United States Court of Appeals for the Federal Circuit

02-1540,-1541,-1542,-1543,-1544,-1545,-1546,-1547,-1548,-1549,
03-1021,-1022,-1023,-1025,-1027

SCHERING CORPORATION,

Plaintiff-Appellant,

v.

GENEVA PHARMACEUTICALS, INC. and NOVARTIS CORPORATION,

and
TEVA PHARMACEUTICALS USA, INC.,

and
ANDRX CORPORATION, ANDRX PHARMACEUTICALS LLC,
and ANDRX PHARMACEUTICALS, INC.,

and
MYLAN PHARMACEUTICALS, INC.,

and
WYETH, ESI-LEDERLE, WYETH PHARMACEUTICALS, and WYETH
CONSUMER HEALTHCARE (formerly American Home Products Corporation,
Wyeth-Ayerst Laboratories, and Whitehall Robbins Healthcare),

and
IMPAX LABORATORIES, INC.,

APOTEX, INC. and NOVEX PHARMA,

COPLEY PHARMACEUTICAL, INC.,

and
GENPHARM, INC.,

Defendants-Appellees.

Robert G. Krupka, Kirkland & Ellis, of Los Angeles California, argued for plaintiff-appellant. Of counsel on the brief were David P. Swenson, Kirkland & Ellis, of Washington, DC; John M. Desmarais, Sandra A. Bresnick, Peter J. Armenio, Maxine Y. Graham, Monica V. Bhattacharyya, and Young J. Park, Kirkland & Ellis, of New York, New York. Of counsel were John F. Hoffman and Arthur Mann, Schering Corporation, of Kenilworth, New Jersey.

Robert D. Bajefsky, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, argued for defendants-appellees Wyeth, ESI-Lederle, Wyeth Pharmaceuticals and Wyeth Consumer Healthcare (formerly American Home Products Corporation, Wyeth-Ayerst Laboratories, and Whitehall Robbins Healthcare). With him on the brief were Barbara R. Rudolph and Matthew J. Mason. Of counsel on the brief were David A. Manspeizer and Lawrence Alaburda, WYETH, of Madison, New Jersey. On the brief was Julie A. Petruzzelli, Venable, Baetjer, Howard, & Civiletti, LLP, of Washington, DC, for defendant-appellee Impax Laboratories, Inc. Of counsel were Peter J. Curtin and James E. Gray. Also on the brief were Edgar H. Haug, Daniel G. Brown, and Porter F. Fleming, Frommer Lawrence & Haug LLP, of New York, New York; for defendant-appellee Genpharm Inc.; Colin A. Underwood, Soloman, Zauderer, Ellenhorn, Frischer & Sharp, of New York, New York, for defendants-appellees Andrx Corporation, Andrx Pharmaceuticals LLC, and Andrx Pharmaceuticals, Inc.; E. Anthony Figg, Joseph A. Hynds, Rothwell, Figg, Ernst & Manbeck, of Washington, DC, for defendant-appellee Mylan Pharmaceuticals, Inc.

Robert S. Silver and William J. Castillo, Caesar, Rivise, Bernstein, Cohen & Pokotilow, Ltd., of Philadelphia, Pennsylvania for defendants-appellees Apotex, Inc. and Novex Pharma.

Thomas L. Creel, Goodwin Procter, LLP, of New York, New York, for defendants-appellees Teva Pharmaceuticals USA, Inc. and Copely Pharmaceutical, Inc. With him on the brief were Frederick H. Rein and Keith A. Zullow.

Douglass C. Hochstetler, Schiff, Hardin & Waite, of Chicago, Illinois, argued for defendants-appellees Geneva Pharmaceuticals, Inc. and Novartis Corporation. With him on the brief were Patricia J. Thompson and Jo-Anne M. Kokoski. Of counsel on the brief was Kevin M. Flowers, Ph.D., Marshall Gerstein & Borun, of Chicago, Illinois.

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

Chief Judge John W. Bissell

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and
IMPAX LABORATORIES, INC.,

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COPLEY PHARMACEUTICAL, INC.,

and
GENPHARM, INC.,

Defendants-Appellees.

