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Schering Corp. v. Geneva Pharmaceuticals, Inc.: Just How Far Can Inherent Anticipation Extend

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SCHERING CORP. V. GENEVA PHARMACEUTICALS, INC.: JUST HOW FAR CAN INHERENT ANTICIPATION EXTEND?

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I. INTRODUCTION

United States patent law precludes obtaining or enforcing patents covering an invention previously in use or described in a printed publication.[1] Where a printed prior-art reference discloses within its four corners all aspects of a subsequently claimed invention, the reference "anticipates" the claimed invention.[2] References that anticipate a claimed invention show that the invention lacks novelty and renders invalid any claim to that described invention.

In a typical anticipation analysis, the challenger (an accused infringer, if in litigation, or the Examiner, if in prosecution) usually tries to show that a single prior-art reference expressly discloses each and every limitation of the asserted claim.[3] Generally, if the prior-art

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1. It has done so for the last two centuries. *See* 35 U.S.C. §§ 102(a), (b) (2000). *See also* Act of July 4, 1836, ch. 357, § 7, 5 Stat. 117; Act of Feb. 21, 1793, ch. 11, §§ 1, 6, 1 Stat. 318; Act of Apr. 10, 1790, Chapter 7, § 1, 1 Stat. 109 (describing an invention as not being "before known or used").

2. Long ago, Judge Learned Hand stated that "[n]o doctrine of the patent law is better established than that a prior patent or other publication to be an anticipation must bear within its four corners adequate directions for the practice of the patent invalidated." Dewey & Almy Chem. Co. v. Mimex Co., 124 F.2d 986, 989 (2d. Cir. 1942).

3. Patent applicants must set forth with particularity the aspects of their invention for which they contend they are entitled to the exclusionary rights granted by a patent. *See* 35 U.S.C. § 112, ¶ 2 (2000). They do so by presenting claims at the end of the patent specification that identifies the subject matter the applicant claims as the invention. Autogiro Co. of Am. v.

reference does not disclose each and every claim limitation, the reference does not anticipate the claim. Sometimes the reference if combined with another prior-art reference may show each claim limitation in a way that renders the claimed invention obvious, and thereby invalid under 35 U.S.C. § 103(a), but the reference by itself still does not anticipate.[4]

Quite often it is easier to prove that a prior-art reference anticipates a claimed invention than to prove that it renders the claimed invention obvious. Obviousness based on a modification of single prior-art reference or a combination of references requires proving, *inter alia*, that a person of ordinary skill in the art would have the motivation to make the modification or combination.[5] Patentees may also try to rebut a *prima facie* case of obviousness by presenting evidence of secondary considerations, such as commercial success, teaching away, unexpected results, or long-felt need, *etc.*[6] Anticipation, on the other hand, requires only showing that each limitation of the claimed invention is found within the four corners of a prior-art reference. Issues of motivation, commercial success,

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United States, 384 F.2d 391, 395–96 (Ct. Cl. 1967) ("The claims of the patent provide the concise formal definition of the invention. They are the numbered paragraphs which 'particularly [point] out and distinctly [claim] the subject matter which the applicant regards as his invention.' 35 U.S.C. § 112."); *see also* Multiform Desiccants, Inc., v. Medzam, Ltd., 133 F.3d 1473, 1476 (Fed. Cir. 1998) ("The claims are concise statements of the subject matter for which the statutory right to exclude is secured by the grant of the patent."). Each claim generally contains a series of claim "limitations," i.e., a clause of a claim that identifies a specific characteristic or aspect of the claimed invention. *See* Lockheed Martin Corp. v. Space Systems/Loral, Inc., 324 F.3d 1308, 1315 n.1 (Fed. Cir. 2003) ("The district court and the parties use the term 'element' to refer to subcategories of claim language. However, '[i]t is preferable to use the term 'limitation' when referring to claim language and the term 'element' when referring to the accused device.'").

4. Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1267 (Fed. Cir. 1991) ("When more than one reference is required to establish unpatentability of the claimed invention[,] anticipation under § 102 can not be found, and validity is determined in terms of § 103."); Scripps Clinic & Res. Found. v. Genentech, Inc., 927 F.2d 1565, 1576 (Fed. Cir. 1991).

5. Abbott Labs. v. Syntron Bioresearch, Inc., 334 F.3d 1343, 1357 (Fed. Cir. 2003) ("Knowledge in the prior art of every element of a patent claim, however, is not of itself sufficient to render [the] claim obvious."); McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1351 (Fed. Cir. 2001); Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1356 (Fed. Cir. 1999).

