

Ottawa, Monday, May 1, 2000

**Inquiry No.: NQ-99-003**

IN THE MATTER OF an inquiry, under section 42 of the *Special Import Measures Act*,  
respecting:

**CERTAIN IODINATED CONTRAST MEDIA ORIGINATING IN OR  
EXPORTED FROM THE UNITED STATES OF AMERICA  
(INCLUDING THE COMMONWEALTH OF PUERTO RICO)**

**FINDING**

The Canadian International Trade Tribunal, under the provisions of section 42 of the *Special Import Measures Act*, has conducted an inquiry following the issuance by the Commissioner of the Canada Customs and Revenue Agency, of a preliminary determination dated December 31, 1999, and of a final determination dated March 30, 2000, respecting the dumping in Canada of iodinated contrast media used for radiographic imaging, in solutions of osmolality less than 900 mOsm/kg H<sub>2</sub>O, originating in or exported from the United States of America (including the Commonwealth of Puerto Rico).

Pursuant to subsection 43(1) of the *Special Import Measures Act*, the Canadian International Trade Tribunal hereby finds that the dumping in Canada of the aforementioned goods originating in or exported from the United States of America (including the Commonwealth of Puerto Rico) has caused material injury to the domestic industry (Member Close dissenting).

Patricia M. Close  
Patricia M. Close  
Presiding Member

Raynald Guay  
Raynald Guay  
Member

Arthur B. Trudeau  
Arthur B. Trudeau  
Member

Michel P. Granger  
Michel P. Granger  
Secretary

The Statement of Reasons will be issued within 15 days.

Place of Hearing: Ottawa, Ontario  
Dates of Hearing: March 28 to 31, 2000  
Date of Finding: May 1, 2000

Tribunal Members: Patricia M. Close, Presiding Member  
Raynald Guay, Member  
Arthur B. Trudeau, Member

Director of Research: Peter Welsh

Lead Researcher: Ken Campbell

Researcher: Dominique Laporte

Economist: Ihn Ho Uhm

Statistician: Julie Charlebois

Counsel for the Tribunal: Michèle Hurteau  
John Dodsworth

Registrar Officer: Gillian E. Burnett

**Participants:** C.J. Michael Flavell, Q.C.  
Geoffrey C. Kubrick  
Christopher J. Kent  
Yasir A. Naqvi  
for Mallinckrodt Canada Inc.

**(Domestic Producer)**

Richard S. Gottlieb  
Darrel H. Pearson  
Jesse I. Goldman  
Jeffery D. Jenkins  
J. Peter Jarosz  
L.S. (Al) Rosen  
Larry Andrade  
Peter Collins  
for Bracco Diagnostics Canada Inc.

Lawrence L. Herman  
Daniel Green  
Craig S. Logie  
for Nycomed Amersham Canada Ltd.

**(Importers)**

Ottawa, Tuesday, May 16, 2000

Inquiry No.: NQ-99-003

**CERTAIN IODINATED CONTRAST MEDIA ORIGINATING IN OR  
EXPORTED FROM THE UNITED STATES OF AMERICA  
(INCLUDING THE COMMONWEALTH OF PUERTO RICO)**

*Special Import Measures Act* - Whether the dumping of the above-mentioned goods has caused material injury or retardation or is threatening to cause material injury to the domestic industry.

**DECISION:** The Canadian International Trade Tribunal hereby finds that the dumping in Canada of iodinated contrast media used for radiographic imaging, in solutions of osmolality less than 900 mOsm/kg H<sub>2</sub>O, originating in or exported from the United States of America (including the Commonwealth of Puerto Rico) has caused material injury to the domestic industry (Member Close dissenting).

Place of Hearing:	Ottawa, Ontario
Dates of Hearing:	March 28 to 31, 2000
Date of Finding:	May 1, 2000
Date of Reasons:	May 16, 2000
Tribunal Members:	Patricia M. Close, Presiding Member Raynald Guay, Member Arthur B. Trudeau, Member
Director of Research:	Peter Welsh
Lead Researcher:	Ken Campbell
Researcher:	Dominique Laporte
Economist:	Ihn Ho Uhm
Statistician:	Julie Charlebois
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Peter Collins  
for Bracco Diagnostics Canada Inc.

Lawrence L. Herman  
Daniel Green  
Craig S. Logie  
for Nycomed Amersham Canada Ltd.

**(Importers)****Witnesses:**

Jean-Pierre Robert  
Vice-President and General Manager  
Mallinckrodt Canada Inc.

Teresa McCrory  
Finance & Administration  
Manager  
Mallinckrodt Canada Inc.

Pierre S. Couture  
Marketing Director  
Imaging  
Mallinckrodt Canada Inc.

Giovanni Venditti  
Director, Market Activities  
Eastern Region  
Mallinckrodt Canada Inc.

Jean-Pierre Huot  
General Manager  
Nycomed Amersham Canada Ltd.

George Bannister  
Finance Manager  
Nycomed Amersham Canada Ltd.

Barry B. Hobbs  
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University Campus

Vincent Oliva  
CHUM – Notre Dame Hospital

David H. Davidson  
Vice-President  
Contract Planning and Development  
Medbuy

Bill O'Driscoll  
Contract Specialist  
Shared Healthcare Supply Services

Marc Lalande  
Manager, Sales and Marketing  
Berlex Canada Inc.

Jean-Robert Marcotte  
Vice-President,  
Client Relations and Corporate Affairs  
Berlex Canada Inc.

John J. Cornille  
President and Chief Executive Officer  
Bracco Diagnostics Inc.

Mark K. White  
Senior Director  
Business Development & Strategic Planning  
Bracco Diagnostics Inc.

Charles B. Feuer  
Senior Product Manager  
X-Ray Contrast Media  
Bracco Diagnostics Inc.

Steven A. Cenziper  
Associate Manager, General Accounting  
Bracco Diagnostics Inc.

J. Walter Kondrosky  
Director, Canada Operations  
Bracco Diagnostics Canada Inc.

Cheryl L. Walsh  
Territory Manager  
Bracco Diagnostics Canada Inc.

Daniel Bourque  
Territory Manager  
Bracco Diagnostics Canada Inc.

Francesco Paolo Pilato  
Chairman of the Board  
Bracco Diagnostics Inc.  
Group Vice-President  
Bracco s.p.a.

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K1A 0G7



Ottawa, Tuesday, May 16, 2000

**Inquiry No.: NQ-99-003**

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respecting:

**CERTAIN IODINATED CONTRAST MEDIA ORIGINATING IN OR  
EXPORTED FROM THE UNITED STATES OF AMERICA  
(INCLUDING THE COMMONWEALTH OF PUERTO RICO)**

TRIBUNAL: PATRICIA M. CLOSE, Presiding Member  
RAYNALD GUAY, Member  
ARTHUR B. TRUDEAU, Member

**STATEMENT OF REASONS**

**BACKGROUND**

The Canadian International Trade Tribunal (the Tribunal), under the provisions of section 42 of the *Special Import Measures Act*,<sup>1</sup> has conducted an inquiry following the issuance by the Commissioner of the Canada Customs and Revenue Agency (the Commissioner) of a preliminary determination dated December 31, 1999, and of a final determination dated March 30, 2000, respecting the dumping in Canada of iodinated contrast media used for radiographic imaging, in solutions of osmolality less than 900 mOsm/kg H<sub>2</sub>O, originating in or exported from the United States of America (including the Commonwealth of Puerto Rico).

On January 4, 2000, the Tribunal issued a notice of commencement of inquiry.<sup>2</sup> As part of the inquiry, the Tribunal sent questionnaires to the Canadian manufacturer, importers and purchasers and to exporters of iodinated contrast media. Respondents provided production, financial, import and market information, as well as other information, for the period from January 1, 1996, to September 30, 1999. From the replies to the questionnaires and other sources, the Tribunal's research staff prepared public and protected pre-hearing staff reports covering those years.

The record of this inquiry consists of all Tribunal exhibits, including the public and protected replies to questionnaires, all exhibits filed by the parties throughout the inquiry and their replies to the requests for information and the transcript of all proceedings. All public exhibits were made available to the parties. Protected exhibits were made available only to independent counsel who had filed a declaration and confidentiality undertaking with the Tribunal in respect of the use, disclosure, reproduction, protection and storage of confidential information on the record of the proceedings, as well as the disposal of such confidential information at the end of the proceedings or in the event of a change of counsel.

Public and in camera hearings were held in Ottawa, Ontario, from March 28 to 31, 2000. The sole domestic producer, Mallinckrodt Canada Inc. (MCI), and two importers, Nycomed Amersham Canada Ltd.

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1. R.S.C. 1985, c. S-15 [hereinafter SIMA].  
2. C. Gaz. 2000.I.86.

(Nycomed) and Bracco Diagnostics Canada Inc. (Bracco), were represented by counsel at the hearing. The Tribunal also heard testimony by radiologists, purchasers of contrast media and an importer who had been subpoenaed by one of the parties.

As a preliminary matter, the Tribunal heard submissions on whether there was more than one class of like goods. The Tribunal ruled during the hearing that there is only one class of iodinated contrast media, as set out in these reasons.

On January 10, 2000, Bracco requested an opportunity to make representations on the public interest question pursuant to subsection 45(2) of SIMA. By letter dated January 31, 2000, the Tribunal advised counsel and parties of record that, in the event of an injury finding, it would consider the question of public interest. Therefore, taking into account the *Guidelines for Public Interest Investigations*, the Tribunal will proceed as follows in respect of the filing of representations on the public interest question. Interested persons wishing to make representations in support of a public interest investigation shall file with the Tribunal, on or before May 29, 2000, their representations, pursuant to subsection 45(2) of SIMA, on whether the Tribunal should make a report on the public interest question to the Minister of Finance. Interested persons wishing to respond to these representations shall file their responses with the Tribunal on or before June 8, 2000. The Tribunal will advise counsel, parties and interested persons, on or before June 14, 2000, whether it is of the opinion that there is a public interest concern worthy of further investigation.

The Tribunal issued its finding on May 1, 2000.

## RESULTS OF THE COMMISSIONER'S INVESTIGATION

The Commissioner's investigation covered all imports of the subject goods during the period from July 1, 1998, to June 30, 1999.

Four companies were identified by the Commissioner as being exporters of the subject goods. The following table shows, by exporter, the quantity of goods dumped and the margin of dumping expressed as a percentage of the normal value.

<b>SUMMARY OF MARGINS OF DUMPING BY EXPORTERS</b>			
<b>Exporter</b>	<b>Quantity of Goods Dumped (%)</b>	<b>Margin of Dumping Range (%)</b>	<b>Weighted Average Margin of Dumping (%)</b>
Searle Ltd.	100	9 to 82	66
Nycomed Inc.	100	46 to 74	56
Bristol-Myers Squibb Company	100	74	74
Mallinckrodt Inc.	100	74	74
<b>All Exporters:</b>			<b>69</b>
Source: Canada Customs and Revenue Agency, <i>Final Determination of Dumping and Statement of Reasons</i> , 30 March 2000, Tribunal Exhibit NQ-99-003-4, Administrative Record, Vol. 1 at 82.34.			

## PRODUCT

### Product Description and Application

The products subject to the Tribunal's inquiry are defined as iodinated contrast media used for radiographic imaging, in solutions of osmolality less than 900 mOsm/kg H<sub>2</sub>O,<sup>3</sup> originating in or exported from the United States of America (including the Commonwealth of Puerto Rico). These are commonly referred to in the industry as low osmolality contrast media (LOCM).

Medical examination of soft tissues or organs by non-surgical means often requires the introduction of a special diagnostic imaging agent which makes the detection system responsive to detail in the tissue of interest. Agents include those used in magnetic resonance imaging (MRI), ultrasound, radionuclide imaging and X-ray technology. The diagnostic agents or radiopaques for X-ray imaging are referred to as contrast media.

