

Acquisition of Organon BioSciences N.V. by Schering-Plough Corporation Technical Backgrounder

This Technical Backgrounder summarizes the main findings of the Competition Bureau's ("Bureau") review of the acquisition by Schering-Plough Corporation ("Schering-Plough") of Organon BioSciences N.V. ("Organon") from Akzo Nobel N.V. ("Akzo") ("proposed transaction"). Akzo is based in the Netherlands and is the parent company to Organon.

This was an international transaction that involved the merging of two large animal health competitors in Canada. Over the course of its review, the Bureau found a high degree of overlap in several specialized product markets where both parties competed. This case is a good example of a situation where it was appropriate for the Bureau to realise the benefits of comity. That is, in this multi-jurisdictional merger, the Bureau coordinated with certain foreign agencies regarding their proposed remedies and concluded that the competition concerns in Canada would be adequately addressed by those remedies. Where appropriate, the Bureau strives to align itself with its foreign counterparts, to the benefit of the parties to the transaction. In this case, the Bureau was satisfied that the divestiture in poultry vaccines required by the U.S. Federal Trade Commission ("FTC"), which would affect the Canadian market, was sufficient to resolve any competition concerns in Canada resulting from this transaction.

Readers should exercise caution in interpreting the Bureau's assessment of this transaction. Enforcement decisions are made on a case-by-case basis and the conclusions discussed in this backgrounder are specific to this merger and are not binding on the Commissioner of Competition ("Commissioner"). The legal requirements of section 29 of the *Competition Act* ("Act") and the Bureau's policies and practices regarding the treatment of confidential information limit its ability to disclose certain information obtained during the course of a merger investigation.

Background

On March 12, 2007, Schering-Plough announced its intention to acquire Organon from Akzo. Over the course of its three-month review, the Bureau interviewed more than 60 industry stakeholders, and worked in cooperation with other jurisdictions, including the FTC and the European Commission's Competition Directorate.

The Parties

Schering-Plough is a global health care company organized around three business segments: prescription pharmaceuticals, consumer health care and animal health. In 2006, Schering-Plough had global sales of approximately C\$10.5 billion with operations in more than 120 countries worldwide, including sales in Canada of approximately C\$512 million.

Organon is a global pharmaceutical company that develops and markets drugs targeting both human and animal therapeutic uses. Organon operates two discrete business units: (i) Organon's

human healthcare business, and (ii) Intervet, which is Organon's animal healthcare business. In 2006, Organon had worldwide sales of approximately C\$5.32 billion, of which approximately C\$111 million was generated in Canada.

Competitive Assessment

The parties overlapped in two main categories: human health and animal health products. Within each product category, the Bureau analyzed the parties' overlapping products, including those in the development stage ("pipeline products").

Human Health

The parties' products were found to be largely complementary in the human health category. Schering-Plough's product lines focused on allergy/respiratory, cholesterol/cardiovascular, anti-infectives and oncology drugs, while Organon's focused on women's health care (gynecology and fertility) and central nervous system treatments.

To assist in defining the relevant product markets, the Bureau referred to the World Health Organization's Anatomical Therapeutic Classification ("ATC") system.¹ The parties' products were found to overlap in the ATC 2 classification for anti-thrombosis drugs² and oncology drugs³; however, after consulting with industry stakeholders, the Bureau concluded that the parties' human health products were not in direct competition, and the merger was unlikely to result in a substantial lessening or prevention of competition in the human health market.

Animal Health

The Bureau devoted significant attention to analyzing the potential effects of the proposed acquisition on the animal health markets. At the time of the merger, Schering-Plough marketed approximately 124 animal health products in Canada, while Organon (Intervet) marketed approximately 88.

Geographic Market

For the purposes of its review, the Bureau defined the relevant geographic market for animal health products as Canada, based in particular on the significance of regulation in the industry.

