# Tamoxifen from the United Kingdom Final Report

Status:Archived

Dumping and Countervailing Duties Act 1988

# Table of Abbreviations

**The following abbreviations are used in this Report**:

| | |
|---|---|
| Act (the) | Dumping and Countervailing Duties Act 1988 |
| Agreement (the) | WTO Agreement on Implementation of Article VI of the GATT 1994 |
| CIF | Cost, Insurance and Freight |
| Chief Executive (the) | Chief Executive of the Ministry of Economic Development |
| CLO | Crown Law Office |
| Douglas | Douglas Pharmaceuticals Limited |
| EBIT | Earnings Before Interest and Tax |
| FOB | Free on Board |
| Generics (UK) | Generics (UK) Ltd |
| IMS | IMS (NZ) Limited |
| LDC | Less Developed Countries |
| LLDC | Least Developed Countries |
| MAT | Moving Average Total |
| Medsafe | New Zealand Medicines and Medical Devices Safety Authority |
| Ministry (the) | Ministry of Economic Development |
| NHS | National Health Service |
| Pac | Forum Island Members of the South Pacific Regional Trade and Economic Co-operation Agreement |
| Pacific | Pacific Pharmaceuticals Ltd |
| PHARMAC | Pharmaceutical Management Agency Ltd |
| Tariff (the) | The Customs Tariff of New Zealand |
| Secretary (the) | Secretary of Commerce |
| VFD | Value for Duty |
| WECO | Whangarei Engineering and Construction Ltd |
| WTO | World Trade Organisation |
| _____ | Indicates Confidential Information Deleted From Text |
| **CONFIDENTIAL** | Indicates Confidential Information Deleted From Tables |

# 1. Proceedings

## 1.1 Proceedings

On 24 July 2000, the Secretary of Commerce (now called the Chief Executive of the Ministry of Economic Development) accepted a properly documented application from Douglas Pharmaceuticals Limited (hereinafter referred to as Douglas), alleging that Tamoxifen Citrate of brand name Genox from the United Kingdom was being dumped and by reason thereof threatening to cause material injury to the New Zealand industry.

On 30 August 2000, the Secretary of Commerce formally initiated an investigation pursuant to section 10 of the Dumping and Countervailing Duties Act 1988 ("the Act"), on being satisfied that sufficient evidence had been provided that:

(a) the goods imported or intended to be imported into New Zealand were being dumped; and

(b) by reason thereof, material injury to an industry was being threatened.

The application was made in respect of one of the brands of tamoxifen imported from the United Kingdom, which won the tender round of New Zealand's Pharmaceutical Management Agency (hereinafter referred to as PHARMAC), which was for sole supply of the market for a three year period. In accordance with section 10 of the Act, the Ministry's investigation was to determine both the existence and effect of the alleged dumping of the Genox brand of tamoxifen from the United Kingdom.

The purpose of this Report is to provide a summary of the matters established by the investigating team as a basis for a determination to be made under section 13 of the Act as to whether or not the goods are being dumped and by reason thereof material injury to an industry has been or is being caused or is threatened. It should be noted that this Report provides a summary only of the information, analysis and conclusions relevant to this investigation, and should not be accorded any status beyond that.

**Grounds for the Application**

Pacific Pharmaceuticals Limited (hereinafter referred to as Pacific) won PHARMAC's tender for sole subsidised supply of tamoxifen to the New Zealand market for three years. The brand Pacific is supplying is Genox. Douglas, and presumably other suppliers of tamoxifen were unsuccessful in the tender. The newly contracted tender price was in the market from 7 July 2000. Up until 30 November 2000, the unsuccessful tenderers were still able to supply their registered brands of tamoxifen to the New Zealand market, if they had lowered their prices to the new price level, and receive a subsidy. After that date they would not receive the subsidy. PHARMAC has stated that this transition period allows the unsuccessful tenderers time for an orderly exit from the market. Douglas has stated that _____ at the new price level and as a result, sales of all other brands of tamoxifen will all but cease. From 1 December 2000, Genox supplied by Pacific is the only brand of tamoxifen subsidised under the Pharmaceutical Schedule.

