied to the later application because it "was never cancelled, revoked, or withdrawn."

Our review of the district court's summary judgment order in this factually complex case presents a relatively straightforward question: whether the district court was correct to conclude, as a matter of law, that the 1973 restriction requirement was applicable to the 1977 application and therefore resulted in the 1978 divisional application.¹ The district court held that it was and that the patent therefore cannot be

¹ The dissent appears to take the position that by issuing the '927 patent the PTO in effect found that the applicant complied with all applicable restriction requirements, and that we should not disturb that determination. In fact, however, the question

cited as a reference against the '927 patent for double patenting purposes. Pharmachemie, on the other hand, argues that the 1973 restriction requirement was not in effect at the time of the filing of the divisional application that matured into the '927 patent, and that the '927 patent therefore cannot be said to have been filed as a result of that restriction requirement.

We agree with Pharmachemie. The '955 continuation application, which was filed in 1977, began a new proceeding in which all of the original claims of the '989 application were once again presented for examination.² In 1977, when the examiner for the '955 application issued the restriction requirement for that application, she did not reinstate or even advert to the 1973 restriction requirement. In fact, the 1977 restriction requirement that she issued at the outset of the prosecution of the '955

whether the requirements of section 121 have been satisfied is a question of law that we have addressed de novo after reviewing the relevant materials. See Geneva, 349 F.3d at 1377; In re Berg, 140 F.3d 1428, 1432 (Fed. Cir. 1988). The approach suggested by the dissent would be inconsistent with the approach we have employed in similar cases in the past. In Geneva, and Gerber, for example, we held that applicants had failed to satisfy the requirements of section 121 based on our analysis of the prosecution history. Even in cases in which we have held that the requirements of section 121 were satisfied, we did so not as a result of deference to the PTO but as a result of our own analysis of the prosecution history. See Symbol Techs., Inc. v. Opticon, Inc., 935 F.2d 1569 (Fed. Cir. 1991); Tex. Instruments Inc. v. U.S. Int'l Trade Comm'n, 988 F.2d 1165 (Fed. Cir. 1993).

² Bristol-Myers has not cited any statutory or regulatory basis for concluding that the 1973 restriction requirement was automatically applicable to the '955 continuation. Bristol-Myers cites several cases and a provision (section 201.07) of the 1972 version of the Manual of Patent Examining Procedure ("MPEP") for the proposition that a continuation application and its parent are "one continuous application, within the meaning of the law." Godfrey v. Eames, 68 U.S. 317, 326 (1864); accord Transco Prods. Inc. v. Performance Contracting, Inc., 38 F.3d 551, 556-57 (Fed. Cir. 1994). Those authorities, however, do not support the proposition for which Bristol-Myers cites them. The cases deal only with the issue of priority, and not with PTO procedure for examining a continuation application in light of its parent. Likewise, the cited MPEP

application was different from, and inconsistent with, the 1973 restriction requirement. The 1977 restriction requirement, unlike the 1973 restriction requirement, grouped compounds together with methods of use and compositions in at least two of the four invention groups, while the 1973 restriction requirement directed that compounds be segregated from methods of use and compositions. Moreover, the examiner examined the method of use and composition claims “for subject matter of [the elected groups] readable on the elected species” as reflected in the subsequent office action. This suggests that the applicant could have complied with the 1977 restriction requirement in a way that would have been contrary to the categories set forth in the 1973 restriction requirement. By imposition of a new and different restriction requirement and failing to make any reference to the restriction requirements imposed in connection with the parent application, the examiner made clear that the previous restriction requirements did not carry over to the '955 application.

Bristol-Myers argues that the examiner in effect adopted the 1973 restriction requirement in the course of the prosecution of the '955 application. Bristol-Myers suggests that the four-way restriction requirement of 1977 incorporated the two-way restriction requirement of 1973 and thus resulted in a six- or eight-way restriction requirement, part explicit and part implicit. There is no indication in the record, however, that the PTO intended one of the two restriction requirements imposed on the '989 application to carry forward to the '955 application, but not the other. Moreover, the record does not indicate that the applicant proceeded under the assumption that the 1973 restriction requirement continued in effect. During prosecution of the '706

section does not address PTO procedure for examining a continuation, but merely sets

divisional application, when a restriction requirement similar to the 1973 requirement appeared in conjunction with a restriction requirement similar to the 1977 restriction requirement, the applicant noted that the two requirements were “somewhat in conflict” and that “any invention elected in accordance with the requirements [of the first] would necessarily involve election of one or more of the groups set forth [in the second].”