LOCM are iodine-based compounds. Iodine is a very effective absorber of ionizing radiation and, as such, is particularly effective in enhancing X-ray images of the human body. The designation of the products as contrast media was derived from the fact that, when the iodine accumulates in the target area, it creates a contrast in the X-ray image, thereby permitting visual examination of the target tissue or organ. Iodinated contrast media may be injected or administered orally, although more than 95 percent of the applications require an injectable solution.

LOCM are sterile, aqueous solutions and are a subset of iodinated contrast media whose chemical structure has the effect of creating fewer adverse side effects than products exhibiting higher osmolality. The chemical structure of the raw materials of each product differs, but all iodinated contrast media are based on an iodine compound in a powdered form. In terms of the molecular structure of the iodine powder used in their manufacture, LOCM may be non-ionic monomers, ionic dimers or non-ionic dimers.<sup>4</sup> Omnipaque, Optiray, Isovue and Ultravist are non-ionic monomers. Hexabrix is an ionic dimer, and Visipaque and Osmovist are both non-ionic dimers. Non-ionic monomers account for the largest part of the LOCM sold in the market.

LOCM must be approved for use by the Therapeutic Products Programme of the Department of Health (Health Canada). Each of the contrast media must be approved for use in a specific medical application (indication) that relates to the characteristics of the product and its concentration.<sup>5</sup> Although there may be some differences in the approved specific indications of the respective LOCM, the approved uses in Canada for each of the LOCM closely resemble each other.<sup>6</sup>

LOCM are sold in single-dose bottles of 100 mL, 150 mL and 200 mL of three different iodine (I) concentration classes, i.e. 240 I mg/mL and below, 300-320 I mg/mL and 350 I mg/mL and over. The most popular size is the 150-mL bottle with the most popular iodine concentration in the 300-320 I mg/mL range.

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3. The osmolality of a solution is a measure of the number of dissolved particles per kilogram of water indicated by milliosmols per kilogram of water and chemically designated as mOsm/kg H<sub>2</sub>O.
  4. Importer's Exhibit C-9 at 2, Administrative Record, Vol. 13.1A; and Manufacturer's Exhibit A-1 (protected), Tab 2, Administrative Record, Vol. 12.
  5. *Transcript of Public Hearing*, Vol. 3, 30 March 2000, at 547; and Tribunal Exhibit NQ-99-003-27A, Administrative Record, Vol. 1A at 253-65.
  6. Manufacturer's Exhibit A-1 (protected), Tab 1, Administrative Record, Vol. 12.



LOCM are also available in single vials (bottles of 50 mL or less), flexible containers and pre-filled syringes for manual injection or for use with power injectors.

The following summarizes the LOCM approved for use in Canada by the Therapeutic Products Programme of Health Canada.

<b>LOW OSMOLALITY IODINATED CONTRAST MEDIA</b>				
<b>Supplier</b>	<b>Brand Name<sup>7</sup></b>	<b>Chemical Structure</b>	<b>Iodine Compound</b>	<b>Patent Expiry Date</b>
MCI	Optiray	Non-ionic monomer	Ioversol	Dec. 31, 2002
MCI	Hexabrix	Ionic dimer	Ioxaglate	Sept. 23, 1997
Nycomed	Omnipaque	Non-ionic monomer	Iohexol	Oct. 5, 1999
Nycomed	Visipaque	Non-ionic dimer	Iodixanol	Oct. 5, 1999
Bracco	Isovue	Non-ionic monomer	Iopamidol	Jan. 9, 1996
Berlex	Ultravist	Non-ionic monomer	Iopromide	Aug. 24, 1999
Berlex	Osmovist	Non-ionic dimer	Iotrolan	June 17, 2003

Source: *Public Pre-hearing Staff Report*, 17 February 2000, Tribunal Exhibit NQ-99-003-6, Administrative Record, Vol. 1 at 93 and 98.

All these LOCM have been subject to patent protection in Canada. Patents for Isovue and Hexabrix expired in 1996 and 1997 respectively, while patents for Omnipaque, Visipaque and Ultravist expired in 1999.<sup>8</sup> Only Osmovist and Optiray are still under patent in Canada. All patented medicines sold in Canada are subject to price monitoring by the Patented Medicine Prices Review Board<sup>9</sup> (PMPRB). When a patented medicine is first sold in Canada, the PMPRB, on the basis of its guidelines, establishes an introductory price that becomes the benchmark price for purposes of reviewing price changes in subsequent years. Then, on the basis of semi-annual reports by patentees, the PMPRB reviews the prices charged to ensure that they do not exceed the limit that it has established. At the time of the review, the PMRB may adjust the prices based on actual sales adjusted for inflation.

### **Production Process**

Iodinated contrast media are manufactured through pharmaceutical production processes in a sterile environment, where an iodine compound in powdered form is combined with other chemicals that buffer and

7. All these brand names are subject to trademarks.

8. *Public Pre-hearing Staff Report*, 17 February 2000, Tribunal Exhibit NQ-99-003-6, Administrative Record, Vol. 1 at 98.

9. The Patented Medicine Prices Review Board is an independent quasi-judicial body created by Parliament in 1987 under the *Patent Act*. The mandate of the PMPRB is to protect consumers and to contribute to Canadian healthcare by ensuring that the prices charged by the manufacturers of patented medicines are not excessive in accordance with statutory criteria. The PMPRB's jurisdiction applies to the factory-gate price at which the manufacturer sells these products to wholesalers, hospitals and pharmacies.

stabilize the formulation. Product formulation is performed by diluting the powder in water using stainless steel tanks and material-handling equipment. Pre-approved and detailed operating instructions are provided for all formulation steps. During and after the formulation of the bulk solution, various in-process tests are performed. If all tests pass the specifications, the tank is approved for filtration. The filtrate is collected in a holding tank, and the bulk batch yield is determined.

Contrast media are packaged in pre-washed glass bottles or vials or plastic syringes. All equipment in contact with the products is made of stainless steel. Product filling is performed by special filling apparatus that is adjusted to deliver a volume that sufficiently exceeds the labelled amount to ensure that the volume meets label requirements. The filled and stoppered glass containers are conveyed to an accumulating table where an aluminium tear-off overseal cap is applied. The sealed containers are loaded onto steel trays and entered into an autoclave for sterilization.

The sterilized products are held in quarantine until tested for conformance to chemical and microbiological specifications. Finally, the approved products are labelled, showing the product name, description, lot number and expiry date. The labelled containers are packaged into shipping containers and transferred to the finished product quarantine area to await shipment to the customers.

## **DOMESTIC INDUSTRY**

MCI, the sole domestic producer of LOCM, is a wholly owned subsidiary of Mallinckrodt Inc. of St. Louis, Missouri. MCI began operations in Canada in 1913 and, over the years, expanded its production lines to include such products as iodides, citrates, stearates, cobalt salts and various contrast media. In 1982, the company received approval from Health Canada to market Hexabrix, an ionic dimer, and production in Canada commenced in 1984. In 1991, the company received approval to produce and market Optiray, a non-ionic monomer. MCI also manufactures high osmolality contrast media (HOCM) marketed under the brand names Conray and Telebrix. All products are manufactured in the company's production facility located in Pointe-Claire, Quebec.

MCI is a contract manufacturer for its U.S. parent, Mallinckrodt Inc., as well as for Mallinckrodt Ireland, a sister company. MCI imports iodine powder for the production of Optiray from its affiliate in Ireland and from an unrelated company for the production of Hexabrix. It formulates the powder into iodinated contrast media for sale in Canada and export markets. The vast majority of production is exported to related companies in Australia, South America, Europe and Japan. A small amount of MCI's sales are made at arm's length to Southeast Asia. MCI sells directly to end users in Canada through its own sales force and sells abroad mainly to its affiliates.

## **IMPORTERS AND EXPORTERS**

Four companies were identified as exporters of LOCM and five as importers.

Nycomed's Omnipaque was introduced into the Canadian market in 1985, followed by imports of Visipaque in 1994. Since 1998, Searle Ltd. (Searle), based in Barceloneta, Puerto Rico, has produced Omnipaque and Visipaque for the Canadian market under a tolling arrangement with Nycomed Imaging AS. The latter also produces these LOCM at its facilities in Norway and Ireland.<sup>10</sup> Prior to 1997, Sanofi Winthrop Canada Ltd. (Sanofi) imported and distributed Nycomed products. In 1997, Picker International

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10. *Transcript of In Camera Hearing*, Vol. 2, 30 March 2000, at 317-18.

Canada Inc. (Picker) was appointed as the distributor and logistics provider for Nycomed's contrast media business in Canada. Iodinated contrast media destined for the Canadian market are shipped directly to Picker. Picker's responsibilities include the importation, warehousing, order taking and invoicing of the subject goods. All contracts, selling prices and terms were and continue to be between Nycomed and the end user. Nycomed is the marketer and distributor for the parent company and other group subsidiaries in Canada. In November 1999, Nycomed became the importer of record for imports of LOCM from Searle.

Bracco, a wholly owned subsidiary of Bracco Diagnostics Inc. (BDI) of Princeton, New Jersey, was incorporated in Canada in 1996 and is the importer and marketer of Isovue. Prior to that year, and commencing in 1988, Isovue was imported by Squibb Canada Inc. BDI produces iodinated contrast media in several other countries.<sup>11</sup> Bracco acts as the Canadian marketing organization for certain of the parent company's products, including LOCM. The goods are produced by Bristol-Myers Squibb Company under a tolling arrangement for Bracco. The logistics provider for the Bracco products in Canada is Livingstone Healthcare Services Inc.

Mallinckrodt Inc., the parent of MCI, manufactures and sells iodinated contrast media mainly in the United States. Mallinckrodt Inc. was established in 1867 and has produced contrast media since the 1940s. Mallinckrodt Inc. has exported small quantities of Optiray products to MCI, primarily in pre-filled syringes and as a transitional measure to meet short-term supply problems. All contrast media imported by MCI are produced by Mallinckrodt Inc. at its facilities in Raleigh, North Carolina. Mallinckrodt Inc. also exports iodinated contrast media worldwide to Europe, Central and South America, Japan, Australia and Asia.

Berlex Canada Inc. (Berlex), a wholly owned subsidiary of Schering A.G. of Berlin, Germany, began importing and marketing non-subject LOCM under the Ultravist and Osmovist brands in 1994. Since March 1999, as a result of an exclusive distribution agreement, MCI has been marketing Berlex contrast media in Canada, although Berlex is still the importer of the goods produced by its parent company.

## **MARKETING AND DISTRIBUTION**

Iodinated contrast media are primarily used in hospitals. Hospitals have formed buying groups or used other mechanisms to negotiate their purchases. While the buying groups are in charge of awarding contracts, the clinical choice of specific contrast media is made by the hospital radiologists. The buying groups issue tender calls or requests for proposal. Suppliers of contrast media submit price proposals, and buying groups negotiate the final purchase prices and terms of the supply agreements. Once evaluated on the basis of pre-determined criteria, a contract is signed with the preferred supplier. However, other suppliers may be chosen to supply certain contrast media in lesser volumes.

Once the agreement is signed, the individual hospitals usually purchase their requirements directly from the supplier or their agents at the agreed-upon contract price. Although there is an anticipated quantity that is expected to be purchased, the contracts do not generally contain volume purchase requirements by the hospitals. The term of a supply contract varies and can extend over several years, usually three to five. Some contracts contain price adjustment clauses permitting the purchaser to benefit from any better offer given to another buying group in Canada. The bidding process is usually confidential, and suppliers do not have access to information that relates to competitor submissions or final contract terms, except in Quebec where a public bidding process is used for all buying groups.

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11. *Transcript of Public Hearing*, Vol. 3, 30 March 2000, at 697.

In establishing selling prices for contrast media, suppliers use published price lists, which contain unit selling prices for each product configuration and container size. Percentage discounts are applied to the list prices in arriving at a final selling price. As well, the suppliers may offer additional incentives, such as educational packages, research and development support, and a variety of discounts and rebates.