Douglas claims that the price level at which the tender was won means that the goods are being dumped. Douglas claims that as a result of the alleged dumping, material injury is resulting from:

- a significant rate of increase in the volume of imports of the allegedly dumped goods, and the likelihood of substantially increased imports from the United Kingdom;
- price undercutting, and likely price depression and price suppression;

which will cause:

- decline in sales;
- decline in market share; and
- decline in profits.

The investigation was initiated by the Ministry based on the applicant's claims of threat of injury arising from the contracted price reduction of the imported Genox brand of tamoxifen. That price reduction has now been in place for some months and the investigation has considered whether actual injury has been caused to the industry. Douglas has stated in its application that the material injury resulting from the importation of allegedly dumped tamoxifen commenced on 12 July 2000 since Pacific dropped the price to the market at that time. It was later established that Pacific dropped its prices on 7 July 2000.

In response to the Essential Facts and Conclusions report, Douglas noted that the tender results were announced on 30 May 2000 and stated that "injury commenced from at least that date". It was stated that this was when Douglas knew that it had lost its business of producing Tamoxifen Citrate for the New Zealand domestic market.

It should be noted that the Ministry approaches investigations on the basis that injury and threat of injury are alternatives, i.e. an industry is either injured or threatened with injury, but both cannot apply at the same time, although an investigation may be required to ascertain which is applicable.

# 1.2 Interested Parties

**New Zealand Industry**

The application was submitted by Douglas. The [Chief Executive of the Ministry of Economic Development] was satisfied that the application was made by or on behalf of the New Zealand industry producing like goods, and had the amount of support required by section 10(3) of the Act.

**Importers and Exporters**

From the information available to the Ministry, the importer and exporter of tamoxifen with brand name Genox, subject to the investigation for the year ended August 2000 were:

**Importer**

Pacific Pharmaceuticals Limited

**Exporter**

Generics (UK) Limited

# 1.3 Imported Goods

The goods which are the subject of the application, hereinafter referred to as tamoxifen, or "subject goods", are:

*Tamoxifen Citrate (with brand name Genox) in any form or presentation.*

The New Zealand Customs Department has stated that Tamoxifen Citrate enters under the following tariff classification:

| | | |
|---|---|---|
| 3004 | | Medicaments (excluding goods of heading No. 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms or packings for retail sale: |
| [*3004.10* | - | *Containing penicillin's or derivatives thereof, with a penicillanic acid structure, or streptomycin's or their derivatives* |
| *3004.20* | - | *Containing other antibiotics:* |
| | - | *Containing hormones or other products of heading No. 29.37 but not containing antibiotics:* |
| *3004.40* | - | *Containing alkaloids or derivatives thereof but not containing hormones, other products of heading No. 29.37 or antibiotics:* |
| *3004.50* | - | *Other medicaments containing vitamins or other products of heading No. 29.36:]* |
| 3004.90 | - | Other |
| *[3004.90.01 00K* | - - | *For veterinary medicine]* |
| | - - | Other |
| *[3004.90.11 00E* | - - - | *Organo-therapeutic glands and other goods of heading No. 30.01 put up in measured doses or in forms or in packings of a kind sold by retail]* |
| 3004.90.19 | - - - | Other |
| | *[. . . .* | *In aerosol containers:* |
| | *02B . . . . .* | *Containing* chlorofluorocarbons |
| | *08A . . . .* | *Other]* |
| | 19G . . . . | Other |

Imports of the goods subject to this application have been free of duty since 1 July 1997.