There was, to say the least, some confusion at various points as to how the various claims should be sorted out for purposes of restriction. But even though at some points restriction requirements were imposed that were similar to, or even identical to, earlier restriction requirements, each requirement was nevertheless separately imposed with respect to each separate application. The record thus does not support the inference that any of the various restriction requirements automatically carried forward, in part or in whole, from one application to the next.³ For that reason, we cannot sustain the district court’s summary judgment order, which was based on the court’s conclusion that the 1973 restriction requirement continued in effect with respect to the continuation application that was filed in 1977. Accordingly, we reverse the district court’s judgment and remand for further proceedings.

forth the requirements of a continuation application.

³ Pointing to the examiner’s statement, in an office action on the ’706 divisional application, that restriction “has been required” between three categories of inventions, Bristol-Myers argues that the statement indicates the examiner considered that at least some of the restriction requirements from previous applications continued to apply to the later applications. We do not agree with Bristol-Myers’ conclusion in that regard. The examiner’s isolated use of the present perfect tense in the 1978 office action is not a sufficient basis from which to infer that the examiner understood, or intended to convey, that a restriction requirement imposed five years earlier, in connection with a grandparent application, continued to be in effect for all applications related to the original ’89 application because it was never formally withdrawn.

In light of the complexity of the factual record in this case, we go no further than to address the ground on which the district court ruled. Whether further analysis of the sequence of applications, restriction requirements, and responses by the applicants may reveal other grounds for concluding that the protection of section 121 should be extended to some or all of the claims of the '927 patent is a matter for the district court to address in the first instance.

VACATED and REMANDED.

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NEWMAN, Circuit Judge, dissenting.

My colleagues have peered deep into the recesses of patent examination, plucked out a routine and unreviewable administrative procedure -- the "restriction requirement" for facilitating examination of complex cases -- and created a new standard of administrative review and a new ground of patent invalidity. I must, respectfully, dissent.

Whether or not the patent applicant here in suit was given proper or consistent restriction requirements by the various examiners, the issuance of these actions was entirely discretionary with the Commissioner. When the examiners accepted the

applicant's elections and the divisional applications filed in compliance therewith, these actions are not rulings of law; they are discretionary actions reviewable, if at all, under the strictures of the Administrative Procedure Act. It is not disputed that the applicant made the required election for each restriction requirement, and that the divisional and continuing applications at issue were accepted by the examiner as properly filed. The district court reviewed these procedures and found that 35 U.S.C. §121 protected the patentee from citation of the earlier patent against the later one:

35 U.S.C. §121. . . . A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them

Thus the district court held that under 35 U.S.C. §121 the patent at issue was not an available reference.

If my colleagues on this panel now intend to require that the minutiae of the various discretionary restriction requirements and the acceptance by the examiners of the applicant's compliances with those requirements are subject to appellate review, the standard of review is that of the Administrative Procedure Act, not the de novo untangling of internal procedures for which my colleagues remand to the district court. See Dickinson v. Zurko, 527 U.S. 150 (1999).¹

¹ The majority opinion, in its footnote 1, misperceives my concern. The issue is not the standard of review of the agency's findings of substantive fact in determining patentability. In holding that "the PTO is an 'agency' subject to the APA's constraints," Zurko, 527 U.S. at 1819, the Court required that matters of agency procedure (such as whether a restriction requirement must be repeated) are delegated to the agency. The APA assigns such procedures, which have no substantive impact, to internal agency management; the panel majority distorts the administrative process in

Restriction Requirements are not Appealable within the PTO

The PTO has myriad procedures to guide and facilitate the conduct of patent examination. Rules of operation are essential to the effective performance of a complex agency with many employees and an enormous volume of work.² The PTO's patent examination procedures fill a three-inch thick Manual of fine print. In addition, PTO regulations fill Volume 37 of the Code of Federal Regulations. Over 3500 scientists and engineers apply these procedures to the most advanced science and technology of the age.

Early in the evolution of patent examination the Patent Office adopted the discretionary "restriction" practice, to simplify the search and examination of complex inventions. In electing to require "restriction" the patent examiner requires the applicant to select a specified aspect of the claimed subject matter, the examiner having first divided the subject matter into groups of claims based on classification for search purposes. The applicant then selects the aspect to be examined, and usually also "traverses" the requirement, a formality grounded in administrative protocols. Examination then proceeds as to the selected subject matter. The non-selected aspects are then removed from consideration in that case; they may be rejoined or they may be moved into one or more divisional applications for examination. Lest the first patent be citable as prior art against a divisional application -- an illogical event that

holding that the agency's examining practices in complex cases receive plenary judicial review and management.

