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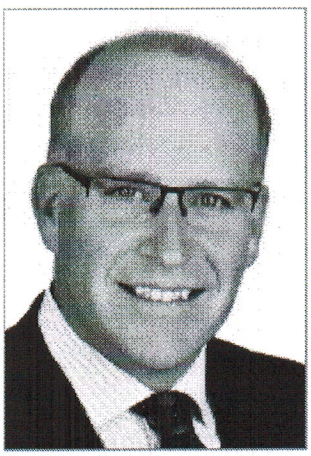
Intellectual Property

The significance of 'pipefill' in two generic drug damages awards

By **Greg McEvoy**



Greg McEvoy

(October 18, 2017, 9:03 AM EDT) -- In early 2017 the Federal Court issued decisions involving two significant damages awards under s. 8 of the Patented Medicines (Notice of Compliance) Regulations. An important component of these damages awards related to the concept of "pipefill."

Section 8 damages awards compensate generic manufacturers for being kept off the market through a regulatory stay petitioned by the innovator companies while the courts decide: (i) whether the generic drug is entitled to a Notice of Compliance (NOC); (ii) whether the patent is valid, and; (iii) whether the generic version of the drug would infringe.

Based on the decision set out in *Apotex Inc. v. Sanofi-Aventis* 2012 FC 553, there are five key steps the court considers to determine the generic's damages for being kept off the market for a period of time (the delay period). These steps require the creation of a hypothetical or "but for" world to determine the amount of sales and profits the generic manufacturer would have earned had it been able to sell its drug during the delay period.

In estimating the market size and the generic's sales and expenses in the "but for" world, the generic's real world experience after it actually comes to market provides valuable information (the proxy period). A key data source economic experts use in reviewing actual sales during the proxy period is IMS data from Quintiles IMS. IMS data is gathered in two forms: 1) the number of prescriptions using pharmacy data; or 2) Canadian Drug Store and Hospital Purchases Audit (CDH), which captures purchases made by pharmacies and hospitals.

Prior court decisions have recognized a discrepancy between sales data reported by IMS compared to "ex-factory" sales reported by the generic manufacturer. "Ex-factory" sales are recoded in the generic's accounting records when product leaves its production facility, while the IMS sales data is recorded either when the prescription is made or the drugstore or hospital purchases the product. Therefore, generic manufacturer's sales to wholesalers are not recorded in IMS data. The sale only gets recorded in the IMS data when the wholesaler sells the product or it is prescribed. Accordingly, much of the initial discrepancy between the ex-factory sales and IMS reported sales relates to the generic's initial sales to wholesalers to stock their inventories or "fill the pipeline."

On March 30, Justice Michael Phelan issued a judgment (*Teva Canada Ltd. v. Pfizer Canada Inc.* 2017 FC 332 (Pregabalin) awarding Teva damages after Pfizer prevented Teva from selling its generic version of the drug Pregabalin (Pfizer's Lyrica). In Pregabalin, Justice Phelan described pipefill as "a volume of sales initially made by the manufacturers to distributors in order to provide them with initial inventory."

Justice Phelan went on to say: "... to the extent that pipefill or inventory adjustments represent sales lost in the BFW [but-for world], they are appropriate. To the extent that they are a disguised method of compensating for double ramp-up, they are not." Ramp-up is the period of time it takes a manufacturer to bring its drug to market and achieve "normal" sales levels after approval.

Justice Phelan accepted Teva's expert's pipefill adjustments subject to the clarification above.

On April 4, Justice James O'Reilly issued a judgment (*Eli Lilly Canada Inc. v. Teva Canada Ltd.* 2017 FC 88 (Olanzapine) awarding Teva damages after Eli Lilly prevented Teva from selling its generic version of the drug Olanzapine (Eli Lilly's Zyprexa). In Olanzapine, Justice O'Reilly described pipefill as the quantity of sales Teva would have made to distributors in the but-for world, not captured in IMS data.

Justice O'Reilly did not agree with Teva's assertion that it should be awarded an amount for pipefill. He agreed with Eli Lilly's expert noting: "... pipefill does not represent lost sales during the liability period ... pipefill represents the differential between retail sales and the quantity of product leaving the factory. That differential represents sales that would have been made outside the liability period....In the but-for world, those sales would have been made, but they would have been made outside the liability period ... and ... should not be included in Teva's losses."

Justice O'Reilly agreed with Eli Lilly's expert that any loss on these delayed sales would be limited to "the "time value of money" *or the* "opportunity cost" based on the fact that those sales would have been made earlier in the but-for world." He reasoned a pipefill adjustment would overcompensate Teva because it would have the effect of awarding lost sales for tablets residing in inventory during the delay period that would be sold in the future.

Justice O'Reilly further addressed the award of compensation for pipefill in the preceding s. 8 cases. He concluded that they were "somewhat ambiguous on the issue of pipefill" and "In none of them was the issue seriously contested or a quantum specifically calculated."

I understand that both cases are under appeal.

Pipefill has been an important consideration in s. 8 decisions. The recent decision by Justice O'Reilly may represent a divergence from prior decisions and give the Federal Court further food for thought on cases pending.

The recent amendments to the PM(NOC) regulations do away with the statutory end date of the delay period. This may allow generics to claim for losses suffered beyond the date of dismissal or discontinuance and could impact any pipefill considerations.

Greg McEvoy is a principal in charge of Cohen Hamilton Steger & Co. Inc.'s *Ottawa office. Since 1991, he has practised exclusively in damages quantification, business valuations and forensic accounting. He testified as an expert in the Olanzapine case noted above.*