There are two main regulators in the Canadian animal health market: (i) Veterinary Drugs Directorate of Health Canada ("VDD") and (ii) the Veterinary Biologics Section of the Canadian Food Inspection Agency ("VBS"). The VDD evaluates and monitors the safety, quality and effectiveness of veterinary drugs and sets standards and promotes the prudent use of drugs.⁴ All veterinary drug submissions to the VDD must also satisfy the requirements under the *Food and Drug Regulations* before they can be marketed in Canada. The VDD reviews all new drug submission in accordance to the guidelines on management of regulatory submissions.⁵

The VBS regulates the manufacturing, importation, testing, distribution and use of veterinary biologics (vaccines) in Canada. To obtain a licence for the provision of biologics in Canada, the manufacturer must provide research data and manufacturing and testing documentation to demonstrate the purity, potency, safety, and efficacy of the product, and to support label claims⁶. The approval process for vaccines is much shorter than pharmaceutical approval by the VDD, taking between six months and two years, depending primarily on the nature and scope of the parties' submissions.

Barriers to Entry

Consistent with the significance of the regulatory approvals as a major factor in the Bureau's geographic market definition analysis, the approval process was also found to create significant barriers to entry in the Canadian animal health markets⁷. These barriers to entry are in addition to other factors, such as lengthy development periods and potentially long customer acceptance periods. Overall, the Bureau concluded that there were significant barriers to entry in the Canadian animal health market.

Product Market

Animal health products include both pharmaceuticals⁸ and biologicals⁹ (vaccines). The indication and therapeutic use of animal health products were used to assist in defining the relevant product markets. The parties overlapped in the sale of pharmaceutical and vaccine products for the following species:

- (i) companion animals
- (ii) cattle
- (iii) swine
- (iv) poultry and
- (v) cross-species¹⁰

(i) Companion Animals

The parties produce competing vaccines in four product markets within the companion animal health sector.¹¹ Of these four markets, canine bordetella vaccines was the only market in which the merging parties would represent more than 35% of total sales; however, the existence of effective remaining competition eliminated any competitive concerns in this market.

(ii) Cattle

The parties overlapped in the supply of growth implants for beef cattle.

Intervet only marketed trenbolone acetate¹² ("TBA") implants, while Schering-Plough only marketed non-TBA implants. TBA implants are predominantly implanted into cattle being fed a high-protein diet in a feedlot during the last stages of growth. By comparison, non-TBA implants are predominantly used in cow/calf operations where the cattle graze on open land and depend

on low-protein grass rather than a high protein diet containing corn or barley. Because these products are implanted at different stages of a cow's life-cycle, customers generally did not view the parties' growth implants as substitutes and the Bureau concluded that these products were not in direct competition.

(iii) Swine

Schering-Plough and Intervet both supplied products for reproductive management. Schering-Plough's product was only administered to pregnant sows to induce labour while Intervet's products were administered to gilts (young female pigs) to initiate ovulation prior to conception. Market contacts confirmed that the parties' products were not substitutable, as they are administered at different stages of the animal's development and fertility cycle. Given these findings, the Bureau concluded that the parties' respective products were not in direct competition with one another.

The parties also overlapped in the sale of three other swine health products;¹³ however, the presence of effective remaining competition eliminated any material competition concerns in these markets.

(iv) Poultry

The parties overlapped in the sale of poultry vaccines; more specifically, they overlapped in the sale of fowl cholera and infectious bursal disease vaccines.

In the market for fowl cholera vaccines, the FTC required the divestiture of Intervet's CHOLERVAC-PM-1 vaccine (among other products) to Wyeth. The divestiture included the rights to distribute the product in Canada. The Bureau was satisfied that the sale of Intervet's fowl cholera vaccine to Wyeth would resolve any outstanding competition concerns in the Canadian market for fowl cholera vaccines.