² In 2002 the PTO received 333,688 new patent applications and granted 162,221 patents. See 2002 United States Patent & Trademark Office Performance & Accountability Rep. at 15. The average pendency was twenty-four months, id., and hundreds of thousands of applications are under examination at any given time.

apparently had occurred -- the 1952 Patent Act precluded this event by enacting §121. Thus the patentee was shielded from this unintended substantive consequence of an examination procedural convenience. In Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc., 98 F.3d 1563 (Fed. Cir. 1996) this court explained:

The purpose of §121 is to accommodate administrative convenience and to protect the patentee from technical flaws based on this unappealable examination practice Section 121, viewed overall, assures that the technicalities of restriction practice are not elevated from their purpose of examination convenience to a potential taint on the validity of the ensuing patents.

Id. at 1568.

In the present case, four different examiners imposed somewhat variant restriction requirements, reflecting their divergent views of how the subject matter should be divided for search and examination. Some examiners grouped all of the platinum compounds together and all of the cancer-treatment uses together; another put the compositions with the compounds, another with the uses; another separated the different kinds of platinum compounds; another included the corresponding composition and use claims with each type of platinum compound. Some required an election of species; some did not.

To each examiner's restriction requirement, the applicant made the requisite election from among the examiner's categories, while duly "traversing" the requirement. None of the examiners objected to the applicant's compliance with any of the restriction requirements. None rejected a later filed application on an earlier one. None of these actions is appealable to the Board of Appeals or the courts. The Court of Customs and Patent Appeals explained that a restriction decision is not an actual rejection on

grounds of patentability, but simply a procedural requirement. The court explained in In re Hengehold, 440 F.2d 1395, 1399 (CCPA 1971):

On considering §§121, 132 and 134 and the intent unmistakably evinced by the clear language therein, it is evident to us that Congress . . . decided not to regard the procedure involved in matters of "division" or "restriction" as a "rejection." Instead, section 121 denominates restriction procedure as a "requirement." . . . It is apparent, then, that Congress intended to differentiate between whatever requirements and objections an examiner might make on the one hand, and matters involving actual rejections of claims on the other, at least insofar as its provision of statutory rights of appeal to the board accruing from such actions in and of themselves.

440 F.2d at 1402-03 (citations omitted). Restriction requirements are like other PTO "requirements" that are "matters of a discretionary, procedural or nonsubstantive nature." Id. at 1403. See also In re Harnisch, 631 F.2d 716 (CCPA 1980):

In the PTO, patent applications are examined for compliance with the statutory provisions of Title 35, United States Code, as set forth in sections 100, 101, 102, 103, and 112. These are considered to be examinations "on the merits." There are also procedural questions arising under section 121 and related PTO rules concerned with "restriction practice."

Id. at 721.

The only remedy available to an applicant who is dissatisfied with the restriction requirement is a petition to the Director for review:

37 C.F.R. §1.144. After a final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may petition the Director to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested (see §1.181).

Such a procedure implements standard administrative practice relative to agency actions. See generally Martin v. Occupational Safety & Health Review Comm'n, 499 U.S. 144, 151 (1991) ("Because applying an agency's regulation to complex or changing

circumstances, calls upon the agency's unique expertise and policymaking prerogatives, we presume that the power authoritatively to interpret its own regulations is a component of the agency's delegated lawmaking powers.").

Indeed, should there be any imperfections in the agency's interpretations or applications of the regulations with respect to the examiner's theory of restriction or compliance by the applicant, they are not grounds of invalidity. See *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956 (Fed. Cir. 1997):

Procedural lapses during examination, should they occur, do not provide grounds of invalidity. Absent proof of inequitable conduct, the examiner's or the applicant's absolute compliance with the internal rules of patent examination becomes irrelevant after the patent has issued.

Id. at 960. Such internal agency procedures are not judicially reviewable. See *Hyatt v. Boone*, 146 F.3d 1348 (Fed. Cir. 1998):

Regularity of routine administrative procedures is presumed, and departure therefrom, should such have occurred, is not grounds of collateral attack. Courts should not readily intervene in the day-to-day operations of an administrative agency, especially when the agency practice is in straightforward implementation of the statute.

Id. at 1355-56.

The presumption of validity would collapse if the PTO's administration of the restriction protocols could be turned into satellite litigation of patent-destroying consequence. In *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350 (Fed. Cir. 1984) the court referred to

the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more [patent] examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents.

Id. at 1359.