6. Graham v. John Deere Co., 383 U.S. 1, 17–18 (1966) ("Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy."); Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573 (Fed. Cir. 1996) ("It is the secondary considerations that are often the most probative and determinative of the ultimate conclusion of obviousness or nonobviousness.").

teaching away, or unexpected results have no relevance in rebutting an assertion of anticipation.[7]

Challengers seeking to invalidate a patent claim for anticipation often find that a prior-art reference, which looks promising at first, falls short of explicitly describing all of the limitations of the claimed invention. Despite the lack of an express disclosure, if the challenger can show that the missing aspect necessarily results from practicing the subject matter explicitly disclosed in the reference, the law will consider the missing aspect inherently present. Thus, the doctrine of inherency allows a *de facto* implicit disclosure to provide missing express disclosure when considering anticipation. Where the combination of the expressly disclosed subject matter and the inherently disclosed subject matter meets each claim limitation of a later-claimed invention, the reference inherently anticipates the later-claimed invention.

Until recently, no reported Federal Circuit case had considered invalidating a patent claim on the basis that the entire anticipatory disclosure was inherently disclosed in a prior-art reference. That changed with the Federal Circuit's recent decision in *Schering Corp. v. Geneva Pharmaceuticals, Inc.*[8]

In *Schering*, the Federal Circuit held that a prior-art reference, allegedly silent on a later-claimed compound, can nevertheless inherently anticipate claims to that compound if the production of the compound necessarily follows from practicing a process described in the reference. Further, the Federal Circuit held that it does not matter that one of skill in the art may not have recognized that the prior-art process inherently produces the later-claimed compound.

This article reviews the law on the doctrine of inherent anticipation. It further examines the panel's decision in *Schering* and the Federal Circuit's later denial of the patentee's petition for an *en banc* hearing. Finally, the article provides some suggestions for drafting claims in view of the decision.

II. SUMMARY OF THE LAW ON ANTICIPATION AND INHERENCY

The patent system exists to increase the scope of public knowledge.[9] As part of this purpose, the validity requirements ensure

7. *See* Celeritas Techs., Ltd. v. Rockwell Int'l Corp., 150 F.3d 1354, 1361 (Fed. Cir. 1998); *In re* Self, 671 F.2d 1344, 1350–51 (C.C.P.A. 1982); *In re* Malagari, 499 F.2d 1297, 1302 (C.C.P.A. 1974); *In re* Wiggins, 488 F.2d 538, 543 (C.C.P.A. 1973).

8. 339 F.3d 1373 (Fed. Cir. 2003).

9. Patents provide incentive for inventors to create new inventions. Upon the expiration

that once subject matter becomes part of the public domain, a patentee may not later take away the public's right to freely practice that subject matter. The validity requirement of novelty and the corresponding doctrine of anticipation provide one means of protecting subject matter already in the public domain.[10]

Under the doctrine of anticipation, a patent claim should not issue, and if issued should not be valid, if a single prior-art reference discloses the invention as claimed and enables one of skill in the art to practice the invention.[11] To anticipate, a single item of prior art must disclose each limitation of the claimed invention.[12]

To protect the public knowledge further, however, the law does not require that a reference must *expressly* disclose all the claim limitations of a challenged claim to anticipate that claim. The Federal

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of the patent term, those inventions pass to the public domain. *See* Pennock v. Dialogue, 27 U.S. (2 Pet.) 1, 19 (1829) ("While one great object [of the patent laws] was, by holding out a reasonable reward to inventors, and giving them an exclusive right to their inventions for a limited period, to stimulate the efforts of genius; the main object was 'to promote the progress of science and useful arts;' and this could be done best, by giving the public at large a right to make, construct, use, and vend the thing invented, at as early a period as possible; having due regard to the rights of the inventor."). *See also* Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998) ("[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time. The balance between the interest in motivating innovation and enlightenment by rewarding invention with patent protection on the one hand, and the interest in avoiding monopolies that unnecessarily stifle competition on the other, has been a feature of the federal patent laws since their inception."); Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979) ("First, patent law seeks to foster and reward invention; second, it promotes disclosure of inventions, to stimulate further innovation and to permit the public to practice the invention once the patent expires; third, the stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public."); Muncie Gear Works v. Outboard Marine & Mfg. Co., 315 U.S. 759, 768 (1942); Beidler v. United States, 253 U.S. 447, 453 (1920) ("The source of the power to grant patents, and the consideration for granting them, is the advantage which the public will derive from them, especially after the expiration of the patent monopoly, when the discoveries embodied in them shall become a part of the public stock of knowledge.").

10. *See* Woodland & Trust v. Flowertree Nursery, Inc., 148 F.3d 1368, 1370 (Fed. Cir. 1998) ("Section 102(a) establishes that a person can not patent what was already known to others. If the invention was known to or used by others in this country before the date of the patentee's invention, the later inventor has not contributed to the store of knowledge, and has no entitlement to a patent.").

