
Anticipation by Inherency

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Background: Inherency

For a patent claim to be valid, it must claim a product or process that is new, useful, and not obvious. A product or process claim is not "new," and is said to be "anticipated," if all material elements of the claim are found in one prior art source. A prior art source may anticipate if an apparently missing element of the claim is inherent in that prior art source.

In relying upon the theory of inherency, one must provide a basis in fact and/or technical reasoning reasonably to support a determination that the allegedly inherent characteristic *necessarily* will be present if the teachings of the prior art are followed. The fact that a prior art article or process may possibly possess the characteristics of the claimed subject matter is not sufficient to anticipate the claimed subject matter. Inherency must be a necessary result and not merely a possibility.

However, and as one recent case illustrates, a prior art source may anticipate even if one of ordinary skill would not have recognized the inherent features in the prior art.

Schering Corp. v. Geneva Pharmaceuticals, Inc.

In *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, a prior art patent, U.S. Patent No. 4,282,233 (the '233 patent), disclosed the antihistamine loratadine (Schering's Claritin® product), which does not cause drowsiness. The more recent patent at issue, U.S. Patent No. 4,659,716 (the '716 patent), covered a

metabolite of loratadine called desloratadine (DCL). The metabolite forms in the patient's body upon ingestion of loratadine. The metabolite DCL is also a non-drowsy antihistamine, and is marketed by Schering as Clarinex®.

The district court found that the prior art '233 patent inherently anticipated the compound claims of the '716 patent because people who took loratadine produced DCL, and therefore DCL was not new. Even though the '233 patent did not disclose DCL, the district court found that DCL was necessarily formed as a metabolite by carrying out the process disclosed in the '233 patent.

On appeal, the Federal Circuit affirmed. The Federal Circuit stated the general rule that a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in that reference. According to the Federal Circuit, an inherent anticipation does not require that a person of ordinary skill in the art recognize the inherent disclosure. The Federal Circuit remarked that DCL is not formed accidentally or under unusual conditions when loratadine is ingested, and that DCL necessarily and inevitably forms from the ingestion of loratadine under normal conditions. Accordingly, the record showed that a patient ingesting loratadine as taught in the prior '233 patent would necessarily metabolize that compound to DCL.

The Federal Circuit noted that, in prior inherency cases, the anticipating prior art reference generally contained an incomplete description of the anticipatory subject matter, i.e., a partial description missing certain aspects. Inherency, in those cases, supplied the missing aspect of the description. Upon proof that the missing description was inherent in the prior art, that single prior art reference anticipated the subject matter claimed in the later patent. However, this case was different; the structure claimed, DCL, was not at all described by the prior '233 patent.

The Federal Circuit stated that since inherency may anticipate as effectively as does an express disclosure, the inherent disclosure can be of the entire

claimed subject matter, not just of a single feature of the claimed subject matter. The extent of the inherent disclosure does not limit its anticipatory effect.

Finally, the Federal Circuit noted generally that this conclusion regarding inherent anticipation does not preclude all patent protection for metabolites of known drugs. However, such metabolites must be claimed in a way that is both new and non-obvious. Bare compound claims that include within their scope the recited compounds as chemical species in any surroundings, including within the human body, may not be "new," even if they have not been recognized. As this case holds, these broad compound claims are inherently anticipated by a prior art disclosure of a process that causes a drug to metabolize into the claimed compound.

To avoid anticipation, the metabolite or its use could be claimed (1) in a pure and isolated form, (2) as a pharmaceutical composition (e.g., with a pharmaceutically acceptable carrier), or (3) as a method of administering the metabolite or the corresponding pharmaceutical composition.

Conclusion

Inherent anticipation of patent claims can occur regardless of the extent to which the prior art describes features of the claims, and regardless of the absence of any prior recognition that the claimed invention previously existed. However, through careful drafting and consideration of what previously existed, what did not previously exist, and how something that previously existed was previously used, effective patent protection for previously existing compounds and their uses may still be available.

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