



# PERSPECTIVE

## Pharma Industry Under Antitrust Scrutiny

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Competition authorities continue to examine various aspects of the pharmaceutical industry. Most recently, the European Commission conducted surprise inspections of certain pharmaceutical companies, seeking evidence of anti-competitive conduct. One issue of concern is the impact on competition of "pay-for-delay" or "reverse payment" patent settlement agreements, whereby branded pharmaceutical manufacturers make payments to generic manufacturers in exchange for delaying their entry. Although this issue has yet to be a specific focus of concern in Canada, recent amendments to the *Competition Act* (to come into force in March 2010) could make it easier for Canada's Competition Bureau to follow the example of its counterparts in other jurisdictions.

### ***United States***

Leading the charge on this issue is the U.S. Federal Trade Commission ("FTC"), which has identified the elimination of "reverse payments" as "one of its highest priorities". In a June 2009 speech, Jon Leibowitz, the Chairman of the FTC, referred to reverse payments as "collusive deals" and estimated that the elimination of these payments could save American consumers U.S. \$35 billion over ten years. The FTC also addressed the issue in its June 2009 interim report on "authorized generics", which deals with generic drugs sold by a brand pharmaceutical manufacturer. According to the FTC, its initial findings suggest that the prices of prescription drugs are lower when authorized generics are available. The report also suggests that agreements to delay introducing authorized and independent generics can harm consumers by delaying price competition between generic and branded pharmaceuticals.

The FTC has been joined in its stand against reverse payments by the U.S. Department of Justice ("DOJ"). In July 2009, at the request of the 2<sup>nd</sup> U.S. Circuit Court of Appeals, the U.S. DOJ filed a brief setting out its views on the legality of reverse payments under U.S. antitrust legislation. In its brief, the U.S. DOJ stated that in light of the "anticompetitive potential of reverse payments ...it is sufficiently clear that such agreements should be treated as presumptively unlawful under Section 1 of the Sherman Act". However, the DOJ qualified its statement by noting that defendants may rebut this presumption by showing that the payments do not unduly restrain competition. The DOJ also declined to take a position in the underlying case (which involves a challenge by drug purchasers to a settlement between Bayer AG and Barr Pharmaceuticals to keep a generic version of the antibiotic Ciprofloxacin off the market). As a result, it remains to be seen whether the

decision of the 2<sup>nd</sup> Circuit will be influenced by the DOJ's position, particularly given that the Court has previously taken a permissive approach to the legality of such settlements.

Consistent with the FTC's and DOJ's recently stated position regarding reverse payments, the Energy and Commerce subcommittee of the US House of Representatives endorsed legislation in June 2009 that would prohibit "pay-for-delay" patent settlements. The Senate Judiciary Committee is considering similar legislation. The push to introduce such legislation has not been without controversy – particularly in light of the differing decisions from U.S. courts on whether "pay-for-delay" settlements violate U.S. antitrust law.

### ***European Union***

The European Commission has been conducting an inquiry into the pharmaceutical sector for the past year. In November 2008, the Commission conducted "dawn raids" against a number of pharmaceutical companies. In July 2009, the Commission issued its final report and simultaneously announced the initiation of formal proceedings against Servier (a pharmaceutical manufacturer) and five generics manufacturers (Krka, Lupin, Matrix Laboratories Limited, Niche Generics and Teva) on suspicion of conduct contrary to Articles 81 and 82 of the EC Treaty. Among other things, the Commission alleges that Servier abused its dominant position by entering into "reverse payment" settlement agreements with the generics manufacturers in respect of its patented cardiovascular medicine.

The Commission's final report calculates that 3 billion EUR could have been saved between 2000-2007 if generic entry had occurred earlier. The report concludes that there are a number of factors which contribute to the delay of entry by generics including the patent filing strategies of the branded pharmaceutical companies, patent litigation and "pay for delay" settlements. The report recommends significant changes to the existing regulatory framework to improve access to generics, including the establishment of a unified specialized patent litigation system across the European Union and a EU community-wide patent.

Perhaps not surprisingly, the report also recommends that competition law scrutiny of the pharmaceutical sector be intensified in the European Union. On the issue of "reverse payment" settlements specifically, the report notes that the Commission will consider "focused monitoring...of those settlements with a potential to adversely affect European consumers" and that the Commission will initiate enforcement action in appropriate cases (such as the proceedings referred to above).

The Commission's efforts in this area remain ongoing. In a speech on September 29, 2009, the European Competition Commissioner stated that the Commission is "capitalising" on the pharmaceutical sector inquiry by bringing new cases and reiterated the importance of the Commission's efforts to "improve the functioning of this sector". In addition, the Commission confirmed on October 6, 2009 that it had conducted surprise inspections of certain pharmaceutical companies including manufacturers of brand name pharmaceuticals. The inspectors are said to have been looking for evidence of restrictive business practices and/or the abuse of a dominant market position.

### ***Canada***

The Canadian Competition Bureau has also recently examined aspects of the pharmaceutical industry in Canada. Specifically, the Bureau issued a report in 2008 on the state of generic drug competition in Canada. The Bureau suggested in this report that while there is active competition between generic manufacturers in Canada, the resulting cost-savings have not been passed on to consumers. In the Bureau's view, the failure to pass on these cost savings is due to the structure of existing private and public drug plans and

the manner in which these plans pay for generic drugs. The Bureau's suggestions for improvements in this area include the adoption of competitive tendering by provincial drug plans and the development of a network of preferred pharmacy providers for private drug plans (where individuals are encouraged to take their prescriptions to be filled at such providers).

"Reverse payment" settlements have yet to be the subject of scrutiny in Canada. However, upcoming amendments to the *Competition Act* could increase the likelihood of "reverse payments" becoming an issue. In particular, the new *per se* conspiracy offence, which comes into force in March 2010, may make it easier to prosecute reverse payment settlements in Canada as unlawful agreements between competitors because the Bureau will no longer be required to demonstrate an "undue lessening of competition" in a relevant market. Even if not caught by the *per se* offence, "reverse payment" settlements could potentially be challenged under a new civil provision to be enacted that authorizes the Bureau to seek remedies from the Competition Tribunal in respect of agreements between competitors that substantially prevent or lessen competition. In addition, given that the Bureau appears to have reinvigorated its enforcement efforts with respect to abuse of dominance (including joint dominance), it is possible that "reverse payment" settlements could be reviewed under the abuse of dominance provisions. With significant new administrative penalties of \$10 million now available where an abuse of dominance allegation has been made out, the threat of such enforcement activity carries with it substantial financial risk.

### **Conclusion**

The combined effect of the policy, legislative and enforcement initiatives described above is to heighten antitrust scrutiny of the global pharmaceutical industry. As a result, pharmaceutical companies should be sensitive to the fact that their conduct (particularly *vis à vis* their competitors) might attract interest from antitrust authorities, including in Canada.

*If you have any questions regarding the foregoing, please contact [George Addy](#), [Anita Banicevic](#), [Mark Katz](#), [Hillel Rosen](#) or any other member of the Competition & Foreign Investment Review Group at Davies Ward Phillips & Vineberg LLP at 416.863.0900 (Toronto) or 514.841.6400 (Montréal).*

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