11. *See* Seymour v. Osborne, 78 U.S. (11 Wall.) 516, 555 (1870); Verve, LLC v. Crane Cams, Inc., 311 F.3d 1116, 1120 (Fed. Cir. 2002) ("Invalidity based on 'anticipation' requires that the invention is not in fact new. A single reference must describe the claimed invention with sufficient precision and detail to establish that the subject matter existed in the prior art."); Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1572 (Fed. Cir. 1992); *In re* Donohue, 766 F.2d 531, 533 (Fed. Cir. 1985).

12. Apple Computer, Inc. v. Articulate Sys., Inc., 234 F.3d 14, 20 (Fed. Cir. 2000) ("Anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention.").

Circuit has instructed that "[a]n anticipatory reference . . . need not duplicate word for word what is in the claims. Anticipation can occur when a claimed limitation is 'inherent' or otherwise implicit in the relevant reference."[13] Accordingly, it has been stated that one "purpose of the rule of inherency is to accommodate common knowledge, knowledge that judges might not know but that would be known to practitioners in the field."[14]

The law defines an inherent characteristic as one that is the "'natural result' flowing from" the teachings or disclosure of the prior art,[15] *i.e.*, a characteristic that is necessarily present and not just a probable result.

The Federal Circuit explained the standard for determining inherency as follows:

> Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.[16]

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13. Standard Havens Prods., Inc. v. Gencor Indus., Inc., 953 F.2d 1360, 1369 (Fed. Cir. 1991); *accord* MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999) ("[A] prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it."); Verdegaal Bros. v. Union Oil Co. of Cal., 814 F.2d 628, 633 (Fed. Cir. 1987); Tyler Refrigeration v. Kysor Indus. Corp., 777 F.2d 687, 689 (Fed. Cir. 1985) (stating that a challenger to the validity of the patent successfully showed that one element not expressly shown in a reference was an inherent feature of the structure in the reference and therefore anticipated the asserted patent).

14. Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Res., 304 F.3d 1221, 1229 (Fed. Cir. 2002), *vacated*, 314 F.3d 1299 (Fed. Cir. Dec. 18, 2002) (*en banc*), *remanded*, 346 F.3d 1051, 1057 (Fed. Cir. 2003). As explained in greater detail below, one of skill in the art need not actually recognize or appreciate the presence of the inherent characteristic in all circumstances for inherency to apply. *See infra* note 25.

15. Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 970 (Fed. Cir. 2001).

16. Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1269 (Fed. Cir. 1991) (quoting *In re* Oelrich, 666 F.2d 578, 581 (C.C.P.A. 1981); *accord* Akamai Techs., Inc. v. Cable & Wireless Internet Serv., Inc., 344 F.3d 1186, 1192 (Fed. Cir. 2003) ("A claim limitation is inherent in the prior art if it is necessarily present in the prior art, not merely probably or possibly present."); Transclean Corp. v. Bridgewood Servs., Inc., 290 F.3d 1364, 1373 (Fed. Cir. 2002) ("Because anticipation by inherent disclosure is appropriate only when the reference discloses prior art that must *necessarily* include the unstated limitation, the Japanese patent cannot inherently anticipate the claims of the '080 patent.") (emphasis in original); Scaltech, Inc. v. Retec/Tetra, L.L.C., 178 F.3d 1378, 1384 (Fed. Cir. 1999) ("Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. However, if the natural result flowing from the operation of the process offered for sale would necessarily result in

Thus, "[o]ccasional results are not inherent."[17]

A challenger can use evidence extrinsic to the prior-art reference to show that the missing item is necessarily present.[18] The challenger may not, however, use extrinsic evidence to supply missing material that is not inherent from the information expressly disclosed.[19] For example, in *Rosco Inc. v. Mirror Lite Co.*,[20] the challenger argued that its design patent on a mirror inherently anticipated a utility patent on a mirror that required a varying radius of curvature.[21] The challenger argued that if it made its mirror in the shape shown in the design

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achievement of each of the claim limitations, the claimed invention was offered for sale."), *appeal after remand*, 269 F.3d 1321, 1330–31 (Fed. Cir. 2001); Finnigan Corp. v. Int'l Trade Comm'n, 180 F.3d 1354, 1366 (Fed. Cir. 1999) (reversing finding of anticipation because testimony demonstrated that it was only a possibility that claimed nonresonance ejection was disclosed in reference and stating "The mere possibility that Figure 2 might be understood by one of skill in the art to disclose nonresonance ejection is insufficient to show that it is inherently disclosed therein.").

17. *MEHL/Biophile*, 192 F.3d at 1365; *accord* Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1297 (Fed. Cir. 2002) (vacating summary judgment of anticipation by inherency since record evidence did not show prior art inherently "created" the image in a computer, as required by the claim, but may have "created" the image manually and then provided it to the computer for further processing, and stating "It is irrelevant that a skilled artisan might possibly use the computer to create the final desired image from the color separations. Inherency does not embrace probabilities or possibilities."); Glaxo, Inc. v. Novopharm Ltd., 52 F.3d 1043, 1047–48 (Fed. Cir. 1995) (stating that claimed invention was not anticipated by inherency in example of reference where it was shown that the allegedly inherent compound was not produced every time when following the teachings of the reference even though validity challenger's expert performed prior art example thirteen times and obtained claimed material); Electro Med. Sys., S.A. v. Cooper Life Sci., Inc., 34 F.3d 1048, 1052 (Fed. Cir. 1994) ("The mere fact that a certain thing may result from a given set of circumstances is insufficient to prove anticipation.").

18. Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1328 (Fed. Cir. 2001) ("[R]ecourse to extrinsic evidence is proper to determine whether a feature, while not explicitly discussed, is necessarily present in a reference. The evidence must make clear that the missing feature is necessarily present, and that it would be so recognized by persons of skill in the relevant art.").

19. Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1335 (Fed. Cir. 2002) ("As we have repeatedly stated, anticipation requires that each limitation of a claim must be found in a single reference. Although we have permitted the use of additional references to confirm the contents of the allegedly anticipating reference, we have made clear that anticipation does not permit an additional reference to supply a missing claim limitation.").

20. 304 F.3d 1373, 1379–81 (Fed. Cir. 2002).

21. A design patent covers an "ornamental design for an article of manufacture." 35 U.S.C. § 171. It only protects the ornamental aspects of the article and not the functional aspects of the design. OddzOn Prods., Inc. v. Just Toys, Inc., 122 F.3d 1396, 1405 (Fed. Cir. 1997) ("A design patent only protects the novel, ornamental features of the patented design. Where a design contains both functional and non-functional elements, the scope of the claim must be construed in order to identify the non-functional aspects of the design as shown in the patent."); Best Lock Corp. v. Ilco Unican Corp., 94 F.3d 1563,1566 (Fed. Cir. 1996) ("[I]f the design claimed in a design patent is dictated solely by the function of the article of manufacture, the patent is invalid because the design is not ornamental.").

patent and used a certain thermoforming process to make the mirror, a varying radius of curvature would inevitably result. The design patent, however, provided no disclosure of any process to make the mirror, and the thermoforming process was not the only way to make the mirror. Hence, it was not inevitable that one of skill in the art would use the thermoforming process to make the mirror. On this basis, the Federal Circuit reversed a district court's finding of anticipation by inherency because the disclosure in the design patent did not show that a mirror with the required radius of curvature would necessarily result from using the disclosure of just the design patent.[22] Accordingly, while the doctrine of inherency permits accounting for a prior-art reference's implicit disclosures in an anticipation analysis, it does not permit filling in missing elements just because one of skill in the art might know of the missing material from some other source.[23]

To provide complete protection of public knowledge, the law of inherency protects the naturally flowing consequences of practicing subject matter already in the public domain even if those consequences are unknown.[24] In other words, inherency does not require prior knowledge, recognition, or appreciation by those of skill in the art of the inherent characteristic, property, or ingredient. Thus, the Federal Circuit has explained that:

> Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.[25]

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22. *Rosco*, 304 F.3d at 1380–81 ("[T]he question is not whether the manufacture of the mirror using this process inherently results in a varying radius of curvature along the major axis, but whether one skilled in the art would read the '357 patent as inherently disclosing the invention of the '984 patent, that is, whether one skilled in the art would read the '357 patent as showing a mirror of varying radius of curvature along the major axis. There is no evidence in the record to support a finding that one skilled in the art would so read the '357 patent.").

23. *Cf.* Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 716 (Fed. Cir. 1984).

24. *See In re* Wiseman, 596 F.2d 1019, 1023 (C.C.P.A. 1979) (fact that inherent function of prior-art device was unknown does not permit an applicant from obtaining a patent on that device by claiming the unknown function since such a patent would remove structure from the public domain).

25. Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347–49 (Fed. Cir. 1999); *accord* Toro Co. v. Deere & Co., 355 F.3d 1313, 1320–21 (Fed. Cir. 2004); *In re* Cruciferous Sprout Litigation, 301 F.3d 1343, 1351 (Fed. Cir. 2002); EMI Group N. Am., Inc. v. Cypress Semiconductor Corp., 268 F.3d 1342, 1349–51 (Fed. Cir. 2001); MEHL/Biophile Int'l Corp. v.

Consequently, even if not known before the patenting of an invention, a later-discovered inherent scientific fact can invalidate the patent on that invention.[26] Indeed, the Federal Circuit has relied upon post-issuance evidence to establish inherency. For example, in *Eli Lilly Co. v. Barr Laboratories, Inc.*, the court relied on evidence generated years after the issuance of a patent to establish inherency to support invalidating a patent on grounds of double patenting.[27]

III. FACTS OF *SCHERING*

Schering Corporation owns U.S. Patent No. 4,282,233 (the '233 patent), now expired, on its highly successful antihistamine called "loratadine." Schering markets loratadine under the trade name CLARITIN™. It also obtained a second patent, U.S. Patent No. 4,659,716 (the '716 patent) claiming, among other things, the chemical compound descarboethoxyloratadine (DCL).

