



Making us crazy!

🌐 *The US Court of Appeals messes with inherent anticipation*

Barry Bretschneider, Morrison & Foerster, reports on a number of CAFC decisions which are challenging the notion of how far inherent anticipation extends

The US Court of Appeals for the Federal Circuit, also known as the CAFC, was established in 1982 in part to bring uniformity in the application of patent law across the United States by replacing the uneven chorus of the regional courts of appeals with a single voice on patent law. The CAFC has fulfilled some of its promise but has not been an unalloyed success. Recently, in deciding important cases on the law of anticipation, the CAFC has injected worrisome controversy into an area that was thought to be relatively free from doubt.

“Anticipation” by the prior art is simply a lack of novelty in view of the prior art as it is defined in 35 USC 102¹, which includes patents and printed publications published before the date of invention or more than one year before the application filing date, public uses or sales more than one year before the application filing date, prior inventions by others in the United States², and so on. For a patent claim to be anticipated by this prior art, it is necessary that a single prior art reference or activity disclose each element of the claim under consideration³. In applying this test, the courts have long found it to be proper to find as prior anticipating art those features which are inherently as well as expressly disclosed in the prior art reference, provided that the anticipation is not “accidental” or “unintended”⁴. That states the “black letter” definition of anticipation under US law; the challenge lately has been to understand just how far the notion of

inherent anticipation extends. In particular, has the CAFC overturned 125 years of settled law in its recent anticipation jurisprudence?

The scope of eligible subject matter for patenting under US law extends to “new and useful” inventions, with the emphasis for our purposes on “new”. But just what is “new”? Perhaps the best recent expression of the concept is that of the US Supreme Court *Bonito Boats* case: “Both the novelty and nonobviousness requirements of federal patent law are grounded in the notion that concepts within the public grasp, or those so obvious that they readily could be, are the tools of creation available to all.”⁵ The question remains, just how do inherent disclosures in the prior art put “concepts within the public grasp”?

“Inherent anticipation”

The quintessential US inherent anticipation case is the 1881 *Tilghman* case⁶, which concerned a process for separating “fat acids” and glycerin from fats and oils by treatment with water at a high temperature and pressure. Responding to the argument that prior art processes had produced the same result as claimed, the Supreme Court stated that it did “not regard the accidental formation of fat acid in Perkins’s steam cylinder from the talloil introduced to lubricate the piston (if the scum which rose on the water issuing from the ejection pipe was fat acid) as of any consequence in this inquiry. What the process was by which it was generated or formed was never fully understood. Those

In summary

- 🌐 Recent decisions on the law of anticipation by the Court of Appeals for the Federal Circuit have injected controversy into an area that was thought to be relatively free from doubt
- 🌐 The courts have traditionally found as prior anticipating art those features which are inherently as well as expressly disclosed the prior art reference
- 🌐 Decisions in cases such as *Schering v Geneva* and *SmithKline v Apotex* have challenged just how far the notion of inherent anticipation extends

engaged in the art of making candles, or in any other art in which fat acids are desirable, certainly never derived the least hint from this accidental phenomenon in regard to any practicable process for manufacturing such acids." The Court concluded that it would be "absurd" to hold that a patent is anticipated because those engaged in the art later recognise that the invention was "accidentally and unwittingly produced whilst the operators were in pursuit of other and different results, without exciting attention and without its even being known what was done or how it had been done." By the same token, the Court concluded in *Eibel Process*, citing *Tilghman*, that "[a]ccidental results, not intended and not appreciated, do not constitute anticipation." In *Eibel Process*, the Court rejected the argument that the invention was anticipated because others in the art of papermaking machinery had previously produced the same effect of avoiding rippling in the paper as it was continuously produced.

The CAFC's predecessor court, the Court of Customs and Patent Appeals, continued this line of precedent in *In re Seaborg*⁷, which dealt with the patentability of the transuranium element americium. In response to the argument that nuclear reactors had inherently produced the element, the CCPA rejected an "extrapolation" of the inherency analysis to find trace amounts of a nuclear isotope produced in a prior art process: "The record before us... is replete with showings that the 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."