Section 3(6) of the Act provides as follows:

For the purposes of this Act, where, during the exportation of goods to New Zealand, the goods pass in transit from a country through another country, that other country shall be disregarded in ascertaining the country of export of the goods.

and section 5(5) provides:

Where—

(a) The actual country of export of goods imported or intended to be imported into New Zealand is not the country of origin of the goods; and

(b) The [Chief Executive of the Ministry of Economic Development] is of the opinion that the normal value of the goods should be ascertained for the purposes of this Act as if the country of origin were the country of export,—

the [Chief Executive of the Ministry of Economic Development] may direct that the normal value of the goods shall be so ascertained.

In the current investigation, the subject goods were produced in and exported from the United Kingdom, direct to New Zealand therefore sections 3(6) and 5(5) of the Act are not relevant.

## 1.4 Investigation Details

In this Report, unless otherwise stated, years are March years and dollar values are New Zealand dollars. In tables, column totals may differ from individual figures because of rounding. The term VFD refers to value for duty for Customs purposes.

The period of investigation for dumping is 1 September 1999 to 31 August 2000 while the investigation of injury involves evaluation of data for the period 1 April 1997 to the latest available information.

In response to the Essential Facts and Conclusions, Blackburn Croft clarified that the date the result of the tender being announced was the date at which injury commenced.

## 1.5 Exchange Rates

Article 2.4.1 of the Agreement provides as follows:

When the comparison under paragraph 4 [of Article 2] requires a conversion of currencies, such conversion should be made using the rate of exchange on the date of sale8, provided that when a sale of foreign currency on forward markets is directly linked to the export sale involved, the rate of exchange in the forward sale shall be used. Fluctuations in exchange rates shall be ignored and in an investigation the authorities shall allow exporters at least 60 days to have adjusted their export prices to reflect sustained movements in exchange rates during the period of investigation.

8 Normally, the date of sale would be the date of contract, purchase order, order confirmation, or invoice, whichever establishes the material terms of sale.

Over the period of investigation Genox was exported from the United Kingdom direct to New Zealand. Generics (UK) invoiced its sales to Pacific in _____ were made.

In examining whether transactions were made at arm's length the Ministry used exchange rate conversions made at the inter-bank rate taken for the OANDA Internet currency converter http:/www.oanda.com.

## 1.6 Disclosure of Information

The Ministry of Economic Development makes available all non-confidential information to any interested party through its Public File system.

Article 6.7 of the Agreement provides as follows:

In order to verify information provided or to obtain further details, the authorities may carry out investigations in the territory of other Members as required, provided they obtain the agreement of the firms concerned and notify the representatives of the government of the Member in question, and unless that Member objects to the investigation. The procedures described in Annex I shall apply to investigations carried out in the territory of other Members. Subject to the requirement to protect confidential information, the authorities shall make the results of any such investigations available, or shall provide disclosure thereof pursuant to paragraph 9, to the firms to which they pertain and may make such results available to the applicants.

A verification visit was made to the following exporter:

Generics (UK) Limited

A copy of the Verification Report was provided to the exporter visited, and a non-confidential copy was placed on the Public File.

Article 6.8 of the Agreement provides as follows:

In cases in which any interested party refuses access to, or otherwise does not provide, necessary information within a reasonable period or significantly impedes the investigation, preliminary and final determinations, affirmative or negative, may be made on the basis of the facts available. The provisions of Annex II shall be observed in the application of this paragraph.

Information was requested, but not received to the extent required from Generics (UK) as explained below.

Information pertaining to domestic prices for the full period of investigation was requested from Generics (UK) to make the comparison between export prices and normal values on a transaction-to-transaction basis. Generics (UK) provided a list of monthly weighted average domestic prices (unadjusted) for the full period of investigation and domestic tax invoices from May 2000 to September 2000.

Generics (UK) argued at the verification visit that Douglas had not complained of the period prior to _____) and _____ as they were considered to be irrelevant. Generics (UK) advised that the allegation of dumping related _____ prices that coincided with Pacific's successful tender with PHARMAC for sole subsidised supply of the New Zealand market and these transactions occurred from _____ onwards.

