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Provincial payer quashes attempted drug evergreening strategy

JANUARY 17, 2020 5 MIN READ

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When patents expire on a patented drug product, paving the way for generic competition, the patentee is faced with the challenge of how to replace the revenues that were achieved with the patented product. Ideally, the company's innovation during the patented product's life cycle will have led to new products poised to grow as the old patented product's revenues decline. Often, however, the company's strategy is to pursue a "product switch," in which the patented product is replaced with a new product that provides little or no therapeutic improvement but for which no generic competition is imminent.

In the face of a product switch, drug payers must decide how to respond. If they list the new product on their formularies, doctors can prescribe the new product and avoid generic substitution, thereby keeping prices high. If they do not list the new product, they may be criticized for failing to keep up with new products.

Alberta's Minister of Health took a unique approach in response to a product switch, and the Minister's decision was the subject of a recent Alberta Court of Queen's Bench ruling. In *Allergan Inc v Alberta (Justice and Solicitor General)*, 2019 ABQB 610, Alberta Health had responded to a brand drug manufacturer's (Allergan) product switch strategy for its bimatoprost product, Lumigan, by categorizing the switched product as interchangeable to the original, thereby preserving the ability for generic products to generate savings on the product.

Allergan first listed its Lumigan RC 0.03% bimatoprost product used to treat glaucoma and ocular hypertension on the Alberta formulary in April 2003. In 2009, with plans to take this 0.03% product off the market, Allergan sought a line extension to list its lower-strength bimatoprost product, Lumigan RC 0.01%. However, Alberta Health was sensitive to allowing the entry of generics to Lumigan RC 0.03% and chose to designate the 0.01% product as interchangeable with Allergan's original Lumigan RC 0.03% product in July 2010. This decision by Alberta Health effectively precluded Allergan from any further market exclusivity for its Lumigan products in Alberta.

In coming to its decision regarding the listing of Lumigan RC 0.01%, an Expert Committee advising the Minister recognized that Allergan was likely submitting this lower-strength bimatoprost product for listing as part of an "evergreening" strategy. Evergreening refers to a strategy used by brand manufacturers to keep generic drugs off the market by patenting new drugs that are slight modifications of older products no longer subject to patent protection. The Canadian patent related to Lumigan RC 0.01% is not set to expire until March 2026, while the patent associated with Lumigan RC 0.03% expired in 2013.[1] Allergan did not challenge Alberta Health's decision to designate Lumigan RC 0.01% as interchangeable with its higher-strength Lumigan product and had Lumigan RC 0.03% delisted from the Alberta formulary in April 2011.

In reviewing the context for the Minister's 2010 decision to designate the 0.01% Lumigan

product as interchangeable with the Lumigan RC 0.03% product, the Court considered the impact of Allergan's potential evergreening strategy and found that the "comment with respect to alleged 'evergreening' in the May 25, 2010 minutes of the Expert Committee was collateral to the Committee's finding that Lumigan RC 0.01% and Lumigan RC 0.03% were shown to be therapeutically equivalent in several studies."[2] However, the Court still highlighted that this "collateral comment relates to the Committee's policy consideration of ensuring generic equivalents."[3]

The Government of Alberta's decision regarding Lumigan RC 0.01% has since enabled generic manufacturers to have 0.03% bimatoprost products designated as interchangeable with Allergan's 0.01% Lumigan product, thereby avoiding infringing the patent that covers Lumigan RC 0.01%. For example, Sandoz's generic Vistitan 0.03% bimatoprost product was listed as interchangeable with Lumigan RC 0.01% on the Alberta formulary on December 1, 2016. This means that a pharmacist will dispense Vistitan 0.03% unless a patient is willing to pay the difference in price for Allergan's Lumigan RC 0.01% product.

The Alberta Court of Queen's Bench did not review the matter at the time the Lumigan RC 0.01% designation was deemed as interchangeable to the higher-strength product. Rather, Allergan challenged the Minister's decision to designate Vistitan 0.03% as interchangeable with Lumigan RC 0.01%. The Court determined that judicial review was inappropriate because the decision at issue was not the final or most recent decision from the Minister on this issue. Following the listing of Vistitan 0.03%, Allergan had resubmitted its Lumigan RC 0.01% submission to be reviewed as a new chemical entity, which was denied by Alberta Health in February 2017. No judicial review of this decision was sought.

Despite its finding that Allergan's application for judicial review was impermissible, the Court proceeded to assess the government's decision to list generic versions of bimatoprost 0.03% as interchangeable with Lumigan RC 0.01%. The Court found that the Minister's decision was unreasonable because the Minister had failed to address the appropriate criteria for interchangeability. The proper interchangeability assessment required the Minister to compare Vistitan 0.03% with Lumigan RC 0.01%, as opposed to Vistitan 0.03% and the original Lumigan 0.03% product. The Court did not form a view on whether the result would necessarily have changed had the appropriate assessment been conducted, and it is unknown at this time whether the Minister has taken note of this decision and conducted a reassessment.

A review of the provincial formularies within other Canadian jurisdictions does not reveal any parallel situations to that facing Allergan in Alberta. In other provinces, Lumigan RC 0.01%, if listed, is the only bimatoprost product on the provincial formulary or is listed as a separate benefit from higher-strength generic bimatoprost products. Nonetheless, this recent decision reveals how the perceived evergreening strategy of a patentee could factor into a provincial government's reimbursement decisions. As provincial drug budgets continue to tighten, formulary decisions that promote generic and biosimilar competition in the face of evergreening strategies can be expected.

For more information on Canadian regulatory approval and funding of generic drug products, contact Nathaniel Lipkus or Jaymie Maddox.

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[1] *Allergan Inc v Canada (Health)*, 2014 FC 566 at paras 1, 5. Canadian Patent 2,585,691 upheld by the Federal Court in 2014 FC 566 and *Apotex Inc v Allergan Inc*, 2014 FC 567, aff'd 2015 FCA

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[2] 2019 ABQB 610 at para 53.

[3] 2019 ABQB 610 at para 53.