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I. INTRODUCTION

The Canadian Competition Bureau (the "Bureau") has been signaling a renewed interest in competition enforcement in the pharmaceuticals industry, and more broadly, issues at the forefront of intellectual property and competition law. While enforcement in this space has seen significant attention from other major antitrust regulators, this marks a shift for the Bureau. Most significantly, the Bureau has commenced an inquiry into whether alleged product-hopping conduct amounts to an abuse of dominance under the *Competition Act*. This article explains product hopping, surveys the major U.S. arguments as to why it may raise competition concerns, and then considers the Bureau's potential case.

In contemplating a product-hopping case, the Bureau joins a crop of recent antitrust enforcement efforts around the globe directed at variations of product hopping conduct. In November 2012, the U.S. Federal Trade Commission ("FTC") filed a brief as *amicus curiae* in the private product hopping case *Mylan Pharmaceuticals, Inc v Warner Chilcott Public Limited Co.* (*"Mylan Pharmaceuticals"*),[2] which recently settled. In July 2010, the European Union General Court upheld the European Commission's finding in a seminal product-hopping case against AstraZeneca. Enforcers in less prominent jurisdictions have also been getting in on the action; in February 2014 the Australian Competition and Consumer Commission announced a product-hopping case against Pfizer, and the U.K. Office of Fair Trading issued a decision against Reckitt Benckiser in April 2011.

II. WHAT IS PRODUCT HOPPING AND WHY IS IT ATTRACTING ANTITRUST ATTENTION?

As the FTC explains, "product hopping" or "product switching" generally involves branded manufacturers introducing new formulations of patented drugs shortly before the patent protection on the older version of the drug expires, then withdrawing from the market the older drug that faces imminent generic competition.[3] The conduct often involves allegedly steering physicians or pharmacists to "hop" demand over to the new branded drug formulation, which is protected by a long-term patent. Because generic drugs tend to rely on substitution rules that allow pharmacies to swap-in the generic equivalent for a branded drug, when physicians stop writing prescriptions for the older drug, this eliminates the possibility of substitution and thus (the FTC argues) the possibility of meaningful generic competition. In its *Mylan*

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[2] 2014 U.S. Dist. LEXIS 21504 (E.D. Pa. Feb. 18, 2014).

[3] The FTC observes the same result as a product withdrawal can be indirectly achieved through the branded company raising price or creating supply shortages of the older product.

Pharmaceuticals amicus brief, the FTC argued such pharmaceutical product redesigns, where the old product is withdrawn, could constitute exclusionary conduct in violation of section 2 of the *Sherman Act*.

Branded pharmaceutical companies maintain that the introduction of a new product formulation and withdrawal of an old one is a business decision based on innovation and profit maximization, and does not constitute anticompetitive conduct. The companies point to jurisprudence outside of the product-hopping context which held "the process of invention and innovation is clearly tolerated by the antitrust laws" and push for an approach where the court is "very skeptical" about claims that competition has been harmed by product improvements.[4] The argument is that courts should be cautious about sanctioning product design changes, lest they dampen the incentives for branded pharmaceutical companies to further innovate.

The FTC counters that although the general rule is judicial deference to product innovation, pharmaceutical product design changes should not be considered *per se* lawful. The FTC is not suggesting that such conduct is *per se* unlawful but rather that it may be subject to challenge in particular circumstances where the anticompetitive effects outweigh the benefits. If anticompetitive harm is shown from the formulation switchover, the harm is then weighed against benefits of the change.[5]

The FTC characterizes the product hop in *Mylan Pharmaceuticals* as being forced by the removal of the old product from the market "preventing consumers from weighing the relative merits of competing products."[6] This absence of consumer choice is seen by the FTC as the essential difference between product switching in the pharmaceutical industry and product switching in other contexts, where U.S. courts have expressed caution over questioning the innovation value of new products on the premise that the switch merely reflects consumer choice. Private cases to date in the United States have similarly focused on whether there was an elimination of consumer choice arising from the branded company's withdrawal of its older product formulation. The FTC has yet to test this theory in a case of its own, and the case in which the FTC filed its *amicus* brief recently settled.

The FTC's approach tasks the court or antitrust enforcers with balancing pro-competitive and anticompetitive effects of a drug formulation change. The harm hinges on skepticism over whether the new drug formulation, which may involve a dosage or formula change, offers a sufficiently improved therapeutic benefit over the older drug formulation. If there is some marginal benefit, the question then becomes whether that benefit is sufficient to make up for the foregone cost savings arising from less generic competition.

