Merck & Co., Inc v. Danbury Pharmacal, Inc
873 F.2d1418 (Fed. Cir. 1989)

Prepared by UNCTAD's Intellectual Property Unit

Summary

The US Court of Appeals for the Federal Circuit affirmed that patents are unenforceable in case of inequitable conduct before the patent office.

The facts

A patent application for a method using cyclobenzaprine to treat certain types of skeletal muscle disorders was issued in 1975 for Merck & Co., Inc (Merck Sharp & Dohme, hereinafter MSD). In 1986, Danbury Pharmacal filed an abbreviated new drug application seeking FDA approval to sell a generic version of cyclobenzaprine for the same purpose. MSD sued Danbury for infringement before the District Court for the Southern District of Indiana. Danbury, in its defense, counterclaimed that the use of cyclobenzaprine would have been obvious in view of the prior art compound amitriptyline and that the patent is unenforceable because MSD withheld prior art disclosures of amitriptyline and misrepresented the side effects of cyclobenzaprine. During the court proceedings, the following facts were established:

1. MSD knew of amitriptyline's muscle relaxant properties, which it disclosed to the Food and Drug Administration (FDA), but withheld that fact from the United States Patent and Trademark office (USPTO). MSD withheld material prior art information concerning amitriptyline and misrepresented cyclobenzaprine's selectivity in response to the examiner's objections to allowing the claims.
2. MSD informed the USPTO that cyclobenzaprine was free of the side effects ordinarily associated with nervous system depressants like depression, muscle weakness or drowsiness, but on the other hand the FDA submissions indicated at least one side effect was drowsiness. The misrepresentations of the side effects were made throughout the patent prosecution.

The district court held MSD's patent unenforceable due to inequitable conduct before the USPTO. MSD appealed to the US Court of Appeals for the Federal Circuit (hereinafter the CAFC). The CAFC affirmed the judgment of the district court.

The legal issues

The main legal issues dealt with by the CAFC related to MSD's statement of prior art and the materialness of its misrepresentations.

1. Regarding the withholding of prior art, the CAFC held that a reasonable examiner would consider the withheld prior art important in deciding whether to issue the patent. In this case, it would clearly have been important since amitriptyline's activity was comparable to cyclobenzaprine's given that they have similar properties and effects.

2. Regarding the misrepresentation, the CAFC expressed the view that MSD's conduct of telling the USPTO that cyclobenzapine was free of side effects was highly misleading, regardless of whether the patent examiner had relied on the drowsiness misrepresentation, since the side effects issue only needs to be within a reasonable examiner's realm of consideration.

3. Regarding the proof of intent on the part of MSD, the CAFC stated that intent does not need to and rarely can be proven by direct evidence, but rather through the showing of acts and the natural consequences of which are presumably intended. By simultaneously submitting amitriotyline data to the FDA, but withholding it from the USPTO, the material misrepresentation to the USPTO of cyclobenzaprine's side effects was presumably intended.

Points of significance

- Under US law, a patent can be held unenforceable if, during the application, the applicant withheld prior art and made misrepresentations in order to mislead the USPTO.
- The TRIPS Agreement contains no minimum standards on the material consequences of inequitable conduct by the patent applicant during patent prosecution.

Key words
Clean hands, withhold prior art, misrepresentation.

Links

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https://law.resource.org/pub/us/case/reporter/F2/897/897.F2d.539.89-1495.89-1473.html