While the suppliers are responsible for the marketing of contrast media, distribution of the products is generally handled by logistics providers that perform a range of tasks on behalf of the suppliers, either nationally or on a regional basis.<sup>12</sup> Services provided by the logistics providers include warehousing, stocking, re-stocking, receiving orders from hospitals, delivering and billing the purchasers. They also distribute other pharmaceutical and medical products.

## POSITION OF PARTIES

### Domestic Industry

The domestic producer of LOCM, MCI, submitted that the case before the Tribunal is fundamentally one of price erosion and lost sales in the Canadian market, as opposed to one of lost profits.

MCI stated that the Canadian market was relatively stable until 1993. However, in early 1994, aggressive bidding at unprecedented low pricing from both Bracco and Nycomed and their predecessors were found in the Canadian market. The initial impact was lost market share due to the dumping of the subject goods by the importers. MCI attempted to maintain market pricing; however, due to continued pricing pressure from both Bracco and Nycomed, particularly in 1995 and 1996, it was forced to meet, head-on, the competition from the dumped subject goods in the Canadian market by offering lower prices for its products. Although it met the competition and recaptured some of its lost market share from the dumped subject goods in late 1996 and in 1997, at significantly reduced margins, the pricing pressures continued unabated through 1998. MCI argued that, for it to remain price competitive, it had to compete aggressively with the major importers, and it did so by lowering its prices. MCI relied on two previous cases<sup>13</sup> to argue that, even if it did price aggressively, it was entitled to follow this strategy to defend its market and to increase its sales. Although the importers were also entitled to price aggressively, MCI argued that they could only do so up to a point, that point being that, when they began to sell the subject goods at dumped prices in Canada, they “crossed the line” and caused MCI material injury.

Among other factors which contributed to price erosion and lost sales were the application of percentage discounts to the list prices on the subject goods and the value-added incentives, such as educational packages, equipment giveaways, volume discounts, rebate programs, discounts on other product lines and the provision of research and development support as part of the pricing of the subject goods. The combined effect of the discounts and the value-added incentives, in MCI’s submission, drove the prices of the subject goods downward.

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12. MCI markets the majority of its products through an in-house sales force except in Newfoundland and for some accounts in British Columbia where the company markets through a logistics provider.

13. See *Commercial Grade Sodium Carbonate, Commonly Known as Soda Ash* (7 July 1983), ADT-7-83 (ADT) [hereinafter *Soda Ash*]; and *Faced Rigid Cellular Polyurethane-Modified Polyisocyanurate Thermal Insulation Board, Finding* (11 April 1997), *Statement of Reasons* (28 April 1997), NQ-96-003 (CITT) [hereinafter *Polyiso Insulation Board*].

Moreover, the buying power of provincial and hospital buying groups and severe budget constraints on the healthcare financing were also key factors in the purchasing and decision-making process. Knowledgeable buyers selected the lowest prices for each of the goods in a bid package which led to an increase in the price sensitivity of the subject goods and to the loss of bids on certain product lines, a practice referred to as cherry-picking. This, in MCI's view, magnified the impact of the dumped prices of the subject goods in the Canadian market. Further, the loss of long-term contracts and lost sales would not only be experienced in the initial year but have an impact for several years until the contracts came up for renewal.

MCI also submitted that the future survival of the production of LOCM in Canada was at stake, in that the dumping of the subject goods from the United States and Puerto Rico could shift production from Canada to other countries better protected from variable cost pricing from the United States, as well as delay the introduction of new products in Canada. The effects of dumping have inhibited product innovation and development of such products, and planned investment in its contrast media production line for the coming years may be deferred pending the outcome of this complaint. Finally, the production facilities for Optiray were located in Canada on the basis of a world product mandate that would be supported by the sale of this product in the Canadian market. In MCI's submission, the dumping of the subject goods by Bracco and Nycomed is an attack not only on its sales in the Canadian market but also on its international competitiveness.

In response to the question of the relevance of the exports of the subject goods produced by MCI, MCI argued that exports are not relevant for the Tribunal's considerations because, under SIMA, the Tribunal must measure the injury that is caused to the domestic production of LOCM for domestic consumption. Exports are an interesting benchmark by which to measure MCI's performance in the Canadian market and may be relevant to the extent that there is an opportunity to measure the relative profitability of every market in the world in relation to the Canadian market. MCI stated that, as many Canadian companies are major exporters, if the Tribunal were to measure injury with respect to domestic goods produced for both domestic and export consumption, the domestic producer could lose the protection to which it is entitled under SIMA. MCI concluded that, if the Tribunal were to take the export performance into consideration where it outperforms the domestic performance, this could lead to the conclusion that the domestic production has not been injured and would, in effect, result in the removal of protection for those goods in Canada.

In conclusion, MCI submitted that the prices will continue to decline if the dumped subject goods are allowed to continue to be imported into Canada and requested a finding of injury or of threat of injury.

### **Importers**

The importers, Nycomed and Bracco, submitted that any injury suffered by MCI is the result of its own making. In particular, MCI began a "price war" in Canada in 1993-94 which destabilized the market. They noted that the unit selling prices and revenues of each party declined during the inquiry period. While the pattern varies, in Nycomed's case, its selling prices declined by the same extent as MCI's prices in 1998-99. However, Nycomed attributed these declines to a generally downward market trend in the LOCM sector.

Bracco submitted that, since 1996, it has been a price follower and not a price leader in the Canadian market. As a result, it has lost sales and market share. It further submitted that, had it pursued a program of price and discounting leadership, this would have caused existing customers to seek equivalent concessions,

further eroding profits. In 1999, its market share in dollars was significantly higher than its market share in litres, which indicated that its pricing was above the industry average.

The importers stated that the lowering of prices was simply a fact of market circumstances and that LOCM prices in Canada and the United States have been steadily dropping in the last decade. The reason for the price decline in LOCM is due to abundant supplies, changing imaging methodologies, as new techniques are perfected, and an increase in concentrated buying power on the part of hospitals. Further, as LOCM are mature products near the end of their technological life cycle, prices come down as the products age in the marketplace. These factors, they argued, are not related to dumping.

The importers noted that the Canadian diagnostic imaging sector is facing major challenges, such as competitive factors and generally declining prices due to budget constraints and market consolidation. Further, the pressure exerted by larger hospital buying groups is a key factor affecting the prices of imaging media. The declining volumes and revenues claimed by MCI are part of a global, particularly North American, trend of flat or declining revenues in the subject goods sector. This is not attributable to alleged dumping, but, in the importers' view, is part of a broader circumstance of increased price pressures and competitive market forces.

The importers pointed to the fact that prices in Canada for the subject goods are set by the PMPRB and that price competition is maintained under the ceiling of PMPRB price levels. Any price suppression or price erosion suffered by MCI is the direct result of these controls. Further, MCI took the opportunity of patents expiring on some of the subject goods to lock in large contracts at low prices.

The importers also argued that MCI's Canadian sales operations for the subject goods were disrupted due to a restructuring of Mallinckrodt Inc.'s global operations from 1996 to 1999. These major changes in the corporate structure, management and operations of Mallinckrodt Inc. had a direct effect on MCI's operations and competitiveness and its management's ability to meet its customer and market needs.

Nycomed argued that MCI's lack of success in contract bidding is the result of inferior evaluation and that Nycomed succeeded at certain accounts because of its overall evaluation and the superior quality of its proposals. For its part, Bracco argued that bundling arrangements, which include value-added services and incentives, such as equipment for diagnostic imaging, educational packages and funding for research projects, reduced the price of the subject goods and could improve a supplier's likelihood of obtaining a contract. The value-added services and incentives have a financial value which is taken into account by the purchaser and the supplier. Bracco submitted that MCI and Nycomed have more extensive contrast media product lines in Canada than Bracco, which permits them to bundle the subject goods. In the case of MCI, it bundles its LOCM with other products, such as Berlex's Ultravist and Osmovist and non-subject goods, to sell a more complete product line. Bracco has limited funds for value-added services and offers a limited range of fill sizes and packaging.

With respect to the issue of export performance of LOCM produced by a Canadian producer, Nycomed submitted that export markets may be a factor in weighing whether there is material injury to the domestic producer of LOCM. If the domestic producer is export-oriented, it may well be that it would not be entitled to the protection from dumping afforded under SIMA, as that protection is an extraordinary remedy which can only occur if the domestic industry can demonstrate that the degree of material injury warrants the application of anti-dumping duties. For its part, Bracco submitted that the Tribunal could take the export performance of the domestic producer into consideration to determine what role, if any, it played in the injury of the domestic production for domestic consumption of LOCM.

Finally, Nycomed requested exclusions for all the subject goods in strengths, sizes and package configurations that are not produced by MCI, as well as an exclusion for Visipaque. Bracco also requested an exclusion for its products.

In conclusion, the importers submitted that the Tribunal should find that there is no material injury or threat of material injury caused by the dumping of the subject goods.

## ANALYSIS

Pursuant to section 42 of SIMA, the Tribunal is required to “make inquiry . . . as to whether the dumping or subsidizing of the goods [to which the preliminary determination applies] . . . has caused injury or retardation or is threatening to cause injury”. “Injury” is defined in subsection 2(1) as “material injury to a domestic industry”. Since its decision in *Caps, Lids and Jars*,<sup>14</sup> the Tribunal has taken the position that injury and threat of injury are distinct findings and that it does not need to make a finding relating to both under subsection 43(1) unless it first makes a finding of no injury. In this inquiry, the Tribunal adopts the same position.

### Class of Goods

The Tribunal was requested, as a preliminary matter, to determine whether the subject goods should be divided into three separate classes of goods. The Commissioner in his preliminary and final determinations of dumping identified the dumped goods as “iodinated contrast media used for radiographic imaging, in solutions of osmolality less than 900 mOsm/kg H<sub>2</sub>O, originating in or exported from the United States of America (including the Commonwealth of Puerto Rico)”.

Prior to the hearing, Nycomed argued that there were three separate classes of LOCM before the Tribunal: ionic dimers, non-ionic dimers and non-ionic monomers. In a letter dated March 27, 2000, the Tribunal informed the parties that it was not persuaded that there was more than one class of goods and that it did not see any reason to vary the product description identified by the Commissioner. However, the Tribunal indicated that it would provide the parties the opportunity to address the issue of class of goods as a preliminary matter at the hearing.

Nycomed argued that scientific literature indicates that the chemical, compositional and clinical properties of ionic dimers, non-ionic dimers and non-ionic monomers, all categories of LOCM, are distinct. As such, they should be treated as separate classes of goods for the purposes of the inquiry.

Bracco argued that the key issue in determining whether there is more than one class of goods is whether the different descriptions of LOCM compete with each other. Bracco took the position that there should only be one class of goods for the purposes of the inquiry.

MCI referred to factors applied by the Tribunal in its decision in *Bacteriological Culture Media*<sup>15</sup> in determining the issue of like goods. MCI argued that all LOCM are marketed in a similar manner, have a similar appearance and employ similar packaging. The method of manufacture is the same, and they are based on a similar chemical structure. LOCM are clearly substitutable, are sold at similar prices and have the same channels of distribution.

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14. *Finding* (20 October 1995), *Statement of Reasons* (6 November 1995), NQ-95-001 (CITT).

15. *Finding* (31 May 1996), *Statement of Reasons* (17 June 1996), NQ-95-004 (CITT).

As the Commissioner identified only one class of goods, margins of dumping were provided with respect to one class of goods as described. The Tribunal notes, however, that it is not bound by the Commissioner's definition of the class of goods. In considering the issue of class of goods, the Tribunal typically looks at the characteristics of the goods, including their physical characteristics, such as appearance, their method of manufacture or composition, their market characteristics, such as substitutability, pricing and distribution channels, and whether the goods fulfil the same customer needs.<sup>16</sup>

The Tribunal notes that each of the three types of LOCM identified by Nycomed is manufactured in a similar manner. They are sold at similar prices and have the same channels of distribution. All LOCM are chemically similar, in that their basic structure involves iodine molecules attached to a benzene ring or rings. The differences in chemical structure that were identified impacted the extent of side effects experienced by the patient, and perhaps some of the medical applications, but not the general purpose for which they are used. LOCM are clearly substitutable for one another in the contrast imaging procedures.

