

Nos. 2006-1213, -1313

United States Court of Appeals
for the
Federal Circuit

AVENTIS PHARMACEUTICALS, INC.,

*Plaintiff/Counterclaim
Defendant-Appellant,*

and

MERRELL PHARMACEUTICALS, INC., AND CARDERM CAPITAL L.P.,

Plaintiffs-Appellants,

v.

BARR LABORATORIES, INC.,

Defendant/Counterclaimant-Appellee,

and

TEVA PHARMACEUTICALS USA, INC.,

Defendant –Appellee.

On appeal from the United States District Court for the District of New Jersey in consolidated case Nos. 01-CV-3627 and 03-CV-0487, Judge Joseph A. Greenway, Jr.

**BRIEF OF PATIENTS NOT PATENTS, INC., AS AMICUS CURIAE IN SUPPORT OF
DEFENDANT-APPELLEES AND AFFIRMANCE OF DISTRICT COURT DECISION**

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TABLE OF CONTENTS

TABLE OF AUTHORITIES	ii
INTEREST OF AMICUS CURIAE.....	iii
SUMMARY OF ARGUMENT.....	1
ARGUMENT.....	i
I. Claim 1 of the ‘353 patent is anticipated by Carr.....	i
II. Genus-species analysis.....	4
A. Background	4
B. Basis for genus-species analysis	5
i. Same Kind	6
ii. Different Scope.....	6
iii. Stable Relationship.....	7
iv. Logical Relation	9
CONCLUSION	11

TABLE OF AUTHORITIES

CASES

<i>Brown v. 3M</i> , 265 F.3d 1349, 60 U.S.P.Q.2d 1375 (Fed. Cir. 2001).	4
<i>In re Bronson</i> , 168 F.2d 548, 78 U.S.P.Q. 63 (CCPA 1948).	6, 9
<i>In re Harnisch</i> , 631 F.2d 716, 206 U.S.P.Q. 300 (CCPA 1980).	10
<i>In re Jennings</i> , 167 F.2d 1014, 77 U.S.P.Q. 613 (CCPA 1948).	5
<i>In re Malagari</i> , 499 F.2d 1297, 182 U.S.P.Q. 549 (CCPA 1974).	3
<i>Merck & Co. v. Biocraft Labs., Inc.</i> , 874 F.2d 804, 10 U.S.P.Q.2d 1843 (Fed. Cir. 1989).	5
<i>Tumblebus, Inc. v. Cranmer</i> , 399 F.3d 754, (6th Cir. 2005).	4
<i>Upsher-Smith Labs., Inc. v. PamLab, L.L.C.</i> , 412 F.3d 1319, 75 U.S.P.Q.2d 1213 (Fed. Cir. 2005).	6

REGULATION

37 CFR § 1.141 (2006)	5
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PATENTS

U.S. Patent No. 4,254,129 (filed Apr. 10, 1979).	1, 2, 3, 5, 7
U.S. Patent No. 6,037,353 (filed Mar. 2, 1995).	1, 2, 3, 7

STATEMENT OF AMICUS CURIAE

Amicus curiae Patients not Patents, Inc. is a 501(c)(3) nonprofit organization based in Washington, D.C. Patients not Patents, Inc. is committed to ensuring access to healthcare through litigation, advocacy and education.

This case is of interest to Patients not Patents, Inc. because the outcome is likely to influence the cost and availability of the drug fexofenadine.

All parties have consented to this motion.

SUMMARY OF ARGUMENT

The district court correctly found that the defendants raised a substantial claim as to whether Claim 1 of the 6,037,353 patent (“the ‘353 patent”) is invalid as inherently anticipated by U.S. Patent 4,254,129 (“the Carr reference”). The prior art Carr reference discloses and claims a method of treating a patient for allergies by administering fexofenadine— a method identical to that claimed in the ‘353 patent. The only difference alleged by the appellants between Claim 1 of the ‘353 patent and the prior art Carr reference is that the latter is directed to the treatment of all patients while the former is directed to the treatment of only liver-impaired patients. Br. of Appellants at 19-20. Although Carr does not specifically teach that fexofenadine may be used to treat allergies in a liver-impaired patient, it is an inherent property of the drug that it can be so used.

In order to obscure an otherwise clear situation of anticipation by inherency, the appellants improperly attempt to apply genus-species analysis to this case. Appellants’ attempt must fail, however, because the case at bar bears virtually none of the indicia that define a genus-species relationship. While both Claim 1 of the ‘353 patent and Claim 7 are directed to methods, they fail to meet other basic premises of the genus-species construction: the generic claim is not broader in

scope than the species claim; the relationship is not independent of context; and no logical reason supports differentiating the claims.

The district court found that a substantial question of validity existed, even in the context of genus-species analysis. However, the court need not have delved into the substance of that analysis because the genus-species framework was inapplicable in the first case.

