PATENT PRIMER

Inherent anticipation

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The doctrine of inherent anticipation, in which anticipation is found despite the absence of express disclosure in a prior art reference, has recently enjoyed a remarkable revival. In the past few years, various three-judge panels of the Court of Appeals for the Federal Circuit have significantly expanded the reach of this doctrine, increasingly affirming the inherent anticipation of claims that had been crafted specifically to extend the scope or the duration of pharmaceutical patent protection.

The traditional doctrine

A US patent claim is anticipated if, and only if, each and every element set forth in the claim is described in a single prior-art reference. A claim is barred by statute if an embodiment having each and every element is placed on sale by any party more than 1 year prior to the patentee's earliest effective filing date.

Two types of anticipation exist: express anticipation of a claim refers to the express disclosure of one element of the claim in a prior-art reference, whereas under the traditional common-law doctrine of inherent anticipation, anticipation can be found even if one of the required claim elements is not expressly described, as long as the missing element inheres in the prior art.

Traditionally, two provisos have circumscribed the reach of this doctrine. First, inherency cannot "be established by probabilities or possibilities". For, example, the mere fact that a certain outcome could result is not sufficient. An element will be found inherent only if it is the "natural result flowing from" the express disclosure, and only if it invariably results in that outcome. Second, century-old Supreme Court precedent has established that accidental or unintentional results, not appreciated as inherent to the claim by a person of ordinary skill in the art, do not constitute anticipation. However, several recent cases discussed below illustrate that the scope for inherent anticipation has been extended and that the converse is now true.

Appreciation no longer required

In the case of *Abbott Laboratories vs Geneva Pharmaceuticals* (Fed. Cir. 1999) Abbott sued various parties that had proposed to market the Form IV anhydrate of Abbott's α-adrenoceptor antagonist drug, terazosin hydrochloride. Abbott owned patent claims that protected both its marketed dihydrate salt as well as various polymorphs of the compound.

On the record before the Federal Circuit, it was undisputed that a company not party to the lawsuit had made at least three sales in the United States of Form IV anhydrate more than 1 year before Abbott's earliest effective filing date, and also that none of the parties to the sales then appreciated the identity of the particular crystalline form involved in the transaction. Despite the lack of such contemporaneous appreciation, the court invalidated Abbott's claim on the Form IV anhydrate, holding that the prior sales had inherently included this polymorph. The court also denied Abbott's contention that the earlier acts had been 'accidental' or 'unwitting', distinguishing the Supreme Court cases as applying only to prior art that produced "no useful ... result."

More recently, a different Federal Circuit panel found that Schering's claims to the orally administrable loratadine metabolite, descarboethoxyloratadine (DCL, marketed as Clarinex), were inherently anticipated by the company's earlier-filed patent disclosing the parent compound (marketed as Claritin). The court expressly 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." (Fed. Cir. 2003)

Entire invention can now be inherent

The *Schering* case is further remarkable for the proposition that the entire invention, rather than a single missing element, can be found to inhere in the prior art, even in a prophetic prior disclosure. Although the prior art supplied no express description 'of any part' of the DCL metabolite, because the formation of the metabolite in readily detectable amounts is the 'natural result flowing' from loratadine administration the court held the prior patent to inherently anticipate claims to DCL as a chemical compound (see BOX).

Methods can inherently anticipate

Prior art methods can inherently anticipate both compounds, as in *Schering*, and later-claimed methods. Yet another panel of the Federal Circuit affirmed the invalidation of an Eli Lilly claim to a "method of blocking the uptake of monoamines by brain neurons" through the administration of fluoxetine hydrochloride (Fed. Cir. 2001). The appeals court affirmed the lower court decision that the claim was inherently anticipated by the disclosure, in another Lilly patent, of a method of treating anxiety with fluoxetine hydrochloride. The Federal Circuit ruled that there was no patentable distinction between administering fluoxetine hydrochloride for treatment of anxiety and the resulting inhibition of serotonin uptake caused by administration of the drug.

CLAIMING METABOLITES IN THE NEW INHERENCY ERA

In the court's conclusion of the Schering case, inherent anticipation did not preclude patent protection for metabolites of known drugs. However, patent protection is available for metabolites of known drugs if claim construction is done effectively. In claims in which compounds are defined by structure only, metabolites might not receive protection because the scope of such claims include chemical species derived from the parent compound in any surroundings, including within the human body as metabolites. Therefore, as the Schering case illustrates, such claims are inherently anticipated by the prior-art disclosure of a parent drug that is metabolized into the claimed compound. It is, however, possible for a skilled patent drafter to construct a compound claim for a metabolite to avoid anticipation by claiming it in its pure, isolated form, as part of a pharmaceutical formulation, or by claiming a novel method of administering the pure, isolated metabolite or its pharmaceutical form.

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