Restriction is a Discretionary Requirement

No statute defines the parameters of the examiner's discretion beyond the authorization of 35 U.S.C. §121, for the subject and scope of this discretion is unrelated to patentability. In In re Hengehold the court explained:

There are a host of various kinds of decisions an examiner makes in the examination proceeding -- mostly matters of a discretionary, procedural or nonsubstantive nature -- which have not been and are not now appealable to the board or to this court [A] requirement for restriction under §121 is now one of those discretionary matters no longer tantamount to a rejection of the claims, . . .

440 F.2d at 1339.

The entrusting of discretionary agency procedures to agency management is a classical administrative practice, requiring judicial restraint. See Vermont Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc., 435 U.S. 519 (1978):

[T]his Court has for more than four decades emphasized that the formulation of procedures was basically to be left within the discretion of the agencies to which Congress had confided the responsibility for substantive judgments.

Id. at 524. In Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 410 (1971) the Court, interpreting the Administrative Procedure Act, stated that internal agency actions are not reviewable if either (1) Congress expressed an intent to prohibit judicial review, or (2) the decision is "committed to agency discretion."

Undoubtedly the procedures surrounding restriction requirements can be complex. An entire Chapter of the Manual of Patenting Examining Procedure is devoted to it.³ By statute it is discretionary, for its purpose is administrative

³ A commentator experienced in the field states: "Many patent examiners and patent practitioners are confused by restriction practice and unity of invention practice in the [USPTO]." Jon W. Henry, Some Comments on "Independent and

convenience, not pitfalls in substantive validity. The fact that four examiners made somewhat inconsistent requirements for restriction does not change the controlling weight of the examiners' steady determination of the applicant's compliance with their requirements. A discretionary action having no substantive consequence and that is unreviewable is not a ground of patent invalidity, and is not subject to collateral attack.⁴

Remand is Inappropriate

The panel majority orders the district court to repeat its review of the restriction process, to search for flaws in the procedure, for my colleagues find it too complex for their appellate decipherment. A complex agency record is not sound reason to discard the required agency deference, or to ask the district court to repeat what the court has already done and ruled upon. Whatever the continuing force of the pre-Zurko "consonance" cases, on which the majority relies, in this case the patents at issue were the product of restriction requirements in which the examiners accepted the applicant's elections and the ensuing divisional applications. The courts lack authority to invalidate

Distinct Inventions of 35 U.S.C. '121 and Unity of Invention (pt. 1), 84 J. Pat. & Trademark Off. Soc'y 745, 748 (2002).

⁴ The majority states by footnote that precedent requires de novo review of not only the lineage of continuing and divisional applications, but also of the correctness of the examiner's issuance of restriction requirements and the examiner's acceptance of the applicant's response to restriction requirements. That is an inapt enlargement of precedent, indeed the case on which the majority relies, Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline, PLC, 349 F.3d 1373 (Fed. Cir. 2003), states that "requirements for restriction under 35 U.S.C. 121 are discretionary with the Commissioner." Id. at 1378 quoting MPEP '803.01. The Manual of Patent Examining Procedure abjures the examiners to exercise care in making restriction requirements, id., but neither the MPEP nor any judicial decision removes the discretion of the Director, formerly termed the Commissioner, nor carves out an exception for restriction requirements into APA review of discretionary actions.

the patent on the basis of an asserted flaw in a discretionary procedure, here proposed after sixteen years. That these restriction requirements were varied and somewhat inconsistent cannot now penalize the patentee, who complied with them and whose compliance was accepted by all of the examiners involved in the examination. See Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 938 (Fed. Cir. 1990) ("[A]ny doubt as to whether the examiner lapsed in his duty [under §121] does not increase the burden on the applicant.")

The sequence of restriction requirements was presented to the district court, who decided the question. It cannot be correct that when the examiner found no flaw in this non-substantive non-appealable procedure, the courts can later conduct a de novo search for some tenuous lapse, and invalidate any patent for which we disagree with the agency's discretionary decision. In Securities & Exchange Commission v. Chenery Corp., 318 U.S. 80 (1943), the Court discussed such discretionary administrative authority:

If the action rests upon an administrative determination -- an exercise of judgment in an area which Congress has entrusted to the agency -- of course it must not be set aside because the reviewing court might have made a different determination were it empowered to do so. But if the action is based upon a determination of law as to which the reviewing authority of the courts does come into play, an order may not stand if the agency has misconceived the law.

Id. at 94.

Compliance with a restriction requirement is an "exercise of judgment," id., and is entrusted to the Director. Each examiner in the case before us determined that the applicant had complied with the requirement that was imposed. The question of

restriction, its correctness and its compliance, cannot now be collaterally attacked as grounds of patent invalidity. The district court's decision should be affirmed.