A comparison on a weighted average basis for the earlier part of the period of the investigation and on a transaction-to-transaction basis for the latter part of the period of

investigation did not appear to the Ministry to be a consistent or appropriate approach. Generics (UK) indicated towards the end of the investigation that it would provide further information in respect of normal values in the earlier period of the investigation, but this had not been received when this report was finalised. The investigation team used normal values provided by the applicant for the period _____, which allowed the Ministry to complete its comparison on a transaction-to-transaction basis for the full period of investigation.

Section 10a of the Act provides as follows:

(1) Subject to subsection (2) of this section, within 150 days after the initiation of an investigation under section 10 of this Act, the [Chief Executive of the Ministry of Economic Development] shall give to the parties to the investigation referred to in section 9(b) of this Act written advice of the essential facts and conclusions that will likely form the basis for any final determination to be made under section 13 of this Act.

(2) Nothing in subsection (1) of this section limits the Official Information Act 1982 or section 10(7) of this Act.

The Essential Facts and Conclusions were provided to interested parties on 19 January 2001. Comments were received from Douglas Pharmaceuticals (through Blackburn Croft), Generics (UK) and Pacific (through Bell Gully), and from PHARMAC.

# 2. New Zealand Industry

Section 3a provides the definition of "industry":

3a. Meaning of "industry"—For the purposes of this Act, the term ‘industry’, in relation to any goods, means—

(a) The New Zealand producers of like goods; or

(b) Such New Zealand producers of like goods whose collective output constitutes a major proportion of the New Zealand production of like goods.

"Like goods" is defined in section 3 of the Act:

"Like goods", in relation to any goods, means—

(a) Other goods that are like those goods in all respects; or

(b) In the absence of goods referred to in paragraph (a) of this definition, goods which have characteristics closely resembling those goods:

## 2.1 Like Goods

In order to establish the existence and extent of the New Zealand industry for the purposes of an investigation into injury, and having identified the subject goods, it is necessary to determine whether there are New Zealand producers of goods which are like those goods in all respects, and if not, whether there are New Zealand producers of other goods which have characteristics closely resembling the subject goods.

The subject goods have been identified in section 1.3 of this Report as:

*Tamoxifen Citrate (with brand name Genox) in any form or presentation.*

Douglas produces Tamoxifen Citrate with the brand name Tamofen for the domestic market, and exports tamoxifen of brand name Tamoxen to the Australian market. Douglas has identified the allegedly dumped goods as being the prescription pharmaceutical Tamoxifen Citrate of the brand name Genox, which was being imported from the United Kingdom. Douglas states that this is a generic drug (not on patent) and that there were other brands of tamoxifen in the market.

Douglas claims that Tamofen is a like good to the Genox being imported.

**Like Goods Considerations**

In deciding like goods issues the Ministry takes into account the following considerations:

a. Physical characteristics, which cover appearance, size and dimensions, components, production methods and technology.
b. Function and usage. This covers consumer perceptions and expectations, end uses, and will lead to any conclusions on the issue of substitutability where relevant.
c. Pricing structures.
d. Marketing issues such as distribution channels and customer advertising.
e. Other. This can include tariff classification if applicable, and any other matters which could be applicable in the circumstances.

The following information has been provided by interested parties about the New Zealand and United Kingdom products.