As such, the Tribunal found that this inquiry relates to one class of goods only, as described by the Commissioner.

## DOMESTIC INDUSTRY AND LIKE GOODS

In conducting an inquiry under section 42 of SIMA, the Tribunal must determine whether the dumping has caused or is threatening to cause "material injury to a domestic industry". The term "domestic industry" is defined in subsection 2(1) as follows:

"domestic industry" means, other than for the purposes of section 31 and subject to subsection (1.1), the domestic producers as a whole of the like goods or those domestic producers whose collective production of the like goods constitutes a major proportion of the total domestic production of the like goods except that, where a domestic producer is related to an exporter or importer of dumped or subsidized goods, or is an importer of such goods, "domestic industry" may be interpreted as meaning the rest of those domestic producers.

The Tribunal must determine whether domestically produced LOCM are like goods to the subject goods, which were defined by the Commissioner as "iodinated contrast media used for radiographic imaging, in solutions of osmolality less than 900 mOsm/kg H<sub>2</sub>O".

Subsection 2(1) of SIMA defines "like goods", in relation to any other goods, as follows:

- (a) goods that are identical in all respects to the other goods, or
- (b) in the absence of any goods described in paragraph (a), goods the uses and other characteristics of which closely resemble those of the other goods.

As discussed earlier under the "Product" and "Domestic Industry" sections, there are various LOCM available on the Canadian market. Two of these products, Hexabrix and Optiray, are manufactured by MCI in Canada. Both products are available in a variety of package sizes and levels of iodine concentration. Based on the evidence, the Tribunal finds that Hexabrix and Optiray produced by MCI are "like goods" for the purposes of this inquiry, as their use and other characteristics closely resemble those of the subject goods.

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16. See, for example, *Stainless Steel Round Bar, Finding* (4 September 1998), *Statement of Reasons* (21 September 1998), NQ-98-001 (CITT) [hereinafter *Round Bar*]; and *Machine Tufted Carpeting, Finding* (21 April 1992), *Statement of Reasons* (6 May 1992), NQ-91-006 (CITT).



In considering if MCI is the “domestic industry” for the purposes of this inquiry, the Tribunal also considered that MCI has, in the past, imported a quantity of the subject goods from its U.S.-based parent. However, if MCI were to be excluded from the domestic industry because of these imports, its exclusion would deny the existence of a domestic industry, as MCI is the sole producer of LOCM in Canada. In previous cases, the Tribunal has refused to exclude a domestic producer in such circumstances.<sup>17</sup> Further, the Tribunal notes that MCI imported a small and declining quantity of the subject goods for sale in Canada during the period of inquiry. Accordingly, the Tribunal finds that MCI constitutes the “domestic industry” for the purposes of this inquiry.

## INJURY AND CAUSALITY

In an inquiry conducted pursuant to section 42 of SIMA, the Tribunal must determine whether the dumped goods have caused injury to the domestic industry. Subsection 37.1(1) of the *Special Import Measures Regulations*<sup>18</sup> prescribes certain factors that the Tribunal may consider in determining whether a domestic industry has been materially injured by dumped imports. These factors include the volume of dumped goods and their effect on prices in the domestic market for like goods and the consequent impact of these imports on a number of economic factors. In this case, these factors include actual or potential declines in output, sales, market share and profits. Subsection 37.1(3) of the SIMA Regulations also requires the Tribunal to consider other factors, including export performance, to ensure that the injury caused by those other factors is not attributed to the dumped imports.

In considering these factors, the Tribunal reviewed developments in the Canadian market for LOCM during the period from 1996 through to the first three quarters of 1999. An examination of the key economic indicators shows that market demand over the inquiry period grew steadily, with an overall increase in volume of 27 percent<sup>19</sup> between 1996 and 1998 and a further increase of 21 percent in the first three quarters of 1999. Within this growing market, sales of MCI products from domestic production also increased and, in fact, outperformed the market in 1998 and 1999. As a result, MCI increased its market share by several points during the inquiry period.

During the period 1996-98, the sales volume of U.S. imports also grew steadily, by 18 percent, with a further increase of 19 percent in the first three quarters of 1999. Sales of Nycomed products accounted for

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17. See *Refined Sugar, Findings* (6 November 1995), *Statement of Reasons* (21 November 1995), NQ-95-002 (CITT).

18. S.O.R./84-927 [hereinafter SIMA Regulations].

19. Evidence adduced by a witness from Bracco (*Transcript of Public Hearing*, Vol. 3, 30 March 2000, at 698-99) indicates that market data for the year 1996 contained in the pre-hearing staff report are inaccurate. Accordingly, the Tribunal has adjusted 1996 sales volumes and values for Bracco on the basis of market studies conducted annually by Canadian Contrast Media Manufacturers (CCMM) (Importer’s Exhibit B-32 (protected), Administrative Record, Vol. 14). Upon review of the CCMM studies, the Tribunal became aware that the 1996 Nycomed data submitted by Sanofi, a third party, were also inaccurate (Importer’s Exhibit C-2 (protected), Annex 1, Administrative Record, Vol. 14.1). Information submitted by Sanofi appears to include low-priced non-subject goods, which resulted in inflated sales volumes and understated average prices for Nycomed products in that year (Tribunal Exhibit NQ-99-003-16.6 (protected), Administrative Record, Vol. 6A at 254-56). Accordingly, the Tribunal also revised the volume and value data for Nycomed in 1996 on the basis of the CCMM studies submitted by Nycomed (Tribunal Exhibit NQ-99-003-16.2A (protected), Administrative Record, Vol. 6 at 259). In support of these adjustments, the Tribunal notes that the market study results for the years 1997 and 1998 (the CCMM studies report values net of rebates, allowances and other discounts) closely approximate the Tribunal’s market data for these years contained in the pre-hearing staff report.

virtually all of the volume gains, having increased by 47 percent between 1996 and 1998 and again by 25 percent in 1999. Sales of imported products by MCI from its U.S. parent declined steadily throughout the inquiry period, while sales of Bracco products also declined between 1996 and 1998, before recovering somewhat in 1999. Although total U.S. import sales lost market share during the inquiry period, sales of Nycomed products gained several points of market share. Sales of non-subject goods imported from Germany by Berlex also participated in this market growth, but total sales and market share remained well below those of the other market players.

This overview of domestic market volumes suggests a positive trend for most market participants, particularly MCI. However, a review of the domestic market in value terms, based on the revised market data, paints a different picture. Between 1996 and 1998, the total market net sales value fell from \$25.3 million to \$20.1 million, a decline of 21 percent, before recovering by 11 percent in the first three quarters of 1999. Over the inquiry period, MCI's total revenues earned on sales from domestic production for domestic consumption increased by 8 percent between 1996 and 1998 and a further 22 percent in the first three quarters of 1999.

A review of average prices, based on the revised market data, reveals the dramatic decline in domestic market selling prices. Between 1996 and 1998, the average unit market selling price fell from \$438 per litre to \$273 per litre, a drop of 38 percent. This decline continued into 1999, which saw a further decrease of 8 percent, to \$246 per litre. MCI's average unit selling prices on sales from domestic production fell in each period of the inquiry. These declines were exceeded by the reduction in average unit selling prices of the subject goods from the United States and non-subject goods from Germany. In 1996, MCI's average unit price was the lowest of the four market participants. In subsequent periods, however, MCI's average unit selling price exceeded the prices of the other suppliers.

The Tribunal also reviewed prices for specific, large-volume products in order to minimize the effects of product mix influences. This analysis was based upon a sampling of sales to 13 large accounts chosen by MCI, Nycomed and Bracco. This review confirms the results noted above with respect to overall average market selling prices. With the exception of the lower-volume 350 I mg media, the average unit selling prices of Nycomed products, which accounted for the majority of sales, were clearly lower than those of MCI products and those of the other market participants' products. The Tribunal also notes, with respect to sales of these specific products at the selected accounts, that, although Bracco's average unit prices<sup>20</sup> were somewhat higher than those of MCI in 1998, by 1999, the price gap had closed significantly.

In summary, it is clear from the evidence that MCI's selling prices have been significantly eroded. The Tribunal must determine whether the dumping has caused this price erosion, as well as any other injury, and whether it constitutes an amount of injury that is material.

MCI argued that there is a clear causal connection between the large margins of dumping found on U.S. imports and the price erosion experienced by MCI. Nycomed and Bracco, however, argued that a number of other factors led to the price declines in the Canadian market. In addressing these conflicting views, the Tribunal carefully assessed the large volume of data submitted by parties, as well as the evidence and testimony adduced during the course of the hearing.

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20. Tribunal Exhibit NQ-99-003-16.5 (protected), Administrative Record, Vol. 6A at 252.2-252.10. Bracco data on sales to the selected accounts have been revised in accordance with the late filing of additional information which was inadvertently not submitted with its questionnaire response.

The Tribunal first considered changes in domestic market demand. As noted, based on the revised market data, the domestic market volume for LOCM grew sharply over the period of inquiry, from roughly 58,000 litres in 1996 to 74,000 litres in 1998. This volume growth continued in the first three quarters of 1999, rising from 56,000 litres in the corresponding period of 1998 to 68,000 litres in 1999. The evidence suggests that this growth is largely attributable to changing demographics, particularly demand created by an ageing population. Further, as the price spread between HOCM and LOCM has narrowed over time, there has been a growing demand by healthcare providers for LOCM, due to the lower incidence of negative patient reactions.<sup>21</sup> The Tribunal does not see a relationship between this growing demand and the downward spiral in prices.

While market demand has been growing, prices for LOCM, based on the revised market data, have been falling at a rapid rate, from an average of \$438 per litre in 1996 to \$246 per litre in 1999. A number of reasons were proffered for the price declines, which, in the opinion of Nycomed and Bracco, had nothing to do with dumping. Among these other factors suggested by the two parties were the impact on prices by buying groups and healthcare budget constraints; the fact that LOCM are now mature products at the end of their technological cycle; the fact that LOCM are effectively considered to be generic products in the Canadian market; and the effect on prices of expiring patents and the role of the PMPRB in suppressing price levels.

Buying groups and healthcare budget constraints no doubt played a role in controlling LOCM price levels. However, the Tribunal notes that buying groups are not a new phenomenon in the Canadian market, nor are provincial government efforts to hold the line on healthcare costs. It was taken in evidence that the buying groups look for the best overall package offer from suppliers, which ultimately translates into the lowest bottom-line price.<sup>22</sup> The use of a Request for Proposal process and, at times, line-by-line cherry picking by customers tend to heighten market competition. However, this competition and the relatively small overall input costs represented by LOCM in total healthcare budgets, which run into the billions of dollars, do not explain the large and continuing decline in LOCM prices.

The Tribunal also considered evidence and claims that LOCM are now mature products and that these products are essentially generic in nature, given the competition among suppliers for what are essentially interchangeable and substitutable goods. While the Tribunal does not dispute these claims, these factors do not explain why other markets, in which the same parties compete, have price levels considerably higher than those in Canada. In this regard, the Tribunal notes that price levels in the United States for LOCM are about 40 percent higher than in Canada,<sup>23</sup> while price levels in Japan are about three times higher than in Canada.<sup>24</sup> Moreover, in spite of the relatively small size of the domestic market, the evidence suggests that Canadian price levels are among the lowest in the world.<sup>25</sup>

Finally, in assessing the effects of other factors, the Tribunal examined the role of patents and the effect of the PMPRB on domestic market prices. While the evidence was conflicting on the price impact of patents which are about to expire, the Tribunal is persuaded that patent expiry, under normal market conditions, leads to lower prices near the end of a product's patent protection period. This proposition is

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21. *Transcript of Public Hearing*, Vol. 1, 28 March 2000, at 62.

22. *Transcript of Public Hearing*, Vol. 3, 30 March 2000, at 572 and 577-78.

23. *Transcript of Public Hearing*, Vol. 1, 28 March 2000, at 42.