DCL is a metabolite of loratadine.[28] This means that as a naturally flowing consequence of ingesting loratadine, a patient will form DCL in the body.[29]

Schering sued eight competitors seeking to market their own

Milgraum, 192 F.3d 1362, 1366 (Fed. Cir. 1999) ("[T]he Polla article's failure to mention hair depilation as a goal is similarly irrelevant. . . . Where, as here, 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."). *See also* Gen. Elec. Co. v. Jewel Incandescent Lamp Co., 326 U.S. 242, 248 (1945) (holding a patent invalid when "the prior art discloses the method of making an article having the characteristics of the patented product, though all the advantageous properties of the product had not been fully appreciated"); Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376 (Fed. Cir. 2001) (affirming summary judgment of anticipation to method claims directed to administering a drug based on a prior-art reference that described each step of the method but did not achieve successful results because the claim was construed as not claiming any specific result and stating that "Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent."); W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1548 (Fed. Cir. 1983) (finding claim invalid under § 102(a) based on another user's use of inventor's prior machine and stating "Gore's operation of the 401 machine must thus be viewed as a consistent, reproducible use of Dr Gore's invention as set forth in claim 1, and it is therefore irrelevant that those using the invention may not have appreciated the results. Were that alone enough to prevent anticipation, it would be possible to obtain a patent for an old and unchanged process.").

26. *See, e.g.*, *In re* Shetty, 566 F.2d 81, 86 (C.C.P.A. 1977) (stating what "may be inherent is not necessarily known"); *In re* Kratz, 592 F.2d 1169, 1174 (C.C.P.A. 1979).

27. *Eli Lilly*, 251 F.3d at 969–70. *See also*, *Atlas Powder*, 190 F.3d at 1348.

28. Loratadine and its metabolite DCL structurally differ only in that loratadine has a carboethoxy group (COOEt) on a ring of nitrogen, whereas DCL has a hydrogen atom on that ring nitrogen. Unlike conventional antihistamines used at the time Schering launched CLARITIN™, both loratadine and its metabolite DCL are nondrowsy antihistamines.

29. In some cases, skilled chemists can synthetically form pure versions of a metabolite in a lab.

versions of antihistamines with loratadine for infringement of the '716 patent. Even though these competitors were not seeking to market DCL, Schering asserted in its suit that by marketing loratadine for the treatment of allergies before the expiration of the '716 patent, these competitors would infringe the '716 patent. Schering contended that infringement existed because loratadine necessarily converts to DCL when administered to patients. This contention spelled Schering's defeat as the district court held the '233 patent inherently anticipated the claims of the '716 patent that were broad enough to cover DCL produced *in vivo* from ingesting generic loratadine.

Schering's '233 patent issued more than a year before the filing date of the '716 patent. Accordingly, the Schering competitors could use the '233 patent as prior art against the '716 patent.[30] While the '233 patent discloses a class of compounds including loratadine, Schering alleged it did not describe DCL or refer to metabolites of loratadine. Nonetheless, during the infringement suit, the competitors moved for summary judgment that the '233 patent inherently anticipated the broad claims of the '716 patent covering DCL when formed inside a patient. The district court construed, and the parties agreed, that claims 1 and 3 of the '716 patent covered DCL in all its forms, including "metabolized within the human body" and "synthetically produced in a purified and isolated form."[31] For purpose of the motion, the district court assumed that the '233 patent did not expressly disclose DCL. Nonetheless, based on the evidence presented, it found that DCL necessarily resulted when a patient ingested loratadine according to the treatment process described in the '233 patent.

The district court based its decision in large part on the extensive evidence presented by the competitors that every human who ingests loratadine will convert it to DCL. This evidence included twenty one clinical studies performed by the competitors in which all 864 patients involved had measurable amounts of DCL in their systems after ingesting loratadine. The evidence also included thirteen clinical studies performed by Schering in which all 144 patients involved had

30. *See* 35 U.S.C. § 102(b)(2000) reciting, in relevant part: "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."