**Physical Characteristics**

The tamoxifen is the active ingredient and the citrate is included only to stabilise the tamoxifen for the purpose of manufacture and shelf life. There are other differences in the composition of the tablets but these do not have any known therapeutic effect. Pacific, in its response to the importer's questionnaire, provided a table comparing the physical characteristics and composition between Genox, the imported product, and Tamofen, the domestic product. The Ministry has amended this table provided by Pacific with more specific information from interested parties as follows:

| | Genox 10 Tablets Pacific) Tamoxifen (as Citrate) | Tamofen Tablets 10mg Tamoxifen (as Citrate) |
|---|---|---|
| | CONFIDENTIAL | CONFIDENTIAL |
| | CONFIDENTIAL | CONFIDENTIAL |
| | CONFIDENTIAL | CONFIDENTIAL |
| | CONFIDENTIAL | CONFIDENTIAL |
| | CONFIDENTIAL | CONFIDENTIAL |
| | CONFIDENTIAL | CONFIDENTIAL |
| Shape | CONFIDENTIAL | CONFIDENTIAL |

| | | |
|---|---|---|
| Diameter | CONFIDENTIAL | CONFIDENTIAL |
| Weight | CONFIDENTIAL | CONFIDENTIAL |
| Debossing; Side 1 | CONFIDENTIAL | CONFIDENTIAL |
| Side 2 | CONFIDENTIAL | CONFIDENTIAL |
| Packaging | CONFIDENTIAL | CONFIDENTIAL |
| | CONFIDENTIAL | CONFIDENTIAL |
| Pack | 30 tablets | 30 tablets |

| | | |
|---|---|---|
| | Genox 20 Tablets (Pacific) | Tamofen Tablets 20 mg (Douglas) |
| | Tamoxifen (as Citrate) | Tamoxifen (as Citrate) |
| | CONFIDENTIAL | CONFIDENTIAL |
| | CONFIDENTIAL | CONFIDENTIAL |
| | CONFIDENTIAL | CONFIDENTIAL |
| | CONFIDENTIAL | CONFIDENTIAL |
| | CONFIDENTIAL | CONFIDENTIAL |
| | CONFIDENTIAL | CONFIDENTIAL |
| Shape | CONFIDENTIAL | CONFIDENTIAL |
| Diameter | CONFIDENTIAL | CONFIDENTIAL |
| Weight | CONFIDENTIAL | CONFIDENTIAL |
| Debossing; Side 1 | CONFIDENTIAL | CONFIDENTIAL |
| Side 2 | CONFIDENTIAL | CONFIDENTIAL |
| Packaging | CONFIDENTIAL | CONFIDENTIAL |
| | CONFIDENTIAL | CONFIDENTIAL |
| Pack | 30 tablets | 30 tablets |

The information in the table shows that there are differences in some of the ingredients used to make up the domestic and the imported tamoxifen. The information available indicates that these ingredients, other than the tamoxifen, have no known influence on the pharmaceutical's effectiveness. The difference in ingredients between the two products reflects the different manufacturing processes used to make the subject goods and the domestically made product. The information provided indicates that the subject goods are manufactured _____ and that Tamofen is made _____. All Tamoxifen Citrate must be manufactured in a toxic substances suite requiring a completely separate facility within the manufacturing plant. Specific procedures must be followed when dealing with cyto-toxic chemicals and significant downtime is required to clean equipment between each production run.

**Function and Use**

The Tamoxifen Citrate brands available in New Zealand are non-steroidal, anti-oestrogenic medicines. They block the actions of oestrogen in the body. Certain types of breast cancer

require oestrogen to grow. Tamoxifen is used to treat and prevent some types of breast cancer. All the brands contain the same active ingredient, tamoxifen, which gives the same therapeutic effect. They are prescribed in oral doses of 20 to 40 mg once daily. There are a number of potential pharmaceutical substitutes currently being trialled (see details under Developments in Technology in Section 4.7 of this report) showing similar or potentially improved effects. From the information available these pharmaceuticals are not yet generally available.

#### Pricing

The pricing of Tamofen in the New Zealand market prior to the implementation of the new tender round price, was the same as that of the subject goods. The pricing between the brands has only changed since Pacific introduced the new lower price to the market.

#### Marketing

Prior to the new price, the information available indicates that all tamoxifen was marketed and distributed in similar ways in the New Zealand market. Both products were offered to pharmacies at the listed price _____

#### Other

Tamoxifen Citrate from all manufacturers is classified under the same tariff item 3004.90.19 19G which includes a range of other medicaments and is not decisive in defining the product.

