North America

Pay-for-delay may be per se crime, Pecman says

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Pallavi Guniganti

Canada's commissioner of competition announced yesterday that reverse-payment settlements among pharmaceutical companies may be reviewed under the Competition Act's *per se* criminal conspiracy provision, as well as the civil agreements and abuse of dominance provisions.

Commissioner John Pecman

This is the first time the Bureau of Competition has ever explicitly said that such agreements could be prosecuted as per se criminal conspiracies.

The policy statement, made at an antitrust conference in Washington, DC, comes as the agency revises its intellectual property enforcement guidelines, a draft of which suggested that certain patent conduct could be prosecuted criminally. That draft was met with outcry from the Canadian Bar Association's competition law section and business groups.

Comissioner John Pecman said at the beginning of his speech that observers may find this approach "somewhat surprising, particularly in light of the US Supreme Court's recent decision in Actavis," which rejected the US Federal Trade Commission's argument that reverse-payment settlements are per se or presumptively illegal. Instead, the court ruled that the agreements should be analysed under the rule of reason.

"While the bureau appreciates the decision, we've taken a decidedly different view in Canada – one that sees us looking at these agreements under either the criminal or civil provisions in the act," Pecman said.

He added that the bureau would likely recommend prosecution if a settlement were between competitors and included markets or products outside the patent litigation being resolved, or if the deal "is beyond the scope of the patent," such as keeping the generic drug maker out of the market even after the current patent term expired.

The bureau would also be inclined towards criminal charges if direct or circumstantial evidence indicates that the settlement is a way for the companies to restrain competition that is not part of a legitimate collaboration or motivated by reasons outside the immediate patent dispute, Pecman said.

Pecman compared a settlement in which a generic drug maker agreed to delay entry beyond the life of the patent in exchange for a payment to a market allocation agreement – something that would be examined under the criminal conspiracy provision.

"Similarly, if the evidence suggested that a payment was strictly to delay or prevent entry, this would also potentially be examined under the criminal provision," he said.

According to a paper on patent settlements released alongside Pecman's speech, the bureau may pursue an inquiry on dual tracks of criminal and civil provisions until it decides which is the appropriate section to be applied.

Davit Akman, at Gowling Lafleur Henderson in Toronto, said the announcement was surprising because it is inconsistent with the bureau's own Competitor Collaboration Guidelines, which state that criminal prosecution is reserved for naked restraints or hard-core cartels, "labels one would be hard pressed to apply to settlements of highly complex patent litigation".

Pecman's comments suggest the bureau has already decided how to apply Canadian antitrust laws to patent litigation settlements rather than waiting for promised public consultations, Akman said.

He believes the significant regulatory differences between Canada and the US “make antitrust scrutiny of so-called ‘reverse payment’ settlements inappropriate” in Canada in the first place, but the bureau’s rejection of Actavis’s reasoning “is concerning, to say the least, and cannot in my view be explained or justified with reference any legal, regulatory or other differences between Canada and the US”.

Davies Ward Phillips & Vineberg partner Adam Fanaki said the bureau’s approach of attempting to declare certain patent dispute settlements per se illegal demonstrates “a troubling propensity” to accept the FTC’s position regarding such agreements, without sufficient regard to its merit or applicability in the Canadian context.

Regulatory lawyer Mark Warner said that if the bureau does charge the deals as criminal conspiracies, he expects to hear the defence bar call for a constitutional challenge. However, given the courts’ high standard for convictions under the criminal provision, he said the bureau probably will proceed civilly in most cases, “absent some rather extraordinary egregious fact pattern,” to maximise its opportunity to succeed.

The commissioner also said he wanted powers similar to the FTC’s to be notified of all patent settlements. In the US, parties to a settlement are required by law to report it, but there is currently no such system in Canada. He said in the absence of a notification system in Canada, the bureau lacks insight into when or if pay-for-delay settlements are occurring.

“The lack of a notification regime in Canada may also explain why the bureau is not as active in enforcement as the FTC in the pharmaceutical sector. Accordingly, I intend to advocate for better information on patent settlements and the need to explore approaches that could be adapted to Canada’s regulatory framework,” Pecman said.

He gave the lunch keynote at George Mason University’s global antitrust and pharmaceuticals conference, which ended yesterday.