Both parties were also active in the infectious bursal disease vaccine market; however, combined low market shares and the effective remaining competition post-merger led the Bureau to conclude that the merger was unlikely to result in a substantial lessening of competition in the relevant market.

(v) Cross-Species

Many products within the animal health market can be used for more than one animal species. In particular, the merging parties overlapped in the following areas:

(a) Euthanasia

Injectible euthanasia products are solutions designed to end the life of an animal. Although both companies supplied injectible euthanasia products, the Bureau determined that they were in separate product markets owing to different product characteristics, including the effect from the

calming agent used by Schering-Plough¹⁴ and the different animals for which the products were used.

(b) Antimicrobials

Antimicrobials destroy or prevent the growth of microbes such as bacteria, mycoplasma or fungi and treat diseases associated with them in both food-producing animals and companion animals. Although the parties were found to have high market shares in the sale of a specific antimicrobial, owing to a large number of substitutable antimicrobials, the Bureau concluded that a significant non-transitory price increase would not be profitable.

(c) Diuretics

The parties also overlapped in the sale of diuretics, products used to reduce the amount of fluid in the animal by diverting water from the blood to the urinary tract. The information obtained from veterinarians indicated that the parties' products were differentiated by usage. Intervet's product is used in short term, acute situations, while Schering-Plough's is prescribed for long term, chronic cases. In these circumstances, the Bureau concluded that the merger was unlikely to result in a substantial lessening or prevention of competition in the relevant market.

(d) Clostridial vaccines

Clostridial vaccines protect against afflictions caused by soil-borne bacteria. These bacteria are relatively difficult to detect and can cause quick deaths. There are a number of clostridial vaccines in Canada, including standard clostridial, clostridial with haemophilus somnus and clostridial with tetanus. At the time of the review, Intervet supplied the first two types of clostridial vaccines, and Schering-Plough was the only supplier of clostridial tetanus vaccines.

The Bureau examined the clostridial vaccines both as a single product market and, as well, as three distinct product markets. Examining clostridial vaccines as distinct product markets eliminated any competitive overlap. When considering clostridial vaccines as a single product market, the Bureau was satisfied that the proposed transaction would not likely result in any competition concerns.

Foreign Competition

The impact of foreign competition on Canada's animal health industry has been mixed. Canada's *Food and Drug Act* allows producers to import animal pharmaceuticals into Canada provided they are for "own-use", i.e., they are not for the purpose of sale.¹⁵ Market contacts confirmed that the importation of products from the US is a competitive alternative to domestic producers; however, they characterized the degree of competition as 'low'.

Coordinated Effects

The proposed transaction will increase the level of concentration in an already concentrated industry with high barriers to entry. As such, the Bureau gave extensive consideration to the possibility that the proposed transaction would increase the likelihood of sustainable coordinated behavior in a number of relevant animal health markets.

There were a variety of factors that the Bureau considered in evaluating whether there was likely to be greater coordination post-merger. While there are a small number of firms with high levels of concentration competing against one another in multiple markets with significant barriers to entry, the Bureau found that coordination would be difficult to effect. In particular, market contacts confirmed that there is a large degree of product differentiation. Products are differentiated by, among other features, the strength of the antigen, route of administration and the number of afflictions they treat. This large degree of product differentiation increases the difficulty for firms to coordinate.

Further, information obtained over the course of the Bureau's review confirmed a number of factors implying that firms in the industry have asymmetric costs. Production costs differ among competitors based on current research and development projects, previous product failures and the number of products awaiting regulatory approval. The Bureau concluded that these cost differences make coordinated behavior more difficult to effect.

In summary, the Bureau did not find sufficient evidence to make an application to the Tribunal to challenge the merger on the basis of coordinated effects.