31. The claims of the '716 patent are also directed to pharmaceutical compositions containing an effective amount of DCL (claims 5, 7, 9, 11, and 12) and methods of treating allergic reactions by administering an effective amount of DCL (claims 14 and 15). As the competitors were not seeking to market DCL, Schering did not assert that they will infringe the pharmaceutical composition or method of treatment claims in the '716 patent.

measurable amounts of DCL in their systems after ingesting loratadine. In fact, Schering's own expert testified that no human has been found who does not metabolize loratadine to DCL.[32] Based on this evidence and applying its construction of the challenged claims as covering DCL formed *in vivo*, the district court granted the competitors' summary-judgment motions that the disclosure in '233 patent inherently anticipated the broad claims of the '716 patent.[33]

IV. THE FEDERAL CIRCUIT'S DECISION ON APPEAL

The Federal Circuit affirmed the district's court's summary judgment of invalidity. It saw no reason to limit the doctrine of inherency to situations only where the inherent disclosure filled in a gap in a prior-art reference. Writing for the court, Judge Rader reasoned that:

> 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.
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> . . . .
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> This court sees no reason to modify the general rule for inherent anticipation in a case where inherency supplies the entire anticipatory subject matter.[34]

Thus, under the Federal Circuit's rationale, the extent to which a prior-art reference discloses inherent subject matter does not limit the applicability of the doctrine of inherency. Instead, a court must focus on whether the alleged inherent subject matter naturally and necessarily results from what the reference does disclose.

The Federal Circuit further supported its ruling by relying on the famous axiom of patent law "that which would literally infringe if later in time anticipates if earlier."[35] It noted that a person may infringe a claim to a metabolite if the person ingests a compound that

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32. Schering Corp. v. Geneva Pharms., Inc., 275 F. Supp. 2d 534, 537 (D.N.J. 2002).
33. *Id.* at 540–43.
34. *Schering*, 339 F.3d at 1379.
35. *Id.* at 1380; *accord Peters v. Active Mfg. Co.*, 129 U.S. 530, 537, (1889).

metabolizes to form the metabolite.[36] Accordingly, a disclosure of ingesting that compound would anticipate a later claim to the metabolite formed from that ingestion.

In Schering's case, the Federal Circuit found that the undisputed evidence showed that DCL necessarily formed whenever patients ingest loratadine under normal conditions.[37] The formation of DCL in a patient did not require unusual conditions, and it did not need an accident of circumstances.[38] Accordingly, the Federal Circuit found that the disclosure of administering loratadine to patients in the '233 patent provided an inherent disclosure of the DCL metabolite.[39] Since the broad claims in the '716 patent covered all forms of DCL, including those formed inside a patient's body, the Federal Circuit concluded that the '233 patent inherently anticipated these claims.[40]

Schering tried to avoid the application of the doctrine of inherency by arguing that one of ordinary skill in the art must recognize and appreciate the inherent disclosure for the doctrine to apply.[41] According to Schering, since at the time of the invention of the '716 patent one of skill in the art allegedly did not appreciate that DCL formed when a patient ingested loratadine, inherent anticipation should not apply. The Federal Circuit rejected this argument. After considering several Supreme Court and Federal Circuit cases, the Federal Circuit instructed that the case law does not require one of skill in the art to recognize the inherent disclosure before the critical date of the challenged patent.[42]

Schering also argued that inherent anticipation based on the publication of the '233 patent should not exist because the process disclosed in the '233 patent had not been publicly used before the

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36. *Schering*, 339 F.3d at 1380 (citing 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."), *and* 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)).

37. *Schering*, 339 F.3d at 1380.

38. *Id.* at 1378.

39. The '233 patent not only distinguished compounds from the prior-art by noting the benefits of using loratadine to treat humans but expressly disclosed the preferred human dosage range.

40. *Schering*, 339 F.3d at 1380.

41. *Id.* at 1377.

42. *Id.* at 1378 (noting that "cases dealing with 'accidental, unwitting, and unappreciated' anticipation also do not show that inherency requires recognition." and citing Eibel Process Co. v. Minn. & Ont. Paper Co., 261 U.S. 45 (1923); Tilghman v. Proctor, 102 U.S. 707 (1880)). *See also supra* note 25.

critical date of the '716 patent.[43] Schering argued that because it only tested loratadine in secret before the critical date, DCL never entered the public domain such that it could be prior art against the '716 patent.[44] The Federal Circuit disagreed that an actual use was required. It instructed that anticipation requires only an enabling disclosure. It does not require the actual creation or reduction to practice of the prior-art subject matter.[45] Accordingly, the court held that the actual administration of loratadine to patients, whether public or secret, before the critical date of the '716 patent is irrelevant.[46] Rather, the '233 patent suffices as an anticipatory reference for purposes of inherency if it discloses in an enabling manner administering loratadine to patient in a way that would necessarily produce DCL within the patient.[47]

Considering whether the '233 patent contains an enabling disclosure of DCL, the Federal Circuit noted that this prior-art patent had to describe only how to make DCL in any form encompassed by a compound claim covering DCL, including DCL as a metabolite in a patient's body.[48] Because the '233 patent discloses administering loratadine to a patient, the inherent result of which is the formation of DCL metabolite, the Federal Circuit held that the '233 patent provides an enabling disclosure for making DCL.[49]

The Federal Circuit further noted that its ruling does not totally preclude an applicant from obtaining valid claims to a purified, isolated, or synthetic form of a metabolite when the prior art shows the use of the base drug.[50] Patent applicants can claim the metabolite in a substantially pure form. Applicants may also claim the metabolite as part of a pharmaceutical composition. In fact, the '716 patent includes such claims.[51] Further, an applicant can claim a method of treatment by administering the metabolite or corresponding pharmaceutical composition. As an example of this tact, the Federal

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43. *Schering*, 339 F.3d at 1380–81. *See also* 35 U.S.C. § 102(b); Scaltech, Inc. v. Retec/Tetra, L.L.C., 269 F.3d 1321, 1327 (Fed. Cir. 2001) ("The date exactly one year prior to the date of application for the patent is known as the critical date.").