### Conclusion

The Tamofen brand produced by the industry is not the same in all respects as the imported Genox. Both brands are similar in that they have the same function and use including the same active ingredient, which gives the same therapeutic effect, and are administered in the same dosages regardless of the brand. There are some common non-active ingredients, all are presented as tablets, they had the same subsidised pricing levels set by PHARMAC prior to the new tender price level, and have similar marketing and distribution systems. The main differences would seem to be some different non-active ingredients making up the tablets and the different processes by which they are made.

On the basis of the information available, the Ministry considers that the tamoxifen tablets produced by Douglas have characteristics closely resembling the subject goods, and are therefore like goods to the subject goods.

## 2.2 New Zealand Industry

The New Zealand producer of like goods is Douglas Pharmaceuticals Limited. The investigation was initiated on the basis that the application met the requirements of section 10(3) with regard to required levels of support, and that the applicant had standing to make an application. Douglas is the only known producer of Tamoxifen Citrate in New Zealand.

## 2.3 Imports of Tamoxifen

Tamoxifen is not separately identified in the Customs Tariff and all imports are not identifiable from the Customs data. The Ministry has therefore used data collected by IMS (NZ) Limited (IMS), a market survey company, to provide more accurate information on the volume of sales which can be used for a close approximation of the volume of imports. The following table shows import volumes into New Zealand on this basis from 1998. MAT (moving average total) October 2000 figures are for a full year to 31 October.

Table 2.1: Imports of Tamoxifen
March Years (30 x 20mg equivalent packs

| | 1998 | 1999 | 2000 | MAT Oct 2000 |
|---|---|---|---|---|
| Subject Goods | | | | |
| - Genox | | Decline | Increase | Increase |
| Other Imports | | | | |
| - Nolvadex | | Decline | Increase | Decline |
| - Estroxyn | | Static | Static | Static |
| Total Imports | | Decline | Increase | Increase |

## 2.4 New Zealand Market

The following table shows the New Zealand market for tamoxifen and is based on the IMS data up to and including October 2000. The IMS data recording the New Zealand Industry's sales is representative of the volume of production.

Table 2.2: New Zealand Market
Years to March (30 x 20mg equivalent packs)

| | 1998 | 1999 | 2000 MAT | Oct 2000 |
|---|---|---|---|---|
| Subject Goods (Genox) | | Decline | Increase | Increase |
| Other Imports | | Decline | Increase | Decline |
| Total Imports | | Decline | Increase | Increase |
| NZ Industry Sales | | Increase | Decline | Decline |
| NZ Market | | Increase | Increase | Increase |

Tamoxifen Citrate is used mainly in the treatment of breast cancer and as such there are only minor changes in the total volume of tamoxifen sold in the New Zealand market over the period. The significant changes are the decline in the industry sales in the MAT October year and the significant increase in volume of imports of the subject goods over the same period.

# 3. Dumping Investigation

Section 3(1) of the Act states:

"Dumping", in relation to goods, means the situation where the export price of goods imported into New Zealand or intended to be imported into New Zealand is less than the normal value of the goods as determined in accordance with the provisions of this Act, and 'dumped' has a corresponding meaning:

# 3.1 Export Prices

Export prices are determined in accordance with section 4(1) of the Act, which states (inter alia) as follows:

(1) Subject to this section, for the purposes of this Act, the export price of any goods imported or intended to be imported into New Zealand which have been purchased by the importer from the exporter shall be —

(a)Where the purchase of the goods by the importer was an arm's length transaction, the price paid or payable for the goods by the importer other than any part of that price that represents -

(i)Costs, charges, and expenses incurred in preparing the goods for shipment to New Zealand that are additional to those costs, charges, and expenses generally incurred on sales for home consumption; and