In the interests of clarity and judicial economy, amicus Patients not Patents urges this Court to address the threshold question of when genus-species analysis should be entertained.

ARGUMENT

I. Claim 1 of the ‘353 patent is anticipated by Carr.

“A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim.” *EMI Group North America, Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350, 60 U.S.P.Q.2d 1423 (Fed. Cir. 2001). Here the patent claim is for “A method of treating a histamine-mediated condition in a patient having impaired liver

function . . . comprising administering to said patient an effective antihistaminic amount of a compound of the formula [fexofenadine].” U.S. Patent No. 6,037,353 claim 1 (filed Mar. 2, 1995). The prior art Carr reference teaches “a method of treating allergic reactions in a patient in need thereof which comprises administering to said patient an effective amount of” fexofenadine. U.S. Patent No. 4,254,129 (filed Apr. 10, 1979). The prior art therefore does not contain an explicit recital that fexofenadine may be used to treat an allergic reaction in a patient having impaired liver function. Appellees argue that Carr nevertheless anticipates because it is an inherent property of fexofenadine that it treats allergies in a person with liver impairment. Br. at 13.

The ‘353 patent notes that it was surprising that fexofenadine did not cause cardiac toxicity in patients with hepatic impairment because toxicity had occurred in patients with hepatic impairment who had been taking a similar drug, terfenadine. Col. 1, lines 52-56. While an unexpected result may figure into obviousness analysis, it is irrelevant to the determination of whether there is anticipation. *See In re Malagari*, 499 F.2d 1297, 1302, 182 USPQ 549 (CCPA 1974) (“If the rejection under § 102 is proper, however, appellant cannot overcome it by showing such unexpected results or teaching away in the art, which are

relevant only to an obviousness rejection”). Either fexofenadine has this property or it does not.

Because there is no dispute that fexofenadine treats allergies in patients with liver impairment, the district court’s analysis should have ended here. Before analyzing the genus-species analysis of the claims as suggested by the plaintiffs, the district court should have determined whether genus-species analysis was appropriate in the first place. Had the court done so, it would have found that such analysis was not appropriate and ended its inquiry.

II. Genus-species analysis

A. Background

Genus-species analysis is a way to logically conceive of information. It is used in a variety of legal contexts, both within and without patent law. *See generally, Fink v. U.S.*, 170 U.S. 584, 586-87 (1898) (custom duties), *Tumblebus Inc. v. Cranmer*, 399 F.3d 754, 762 n.10 (6th Cir. 2005) (trademark). In patent law, it is applied in several areas such as utility, *In re Cavillito*, 282 F.2d 357, 361-62, 127 U.S.P.Q. 202 (CCPA 1960), anticipation, *Brown v. 3M*, 265 F.3d 1349, 1353,

60 U.S.P.Q.2d 1375 (Fed. Cir. 2001), obviousness, *Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807, 10 U.S.P.Q.2d 1843 (Fed. Cir. 1989)); double patenting, *In re Jennings*, 167 F.2d 1014, 1016, 77 U.S.P.Q. 613 (CCPA 1948), and restriction practice, 37 CFR § 1.141 (2006), among others.

However, genus-species analysis should be performed with care to avoid giving to a private party that which is already in the public domain. If this Court upholds the validity of the '353 patent, it would set a dangerous precedent in which drug makers could indefinitely extend their monopolies by patenting a method of treatment on each of an infinite number of subpopulations which may respond differently to treatment. Subpopulations such as the elderly, children and renally-impaired patients often metabolize drugs in different ways or to different degrees. The resulting drug patent evergreening would inflict a heavy burden on the public in terms of the cost of medications.

B. Basis for genus-species analysis

A genus-species analysis, like any other logical construction, is only applicable where each of its underlying premises has been met. The genus and species must be of the same kind, but with different scope, and in a stable and

logical relationship to each other. Where any of these conditions are not met, genus-species analysis should not apply.

i. Same Kind

First, the genus and species must be of the *same kind*. The Court of Customs and Patent Appeals recognized this principle in *In re Bronson*, 168 F.2d 548, 78 U.S.P.Q. 63 (1948), holding that for a genus-species relationship to exist, the claims must be in the same statutory class. There is no dispute that the claims at issue in this case are both directed to methods.

ii. Different Scope

Second, the genus must be broader in scope than the species. Obviously a species cannot be broader in scope than a genus. Genus and species also *cannot be of the same scope*. This Court has long-recognized this principle, but the point was made most recently in *Upsher-Smith Labs., Inc. v. Pamlab, L.L.C.*, 412 F.3d 1319, 1323, 75 U.S.P.Q.2d 1213 (Fed. Cir. 2005). In *Upsher-Smith*, this Court considered whether the optional inclusion of an element anticipated a later patent which specifically excluded the element. *Id.* at 1322. In finding that the patent was anticipated, this Court rejected Upsher-Smith's argument that a genus-species

analysis should be applied. *Id.* at 1323. This Court stated, “[T]his [genus-species] principle is not applicable to the facts of this case because the asserted claims . . . are not limited to a ‘species’ of the composition taught by the European application. The compositions claimed . . . are as equally broad as the compositions taught by the European patent application without antioxidants.” *Id.*