24. *Transcript of Public Hearing*, Vol. 4, 31 March 2000, at 742.

25. Manufacturer's Exhibit A-6 (protected), Administrative Record, Vol. 12; and *Transcript of Public Hearing*, Vol. 2, 29 March 2000, at 335.

supported by events in the U.S. market where generic products are now being offered in competition with LOCM sold by Mallinckrodt Inc., Nycomed and Bracco.<sup>26</sup> However, it is clear from the evidence that generic LOCM are not considered a threat in Canada because of the precipitously low market prices.<sup>27</sup> In effect, these low prices have insulated the domestic market from the appearance of new entrants.

In the Tribunal's view, it is also clear from the evidence that the price erosion witnessed in the Canadian market cannot be attributed to the activities of the PMPRB. The PMPRB's jurisdiction is limited to establishing non-excessive prices on patented medicines. The PMPRB exercises its authority based on prescribed factors set out in its guidelines,<sup>28</sup> including the review of historical market price performance of the patented products. If prices decline, as has been the case with LOCM, the non-excessive price will also decline. Accordingly, it is not the decisions of the PMPRB that cause the price declines in the marketplace. The evidence indicates that, once prices decline, the PMPRB limits the amount by which the prices can increase in the future. The Tribunal notes that LOCM marketed by Nycomed and Bracco in Canada are no longer protected by patents and, therefore, do not fall within the PMPRB's jurisdiction. There was no evidence, however, that Nycomed, the dominant market player, or Bracco attempted to test the market with price increases during the period of inquiry.

It was submitted by Nycomed that its success in gaining contracts was enhanced by its ability to offer a full range of products, its superior value-added packages, and better marketing and distribution through its logistics provider, Picker International. The evidence, however, does not reveal that MCI was disqualified from any bids because it was unable to supply the customer's requirements. Indeed, at least since early 1999, MCI has been able to offer a full range of products as a result of its distribution arrangement with Berlex.<sup>29</sup> Moreover, the evidence suggests that customers will purchase on a line-item basis as the need requires, thereby purchasing from more than one supplier to fill their requirements.<sup>30</sup>

With respect to value-added incentives,<sup>31</sup> the Tribunal notes that such incentives are offered by all suppliers and often amount to tens of thousands of dollars in a single contract. Value-added benefits which accrue to the purchaser include financial offerings for educational and research purposes, additional allowances and free products. While Nycomed may offer the largest value-added packages, it is clear to the Tribunal that these benefits are little more than price incentives designed to gain sales and which result in lower net prices to the customer.<sup>32</sup> In the Tribunal's view, such incentives simply amplify the price erosion which has occurred in the domestic market.

The Tribunal is also not persuaded that Nycomed's use of Picker International provides it with superior marketing and distribution. MCI canvasses the market through its own sales force in all areas except Newfoundland and some accounts in British Columbia. There was no evidence which would suggest that MCI has been limited in its ability to service the entire domestic market. A review of bid proposals reveals

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26. *Transcript of Public Hearing*, Vol. 2, 29 March 2000, at 441-42; and *Transcript of Public Hearing*, Vol. 3, 30 March 2000, at 689-90.

27. *Transcript of Public Hearing*, Vol. 1, 28 March 2000, at 73-75.

28. Tribunal Exhibit NQ-99-003-26A, Compendium A, Administrative Record, Vol. 1A at 166-212.

29. Manufacturer's Exhibit A-17 (protected), Administrative Record, Vol. 12.

30. Manufacturer's Exhibit A-2 at 16, Administrative Record, Vol. 11.

31. Pricing data collected by the Tribunal reflect net net prices, excluding any monetary value-added incentives.

32. *Transcript of Public Hearing*, Vol. 3, 30 March 2000, at 578 and 586-89.

that MCI offered LOCM at all accounts, including a Newfoundland account through its logistics provider in that province.<sup>33</sup>

It was submitted that MCI contributed to the injury that it may have suffered because of its pricing activities in Quebec under the “*gré à gré*” purchasing program. Under this program, which the Quebec government instituted in April 1997, Quebec-based manufacturers were afforded the opportunity to extend contracts with government entities for a period of up to five years. It was submitted that MCI utilized this program but, in the process, locked itself into long-term contracts at depressed price levels. The record indicates, however, that MCI renewed these contracts at competitive market prices in effect at that time - a requirement that was stipulated by the program.<sup>34</sup> As well, the record indicates that the Quebec government buying groups utilize a public tendering process. The transparency of this process provided MCI with the knowledge that it needed to confirm the market prices - that it had to meet.

The Tribunal recognizes the inherent difficulty in attempting to quantify the depressive price effects of these “other factors”. While it may be accepted that, taken as a whole, these factors did play a role in domestic price levels, in the Tribunal’s opinion, the magnitude of the price erosion evident in the price declines in the Canadian market from 1996 to 1999 points directly to the substantial margins of dumping found on the Nycomed and Bracco products.

During the course of the hearing, considerable debate focused on claims that the Canadian market was experiencing a “price war”, about who started the war and who led prices down. In the Tribunal’s view, it is irrelevant who initiated the “price war”. What is clear is that all suppliers of LOCM were pricing aggressively, as they sought to gain or maintain sales and market share. As the Tribunal has found in other cases,<sup>35</sup> the domestic industry has the right to reduce its prices to try to increase its market presence through increased sales and market share, and the importers have the same right, up to a point. However, once the imported product is offered at dumped prices which cause injury to the domestic industry, the line is crossed. The Tribunal is persuaded that, in the case at hand, given the high margins of dumping, the line has clearly been crossed, resulting in material injury in the form of price erosion.

The Tribunal now addresses the extent to which these eroded injurious prices have had an impact on the domestic industry. On the basis of the revised 1996 data,<sup>36</sup> average unit selling prices fell by \$192 per litre over the course of the inquiry period, while MCI’s average unit prices fell by \$137 per litre. Based on MCI’s domestic sales volume in the first nine months of 1999,<sup>37</sup> the price erosion incurred by MCI during that period alone amounts to well over \$2 million, compared to a situation where 1996 price levels had been maintained.<sup>38</sup> Moreover, even if MCI had maintained its average prices of 1998, it is clear that the eroded prices would still have had a significant negative impact on the company’s sales revenue in the first nine months of 1999. In the Tribunal’s view, whether the basis of comparison of price levels is 1996 or

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33. *Protected Pre-hearing Pricing Report*, 1 March 2000, Tribunal Exhibit NQ-99-003-7.1 (protected), Administrative Record, Vol. 2 at 90-106; and *Transcript of Public Hearing*, Vol. 1, 28 March 2000, at 53.

34. *Transcript of Public Hearing*, Vol. 1, 28 March 2000, at 45-46.

35. *Supra* note 13.

36. *Supra* note 19.

37. *Protected Pre-hearing Staff Report*, revised 29 February 2000, Tribunal Exhibit NQ-99-003-7A (protected), Administrative Record, Vol. 2 at 84.

38. Because MCI’s Canadian market sales are confidential, the Tribunal cannot release the percentage that this \$2 million would represent, except to note that it would account for a very substantial portion of the company’s domestic sales value.

even 1998, the evidence indicates that MCI suffered injury in the form of eroded prices and that the injury was material. Moreover, it is clear that, but for the high margins of dumping, market prices in 1999 would have been significantly higher and the extent of the price erosion incurred by MCI would have been significantly reduced. In the Tribunal's view, the magnitude of the differences in prices and their effects on revenues would have been material. Accordingly, the Tribunal is persuaded that the dumping caused the price erosion and material injury suffered by MCI.

In argument, MCI noted that this is not a case about lost profits, a proposition with which the Tribunal partially concurs. By and large, MCI's production costs for LOCM are greatly influenced by transfer pricing policies established with related companies. MCI acquires its iodine powder for the production of Optiray, its largest volume product, from a sister company located in Ireland. While the evidence suggests that the selling prices of the powder by the Irish company to MCI fell sharply between 1996 and 1999,<sup>39</sup> no direct relationship could be determined between MCI's gross margins and its sales revenues due to the transfer price policy. As a result, the Tribunal is unable to draw conclusions as to whether MCI has suffered financial injury on sales of Optiray, except that the revenues earned on sales of Optiray were affected by the dumping.

However, MCI produces Hexabrix from an iodine powder purchased at arm's length from a supplier located in France. An examination of MCI's financial statements on domestic sales of Hexabrix reveals a significant deterioration on its financial results for this product. These statements show that gross margins earned on sales of Hexabrix fell by more than 50 percent between fiscal 1997 and 1999. As a consequence, the net profits earned on Hexabrix sales in 1997 became losses in fiscal 1998 and 1999. The Tribunal notes that Hexabrix sales, although lower in volume than Optiray, still represent a significant proportion of MCI's domestic sales revenues.<sup>40</sup>

The evidence also persuades the Tribunal that the low domestic market prices have inhibited MCI's ability to market LOCM in Ultraject® syringes. This innovative packaging provides ease of use in administering LOCM by users, but sells at a price premium due to the more expensive container. The Tribunal notes that approximately 30 percent of MCI's export sales of LOCM are made in these syringes.<sup>41</sup> In spite of the fact that this product has been highly successful in export markets, MCI has been unable to market Ultraject® syringes in Canada to any significant degree. In the Tribunal's view, MCI's inability to establish a market presence for this product is directly related to the low prices found in the Canadian market caused by the dumping of imported products.

The Tribunal reviewed the contract pricing at 10 large buying groups to determine whether a causal connection existed between the successful bidder and the price offered.<sup>42</sup> It is recognized that several criteria are considered in evaluating competing bids, including supplier and product preference, package configurations, value-added benefits and so on. However, the evidence strongly suggests that "everything being equal, price prevails".<sup>43</sup> In 9 of the 10 accounts reviewed, the low bid won the contract. Moreover,

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39. *Protected Pre-hearing Staff Report*, 17 February 2000, Tribunal Exhibit NQ-99-003-7 (protected), Administrative Record, Vol. 2 at 45.

40. Manufacturer's Exhibit A-3 (protected), Attachment 1, Administrative Record, Vol. 12.

41. *Protected Pre-hearing Staff Report*, 17 February 2000, Tribunal Exhibit NQ-99-003-7 (protected), Administrative Record, Vol. 2 at 25.

42. *Protected Pre-hearing Pricing Report*, 1 March 2000, Tribunal Exhibit NQ-99-003-7.1 (protected), Administrative Record, Vol. 2 at 90-106.

43. Tribunal Exhibit NQ-99-003-22.21 (protected), Administrative Record, Vol. 6.2G at 125.

responses to the Tribunal's purchaser's questionnaire are replete with references to acceptance of the lowest price in the award of contracts.<sup>44</sup> It was argued that Nycomed or Bracco had an incumbency advantage at many of these accounts which instilled a price premium of 2 to 5 percent.<sup>45</sup> However, in only 1 account did the low bid not win the award and, in that instance, the price difference with the successful bidder was less than 2 percent. In fact, in virtually all the contracts considered, the price spread between the winner and the incumbent exceeded the incumbency premium by a substantial amount. The pricing behaviour of Nycomed and Bracco is confirmed by the references to the aggressive price offers made by the two companies at several accounts.<sup>46</sup>

With respect to MCI's allegations of lost sales at specific accounts, the Tribunal has carefully reviewed the record and is not convinced that, as a whole, these allegations can be sustained. As noted, over the course of the inquiry period, MCI increased its sales volume, which suggests that, as in any competitive market, the company won some contracts and was unable to gain others due to factors not necessarily related to price. However, a significant exception to this general proposition was the loss of the contract at the Calgary Regional Health Authority, a provincial government buying group. The evidence clearly shows that this contract, which had formerly been supplied by MCI, was taken by Nycomed on the basis of its low price offering made possible by dumping. The Tribunal notes that there was a substantial price difference between MCI's bid and Nycomed's bid.<sup>47</sup> In the Tribunal's opinion, the loss of this one account was of a sufficient financial magnitude to warrant a finding of material injury.