44. *Schering*, 339 F.3d at 1380–81.

45. *Id.*

46. *Id.*

47. *Id.*

48. *Id.* at 1381.

49. *Id.*

50. *Id.*

51. *See, e.g.*, Claim 5 of the '716 patent, which recites "An antihistaminic pharmaceutical composition which comprises an antihistaminic effective amount of a compound as defined in claim 1 in combination with a pharmaceutically acceptable carrier."

Circuit noted that the '233 patent did not inherently anticipate the narrower claims in Schering's '716 patent covering methods of administering DCL.

Finally, the Federal Circuit upheld the district court's finding that there was no genuine issue of material fact about whether ingestion of loratadine necessarily produces DCL. The Federal Circuit found that the district court's conclusion was supported by extensive evidence, including thirteen clinical studies performed by Schering in which all 144 patients involved had measurable amounts of DCL in their systems after ingesting loratadine. Similarly, appellees reported 21 clinical studies in which all 864 patients involved had measurable amounts of DCL in their systems after ingesting loratadine.[52]

In sum, the Federal Circuit favored the principle of guarding against removing subject matter from the public domain when it decided that inherency can apply even if a prior-art reference fails to explicitly describe anything of the later-claimed invention if the practice of the prior art would necessarily produce the later-claimed invention. For these reasons, the court saw no reason to modify the general rule for inherent anticipation where inherency supplies the entire anticipatory subject matter.[53]

V. THE DENIAL OF AN EN BANC HEARING

After the panel's decision, Schering sought a combined petition for panel rehearing and rehearing *en banc*. The Federal Circuit denied both petitions.[54] Judge Newman and Judge Lourie wrote separate dissents from the denial of the petition for rehearing *en banc*.

In her dissent, Judge Newman opined that the panel's decision departed from the established law of anticipation because, in her view, no precedent supported the position that "a product whose existence was not previously known and that is not in the prior art is always unpatentable on the ground that it existed undiscovered."[55] Summarizing precedent, she concluded that the common thread in all applications of inherent anticipation initially concerns "whether the

52. The court noted that this data conforms with Schering's own expert, who testified that no human has been found that does not metabolize loratadine to DCL. *Schering*, 339 F.3d at 1382.

53. *Id.* at 1379.

54. Schering Corp., v. Geneva Pharms., Inc., 348 F.3d 992 (Fed. Cir. 2003).

55. *Id.* at 993.

thing that is claimed was disclosed in a single prior-art reference."[56] By noting the importance that the reference disclose the "thing", i.e. subject matter of the claimed invention as opposed to the limitations of the claimed invention, Judge Newman appears to support limiting the application of inherent anticipation to filling in gaps in a reference. Under this view, inherent anticipation would not apply where the reference contains no express disclosure of the subject matter later claimed because the "thing" is not disclosed.

Judge Newman also expressed concern with the rejection of the contention that "inherent anticipation requires recognition in the prior art."[57] Focusing on the definition of "invention" of 35 U.S.C. § 100(a), as including "discovery", she also stated that the patent laws have long established that "an inventor may discover something that already existed."[58] Hence, in her view, a rule of law that precludes patenting a discovery on the grounds that it already existed where one of skill in the art did not already recognize the discovery violates prior precedent.[59]

Judge Lourie separately dissented. He opined that because the panel's decision "effectively preclud[es] virtually all patents on human metabolites of drugs," exceptional circumstances existed warranting consideration by the full court.[60] He also suggested that whether inherent anticipation should lie may depend on the prior use of the pharmaceutical product. In his view, actual commercial use of the drug product could justify finding inherent anticipation. But a mere publication of information relating to a drug product without any actual commercial use of that product might not. He stated:

> I do not question that when a pharmaceutical product has been *in actual public use* prior to the filing of a patent application on its

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56. *Id.* at 994 (emphasis added).

57. *Id.* at 995. Judge Newman expressed her view of inherency requiring recognition in authoring the panel opinion in Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Res., 304 F.3d 1221, 1228 (Fed. Cir. 2002) ("When anticipation is based on inherency of limitations not expressly disclosed in the assertedly anticipating reference, it must be shown that the undisclosed information was known to be present in the subject matter of the reference."). That decision, however, was later vacated. Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Res., 314 F.3d 1299 (Fed. Cir. Dec. 18, 2002) (*en banc*), *remanded*, 346 F.3d 1051, 1057 (Fed. Cir. 2003).