The recognition requirement

In the cases leading up to the CAFC's recent watershed cases, the court "oscillated," to use Prof. Chisum's apt expression⁸, on whether inherent anticipation required some showing that persons of ordinary skill in the art recognised the prior existence of the inherently anticipating feature. In a 2001 case⁹, one CAFC panel went so far as to find that it "may be sensible" that a person of ordinary skill in the art must recognise inherently anticipatory matter in the prior art when the allegedly disclosed matter is a structure or a method step but that the recognition requirement does not apply where the allegedly disclosed matter is a "theoretical mechanism" or a "law of nature".

In addition to the issue of recognition, inherent anticipation implicates the vitality of the principle that anticipatory prior art patents and printed publications must enable a person of ordinary skill in the art to make and use the later claimed invention. As the CAFC stated in *In re Paulsen*, "[T]he reference must be enabling and describe the applicant's claimed invention sufficiently to have placed it in the possession of a person of ordinary skill in the field of the invention."¹⁰ However, does that person even have to know that the invention is anticipated?

The CAFC's decision in *Schering v Geneva*¹¹ represents a recent step up the slope

toward unrecognised, unenabled inherent anticipation. Schering's '716 patent covered descarboethoxyloratidine (DCL), a metabolite of loratidine (which is better known in the United States as Claritin®), certain analogs and salts. Schering's prior art '233 patent disclosed and claimed loratidine itself and other, related compounds. Geneva moved for, and secured, summary judgment in the trial court that the '233 patent anticipated the claims of the '716 patent in suit. The trial court had construed the involved claims of the '716 patent to cover DCL in all its forms, including as "metabolized in the human body". On appeal, the CAFC affirmed,

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holding that the '233 patent inherently anticipated the '716 patent claims because DCL necessarily and inevitably forms in the human body when loratidine is ingested. That seems to be a reasonable view of the facts, one as to which the CAFC found no genuine issue to exist. However, in reaching what might appear to be a reasonable result, the court read its precedent in a fashion that many find unsettling.

The court first rejected the "contention that inherent anticipation requires recognition in the prior art", distinguishing *Tilghman* and *Eibel* on the basis that the records in those cases "did not show conclusively" that the claimed process occurred in the prior art. The court deflected Schering's reliance on the often-cited *Continental Can*¹² case by stating that the case "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 all fairness to Schering, that is not quite what Schering argued; Schering had instead argued that no person of ordinary skill in the art could have recognised the production of DCL by metabolism at all from the disclosure of the '233 patent.

The court did recognise this aspect of the case by stating 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." In other words, unlike *Continental Can*, the alleged inherent disclosure did not fill a gap but instead constituted the entirety of the anticipatory disclosure. That did not detain the court, because, in its view, it saw "no reason to modify the general rule for inherent anticipation in a case where inherency supplies the entire anticipatory subject matter."

Finally, the court recognised that "[a]nticipation does not require the actual creation or reduction to practice of the prior art subject matter;

anticipation requires only an enabling disclosure. **
** 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, eg, DCL as a metabolite in a patient's body. The '233 patent discloses administering loratidine to a patient. A person of ordinary skill in the art could practice the '233 patent without undue experimentation. The inherent result of administering loratidine to a patient is the formation of DCL. The '233 patent



thus provides an enabling disclosure for making DCL." Notwithstanding the Schering court's rejection of the perceived standards of recognition set forth in prior case law, this aspect of Schering did not provoke widespread alarm, although it did provoke the dissents of two judges when the full court denied rehearing.