In submissions and arguments made by Bracco, it was claimed that Bracco products have not generally competed with MCI products in the Canadian market due, in part, to its limited market coverage and product range. The record indicates that Bracco's sales and market share declined during the course of the inquiry period. It is clear, however, that Bracco has maintained a significant presence in the domestic market and has plans to expand its presence in the future.<sup>48</sup> Moreover, an examination of the contract data submitted by purchasers reveals Bracco's presence and, in a number of instances, its success in gaining sales through low price offers. In the Tribunal's view, these low price offers contributed significantly to the price erosion and consequent injury suffered by MCI.

Finally, the Tribunal will briefly address the issue of export performance. In determining the impact of dumped imports on the domestic industry, the Tribunal has regard to the factors found at Article 3.4 of the *Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994*<sup>49</sup> and to subsection 37.1(1) of the SIMA Regulations. The Tribunal may take into consideration, in its analysis, a

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44. See, for example, Tribunal Exhibit NQ-99-003-22.8 (protected), Administrative Record, Vol. 6.2C at 2; Tribunal Exhibit NQ-99-003-22.9 (protected), Administrative Record, Vol. 6.2C at 21; Tribunal Exhibit NQ-99-003-22.11 (protected), Administrative Record, Vol. 6.2D at 65; and Tribunal Exhibit NQ-99-003-22.21 (protected), Administrative Record, Vol. 6.2G at 128.

45. *Transcript of Public Hearing*, Vol. 2, 29 March 2000, at 336-37.

46. See, for example, Tribunal Exhibit NQ-99-003-22.14 (protected), Administrative Record, Vol. 6.2F at 6; Tribunal Exhibit NQ-99-003-22.20 (protected), Administrative Record, Vol. 6.2F at 133; Tribunal Exhibit NQ-99-003-22.21 (protected), Administrative Record, Vol. 6.2G at 129; and Tribunal Exhibit NQ-99-003-22.23 (protected), Administrative Record, Vol. 6.2G at 197.

47. *Protected Pre-hearing Pricing Report*, 1 March 2000, Tribunal Exhibit NQ-99-003-7.1 (protected), Administrative Record, Vol. 2 at 105.

48. Tribunal Exhibit NQ-99-003-16.5 (protected), Administrative Record, Vol. 6A at 178-79.

49. Annex 1A to the *Agreement Establishing the World Trade Organization*, 15 April 1994 (entered into force 1 January 1995) [hereinafter WTO Anti-dumping Agreement].

range of economic factors and indices that have a bearing on the state of the domestic industry, including actual or potential decline in output, sales, market share, profits, productivity, return on investment or utilization of capacity, actual or potential negative effects on cash flow, inventories, employment, wages, growth or the ability to raise capital.

In addition, in determining the effects of dumped imports on the domestic industry, the Tribunal has regard to Article 3.5 of the WTO Anti-dumping Agreement, which states, in part, that, in demonstrating a causal relationship between the dumped imports and the injury to the domestic industry, “[t]he authorities shall also examine any known factors other than the dumped imports which at the same time are injuring the domestic industry, and the injuries caused by these other factors must not be attributed to the dumped imports”. Article 3.5 provides a non-exhaustive list of factors to be examined, including the export performance of the domestic industry.<sup>50</sup> These factors were incorporated into Canadian legislation at subsection 37.1(3) of the SIMA Regulations.<sup>51</sup>

It is clear from the WTO Anti-dumping Agreement and the SIMA Regulations that the Tribunal can examine the export performance of the domestic industry to determine whether the exports of the like goods, which account, in this case, for a vast majority of the total domestic production, constitute an additional factor which caused injury to the domestic industry at the same time as the dumping of the subject goods in the domestic market. If so, then the Tribunal must not attribute this injury to the dumped imports.

In its consideration of the export performance of the like goods, the Tribunal may examine a situation where the volume of exports of like goods produced by the domestic industry decreases during the period of investigation and where this decrease affects the productivity of the domestic industry. Where this decrease in the export performance was the result, for example, of a contraction of the export demand of the like goods produced by the domestic industry, this may be one of several factors, unrelated to the dumped subject goods, which could cause injury to the domestic industry. The reverse is also true. In this case, the evidence clearly shows that the exports of the like goods are an important component of the total domestic production of like goods. Moreover, the volume of exports increased during the Tribunal’s period of inquiry. This increased volume of exports has allowed the domestic industry to distribute its fixed costs over more units, thereby reducing its average fixed unit costs for all like goods. In this case, this applies directly to the

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50. Article 3.5 of the WTO Anti-dumping Agreement reads, in part :

Factors which may be relevant in this respect include, *inter alia*, the volume and prices of imports not sold at dumping prices, contraction in demand or changes in the patterns of consumption, trade-restrictive practices of and competition between the foreign and domestic producers, developments in technology and the export performance and productivity of the domestic industry.

51. (3) For the purposes of determining whether the dumping or subsidizing of any goods has caused injury or retardation or is threatening to cause injury, the following additional factors are prescribed:

- (a) whether a causal relationship exists between the dumping or subsidizing of any goods and injury, retardation or threat of injury, on the basis of
  - (i) the volumes and prices of imports of like goods that are not dumped or subsidized,
  - (ii) a contraction in demand for the goods or like goods;
  - (iii) changes in patterns of consumption of the goods or like goods,
  - (iv) trade-restrictive practices of, and competition between, foreign and domestic producers,
  - (v) developments in technology,
  - (vi) the export performance and productivity of the domestic industry in respect of like goods, and
  - (vii) any other factors that are relevant in the circumstances; and
- (b) whether any factors other than the dumping or subsidizing of the goods has caused injury or retardation or is threatening to cause injury.



production of Optiray, one of the two products in the like goods category, which is sold extensively in the export market. Far from being a source of injury in this case, the domestic industry's export performance has benefited its overall performance and has helped to offset the injurious effects of dumping in the domestic market. In the Tribunal's view, the effects of the domestic industry's export performance, albeit favourable, does not negate the material injury caused directly by the dumping of the subject goods through price erosion and lost sales in the domestic market.

The issue of export performance has already been addressed by the Tribunal in a previous case.<sup>52</sup> In that case, exports "in the view of the Tribunal, [were] unrelated to the issues of dumping into Canada and of injury to domestic production. Moreover, and notwithstanding repeated statements that the car industry is a North American industry which encompasses exports and imports on the basis of rationalized production, GM Canada and Ford Canada centred their case on, and counsel argued that the complainants were concerned with, injury to domestic production for domestic consumption. The Tribunal agrees with this position".<sup>53</sup> The Tribunal adopts this position in the present case, a position which reflects the Tribunal's practice and established jurisprudence since the *Cars* case.

In summary, it is clear from the evidence that dumping has caused injury to MCI, which the Tribunal considers material, primarily in the form of price erosion. Moreover, this price erosion, when combined with the lost sale noted above, has impacted the company's financial results and has limited its ability to market LOCM in Ultraject® syringes in Canada.

## REQUESTS FOR EXCLUSION

Nycomed requested that, should the Tribunal find injury, an exclusion from the finding be granted for its product, Visipaque, as well as for all LOCM that it imports in strengths, package sizes and configurations not made by MCI. Bracco requested that its imports of LOCM also be excluded from the finding.

It is well established that the Tribunal has discretion to grant exclusions under subsection 43(1) of SIMA.<sup>54</sup> The Tribunal has granted product exclusions in circumstances when, for instance, the domestic industry does not produce the particular product.<sup>55</sup> The Tribunal also considers factors such as whether there is any domestic production of substitutable or competing goods,<sup>56</sup> whether the domestic industry is an "active supplier" of the product or whether it normally produces the product.<sup>57</sup>

In requesting an exclusion for Visipaque, Nycomed argued that it is qualitatively different and distinguishable from the like goods produced by MCI and that no product with the properties of Visipaque is

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52. *Cars Produced by or on Behalf of Hyundai Motor Company, Seoul, Republic of Korea, or by Companies With Which it is Associated, Finding* (23 March 1988), *Statement of Reasons* (7 April 1988), CIT-13-87 (CIT) [hereinafter *Cars*].

53. *Ibid.* at 15-16.

54. *Certain Cold-rolled Steel Sheet Originating in or Exported from the United States of America (Injury) (United States v. Canada)* (1994), CDA-93-1904-09 (Ch. 19 Panel) at 54. See, also, *Hetex Garn A.G. v. The Anti-dumping Tribunal*, [1978] 2 F.C. 507 (FCA).

55. See, for example, *Certain Flat Hot-rolled Carbon and Alloy Steel Sheet Products, Finding* (2 July 1999), *Statement of Reasons* (19 July 1999), NQ-98-004 (CITT). See, also, *Round Bar*, *supra* note 16.

56. See, for example, *supra* note 16.

57. *Round Bar*, *ibid.*

available from Canadian production. MCI produces goods that are non-ionic monomeric media (Optiray) and ionic dimeric media (Hexabrix). Visipaque is a non-ionic dimeric product with chemical properties and clinical characteristics distinguishable from the domestically produced goods. Visipaque, therefore, Nycomed argued, is qualitatively distinct in clinical terms and in terms of its structure and composition. However, MCI stated that the evidence shows that Visipaque is an alternative to Hexabrix and that Visipaque is not considered by users of LOCM to be indispensable.

While the evidence indicated that Visipaque, as a non-ionic dimer, had different chemical properties than other LOCM, the Tribunal considers that all LOCM are substitutable for each other. The main advantage of Visipaque, as a product, relates to the reduced negative impact on the patient from its use. While some witnesses expressed a preference for Visipaque, it is clear that some purchasers preferred other products. The Tribunal sees no reason to grant the exclusion for Visipaque.

With respect to the broader request for exclusion, Nycomed submitted that exclusions have been granted for specific categories and types of goods, in particular, configurations or sizes, if they are not produced by the domestic producer. In this case, MCI manufactures a limited range of LOCM in a limited number of specifications. For example, it does not make products in flexible packages, such as pouches or bags, nor does it produce LOCM in a range of sizes and strengths. For these reasons, the exclusion is requested.

MCI argued that to grant Nycomed's request for an exclusion based on package size and concentration would permit the Tribunal's finding to be circumvented by importing product in the excluded size and concentration.

The Tribunal is of the view that the fact that LOCM are packaged in varying strengths, sizes and configurations does not detract from the substitutability of these products. The Tribunal notes that the evidence suggests that the market exhibits a preference for certain concentrations and package sizes of LOCM. For example, the evidence suggests that Nycomed's best seller is the 150-mL size of 300 I mg/mL concentration. However, Nycomed did not establish to the Tribunal's satisfaction that MCI's products do not share the range of clinical needs of the users of these products.

Therefore, the Tribunal does not grant an exclusion to Nycomed for products that it imports in sizes and concentrations not produced and sold by MCI in Canada.

Bracco argued that its LOCM have a limited market coverage and product range and do not generally compete with MCI's product line in the Canadian market. For example, Bracco noted that it does not produce a product that competes with Hexabrix,<sup>58</sup> nor does Isovue 370 compete with Optiray 350.<sup>59</sup> Further, Bracco argued that its sales are concentrated in certain areas of the country, notably Saskatchewan and the Maritimes. Therefore, Bracco requested an exclusion for its products, should the Tribunal make an injury finding.

As noted above, it is clear from the record that Bracco has maintained a significant presence in the domestic market and has plans to expand its presence in the future. Moreover, an examination of the contract data submitted by purchasers reveals Bracco's presence and, in a number of instances, its success in gaining

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58. *Transcript of Public Argument*, 31 March 2000, at 90.

59. *Transcript of Public Argument*, 31 March 2000, at 88-89.

sales through low price offers. In the Tribunal's view, these low price offers contributed significantly to the price erosion and consequent injury suffered by MCI.

Further, the Tribunal is of the view that, while LOCM may be packaged in varying sizes and concentrations, they are generally substitutable. Bracco is clearly a competitor of MCI in this product market and, therefore, the Tribunal does not grant the request for exclusion.