58. *Schering*, 339 F.3d at 994 (citing 35 U.S.C. § 100(a) (2000) ("The term 'invention' means invention or discovery.")).

59. Judge Newman relied on the purported record evidence that no reference showed the claimed descarbethoxyloratadine (or DCL), or that a person of ordinary skill would have known that DCL is formed *in vivo* upon ingestion of loratadine. *Schering*, 348 F.3d at 995.

60. *Id.*

> metabolite, the metabolite will also have been in public use and hence will be unpatentable. The holding of this case, however, goes much further, mandating that the mere issuance of the patent on the product—or any other publication of that product—inherently anticipates claims to the metabolite merely by disclosing that the product can be administered to a patient, on the theory that such administration would inevitably cause the human body to "make" the metabolite.[61]

Judge Lourie did not focus his dissent on the specific precedent relating to inherent anticipation, *per se*, but to the level of disclosure required to preclude patenting a metabolite of a known pharmaceutical based on the disclosure of the pharmaceutical.

According to Judge Lourie, "merely . . . disclosing [in a patent] that the [pharmaceutical] product can be administered to a patient, on the theory that such administration would inevitably cause the human body to 'make' the metabolite," is not an enabling disclosure.[62] While acknowledging that such statements on how to make and use the claimed pharmaceutical product may have satisfied the requirements of 35 U.S.C. § 112 for the product, Judge Lourie believed that they do not provide an enabling disclosure of how to make any metabolites "sufficiently to anticipate them by inherency."[63] Thus, he stated that in his view, "to hold that a patent on a product, with a minimal disclosure of administering it to a human or other subject, anticipates a later application of a metabolite, of which no mention appears whatsoever in the patent, cannot be correct."[64]

VI. DRAFTING CLAIMS IN VIEW OF *SCHERING*

The ruling in *Schering* shows that the law will not generally allow a pioneer-drug manufacturer to obtain a *de facto* extension of a patent on a drug by claiming in a later patent a chemical composition necessarily formed when a patient simply ingests the drug in its usual course of treatment. If the creation of a synthetic form of metabolite has novelty, patent law can protect the claims drawn to the synthetic metabolite. Under *Schering*, it cannot protect the metabolite if claimed so broadly that the claim covers metabolites naturally forming in a patient when following a known treatment procedure

61. *Id.* at 996 (emphasis in original).
62. *Id.*
63. *Id.*
64. *Id.* at 956.

disclosed in the alleged anticipatory reference.[65] Indeed, Judge Rader stated in *Schering* that claims narrowly drawn to a purified, isolated, or synthetic form of the metabolite or a method of administering the metabolite would not generally be inherently anticipated by the use of the drug product. He explained:

> [T]his 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.
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> . . . .
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> A skilled patent drafter . . . 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 . . . , 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.[66]

Although *Schering* involved a pharmaceutical compound, its application may extend to other technologies. Patent practitioners in all fields, therefore, should try to include claims of varying scope, including claims to a pure or synthetic form of the invention or to different methods of using the invention, if the issue of inherent anticipation could arise.

For example, in the field of nanotechnology,[67] the issue of patentability may turn on whether the nanolevel properties of known materials are inherent to the material or whether new or improved properties, or both, result when the known material is manipulated on the nanolevel.[68] It is possible that, in a particular case, a challenger

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65. Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1381 ("[M]etabolites 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.").

66. *Id.*

67. Nanotechnology is broadly defined as research and development at the atomic or molecular scale. It is one of today's fastest growing technologies. In its broadest sense, nanotechnology embraces a multidisciplinary combination of chemistry, physics, electronics, and engineering. The ability to design materials at this "nanolevel" has led, and continues to lead, to many novel products with wide-ranging applications.

68. Attractive forces, such as van der Waal and Columb forces, that ordinarily play a

could show that the nanolevel properties of a nanomaterial are inherent to that material in its known macro state. If a patent covering the nanomaterial had broad claims only to the nanolevel properties, the claims might not withstand an inherent-anticipation challenge under *Schering*. But if the patent also included claims to the "synthetic" aspects of the invention such as the specific size of material or the solution of new problems caused by the reduction in size, the law on inherency, even after *Schering*, would probably not defeat patentability.[69]

VII. CONCLUSION

Schering clarifies the extent that the doctrine of inherent anticipation can apply. Those who prosecute patent applications, and those who litigate patents, need to be mindful of its rule to avoid being blind-sided by an inherent disclosure.

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minor role in bulk material, can have significant effect on materials in the nanosize, and thereby result in a nanomaterial that behaves drastically different from its corresponding macromaterial.

69. In many nanotech inventions, the decrease in size creates new problems that did not exist at the macro-scale. This decrease may require the development of new manufacturing methods or new materials.

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