DECIDED: August 1, 2003

Before RADER, Circuit Judge, PLAGER, Senior Circuit Judge, and BRYSON, Circuit Judge.

RADER, Circuit Judge.

On summary judgment, the United States District Court for the District of New Jersey determined that claims 1 and 3 of U.S. Patent No. 4,659,716 (the '716 patent) are invalid. Schering Corp. v. Geneva Pharm., Inc., No. 98-1259 (D.N.J. Aug. 8, 2002). Because the district court correctly found that U.S. Patent No. 4,282,233 (the '233 patent) inherently anticipates claims 1 and 3 of the '716 patent, this court affirms.

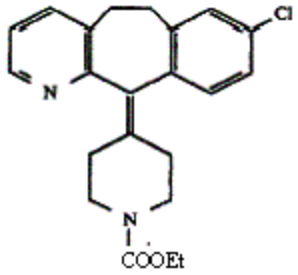
I.

Schering Corporation (Schering) owns the '233 and '716 patents on antihistamines. Antihistamines inhibit the histamines that cause allergic symptoms.

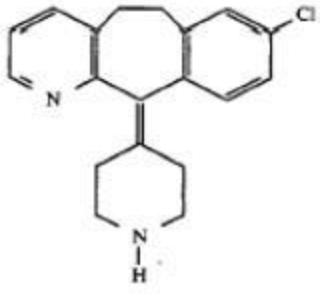
The prior art '233 patent covers the antihistamine loratadine, the active component of a pharmaceutical that Schering markets as CLARITIN™. Unlike conventional antihistamines when CLARITIN™ was launched, loratadine does not cause drowsiness.

The more recent '716 patent at issue in this case covers a metabolite of loratadine called descarboethoxyloratadine (DCL). A metabolite is the compound formed in the patient's body upon ingestion of a pharmaceutical. The ingested pharmaceutical undergoes a chemical conversion in the digestion process to form a new metabolite compound. The metabolite DCL is also a non-drowsy antihistamine. The '716 patent issued in April 1987 and will expire in April 2004 (the '233 patent issued in 1981 and has since expired). See 35 U.S.C. § 154(c)(1) (2000) (defining the term of a patent in force before June 8, 1995, as the greater of twenty years from the earliest U.S. priority date or seventeen years from grant).

Structurally, loratadine and its metabolite DCL differ only in that loratadine has a carboethoxy group (i.e., -COOEt) on a ring nitrogen, while DCL has a hydrogen atom on that ring nitrogen:



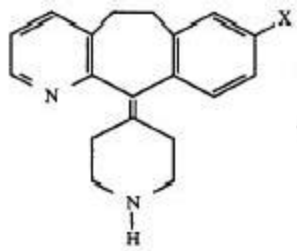
Loratadine ('233 patent)



DCL ('716 patent)

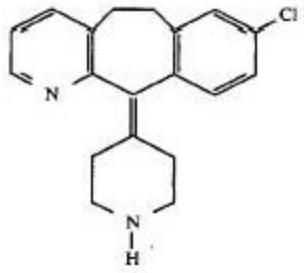
Claim 1 of the '716 patent covers DCL (for X = Cl), its fluorine analog, and their salts; claim 3 covers only DCL and its salts:

1. A compound of the formula



or a pharmaceutically acceptable salt thereof, wherein X represents Cl or F.

3. A compound having the structural formula



or a pharmaceutically acceptable salt thereof.

The ’233 patent issued on August 4, 1981, over one year before the earliest priority date of the ’716 patent, February 15, 1984. The ’233 patent is thus prior art to the ’716 patent. See 35 U.S.C. § 102(b) (2000) (“A person shall be entitled to a patent unless . . . the invention was patented . . . in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States.”). The ’233 patent discloses a class of compounds including loratadine (disclosed in Example 1B). ’233 patent, col. 3, ll. 5-12. The ’233 patent claims loratadine in claim 7. Id., col. 6, ll. 38-40. The ’233 patent claims four other compounds in claims 8-11. Examples 6-7 are prophetic[1] examples of pharmaceutical compositions (a

syrup and a tablet), each containing an unidentified "active compound." The '233 patent does not expressly disclose DCL and does not refer to metabolites of loratadine.