## CONCLUSION

For the foregoing reasons, the majority finds that the dumping in Canada of iodinated contrast media used for radiographic imaging, in solutions of osmolality less than 900 mOsm/kg H<sub>2</sub>O, originating in or exported from the United States of America (including the Commonwealth of Puerto Rico), has caused material injury to the domestic industry.

Raynald Guay

Raynald Guay  
Member

Arthur B. Trudeau

Arthur B. Trudeau  
Member

## DISSENTING OPINION OF MEMBER CLOSE

Unlike my colleagues, I do not find that there was material injury to the domestic industry caused by the dumping in Canada of LOCM products by U.S. pharmaceutical companies. With respect to price erosion, I attach more weight than do my colleagues to the other factors at play in the Canadian and international markets between 1996 and 1999. In my view, those factors, not the dumping, caused the price erosion in Canada. Further, I do not find that the low price levels in Canada are due to the dumping or that they have prevented product development in Canada, nor do I find that the loss of the Calgary Regional Health Authority contract was necessarily due to dumping. In my opinion, MCI does not have the profile of an injured company; rather, it outperformed the Canadian market, its U.S. parent and its 1999 fiscal targets.

I will discuss these points in turn. First, I would like to note that the price erosion, even the extent of the price erosion, was not an isolated phenomenon specific to the Canadian market. The evidence clearly showed that similar declines in the prices of contrast media, unrelated to dumping, were occurring in other markets around the world. In the United States, Mallinckrodt Inc.'s prices for Optiray have dropped 60 percent in the past four years,<sup>60</sup> as "managed care organizations press health-care providers to hold down costs, hospitals are banding together in buying groups to gain purchasing clout, and suppliers' selling prices are being forced down".<sup>61</sup> In Japan, the prices have decreased by 38.8 percent since April 1, 1995. This time it was not the market but the government that lowered the prices of LOCM to offset costs at the 65 percent of the hospitals that it runs.<sup>62</sup> Europe and Australia have been suffering similar declines as a consequence of the tendering process that is driving the same four companies that sell in the Canadian market to offer outrageously low prices,<sup>63</sup> as the LOCM are coming to, or are already at, the end of their patent protection period.

Canada was not immune. Since 1996, if not before, when Isovue, the product imported by Bracco, went off patent,<sup>64</sup> MCI, Nycomed, Bracco and Berlex have been aggressively involved in outbidding each other in the Canadian market. The Tribunal heard evidence that this is not unusual. In the last two to four years of the protection period for a patent, pharmaceutical companies attempt to protect their products by extending contracts beyond the protection period.<sup>65</sup> During such a period, it is also "not unusual" to see the prices of pharmaceuticals fall by 70 to 80 percent.<sup>66</sup>

As the evidence suggested, the market for LOCM can be described as a "genericized market".<sup>67</sup> Whether the generics actually enter the market is irrelevant. Once a patented product is nearing the end of its product cycle and a generic product is at the approval stage, companies can, as happened in this case with Mallinckrodt Inc. in the United States, put in place a market strategy to combat "the potential for generic competitive products" by lowering prices to a level that would be unattractive to entry for the generic

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60. Importer's Exhibit C-1, Tab 2 at 1, Administrative Record, Vol. 13.1.

61. Mallinckrodt Inc.'s 1999 10-K Report, Importer's Exhibit C-1, Tab 4 at 8 and Tab 2 at 1, Administrative Record, Vol. 13.1.

62. *Transcript of Public Hearing*, Vol. 4, 31 March 2000, at 741 and 760.

63. *Transcript of Public Hearing*, Vol. 3, 30 March 2000, at 657-58.

64. The patents for five of the seven LOCM sold in Canada have expired.

65. *Transcript of Public Hearing*, Vol. 3, 30 March 2000, at 622.

66. *Transcript of Public Hearing*, Vol. 3, 30 March 2000, at 619.

67. *Transcript of Public Hearing*, Vol. 2, 29 March 2000, at 365.

products.<sup>68</sup> In 1996, MCI's parent corporation, Mallinckrodt Inc., captured the large \$200 million U.S. Premier account by offering an additional 30 percent discount on prices prevailing on the subject goods in the U.S. market,<sup>69</sup> just as generic competition was about to cause considerable price reductions. Mallinckrodt Inc. subsequently lowered its prices for the subject goods by 20 percent on this U.S. contract.<sup>70</sup>

Similar to what was happening in the United States, Europe and Japan, suppliers in Canada have also felt the effects of spiralling healthcare costs.<sup>71</sup> Increasing pressures on provincial healthcare budgets, which, the evidence suggested, were exacerbated by reduced growth in transfer payments from the federal government since 1995, have left provincially funded hospitals under pressure to cut costs.<sup>72</sup> Unlike my colleagues, I do not dismiss these costs. While recognizing that the savings to be achieved through lower LOCM prices may not be significant for total healthcare budgets, it is clear from the evidence that some hospitals continue to buy lower-cost ionics, non-subject goods, despite their known greater side effects, and the pressure is felt by other hospitals to revert to these lower-cost ionics.<sup>73</sup> Even MCI recognized this impact.<sup>74</sup>

As a result of these price pressures, Canada, like the United States, has seen the emergence of increasingly powerful and consolidated buying groups<sup>75</sup> (e.g. Medbuy) in the last several years. These buying groups, the evidence showed, "are leading the price trend" by providing increasing financially attractive and value attractive contracts to Canadian hospitals.<sup>76</sup>

Nor do I discount the effect on price erosion of the imports by Berlex of non-subject LOCM from Germany. Berlex maintained its market share during the period investigated by the Tribunal. Given the highly competitive nature of the market, I conclude that Berlex was an active participant in bidding with its competitors. These bids contributed to the price erosion, as is demonstrated by the data that Berlex provided to the Tribunal.<sup>77</sup>

Nor can the attempt by MCI to break into the Canadian market with Optiray be discounted in the lowering of prices in the Canadian market. In order to increase market share by gaining new contracts, a bid

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68. *Transcript of Public Hearing*, Vol. 3, 30 March 2000, at 692; and Mallinckrodt Inc.'s 1999 10-K Report, Importer's Exhibit C-1, Tab 4 at 8, Administrative Record, Vol. 13.1.

69. *Transcript of Public Hearing*, Vol. 3, 30 March 2000, at 691; and Mallinckrodt Inc.'s 1999 10-K Report, Importer's Exhibit C-1, Tab 4 at 7-9, Administrative Record, Vol. 13.1.

70. Importer's Exhibit B-3 at 7-9, Administrative Record, Vol. 13.

71. Department of Industry, Medical Imaging Discussion Paper, Importer's Exhibit C-1, Tab 8, section 4.3, Administrative Record, Vol. 13.1 at 2 of 4.

72. Importer's Exhibit B-5 at 11-12, Administrative Record, Vol. 13.

73. The 1996 Heywood Study presented as evidence noted that Canada used more of these HOCM ionics than any other developed country and quoted a hospital radiologist as saying that the switch would cost the hospital \$400,000, which was not worth it, given that, to find the money, it would have to close beds. Tribunal Exhibit NQ-99-003-15.5B, Administrative Record, Vol. 5A at 160.

74. Tribunal Exhibit NQ-99-003-10.1H (protected), Administrative Record, Vol. 4A, Section E at 181.

75. Department of Industry, Medical Imaging Discussion Paper, Importer's Exhibit C-1, Tab 8, section 4.3, Administrative Record, Vol. 13.1. See, also, *Transcript of Public Hearing*, Vol. 3, 30 March 2000, at 567.

76. *Transcript of Public Hearing*, Vol. 3, 30 March 2000, at 577-78.

77. *Protected Pre-hearing Staff Report*, revised 29 February 2000, Tribunal Exhibit NQ-99-003-7 (protected), Administrative Record, Vol. 2 at 49; and Tribunal's Exhibit NQ-99-003-16 (protected), Administrative Record, Vol. 6 at 1-15.

of at least 2 to 5 percent lower than the incumbent's bid is required.<sup>78</sup> Prior to 1990, MCI was a relatively small player in the Canadian LOCM market, supplying only Hexabrix. Its contrast media business consisted primarily of HOCM. In the early 1990s, MCI commenced production of Optiray in Canada for sale domestically and abroad. There is ample evidence documenting MCI's aggressive pricing in its efforts to establish Optiray in the Canadian market.<sup>79</sup> When it entered the Canadian market, Optiray was list priced below its two main competitors, Omnipaque and Isovue.<sup>80</sup> Data on prices for several contracts show sharp declines in prices by MCI from list to half of list prices by the mid-1990s.<sup>81</sup> In 1996, when MCI had the lowest price in the market,<sup>82</sup> importers still held most of the contracts. Nycomed, Bracco and Berlex accounted for the vast majority of sales in all regions of Canada, except Quebec and British Columbia. At that time, MCI undertook a major expansion to fulfil an export product mandate to supply Optiray to Mallinckrodt Inc. affiliates around the world.<sup>83</sup> Counting on the domestic sales of Optiray to make a significant contribution to fixed costs in order to permit these export sales to be more competitive,<sup>84</sup> MCI continued its aggressive pricing.<sup>85</sup>

I agree that it is difficult to quantify or segregate these effects on the price erosion of LOCM in the Canadian market in the last three years. Nevertheless, given the fact that there are so many other factors and that the price for these products fell to the same if not a greater extent around the world where dumping was not a factor, it is my opinion that dumping was not the cause, or even a material cause, of the price erosion.

Furthermore, I do not find the low price level in Canada to be particularly relevant to injury in this case. It is not surprising that the price differential between LOCM in the Canadian and U.S. markets is about 40 percent. After all, patented drug prices in Canada, overall, are about 47 percent lower than those in the United States.<sup>86</sup> There was no concern about dumping when the ceiling levels were set by the PMPRB in the mid-1990s and companies were selling at list prices. It was at these ceiling prices that MCI decided to start producing Optiray, its most important LOCM in Canada. It is only now that prices have fallen, in the same way that they have fallen around the world, that price levels seem to be a problem for MCI.

Unlike my colleagues, I am not persuaded of the importance of these low prices in inhibiting new products, such as Ultraject®, from entering the market or being developed. As late as 1998, price did not appear to be an issue for the introduction of Ultraject® into the market.<sup>87</sup> Moreover, clinical acceptance is crucial for the introduction of a new product or kind of packaging,<sup>88</sup> and the record was not clear that MCI

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78. *Transcript of Public Hearing*, Vol. 2, 29 March 2000, at 337.

79. Importer's Exhibit B-5, Tab 5 at 9, Administrative Record, Vol. 13; and Importer's Exhibit C-1, Tab 1, Administrative Record, Vol. 13.1.

80. Importer's Exhibit B-5, Tab 5 at 10, Administrative Record, Vol. 13.

81. Importer's Exhibit C-1, Tab 1, Administrative Record, Vol. 13.1.

82. *Supra* note 19.

83. Tribunal Exhibit NQ-99-003-RI-1 (protected), Administrative Record, Vol. 10 at 163-98.

84. Manufacturer's Exhibit A-1 (protected) at 31, Administrative Record, Vol. 12.

85. *Protected Pre-hearing Pricing Report*, 1 March 2000, Tribunal Exhibit NQ-99-003-7.1 (protected), Administrative Record, Vol. 2 of 15 at 90-106. See, also, Importer's Exhibit C-1, Tab 1, Administrative Record, Vol. 13.1.

86. Department of Industry, Pharmaceuticals Industry Report, 1999 quoting the PMPRB, Importer's Exhibit C-3, Tab 7 at 2 of 15, Administrative Record, Vol. 13.1.

87. Tribunal Exhibit NQ-99-003-10.1H (protected), Administrative Record, Vol. 4A at 184 and 186; and Tribunal Exhibit NQ-99-003-RI-1 (protected), Administrative Record, Vol. 10 at 96.