In terms of effect on competition, Warner Chilcott argued in filings for *Mylan Pharmaceuticals* that the new drug formulation is either an improvement, and thus enhances competition or, at worst, it has a neutral effect because one formulation replaces another. Product-hopping cases can thus present a thorny proposition of determining whether the

[4] *Berkey Photo, Inc v Eastman Kodak Co* 603 F.2d 263, 281 (2nd Cir. 1979).

[5] *Mylan Pharmaceuticals, supra note 2,* FTC Brief as *Amicus Curiae* at 13, referring to *Abbott Labs v Teva Pharms USA, Inc* 432 F Supp. 2d 408, 422 (D Del. 2006) and the analytical approach applied in *United States v Microsoft Corp* 253 F 3d 34 (DC Cir. 2001) (en banc).

[6] *Id.* at 13.

innovation is credible from an antitrust perspective, in the context of an already complex regulatory regime where false positives create the risk of chilling innovation among branded pharmaceutical companies.

III. THE CANADIAN COMPETITION BUREAU INQUIRY INTO PRODUCT HOPPING

The Bureau is currently investigating whether Alcon Canada Inc. ("Alcon") abused a dominant position in the supply of prescription drugs for the treatment of allergic conjunctivitis through product-hopping conduct.[7] Alcon Canada Inc. sells two prescription eye-drop products for the treatment of allergic conjunctivitis in Canada. One, Patanol, is nearing the end of its patent protection. Apotex Inc., a generic drug company, received approval to market a generic version of Patanol (which was challenged by Alcon in separate proceedings). The other product, Pataday, is newer, and at the beginning of its patent protection period in Canada. Although the products have the same active ingredient, the older product requires use twice a day while the new product requires use only once a day.

The Bureau argues Alcon withdrew the supply of its older drug, Patanol, in advance of the imminent entry of a generic substitute. The Bureau's theory of abuse seems to be based on this withdrawing supply of the older drug and switching of physician demand to the new drug, in order to prevent effective generic entry. The Commissioner of Competition ("Commissioner") obtained a court order for the production of records and a written information return from Alcon in order to advance his inquiry. Alcon argued against the issuance of the order, claiming that its decision to cease marketing the older drug was not an anticompetitive act constituting an abuse of dominance. It argued further, if there was an abuse of dominance, the inquiry was premature or the issues had been resolved, because Alcon had agreed to recommence supplying Patanol in Canada.

The Bureau's case as currently framed could raise difficult questions on the assessment of pro-competitive benefits and any anticompetitive harm arising from incremental innovation, as seen in U.S. cases. It appears that Apotex remained free to compete on the basis of its generic version of the older drug, which may make the anticompetitive harm more difficult to establish. This is in contrast to product-hopping cases in jurisdictions such as the European Union and the United Kingdom, where seminal cases involved additional action by the branded pharmaceutical company beyond the mere discontinuance of sales of the branded version, such as withdrawing market authorizations for the old branded drug in order to block even the possibility of competition from the generic version of that older drug.

The decision to issue the production order in the Alcon investigation is not an endorsement by the court of the Commissioner's theory of the case. However, if the case proceeds, it would be a rare example of the Commissioner adopting an argument of more than "mere exercise" of patent rights. Alcon was required to produce records and written returns within 60 days of the order issued on December 21, 2012. Although such deadlines may be extended on consent of the Commissioner, it seems that, a year later, there has been plenty of time for production and review of the records. The status of the case is thus somewhat unclear, but it is understood to be ongoing.

[7] *See, Commissioner of Competition v Alcon Canada Inc, Federal Court of Canada*, Court File No T-2223-12.

The Alcon investigation comes alongside developments that signal a new willingness of the Bureau to wrestle with the often-complex intersection of intellectual property law and competition law. In November 2013, the Bureau held a workshop on competition issues in the pharmaceutical sector, which included sessions on reverse payment settlements, international perspectives on antitrust in pharmaceuticals, and pharmaceutical life-cycle management strategies.

New guidance on intellectual property law and competition enforcement is also anticipated. The current Intellectual Property Enforcement Guidelines ("IPEGs") date to 2000, long before issues like product hopping were at the forefront of competition enforcement. The Bureau's newfound enthusiasm is in contrast to a historically restrained approach, at least compared to agencies in other jurisdictions, to issues in the pharmaceutical industry and, in particular, cases that raise questions over the reconciliation of patent law and competition law. Even if the Alcon case does not ultimately proceed, the Bureau seems newly poised to delve into enforcement in this area.