The numerous defendants-appellees sought to market generic versions of loratadine once the '233 patent expired. Seeking regulatory approval, each appellee submitted an application to the Food and Drug Administration (FDA). See 21 U.S.C. § 355(b), (j) (2000). Because Schering included the '716 patent in the Orange Book listing for loratadine, the applications also contained a certification that the '716 patent was invalid. See id. § 355(b)(2)(A), 355(j)(2)(A)(vii). The appellees notified Schering of the FDA filings. See id. § 355(b)(3)(B), 355(j)(2)(B)(ii).

After receiving notice of the FDA filings, Schering filed suit for infringement. See 35 U.S.C. § 271(e)(2)(A) (2000). After discovery, the parties filed cross motions for summary judgment on the validity issue. The district court construed claims 1 and 3 of the '716 patent to cover DCL in all its forms, including "metabolized within the human body" and "synthetically produced in a purified and isolated form." The parties agreed to that construction. Applying that claim construction, the district court found that the '233 patent did not expressly disclose DCL. Nonetheless, the district court also found that DCL was necessarily formed as a metabolite by carrying out the process disclosed in the '233 patent. The district court concluded that the '233 patent anticipated claims 1 and 3 of the '716 patent under 35 U.S.C. § 102(b). The district court therefore granted the appellees' motions for summary judgment of invalidity. Schering timely appealed to this court under 28 U.S.C. § 1295(a)(1) (2000).

II.

This court reviews a grant of summary judgment without deference. Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1323 (Fed. Cir. 2001). In reviewing a summary judgment determination, this court draws all reasonable inferences in favor of the non-movant. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986).

A.

A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987). Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991).

At the outset, this court rejects the contention that inherent anticipation requires recognition in the prior art. Schering relies on Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education & Research, 304 F.3d 1221 (Fed. Cir. 2002) for that proposition. This court has since vacated Elan. See 314 F.3d 1299 (Fed. Cir. 2002). Other precedents of this court have held that inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure. E.g., In re Cruciferous Sprout Litig., 301 F.3d 1343, 1351 (Fed. Cir. 2002); Mehl/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1366 (Fed. Cir. 1999) ("Where . . . the result is a necessary consequence of what was deliberately intended, it is

of no import that the article's authors did not appreciate the results."); Atlas Powder, 190 F.3d at 1348-49 ("Because 'sufficient aeration' was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention. . . . An inherent structure, composition, or function is not necessarily known."). Thus, recognition by a person of ordinary skill in the art before the critical date of the '716 patent is not required to show anticipation by inherency. The district court therefore did not err in allowing for later recognition of the inherent characteristics of the prior art '233 patent.

Contrary to Schering's contention, Continental Can does not stand for the proposition that an inherent feature of a prior art reference must be perceived as such by a person of ordinary skill in the art before the critical date. In Continental Can, this court vacated summary judgment of anticipation of claims reciting a plastic bottle with hollow ribs over a prior art reference disclosing a plastic bottle. The record contained conflicting expert testimony about whether the ribs of the prior art plastic bottle were solid. The accused infringer's expert testified that the prior art plastic bottle was made by blow molding, a process that would inherently produce hollow ribs. The patentee's experts testified that the prior art plastic bottle had solid ribs. The patentee disputed whether the blow molding inherently produced hollow ribs. Given the disputed material fact, this court vacated the summary judgment as improper. Continental Can, 948 F.2d at 1269. Continental Can makes no reference to whether the inherent feature, hollow ribs, was recognized before or after the critical date of the patent at issue. Read in context, Continental Can stands for the proposition that inherency, like anticipation itself, requires a determination of the meaning of the prior art. Thus, a court may consult artisans of ordinary skill to ascertain their understanding about subject matter disclosed by the prior art, including features inherent in the prior art. A court may resolve factual questions about the subject matter in the prior art by examining the reference through the eyes of a person of ordinary skill in the art, among other sources of evidence about the meaning of the prior art. Thus, in Continental Can, this court did not require past recognition of the inherent feature, but only allowed recourse to opinions of skilled artisans to determine the scope of the prior art reference.