Conclusion

While a number of factors surrounding the proposed transaction initially raised competition concerns, the Bureau's analysis revealed that the proposed transaction was unlikely to lead to a substantial lessening or prevention of competition in any relevant market. In the product markets where the parties directly competed, the established effective remaining competition was sufficient for the Bureau to conclude that the parties would not likely be able to unilaterally exercise market power post-merger, except in the fowl cholera vaccine market, where the Bureau was satisfied that the FTC's divestiture of Intervet's fowl cholera vaccine would resolve any competition concerns in Canada. As to coordinated effects, while the Bureau found factors that could potentially facilitate coordination, there were material opposing indicators such that the Bureau did not find sufficient evidence that coordinated behavior would be more likely or effective as a result of the merger.

Pursuant to section 97 of the Act, the Commissioner has up to three years to file an application with the Tribunal to challenge a merger that has been substantially completed, should the merger prevent or lessen competition substantially in a market.

Endnotes:

¹ World Health Organization. <http://www.whooc.no/atcddd/>

² In Canada, Schering-Plough produces an *anti-platelet* drug, Integrilin, which inhibits thrombosis by preventing platelet aggregation (i.e., prevention of blood clots). Integrilin is only approved for use in the main arteries of the heart. Organon produces two *anti-coagulant* drugs, Hepalean (heparin-based), and Orgaran (non-heparin based), used in the prevention and treatment of venous thrombosis. There was no lessening of competition in respect of these products given that anti-platelet drugs are not functionally interchangeable with anti-coagulants.

³ Organon Canada markets OncoTice for the treatment of superficial bladder cancer. OncoTice is a bacillus calmette-guerin (“BCG”), an immunotherapeutic agent that is indicated and marketed for use against higher-grade superficial (papillary) tumours. Schering-Plough does not market a BCG product; however, one of Schering-Plough Canada’s products, Intron A, an Interferon-Alpha 2 product (indicated for the treatment of melanoma), may be used in some limited cases for the treatment of bladder cancer. Contacts with the medical community confirmed that Schering-Plough’s product and Organon’s product are complementary in nature and are not direct substitutes for one another.

⁴ Veterinary Drugs Directorate. http://www.hc-sc.gc.ca/dhp-mps/vet/index_e.html

⁵ Health Canada, Drugs & Health Products. http://www.hc-sc.gc.ca/dhp-mps/consultation/vet/consultations/past-anterieures/reg/index_e.html

⁶ Canadian Food Inspection Agency. <http://www.inspection.gc.ca/english/anima/vetbio/ref/vb410e.shtml>

⁷ Not all new animal health products developed by pharmaceutical companies are immediately available in Canada owing to the relative size of the Canadian market and the additional time and financial resources required to obtain regulatory approval.

⁸ “Pharmaceuticals” encompass a wide group of products that contain a variety of active ingredients to treat a large range of animal diseases. Primary areas treated by pharmaceuticals are parasiticides, antimicrobials, endocrine treatments, non-steroidal and steroidal anti-inflammatory drugs, analgesics and enhancers that improve the growth rate of animals.

⁹ “Biologicals” are used to trigger an immune response against viral and bacterial diseases in animals, as well as against certain parasitical or fungal infections. Animal health biologicals can be distinguished according to the following factors: species, indication specific to the individual disease, whether it is a single or multiple pathogen, and whether it is a live or inactivated vaccine.

¹⁰ Products indicated for more than one animal species.

¹¹ Feline combination, canine combination, canine parvovirus and canine bordetella vaccines.

¹² TBA is an anabolic agent that works in a manner similar to testosterone in humans.

¹³ Swine vaccines against E. coli, mycoplasmas and swine influenza.

¹⁴ The euthanasia product supplied by Intervet has the effect of paralysing the respiratory centre of the animal resulting in an almost immediate death as the circulatory system rapidly collapses. The product supplied by Schering-Plough uses a calming agent combined with anaesthesia to put the animal to sleep before death.

¹⁵ Food and Drug Act; Part C, s. C.01.004.1. http://www.hc-sc.gc.ca/fn-an/legislation/acts-lois/fda-lad/index_e.html