The steeper slope

The CAFC, however, went much farther than Schering earlier this year in *SmithKline v Apotex*¹³, casting doubt on the viability of the enablement requirement as well and creating heightened uncertainty in the pharmaceutical industry. SmithKline's '723 patent, which claimed the priority of an October 1985 British filing date, claimed "crystalline paroxetine hydrochloride [PHC] hemihydrate," which is more stable than anhydrous PHC. Ferrosan's prior art '196 patent discloses paroxetine and its salts. The district court did not make fact findings as to when Ferrosan first recognised the existence of PHC hemihydrate, but the CAFC inferred from the record that "traces of PHC hemihydrate in PHC anhydrate pills were not detectable in amounts less than five percent before 1985. However, [SmithKline's scientist] Curzons undisputedly made his serendipitous discovery of PHC hemihydrate while making PHC anhydrate presumably pursuant to the teachings of the '196 patent. Moreover, although Curzons does not claim to have discovered PHC hemihydrate until March 1985, further review of samples of SmithKline's PHC anhydrate revealed that SmithKline's Harlow plant had unwittingly made PHC hemihydrate as early as December 1984. These undisputed facts conclusively establish that PHC anhydrate made in accordance with the '196 patent converts into PHC hemihydrate both with and without seeding."

Recognising that the trial court did not address inherent anticipation, which apparently was not argued on appeal, the CAFC nonetheless found the '723 patent invalid because of inherent anticipation. The Court cast aside evidence that no one prior to SmithKline's invention of PHC hemihydrate had any idea that such a form even existed or knew how to make such a form, finding that since one cannot make PHC in any form without inevitably making some PHC hemihydrate, the '196 patent anticipated the '723 patent claims. In one stroke the CAFC put both the recognition and enablement requirements for inherent anticipation aside, without erecting an analytical framework to replace them.

As recently as October 5, 2005, the CAFC compounded the uncertainty created by *SmithKline* by finding a prior art article to be an inherent anticipation because it *did* enable persons of ordinary skill in the art to practice the inherently disclosed subject matter, thus implicitly agreeing that enablement is a requirement of inherent anticipation.¹⁴

Where do we go from here?

As this article demonstrates, the state of the law of inherent anticipation is fraught with uncertainty that only consideration by the full CAFC may resolve. However, given the uneven results of recent *en banc* CAFC decisions like *Knorr-Bremse*¹⁵ and *Phillips*¹⁶, full-court resolution of inherent anticipation may simply perpetuate the current muddle. Unfortunately,

the patent reform legislation currently pending in Congress does nothing to address the problem since the Committee's bill uses the language of current law ("patented or described in a printed publication") to define the nature of anticipating prior art disclosures. Therefore, the law of inherent anticipation in the United States is making many members of the bar "crazy", and their clients nervous. ☹

Notes

- 1 *Diamond v Diehr*, 450 U.S. 175, 189 (1981).
- 2 Activities in WTO or NAFTA countries qualify as prior art under 35 USC 102(g)(1) only in patent interferences in the PTO and not in patent infringement actions.
- 3 *Minnesota Mining and Manufacturing Co. v Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559 (Fed. Cir. 1992).
- 4 *Eibel Process Co. v Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923).
- 5 *Bonito Boats Inc. v Thunder Craft Boats Inc.*, 489 U.S. 141, 156 (1989).
- 6 *Tilghman v Proctor*, 102 U.S. 707 (1881).
- 7 328 F.2d 996, 998-99 (CCPA 1964).
- 8 1 *Chisum on Patents* § 3.03[2][c].
- 9 *EMI Group North America, Inc. v Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350-51 (Fed. Cir. 2001).
- 10 30 F.3d 1475, 1478 (Fed. Cir. 1994).
- 11 *Schering Corp. v Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373 (Fed. Cir.), reh. denied, 348 F.3d 992 (Fed. Cir. 2003).
- 12 *Continental Can Co. v Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).
- 13 *SmithKline Beecham Corp. v Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005).
- 14 *Novo Nordisk Pharmaceuticals, Inc. v Bio-Technology General Corp.*, Fed. Cir. App. No. 04-1581, decided 5 October, 2005, slip op. at 15-16.
- 15 *Knorr-Bremse*, 383 F.3d 1377 (Fed. Cir. 2004) (en banc).
- 16 *Phillips v AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

About the author

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Neither the author nor his firm represents any of the parties in the recent cases discussed in this article.



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