Kluwer Competition Law Blog

Product hopping: The competition law risks of launching new product formulations

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'Product hopping', or 'evergreening', are expressions used (by antitrust authorities and industry respectively) to describe strategies employed by pharmaceutical companies to protect sales of a successful drug on the verge of losing patent protection. For example, a pharmaceutical company might introduce a new formulation of the drug before it faces significant competition from a generic alternative.

There is nothing inherently wrong with product hopping. The European Court of Justice has recognised that it is legitimate for pharmaceutical companies to adopt strategies seeking to minimise the erosion of their sales when faced with competition from generic products.[1] In addition, the development of a new and improved formulation of a drug can be extremely beneficial, both to the patients that might find it more effective, and to society as a whole for the jobs created in researching, manufacturing and marketing the new product.

However, there is a growing line of case law in the US and Europe that illustrate the competition law risks involved with product hopping. In all of these cases, the issue has not been the introduction of a new formulation. Instead, it has been other specific elements of the strategies employed by pharmaceutical companies to encourage consumers to switch to the new formulation that have caught the attention of the courts and regulators, particularly where this has prevented consumers from having a choice between a branded drug and generic version.

Europe

Cases in Europe offer some clear examples of this. When withdrawing Losec capsules in favour of new Losec tablets, AstraZeneca deregistered its marketing authorisation for Losec capsules in several EU Member States. This prevented generics manufacturers from relying upon the clinical trials conducted for Losec capsules when applying for authorisation for a generic version, making it for more difficult for generics to enter the market. The deregistrations, in the absence of any objective justification, were found to be an abuse of a dominant position.[2]

In the UK, Reckitt Benckiser replaced its original Gaviscon product with a new version, Gaviscon Advance. This was done after the original patent had expired but before a generic name for the original product had been published, with the result that prescriptions could only be written for the new branded product. In finding that this was an abuse, the UK regulator held that it would have been commercially irrational to withdraw the original product had it not been for the anticipated

benefits of delaying generic competition.[3]

In both cases, the introduction of the new product was not anti-competitive, however, the combination of that and the exploitation of the underlying regulatory framework was found to breach competition law.

USA

In the US, the focus has also been on actions by pharmaceutical companies that remove the consumer's ability to choose.

In *State of New York v Actavis*,[4] a US Appeal Court drew a distinction between a 'soft switch' and a 'hard switch'. Actavis manufactured a successful twice-daily Alzheimer's drug, Namenda IR. In 2013, it introduced a once-daily version, Namenda XR. The new drug contained the same active ingredient, memantine. Actavis began an aggressive marketing campaign to switch patients on to Namenda XR, and made use of rebates to offer it at a low price. This was the soft switch. Then, in August 2014, a year before it was due to lose patent protection on Namenda IR, Actavis discontinued it. The Court described this as a hard switch; the discontinuation left Namenda XR as the only option for patients before the entry of a generic version of Namenda IR. The court held that the hard switch crossed the line from persuasion to coercion, and was anti-competitive.

More recently, in early September 2017, the US District Court for the Eastern District of Pennsylvania denied Indivior's motion to dismiss a claim brought against it by the State of Wisconsin (along with a number of other States) alleging anti-competitive behaviour relating to its marketing and sale of Suboxone.[5] In finding that Wisconsin had a plausible claim, the court noted that Indivior had near simultaneously introduced a new Suboxone film, removed its Suboxone tablets from the market, and engaged in a marketing campaign to disparage Suboxone tablets. This was done before the entry of generic competitors into the relevant market, leading to a restriction of the ability of consumers to choose between the branded products and a generic alternative.

Interestingly, although the plaintiffs characterise Indivior's conduct as a hard switch, the generic alternative to Suboxone tablets had been on the market for almost two weeks before the tablets were withdrawn. Arguably, Suboxone tablet prescriptions could simply have been replaced with generic tablets at this point. However, realistically this could only occur for patients who needed to renew their prescriptions in that short period of time. In addition, the plaintiffs claim that even by the time generic tablets received FDA approval in February 2013, 85% of Suboxone prescriptions were already for film instead of tablets. If this case proceeds to trial, the focus may therefore be on the soft switch elements to Indivior's strategy: the disparagement of tablets leading to the rapid take-up of film. In denying the motion to dismiss, the judge noted that summary judgment record might be different, suggesting that he wasn't completely convinced by the merits of the plaintiffs' case.

Will the case law develop further?

It's possible that in the future we may see competition authorities or courts seeking to penalise conduct that is closer to a soft switch than hard switch. After all, in France in 2016, the Cour de Cassation upheld the €40.6m fine imposed on Sanofi-Aventis by the French Competition Authority in May 2013.[6]Sanofi-Aventis was found to have denigrated generic competitors of its drug Plavix

in its communications with doctors and pharmacists; it encouraged them to indicate on Plavix subscriptions that the drug was “non-substitutable”. This was not a hard switch – there was a generic alternative available, but the conduct had a similar effect to a hard switch; it partially foreclosed generic entry to the French clopidogrel market (leading to a softening of competition, as Sanofi lost market share to generics much more slowly than it otherwise would have).

For now though, it remains the case that pharmaceutical companies can continue to take steps to extend the lifetime of their product ranges, as long as they are careful to ensure that any introduction of a new formulation is not supported by a strategy that limits the ability of generics of the earlier formulation to enter the market. Where companies avoid that potential pitfall, the introduction of new formulations benefits patients: and pharmaceutical companies’ promotion of those positive attributes epitomises legitimate competition on the merits.

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