Cases dealing with "accidental, unwitting, and unappreciated" anticipation also do not show that inherency requires recognition. See Eibel Process Co. v. Minn. & Ontario Paper Co., 261 U.S. 45 (1923); Tilghman v. Proctor, 102 U.S. 707 (1880). In contrast to the present case, the record in Eibel and Tilghman did not show that the prior art produced the claimed subject matter. The patent at issue in Tilghman claimed a method of forming free fatty acids and glycerine by heating fats with water at high pressure. In Tilghman, the record did not show conclusively that the claimed process occurred in the prior art. In reviewing the prior art, the Court referred hypothetically to possible disclosure of the claimed process. For example, the Court stated "[w]e do not regard the accidental formation of fat acid in Perkins's steam cylinder . . . (if the scum which rose on the water issuing from the ejection pipe was fat acid) as of any consequence in this inquiry." Tilghman, 102 U.S. at 711. In Eibel, the Court found no evidence of the claimed subject matter in the prior art. Eibel, 261 U.S. at 66 ("[W]e find no evidence that any pitch of the wire . . . had brought about such a result . . . and . . . if it had done so under unusual conditions, accidental results, not intended and not appreciated, do not constitute anticipation.").

Applying an inherency principle in the context of an on sale bar under 35 U.S.C. § 102(b), this court has distinguished Eibel and Tilghman. See Abbott Labs. v. Geneva Pharms., Inc., 182 F.3d 1315, 1319 (Fed. Cir. 1999) ("If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the

transaction recognize that the product possesses the claimed characteristics."); Scaltech, Inc. v. Retec/Tetra, LLC, 269 F.3d 1321, 1330 (Fed. Cir. 2001) ("[A]ppreciation of the invention is not a requirement to trigger the statutory [on sale] bar."). In those cases, the product sold or offered for sale had an inherent, but unrecognized, feature that was a limitation of the asserted claims. Id. Thus, this court has distinguished Eibel and Tilghman, which therefore do not bind this court to find no anticipation because skilled artisans did not recognize that the prior art '233 patent inherently produced the claimed invention, DCL.

In the context of accidental anticipation, DCL is not formed accidentally or under unusual conditions when loratadine is ingested. The record shows that DCL necessarily and inevitably forms from loratadine under normal conditions. DCL is a necessary consequence of administering loratadine to patients. The record also shows that DCL provides a useful result, because it serves as an active non-drowsy antihistamine. In sum, this court's precedent does not require a skilled artisan to recognize the inherent characteristic in the prior art that anticipates the claimed invention.

B.

This court recognizes that this may be a case of first impression, because the prior art supplies no express description of any part of the claimed subject matter. The prior art '233 patent does not disclose any compound that is identifiable as DCL. In this court's prior inherency cases, a single prior art reference generally contained an incomplete description of the anticipatory subject matter, i.e., a partial description missing certain aspects. Inherency supplied the missing aspect of the description. Upon proof that the missing description is inherent in the prior art, that single prior art reference placed the claimed subject matter in the public domain. This case does not present the issue of a missing feature of the claimed invention. Rather, the new structure in this case, DCL, is not described by the prior '233 patent.

Patent law nonetheless establishes that a prior art reference which expressly or inherently contains each and every limitation of the claimed subject matter anticipates and invalidates. See, e.g., EMI Group N. Am., Inc., v. Cypress Semiconductor Corp., 268 F.3d 1342, 1350 (Fed. Cir. 2001) ("A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim."); Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."). In these prior cases, however, inherency was only necessary to supply a single missing limitation that was not expressly disclosed in the prior art. This case, as explained before, asks this court to find anticipation when the entire structure of the claimed subject matter is inherent in the prior art.

Because inherency places subject matter in the public domain as well as an express disclosure, the inherent disclosure of the entire claimed subject matter anticipates as well as inherent disclosure of a single feature of the claimed subject matter. The extent of the inherent disclosure does not limit its anticipatory effect. In general, a limitation or the entire invention is inherent and in the public domain if it is the "natural result flowing from" the explicit disclosure of the prior art. See Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 970 (Fed. Cir. 2001); see also In re Kratz, 592 F.2d 1169, 1174 (CCPA 1979) (suggesting inherent anticipation of a compound

even though the compound's existence was not known).