88. *Transcript of Public Hearing*, Vol. 3, 30 March 2000, at 549 and 609.

had undertaken the marketing efforts required to secure its acceptance in hospitals. As far as product development is concerned, the evidence in cross-examination was that MCI does not have any R&D capability in Canada for LOCM.<sup>89</sup> Hence, I also conclude that low prices did not prevent product development.

While I agree with my colleagues that the allegations of lost sales cannot be sustained, I do not agree with the exception to their reasoning. MCI, I maintain, was not injured by a lost sale to the Calgary Regional Health Authority due to dumping. Although MCI lost this specific account to Nycomed in 1999, it could just as easily have lost it to undumped imports. Berlex also bid the required 2 to 5 percent lower than MCI on the contract.<sup>90</sup> One can just as easily single out another contract, this time won by MCI on the basis of its lowest bid. The 1998 Capital Health Region contract, for instance, is of a greater value than the Calgary Regional Health Authority contract.<sup>91</sup>

I agree with my colleagues that it is impossible to draw conclusions as to whether or not MCI has suffered financial injury on sales of Optiray, given the transfer price policy in place for the supply of the iodine powder, ioversol, from Ireland. I am not, however, of the view that the evidence reveals or suggests a link between losses of operating income reported on sales of Hexabrix and the dumping in the Canadian market. Moreover, the sales of Hexabrix, not being the dominant LOCM for MCI and a negligible export product,<sup>92</sup> are insignificant to an injury calculation.<sup>93</sup> Hexabrix complements MCI's sales of Optiray; it is not determinative of injury to MCI.

My colleagues rely on both the *Soda Ash* and *Polyiso Insulation Board* cases,<sup>94</sup> which allow that the Canadian producer can gain market share and, at the same time, be injured. The problem with those precedents, in this case, is that MCI does not have the profile of an injured company. It not only gained market share in each year of the inquiry period but outperformed the market as a whole. It increased its volume of sales and also increased the overall value that it derived from those sales, and this, notwithstanding the loss of the Calgary Regional Health Authority contract.

MCI increased its sales by 50 percent between 1996 and 1998 and by a further 28 percent in the first nine months of 1999. In the process, it increased its market share by over one third between 1996 and 1999.<sup>95</sup> Not only was MCI successful in gaining market share, it also increased the overall value that it derived from those sales by 22 percent between the interim 1998 and 1999 periods, compared to 11 percent for the rest of the market.<sup>96</sup> What may be even more important is that, between fiscal 1998 and 1999, the rate

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89. *Transcript of Public Hearing*, Vol. 1, 28 March 2000, at 54-55.

90. *Protected Pre-hearing Pricing Report*, 1 March 2000, Tribunal Exhibit NQ-99-003-7.1 (protected), Administrative Record, Vol. 2 at 105.

91. *Protected Pre-hearing Pricing Report*, 1 March 2000, Tribunal Exhibit NQ-99-003-7.1 (protected), Administrative Record, Vol. 2 at 100 and 103.

92. *Protected Pre-hearing Staff Report*, 17 February 2000, Tribunal Exhibit NQ-99-003-7 (protected), Administrative Record, Vol. 2 at 25.

93. See aid to argument filed by Bracco (protected), Tab G, Administrative Record, Vol. 18, on which the figures for Hexabrix and Optiray are reversed; and Manufactured Exhibit A-3 (protected) Attachment 1.

94. *Supra* note 13.

95. *Supra* note 19; and *Protected Pre-hearing Staff Report*, revised 29 February 2000, Tribunal Exhibit NQ-99-003-7 (protected), Administrative Record, Vol. 2 at 31.

96. *Protected Pre-hearing Staff Report*, revised 29 February 29, 2000, Tribunal Exhibit NQ-99-003-7 (protected), Administrative Record, Vol. 2 at 32.

of increase in MCI revenues from sales in the Canadian market was 10 times that of the imaging segment of its U.S. parent during the same period.<sup>97</sup> While Mallinckrodt Inc.'s sales of imaging products actually declined by 1 percent between the second quarter of fiscal 1999 and the second quarter of fiscal 2000,<sup>98</sup> MCI's volume overshot its fiscal 1999 target by 65 percent, even before year end.<sup>99</sup>

MCI's market performance in like goods is not, in my opinion, that of a company lowering its prices to protect its market share from dumped imports, but that of a company lowering its prices to break into the market, then gain market share from the incumbents, and increasing its overall revenues in the process. The evidence shows an aggressive marketing strategy for Optiray on the part of MCI. The aggressive pricing contributed to the price erosion, at a time when prices were vulnerable, given that the patent protection was ending. Therefore, I do not find that MCI, while outperforming the market as well as its parent Mallinckrodt Inc.'s imaging segment, overshooting its fiscal 1999 volume targets and experiencing increased revenues, has been materially injured by the dumping.

At the hearing, the Tribunal requested the party's views concerning how, in the injury analysis, the Tribunal should deal with the fact that most of MCI's domestic production is exported and most of the value earned on domestic production comes from exports. Having considered the party's submissions, I am of the view that, before coming to a determination of injury, it is incumbent on the Tribunal to consider the impact that the dumping has on the entirety of domestic production, including domestic production of like goods that are exported, where, in the Tribunal's view, the exports are of sufficient magnitude to affect the causal relation between dumping and injury.

In the overwhelming majority of cases<sup>100</sup> before the Tribunal, export sales are overshadowed by domestic sales. As a result, the Tribunal's focus is typically on domestic production for domestic consumption. But, in a case such as this one, where the vast majority of the domestic production of like goods is exported, I am persuaded that, before coming to a conclusion of injury, the impact that the dumping has had on the entirety of domestic production, including the domestic production of like goods that are exported, has to be considered.

SIMA requires the Tribunal to determine whether the domestic industry has suffered material injury. The domestic industry is defined in the legislation as the domestic producers of like goods. Nothing in SIMA or the WTO Anti-dumping Agreement directs the Tribunal to determine whether dumping has materially injured only the domestic production that is related to domestic consumption. I note that section 37.1 of the SIMA Regulations prescribes a number of factors that the Tribunal is to consider in an injury inquiry. Some of these factors clearly relate only to domestic sales for domestic consumption, for example, price and market share. Others, such as export performance, productivity, return on investments, utilization of capacity,

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97. *Ibid.*; and Mallinckrodt Inc.'s 1999 Annual Report, Tribunal Exhibit NQ-99-003-24.2, Administrative Record, Vol. 5.3 at 55.

98. Mallinckrodt Inc.'s Fiscal 2000 Q2 Earning Release, 25 January 2000, Importer's Exhibit C-1, Tab 3, Administrative Record, Vol. 13.1.

99. *Public Pre-hearing Staff Report*, 17 February 2000, Tribunal Exhibit NQ-99-003-6, Administrative Record, Vol. 1 at 106; and Tribunal Exhibit NQ-99-003-RI-1 (protected), Administrative Record, Vol. 10 at 96.

100. The Tribunal has not seen exports forming this great a percentage of domestic production since the *Cars* case in 1987, *supra* note 52. I agree that export performance, in that case, was unrelated to the dumping in Canada and to the injury to the domestic industry, because the Tribunal found no injury to the domestic industry. I note as well that the present case is differentiated from *Cars* in that, in *Cars*, the industry did not make exports an issue, contrary to this case.



employment, inventories or the ability to raise capital, can hardly be evaluated without taking into account the domestic production of like goods in its entirety.

SIMA provides for the application of extraordinary duties when the Tribunal concludes that there has been material injury to the domestic production of like goods. When there has been injury only to a small percentage of that production, it is incumbent on the Tribunal, in my opinion, to consider whether the injury caused to that small portion of domestic production is sufficient to materially injure the domestic production in its entirety. In this case, I have already concluded that dumped imports have not caused material injury to MCI's sales or revenues in Canada. MCI's growing export sales and revenues<sup>101</sup> for like goods only reinforce my conclusion that MCI does not have the symptoms of an injured company.

What then about future threat of injury? Although the witness for Nycomed, the largest pharmaceutical company in the market, claimed that prices must have now bottomed out, there is no guarantee that competition will not continue to drive prices down further. Nevertheless, I do not believe that MCI will be materially injured in the immediate future.

MCI has, in a perverse way, an opportunity to gain from the low and even possibly lower prices in the marketplace. The provinces in which MCI has the strongest presence are also those still using the highest proportion of HO�CM, products with greater side effects than LOCM. The prices of these products are now close enough to provide the possibility of switching to LOCM.<sup>102</sup> MCI should be able to obtain this switchover business without lowering its LOCM prices further and, in the process, gain volume, market share and revenue on LOCM sales.

MCI's sales of LOCM should also be able to grow in volume, based on the contracts that it now has. The market is growing, both domestically and worldwide, as the ageing population requires more contrast media procedures to be performed. More volume in the future, as in the past, will equate to more revenues.<sup>103</sup> The contracts recently signed by MCI will continue for several years. For instance, the "gré à gré" contracts that MCI signed in Quebec were for 5 years; therefore, they do not come up for renewal until 2002. Hence, for the next several years, MCI should be able to increase its volume and revenues without lowering unit prices. The Tribunal was provided with no evidence that would lead me to conclude that a material number of contracts are coming up for renewal in the near future.

As stated above, MCI counted on the fact that the domestic market would provide a significant contribution to fixed costs to permit export sales to be more competitive. I do not foresee, nor was there any evidence provided, that the plant is about to close down because the unit price is lower, especially with increased volume and revenues from domestic sales. This would fly in the face of the increased domestic market share and revenues earned in Canada following a corporate strategy to gain volume.<sup>104</sup> Moreover, the Canadian plant was, after all, built primarily for export production, not to serve the Canadian market.<sup>105</sup> In my opinion, it will be the cost of production in Canada, not lower prices, that will influence any decision to move this production abroad. And, for the most part, the cost of production is in the hands of the transfer

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101. *Protected Pre-hearing Staff Report*, revised 29 February 2000, Tribunal Exhibit NQ-99-003-7 (protected), Administrative Record, Vol. 2 at 43.

102. Tribunal Exhibit NQ-99-003-15.5B, Administrative Record, Vol. 5A at 157-58.

103. *Transcript of Public Argument*, 31 March 2000, at 49.

104. Tribunal Exhibit NQ-99-003-RI-1 (protected), Administrative Record, Vol. 10 at 84-85 and 96; and *Transcript of In Camera Hearing*, 29 March 2000, Vol. 1 at 35-36.

105. Tribunal Exhibit NQ-99-003-RI-1 (protected) Administrative Record, Vol. 10 at 164.

policies of Mallinckrodt Inc., not the market. Just as these transfer policies have insulated MCI in the past by guaranteeing a fixed gross margin whatever the level of its revenues, so too, in the future, will corporate policies determine the profitability and viability of MCI.

There was, moreover, evidence of the scope for MCI to reduce the cost of Optiray that it sells in Canada. The real cost of the ioversol, the iodine component that makes up 90 percent of the raw material costs, has been reduced significantly by the alternate synthesis ioversol.<sup>106</sup> This new lower-cost ioversol is not imported by MCI for domestic production, but only for export sale. MCI could, by having it approved, begin to import it for production for domestic consumption and, thereby, allow for a significant reduction of its cost of production in the future.

Even with the continuation of dumping, MCI, in my opinion, will not be injured in the foreseeable future. It may even be better positioned with its recent strategic alliance with Berlex. The broadened product range that has resulted from this strategic alliance<sup>107</sup> will no doubt assist it in pursuing its objective of expanding its share of the Canadian market.

To conclude, for the reasons stated above, I am of the opinion that the dumped LOCM from the United States has not caused material injury or retardation to MCI's production of LOCM, nor is there a threat of such injury in the foreseeable future.

Patricia M. Close

Patricia M. Close

Presiding Member

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106. *Transcript of Public Hearing*, Vol. 1, 28 March 2000, at 214-16; and Mallinckrodt Inc.'s 1997 Annual Report, Tribunal Exhibit NQ-99-003-24.2, Administrative Record, Vol. 5.3 at 169.

107. Tribunal Exhibit NQ-99-003-RI-1 (protected), Administrative Record, Vol. 10 at 289-313.