As noted above, both of the claims at issue are of the method kind. The claim of the Carr patent is directed to a method for treating patients suffering from allergies, the same as Claim 1 of the ‘353 patent. Therefore, the claims are of the same scope, and genus-species analysis should not apply.

iii. Stable Relationship

Third, the genus-species relationship must be *stable*. A species cannot go from being inside a genus to outside of a genus, or vice versa, depending on circumstances. This principle is best illustrated in *Eli Lilly & Co. v. Barr Labs., Inc.*, 222 F.3d 973, 55 U.S.P.Q.2d 1609 (Fed. Cir. 2000). In that case, Lilly owned two patents, the later of which it alleged to be a species of the earlier genus patent. The earlier patent claimed fluoxetine and thousands of other compounds, while the claims of the later patent covered only the compound fluoxetine. Lilly argued that

because the earlier patent claimed thousands of compounds, it would not have been obvious to a person having ordinary skill in the art to make and use one particular compound, fluoxetine. This Court rejected Lilly's assertion, holding that Lilly could not disavow its earlier compliance in the first patent with the written description and enablement requirements. *Id.* at 986-87. In other words, Lilly could not assert a genus-species relationship to protect the validity of a narrower patent while enjoying the protection of the earlier, broader patent which it claimed to have possessed and enabled the public to make or use.

Similarly, in the present case, Aventis is the real party in interest which owns both the broad patent on treating allergies in all patients and the narrower patent on treating allergies in liver-impaired patients. For the broader patent to be valid, Aventis's predecessor in interest must have been in possession of, and enabled an ordinarily skilled practitioner to use, the claimed method for all patients. Just as in *Lilly*, Aventis here attempts to circumvent its earlier compliance with these statutory requirements by claiming a genus-species relationship between the patent claims. Aventis should therefore be estopped from arguing that a genus-species relationship exists between the two patents, while at the same time denying a necessary predicate of its analytical construction.

iv. Logical relation

Fourth, the species must *relate* to the genus through a logical differentia. The differentia is what distinguishes a species from the genus and from other species in the genus. For example, the relationship, or differentia, between the genus “animal” and the species “human” may be stated as “a human is an animal which is rational.” Rationality is one characteristic that uniquely identifies humans in the genus of animals. Of course, there are other characteristics which distinguish humans from all other animals, so many definitions of “human” are possible. However, the existence of *some* differentia is the *sine qua non* of genus-species relationships.

Without a differentia, no coherent understanding of a species is possible, and vice versa. Consider, for example, that no differentia exists for the proposition, “navy blue, cyan, orange, and white are colors which are . . .” because there is no logical connection between the colors listed, other than that they are colors.

The requirement that a species must be a coherent organization in order for a genus-species relationship to form is reflected in the case law of this Court’s predecessor. *See In re Bronson*, 168 F.2d 548 (“a generic claim . . . must

comprehend the *organization* covered in each of the species claims,” emphasis added). In *In re Harnisch*, 631 F.2d 716, 719, 206 U.S.P.Q. 300 (CCPA 1980) the solicitor argued that a Markush group is improper where the group is “repugnant to accepted principles of scientific classification.” The court applied this standard and found that the group of compounds was not repugnant to scientific classification because they were all dyes. *Id.* at 723. The court described its holding as applying, not to Markush practice, but to the general concept of unity of invention. *Id.* at 721. Accordingly, some identifiable characteristic must define a species in a claim.

In the present case, the alleged genus would be “a method of treating patients for allergies” and the asserted species could be generalized as “a method of treating liver-impaired patients for allergies.” There is no logical differentia because there is nothing that could complete the sentence, “A method of treating patients for allergies is a method of treating liver-impaired patients for allergies which is . . .” The methods are identical. See *In re Benbow*, 64 F.2d 139 (CCPA 1933) (rejecting genus-species analysis where alleged specific form “is not distinct and separable from the so-called generic invention”). Also note that it would be improper to define the genus as a “patient” and the species as “a patient having impaired liver function” because patients are not being patented. See *supra*, II.i.

The principles of same kind, different scope, stability and logical relation do not exhaust the list of logical predicates for a genus-species analysis. However, they are necessary to any definitional system that relies on a genus-species framework. Without some restrictions on when this framework is proper, a clever claim drafter could dodge almost any anticipatory reference.

CONCLUSION

For the foregoing reasons, the decision denying a preliminary injunction should be affirmed.