In reaching this conclusion, this court is aware of In re Seaborg, 328 F.2d 996 (CCPA 1964). In that case, this court's predecessor considered claims drawn to an isotope of americium made by nuclear reaction in light of a prior art patent disclosing a similar nuclear reaction process but with no disclosure of the claimed isotope. The court reversed a United States Patent and Trademark Office rejection of the claims for lack of novelty. This court's predecessor found that the prior art process did not anticipate the claims because the process would have produced at most one billionth of a gram of the isotope in forty tons of radioactive material, i.e., the isotope would have been undetectable. Id. at 998-99 ("[T]he claimed product, if it was produced in the Fermi process, was produced in such minuscule amounts and under such conditions that its presence was undetectable."). In this case, DCL forms in readily detectable amounts as shown by the extensive record evidence of testing done on humans to verify the formation of DCL upon ingestion of loratadine.

This court sees no reason to modify the general rule for inherent anticipation in a case where inherency supplies the entire anticipatory subject matter. The patent law principle "that which would literally infringe if later in time anticipates if earlier," Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1378 (Fed. Cir. 2001), bolsters this conclusion. Similarly, "if granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated." Atlas Powder, 190 F.3d at 1346. "The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle." Id. at 1348. Thus, inherency operates to anticipate entire inventions as well as single limitations within an invention.

Turning to this case, the use of loratadine would infringe claims 1 and 3 of the '716 patent covering the metabolite DCL. This court has recognized that a person may infringe a claim to a metabolite if the person ingests a compound that metabolizes to form the metabolite. See Hoechst-Roussel Pharms., Inc. v. Lehman, 109 F.3d 756, 759 (Fed. Cir. 1997) ("[T]he right to exclude may arise from the fact that when administered, [the accused product] metabolizes into another product . . . which Hoechst has claimed."); see also Zenith Labs., Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1421-22 (Fed. Cir. 1994) (stating that a compound claim could cover a compound formed upon ingestion). An identical metabolite must then anticipate if earlier in time than the claimed compound.

The record shows that the metabolite of the prior art loratadine is the same compound as the claimed invention. Claims 1 and 3 are compound claims in which individual compounds are claimed in the alternative in Markush format. DCL is within the scope of claims 1 and 3. Because the prior art metabolite inherently disclosed DCL, claims 1 and 3 are anticipated and invalid. In other words, the record shows that a patient ingesting loratadine would necessarily metabolize that compound to DCL. That later act would thus infringe claims 1 and 3. Thus, a prior art reference showing administration of loratadine to a patient anticipates claims 1 and 3.

C.

This court next examines whether Schering's secret tests of loratadine before the critical date placed DCL in the public domain. Before the critical date, Schering only tested loratadine in secret. Thus, according to Schering, "DCL was not publicly used, or described in any printed publication, until after February 15, 1983, the critical date for the '716 patent under 35 U.S.C. § 102(b)." Schering thus argues that DCL did not "exist" in the public domain such that DCL could be prior art against the '716 patent.

Anticipation does not require the actual creation or reduction to practice of the prior art subject matter; anticipation requires only an enabling disclosure. In re Donohue, 766 F.2d 531, 533 (Fed. Cir. 1985). Thus, actual administration of loratadine to patients before the critical date of the '716 patent is irrelevant. The '233 patent suffices as an anticipatory prior art reference if it discloses in an enabling manner the administration of loratadine to patients.

Thus, this court examines whether the '233 patent contains an enabling disclosure of DCL. A reference may enable one of skill in the art to make and use a compound even if the author or inventor did not actually make or reduce to practice that subject matter. Bristol-Myers, 246 F.3d at 1379; see also In re Donohue, 766 F.2d at 533 (sustaining an anticipation rejection over a reference disclosing a compound and other references disclosing sufficient information to make that compound). Indeed, information arising after the critical date may show that the claimed subject matter, as disclosed in a prior art reference, "was in the public's possession." Bristol-Myers, 246 F.3d at 1379 (citing In re Donohue, 766 F.2d at 534).

