Is the government hopping over the line with its product-hopping stance?

THE CASE:
People of the State of New York v Actavis
The US Court of Appeals for the Second Circuit
28 May 2015

The legal rationale underlying the decision to prevent product hopping deserves some careful inspection. **Erica Pascal**, **Steven Levitsky** and **Bertold Bar-Bouyssiere** take a closer look

In general, under US law, a competitor has no duty to help another compete. The Supreme Court of the US has cautioned that although the Sherman Act "is indeed the Magna Carta of free enterprise… it does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition."[1] There are very good reasons for this rule: it encourages product innovation and prevents parasitic free riding.

Yet just recently, the US Court of Appeals for the Second Circuit required a pharmaceutical company to continue selling a product the company wanted to replace with a newer improved version. The court concluded that anti-trust law required the plaintiff to continue selling the older version so that its generic competitors could compete through state pharmaceutical substitution laws. This decision could have a wide-ranging impact, not just in the pharmaceutical industry, but could also potentially affect competition in any other market and thereby distort anti-trust law.

There is no question that competition in the pharmaceutical market has been and continues to be a hot button topic. Drug pricing finds its way into the headlines almost daily and the social and political issues at the heart of the debate cannot be discounted. But setting these aside temporarily, the legal rationale underlying the decision to prevent product hopping deserves some careful inspection. Should the courts broadly gerrymander antitrust laws to achieve a desired outcome in this one market? Or is it better and smarter to deal with that issue through legislation directed to the specific debate at hand?

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To be clear, in this recent case, the withdrawal of the branded version would *not* have prevented the sale of the generic versions. It would only have changed the way the generics were sold. Current state laws permit and often compel a pharmacist to automatically substitute the cheaper generic version of the drug when the patient presents a prescription for the branded version. If the branded version was withdrawn from the market the prescriptions would need to specify the generic name of the drug, since automatic substitution would no longer occur. This could require the generic companies to dedicate marketing resources to promoting these versions, rather than piggy-backing on the branded version's promotions. The pricing structure for the generic versions would also change in the absence of a branded version, based on the tiered system pharmacies typically use to price drugs according to the availability of interchangeable branded and generic versions. At its core, the withdrawal of the branded version could lead to higher prices for the generic versions.

Anti-trust laws

Imposing changes in anti-trust laws just to facilitate competition in the pharmaceutical industry undermines the basic rule that a company does not need to help its competitors. This is a fundamental principle of US anti-trust law. The US long ago abandoned the essential facilities doctrine, which required a competitor to provide equal access to its own property at a fair price (eg, sports arenas being forced to share their arena with competing teams or telephone companies sharing a distribution network). More importantly, the US does not subscribe the European theory of a dominant position, which endows a company with a dominant share in the relevant product and geographical market with a special responsibility to ensure that its conduct does not distort competition.[2] Under EU law, a dominant company may still compete on the merits but the question, as always, is where to draw the line. In the now decade-old *AstraZeneca* decision, the European Commission found product hopping to be abusive, but that case had some particular facts. Since then, regulations have

been changed at the EU level to make product hopping irrelevant.

The American approach is based on a belief in competition on the merits that lets the public and the markets dictate the balance between competitors' products. In contrast, the European approach imposes a regulatory-type duty on a dominant company to help its competitors, even when it hurts the company's own sales.

The recent product-hopping decision not only castrates anti-trust law but also undermines patent law, which grants the patent holder the right to exclude competitors. This permitted monopoly is what encourages investment in innovation. In exchange for monopoly protection, the public benefits from the massive economic commitments on the part of the patent owner that are necessary to develop new drugs. Once the patents covering a drug expire any company can then market the drug, provided it gets regulatory approval from the Food and Drug Administration. The Hatch-Waxman statute also provides a mechanism for earlier generic entry by allowing market entrants to challenge the patents before their expiration without liability for monetary damages.[3]

In this case, the Hatch-Waxman procedures and the natural expiration of the patents were available to the generic competitors. The patents on the older version of the drug were near expiration while the newer version – a longer-acting formulation of the drug – had its own set of patents providing a new period of exclusivity. These newer patents would be open to challenge under the Hatch-Waxman framework. But the court's decision forces the patent holder to continue to produce its older product just to let generic versions enter with lower pricing and compete against its newer version. The patent holder is essentially punished for improving its product.

One could argue that this issue could be side stepped by simply letting the market decide. That would mean keeping both branded versions of the drug, the older formulation and the improvement, on the market. But in a broader context, this would just perpetuate obsolete products – an ironic stance given that patent and anti-trust laws are intended to encourage innovation. How far could such a rationale reach? For example, could a company that makes computer operating systems be forced to restore obsolete versions of its software so that other companies could sell older versions of applications that only run on those older systems? Could Microsoft be forced to bring back DOS so that users could run DOS-based Word Perfect 5.1? Could Microsoft be liable to anti-trust attack because it periodically upgrades its operating systems and makes it costly for smaller companies that compete with Microsoft applications to constantly rewrite their software?

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Summary

Even if this recent decision is limited only to its current context of branded/generic drug competition – which is unlikely – addressing the problem through court decisions provides an all-too fertile ground for perverting antitrust and patent law. If the public and the government aim to rein in healthcare costs by regulating how branded and generic drug companies compete, legislation directed to the specific issues is a more direct and precise tool. In this manner, if a competitor does have a duty to help another compete, at least this duty is made clear at the outset. This is a fundamental issue to our economy. Competitors have a right to know what the rules are before they invest hundreds of millions of dollars creating new products.

Footnotes

1. *Verizon Communications Inc v Law Offices of Curtis V Trinko, LLP,* 540 US 398, 416 (2004).
2. http://ec.europa.eu/competition/antitrust/procedures_102_en.html
3. The Hatch-Waxman statute permits generic entrants to challenge the patents before actually entering the market. This framework is intended to allow generic challengers to get a ruling on the patents before incurring any potential liability for damages should the patents be found valid and infringed.

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