



UNIVERSITY OF
MARYLAND
SCHOOL OF LAW

**PATENT LAW
UPDATE**

***Mylan Pharms.,
Inc.
v.
Thompson***

No. 01-1257
Federal Circuit
Oct. 12, 2001

*"[Neither the
patent laws nor
the Hatch-
Waxman
Amendments
allow] an
accused
infringer to
defend against
infringement
[under 35
U.S.C.
§ 271(e)(2)] by
challenging the
propriety of the
Orange Book
listing of the
patent."*

On October 12, 2001, the Federal Circuit reversed the district court's preliminary injunction directing Bristol-Myers Squibb to take measures to delist U.S. Patent No. 6,150,365 from the U.S. Food and Drug Administration's "Orange Book," and directed the FDA to grant final approval of Mylan's abbreviated new drug application (ANDA) for a generic version of buspirone. The Federal Circuit noted:

[T]he FDA . . . publishes a listing of the drug and patents on the drug's approved aspects in Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book." [A]n applicant seeking to market a generic version of a listed drug must make a certification as to each patent listed in the Orange Book When an ANDA contains a Paragraph IV certification, the ANDA applicant must give notice to the patentee and must provide detailed bases for its belief that the patent is invalid, unenforceable, or not infringed. . . .

The Hatch-Waxman Amendments . . . do not include any explicit provisions either enabling or prohibiting an action to challenge a patentee's listing of a patent in the Orange Book. . . . According to the FDA's regulations, however, "[u]nless the application holder withdraws or amends its patent information in response to FDA's request, the agency will not change the patent information in the list" and an ANDA applicant must still make certifications for each patent despite its disagreement. . . .

Mylan and the FDA concede that there is no cause of action to delist a patent from the Orange Book. They also concede that such an action would be a private right of action barred by the [Federal Food, Drug, and Cosmetic Act (FFDCA)]. They submit, however, that Mylan's cause of action, and the basis for our jurisdiction and declaratory relief, arises under the patent laws as a defense to patent infringement. . . .

Mylan argues that had it filed an ANDA with a Paragraph IV certification, it would have been charged with infringing the '365 patent. One of the defenses, which Mylan argues would be available to it in Bristol's hypothetical patent infringement suit, is that Mylan should not have been required to file a Paragraph IV certification in the first instance because the '365 patent did not claim BuSpar or an approved method of using BuSpar, and accordingly, Bristol improperly submitted the '365 patent for listing in the Orange Book. This assertion, however, is not a recognized defense to patent infringement. . . .

[In addition, the Hatch-Waxman Amendments contain no] explicit provisions allowing an accused infringer to defend against infringement by challenging the propriety of the Orange Book listing of the patent. Section 271(e)(4) authorizes specific remedies available to the patentee for the act of infringement of submitting an ANDA, but does not contemplate any remedies to the accused applicant

[A]s part of its inherent power to give effect to a judgment, a court may order the delisting of a patent in the context of a properly filed patent infringement suit. [There is, however, no] authority to hear an independent cause of action seeking delisting outside a properly filed patent case.