An anticipatory reference need only enable subject matter that falls within the scope of the claims at issue, nothing more. To qualify as an enabled reference, the '233 patent need not describe how to make DCL in its isolated form. The '233 patent need only describe how to make DCL in any form encompassed by a compound claim covering DCL, e.g., DCL as a metabolite in a patient's body. The '233 patent discloses administering loratadine to a patient. A person of ordinary skill in the art could practice the '233 patent without undue experimentation. The inherent result of administering loratadine to a patient is the formation of DCL. The '233 patent thus provides an enabling disclosure for making DCL.

D.

Finally, this court's conclusion on inherent anticipation in this case does not preclude patent protection for metabolites of known drugs. With proper claiming, patent protection is available for metabolites of known drugs. Cf. In re Kratz, 592 F.2d 1169, 1174 (CCPA 1979) (stating that

a naturally occurring strawberry constituent compound does not anticipate claims to the substantially pure compound); In re Bergstrom, 427 F.2d 1394, 1401-02 (CCPA 1970) (stating that a material occurring in nature in less pure form does not anticipate claims to the pure material).

But those metabolites may not receive protection via compound claims. In this case, for instance, claims 1 and 3 broadly encompass compounds defined by structure only. Such bare compound claims include within their scope the recited compounds as chemical species in any surroundings, including within the human body as metabolites of a drug. As this case holds, these broad compound claims are inherently anticipated by a prior art disclosure of a drug that metabolizes into the claimed compound.

A skilled patent drafter, however, might fashion a claim to cover the metabolite in a way that avoids anticipation. For example, the metabolite may be claimed in its pure and isolated form, as in Kratz and Bergstrom, or as a pharmaceutical composition (e.g., with a pharmaceutically acceptable carrier). The patent drafter could also claim a method of administering the metabolite or the corresponding pharmaceutical composition. The ’233 patent would not provide an enabling disclosure to anticipate such claims because, for instance, the ’233 patent does not disclose isolation of DCL.

The ’716 patent contains claims 5-13 covering pharmaceutical compositions and claims 14-16 covering methods of treating allergic reactions by administering compounds that include DCL. These claims were not found anticipated by the ’233 patent.

III.

The district court found that “there is no genuine issue that the consumption of loratadine by humans, with a wide variety of health statuses, necessarily results in the natural production in the human body of the DCL metabolite.” This court must also examine the record for any genuine issue of material fact about whether ingestion of loratadine necessarily produces DCL. The record does, for instance, contain expert testimony, including a proposed metabolic scheme and animal data, that questions whether ingestion of loratadine always forms DCL.

A dispute about a material fact is genuine “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). In this case, the evidence supporting the district court’s conclusion is extensive. In thirteen clinical studies that Schering ran before May 1, 1987, all 144 patients involved had measurable amounts of DCL in their systems after ingesting loratadine. The district court found “no reports in any of the studies of any individual who did not metabolically produce DCL following the administration of loratadine.” The appellees reported twenty-one clinical studies in which loratadine was administered to a total of 864 patients, all of whom formed measurable amounts of DCL in their systems. In addition, the record shows that since 1985 Schering’s technical articles and Securities and Exchange Commission filings referred to DCL as the metabolite of loratadine. Also the Food and Drug Administration, the corresponding European agency, the Physician’s Desk Reference, and Schering’s CLARITIN™ package insert referred to DCL as the major metabolite of loratadine.

The record presents no data on humans to show that a genuine factual dispute exists about the

formation of DCL after ingesting loratadine. Indeed Schering's own expert testified that no human has been found that does not metabolize loratadine to DCL, and that "[t]here is no scientific data in the published literature that says that DCL is not formed from loratadine in humans." Based on this record, no reasonable jury could find that DCL is not produced when a human ingests loratadine. This court therefore discerns no genuine issue of material fact.

CONCLUSION

The district court did not err in finding that the '233 patent discloses administering loratadine to a patient, and that DCL forms as a natural result of that administration. The district court correctly concluded that DCL is inherent in the prior art. Without any genuine issues of material fact, the district court correctly granted summary judgment that claims 1 and 3 are invalid as anticipated by the '233 patent.

COSTS

Each party shall bear its own costs.

AFFIRMED

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[1] Prophetic examples are set forth in the present tense to indicate that they were not carried out. Atlas Powder Co. v. E. I. Du Pont de Nemours & Co., 750 F.2d 1569, 1578 (Fed. Cir. 1984).