Purepac Pharmaceutical Company v. Michael A. Friedman, Acting Commissioner of Food and Drug Administration
U.S. Court of Appeals for the District of Columbia Circuit - 162 F.3d 1201 (D.C. Cir. 1998)
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Summary

In this case, a United States district court ruled that successfully defending a patent infringement dispute is not a necessary requirement for a generic manufacturer to benefit from a 180-day exclusivity period. US law provides, under certain circumstances, a 180-day period of exclusivity to reward the first launch of a generic copy of an originator drug.

The facts

The application by the pharmaceutical company Purepac to market its generic drug ticlopidine hydrochloride was tentatively approved by the FDA, and although ready for final approval, the FDA withheld action. According to the FDA, Purepac must wait until the first applicant for generic ticlopidine, Torpharm, markets its product during a 180-day exclusivity period. Purepac took legal action and sued for an injunction and declaratory judgment challenging the validity of the FDA ruling and claiming that Torpharm was not entitled to the 180-day exclusivity period because it had not been sued for patent infringement by the originator firm.

The legal issues

The legal issue was whether the right for a generic first comer to benefit from a 180-day exclusivity period requires a prior suit for patent infringement. In its analysis the court (1) explained the regime of regulatory approval of patented originator and generic medicines in the United States, (2) explained the provision triggering generic exclusivity, (3) presented the parties' arguments and (4) finally answered whether an earlier suit for patent infringement is required in order to benefit from the 180-day exclusivity.

1. An applicant seeking to market a new drug in the United States must file a "New drug application" (NDA), which must include full reports of investigations of the drug's safety and efficacy. An applicant for a generic drug may submit an "Abbreviated new drug application" (ANDA) which is less demanding and may rely on the safety and efficacy studies already submitted by the originator in the NDA. An ANDA must also include a certification that, for each of the patents applicable to the pioneer drug, the proposed generic drug would not infringe the patent because the patent is invalid or will not be infringed by the manufacturer's use or sale of the generic drug for which the ANDA is submitted. The patent holder must be notified of such ANDA certification. FDA approval may be effective immediately, unless a patent infringement suit is brought against the applicant within forty-five days from

the date the patent owner or patent application holder received notice of the ANDA certification. The latter is referred to as “patent linkage”, as it links generic drug approval to the patent status of the originator drug.

2. The FDA's original regulation provides: "if an abbreviated new drug application contains a certification that a relevant patent is invalid, unenforceable or will not be infringed and the application is for a generic copy of the same listed drug for which one or more substantially complete abbreviated new drug applications were previously submitted containing a certification that the same patent was invalid, unenforceable or would not be infringed and the applicant submitting the first application has *successfully defended against a suit for patent infringement brought* within 45 days of the patent owner's receipt of notice submitted, approval of the subsequent abbreviated new drug application will be made effective…"
3. The Court summarized the positions of the parties as follows:
    a. Purepac claimed that the first generic applicant was entitled to the 180-day exclusivity period only after it had successfully defended against a patent infringement suit.
    b. The FDA issued a 'Guidance to Industry' in accordance with case law precedent (i.e. the “Mova” case), which removed the successful defense requirement from the regulation.
    c. Purepac still held that Torpharm was not entitled to a 180-day exclusivity since it had not been sued for patent infringement, and further noted that the FDA still had to require, as a condition for exclusivity, that the first generic applicant be sued for patent infringement, although the FDA could no longer insist that the applicant defend the suit successfully, due to the FDA’s own 'Guidance to Industry'.
    d. The FDA claimed that the Guidance also held that a first applicant, like Torpharm, did not have to be sued at all in order to be entitled to the exclusivity period.
    e. Purepac claimed the FDA had gone beyond its mandate and wrongfully amended the regulation. According to the precedent in Mova, Purepac claims that what was to be changed in the regulation is the requirement that the first applicant "successfully" defend the lawsuit, and, due to this, the FDA had no grounds to change the regulation the way it did.
4. The Court held the FDA's revised system to be consistent with the precedent in Mova. The Court ruled that it is not required for the first generic applicant to be sued by the patent holder in order to benefit from market exclusivity. In its view, such requirement would be irrational.

Points of significance

- Under the law of the United States, it is not required for a first applicant of generic drug approval to be sued in a patent infringement claim in order to benefit from the 180-day market exclusivity period.
- The United States has a “patent linkage” system in place, according to which the drug regulator cannot approve a generic drug if a patent holder claims patent infringement, should the generic drug be approved to the market.

- The TRIPS Agreement provides no reference to patent linkage. It leaves WTO Members free to decide whether to implement a patent linkage regime. Other large jurisdictions such as the European Union do not practice patent linkage. In the EU, a patent holder can challenge the generic drug for infringement after the generic is approved to the market.

Key words:
Patent linkage, exclusivity, prior patent suit, Abbreviated New Drug Application (ANDA).

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