

# On Access and Accountability — Two Supreme Court Rulings on Generic Drugs

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In June, the U.S. Supreme Court issued two rulings regarding the marketing of generic drugs that may alter the pharmaceutical business landscape. First, in *Federal Trade Commission v. Actavis*, the Court confronted the law governing a controversial pharmaceutical marketing practice known as reverse payment agreements, or pay for delay.<sup>1</sup> This practice occurs when a generic drug company identifies a vulnerable patent held by a brand-name drug manufacturer and seeks approval from the Food and Drug Administration (FDA) for a generic version before the patent expires, provoking a lawsuit for infringement. The two companies then forge a settlement whereby the brand-name company pays the generics firm to delay commercialization of its product. Extending the monopolies of brand-name companies in this way reportedly costs consumers more than \$3.5 billion per year.<sup>2</sup> Since such settlements suppress competition, the Court sent the case back to the district court to be evaluated according to the “rule of reason,” one of the standards for determining whether an action violates antitrust law.

Second, in *Mutual Pharmaceutical v. Bartlett*, the Court ruled that generics manufacturers are substantially immune from civil claims regarding injuries caused by their products — a decision that eliminates a primary incentive for evaluating safety and design defects before marketing a generic product.<sup>3</sup>

The patent at issue in *Actavis* — on a gel form of previously manufactured synthetic testosterone —

was challenged on the grounds that it lacked novelty. The parties settled using a reverse payment agreement, whereby the brand-name company Solvay Pharmaceuticals, acknowledging that the patent challenge was credible, paid Actavis to delay releasing its generic version, albeit not beyond the original life of the patent. Such agreements — raising issues of both patent and antitrust law — are a byproduct of the 1984 Hatch–Waxman Act, which was designed to encourage production of low-cost generic drugs while respecting the incentives that patents provide. In *Actavis*, the Federal Trade Commission (FTC) argued that pay-for-delay agreements amount to illegal conspiracies to restrain trade, in violation of antitrust laws.

When pharmaceutical companies discover a new drug, they routinely seek patent protection, which allows them exclusive marketing rights for 20 years from the filing of the application. To be eligible for patent protection (so that the company can reap monopoly profits for the duration), the discovery must be novel, nonobvious, useful, and “enabled” — that is, fully and completely described so that any person skilled in the art can make and use the invention.<sup>4</sup>

Hatch–Waxman, to encourage competition among generics manufacturers, established a regulatory mechanism for expedited approval of generic drugs — the Abbreviated New Drug Application (ANDA). The ANDA process allows generics whose manufacturers can demonstrate chemical equivalence to a brand-

name drug to “piggyback” on that drug’s FDA approval. Since the FDA will not approve an ANDA if it infringes on a brand-name drug’s apparently legitimate patent, the timing of the ANDA is critical. One option, of course, is for the generics company to postpone submission of its ANDA until the patent has nearly expired. But Hatch–Waxman entices generics manufacturers not to wait but to immediately pursue drugs with “weak” patents, whose validity may be vulnerable to challenge on the basis of novelty, utility, or another factor. Hatch–Waxman provides a framework for litigating those questions before the generic product is commercialized — after which its maker would be risking a lawsuit for infringement.

A brand-name drug company that is confronted with a patent challenge has little choice but to initiate aggressive litigation to protect its patent and its monopoly profits. Since weak patents are generally targeted for ANDA contests and patent litigation is notoriously costly and unpredictable, it’s not surprising that ANDA litigation is often resolved through settlement. The compromise typically entails a formula whereby the brand-name company pays the generics company (often millions of dollars per year) to delay its product’s release, allowing the brand-name company to maintain its monopoly longer. Both companies benefit financially from the compromise.

Noting that the “root of the problem lies in the perverse re-

distribution of incentives created by the Hatch–Waxman Act,” the FTC argued in *Actavis* that all reverse-payment agreements should be individually scrutinized according to a standard that presumes they are anticompetitive. The FTC urged the Court to consider such settlements suspect because they enable a brand-name manufacturer to “co-opt its rival by sharing the monopoly profits that result from an artificially prolonged period of market exclusivity.” *Actavis* countered that its agreement represented a legitimate settlement of an ongoing patent dispute and was consistent with patent law, since Solvay’s monopoly didn’t extend beyond the patent’s life.

Substantially favoring the FTC’s position, the Court held that reverse-payment settlements are not immune from antitrust scrutiny, but it also declined to conclude that they should be presumed unlawful. Although the Court acknowledged that its ruling may require courts to delve into the anticompetitive consequences of these complex settlements, public policy dictates against the alternative of allowing the two competing companies to divide large monopolistic profits, to the detriment of consumers.

In *Bartlett*, the Court examined generic drug manufacturers’ constitutional protections against state-law tort claims. In a 2011 case, *PLIVA v. Mensing*, the Court had ruled that “failure-to-warn” claims could not be brought against generics manufacturers. In *PLIVA*, although the label for the drug in question, metoclopramide, provided insufficient warning about a particular side effect (tardive dyskinesia), the FDA requires that generic drug labels be consistent with the label of

the brand-name equivalent. The Court therefore held that state-level failure-to-warn claims against generics manufacturers are preempted by federal law — and indeed that *PLIVA* could not possibly comply with both federal and state law, since it could not legally modify its drug label. In contrast, in *Wyeth v. Levine* (2009), the Court ruled that failure-to-warn claims may be brought against brand-name drug manufacturers, because they do have the legal authority to modify their labels.<sup>5</sup>

The question in *Bartlett* was whether “design defect” claims against generics manufacturers are also preempted. Karen Bartlett developed toxic epidermal necrolysis while taking the generic nonsteroidal antiinflammatory agent sulindac and claimed that the drug’s design was defective. In a 5-to-4 decision, the Court ruled that this type of claim was also preempted, since the alleged defect was related to the adequacy of the drug label that had failed to warn the patient about this side effect. Justices Sonia Sotomayor and Stephen Breyer both issued strong dissents. Sotomayor emphasized that companies may still be liable for misbranding if they continue to sell a drug that new information has shown to be dangerous.

The Court’s ruling in *Bartlett* further extends the constitutional protection provided to generics manufacturers against state-level tort claims — protection not provided to brand-name manufacturers. The disparate rulings for brand-name and generic drugs may seem illogical but stem from the absence of specific FDA guidance. Both opinions called on Congress to address the preemption law.

For consumers, *Actavis* and *Bartlett* have mixed implications. The *Actavis* ruling favors consumers, who may see earlier access to generic equivalents and reduced drug costs. The *Bartlett* ruling, however, leaves generics companies unaccountable to consumers — but it has apparently prompted the FDA to consider revising its own labeling rule. Days after the Court’s decision, the agency released a proposed revision that would “create parity” in the ability of brand-name and generic drug companies to control their labels’ contents. If the proposed rule is adopted, it may increase the cost of generic drugs, since companies will be accountable for their labels’ contents and so will have to invest more heavily in their own safety studies. If the *Bartlett* ruling stands, the cost of generic drugs may be reduced, since companies won’t be liable for most of the harm caused by their products. Since nearly four of five prescriptions are now filled with generic drugs, the impact of these decisions on this already large and growing industry can be expected to be substantial.

Disclosure forms provided by the authors are available with the full text of this article at [NEJM.org](http://NEJM.org).

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1. 570 U.S. \_\_\_\_ (2013).
2. Pay-for-delay: how drug company pay-offs cost consumers billions (<http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>).
3. 570 U.S. \_\_\_\_ (2013).
4. 35 USC 101-103, 112.
5. 555 U.S. (2009).

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