(ii)Any other costs, charges, and expenses resulting from the exportation of the goods, or arising after their shipment from the country of export;or

Section 4(1)(b) of the Act provides as follows:

(b) Where the purchase of the goods by the importer was not an arm's length transaction, and the goods are subsequently sold by the importer in the condition in which they were imported to a person who is not related to the importer, the price at which the goods were sold by the importer to that person less the sum of the following amounts:

(i) The amount of any duties and taxes imposed under any Act; and

(ii) The amount of any costs, charges, or expenses arising in relation to the goods after exportation; and

(iii) The amount of the profit, if any, on the sale by the importer or, where the [Chief Executive of the Ministry of Economic Development] so directs, an amount calculated in accordance with such rate as the [Chief Executive of the Ministry of Economic Development] determines as the rate of profit on the sale by the importer having regard to the rate of profit that would normally be realised on sales of goods of the same category by the importer where such sales exist.

In relation to arm’s length transactions, section 3(2) and 3(3) of the Act provide as follows:

(2) For the purposes of this Act, a purchase or sale of goods shall not be treated as an arm's length transaction if -

(a) There is any consideration payable for or in respect of the goods other than their price; or

(b) The price is influenced by a relationship between the buyer, or a related person, and the seller, or a related person; or

(c) In the opinion of the [Chief Executive of the Ministry of Economic Development], the buyer, or a person related to the buyer, will, directly or indirectly, be reimbursed, be compensated, or otherwise receive a benefit for, or in respect of, the whole or any part of the price.

(3) Where goods are imported into New Zealand and are purchased by the importer from the exporter (whether before or after exportation) for a particular price and the [Chief Executive of the Ministry of Economic Development] is satisfied, after having regard to -

(a) The amount of the price paid or to be paid for the goods by the importer; and

(b) Such other amounts as the [Chief Executive of the Ministry of Economic Development] determines to be costs necessarily incurred in the importation and sale of the goods; and

(c) The likelihood that the amounts referred to in paragraph (a) and paragraph (b) of this subsection will be able to be recovered within a reasonable time; and

(d) Such other matters as the [Chief Executive of the Ministry of Economic Development] considers relevant,-

that the importer, whether directly or through a related person, sells those goods in New Zealand (whether in the condition in which they were imported or otherwise) at a loss, the [Chief Executive of the Ministry of Economic Development] may treat the sale of those goods as indicating that the importer or a related person will, directly or indirectly, be reimbursed, be compensated, or otherwise receive a benefit for, or in respect of, the whole or any part of the price for the purposes of subsection (2)(c) of this section.

Sections 3(4) and (5) of the Act refer to relationships as follows:

(4) For the purposes of this Act, a person shall be deemed to be related to another person if -

(a) One of them directly or indirectly controls the other (within the meaning of subsection (5) of this section); or

(b) Both of them are directly or indirectly controlled by a third person (within that meaning); or

(c) Together they directly or indirectly control a third person (within that meaning).

(5) For the purposes of subsection (4) of this section, a person controls another person if the first-mentioned person is in a position, whether legally or operationally, to exercise restraint or direction over the other person.

In relation to the use of best information available in ascertaining export price and normal value, section 6 of the Act provides as follows:

(1) Where the [Chief Executive of the Ministry of Economic Development] is satisfied that sufficient information has not been furnished or is not available to enable the export price of goods to be ascertained under section 4 of this Act, or the normal value of goods to be ascertained under section 5 of this Act, the normal value or export price, as the case may be, shall be such amount as is determined by the [Chief Executive of the Ministry of Economic Development] having regard to all available information.

(2) For the purposes of subsection (1) of this section, the [Chief Executive of the Ministry of Economic Development] may disregard any information that the [Chief Executive of the Ministry of Economic Development] considers to be unreliable.

## Generics (UK) Limited

Generics (UK) is a pharmaceutical manufacturer producing tablets and capsules for the United Kingdom market as well as for export to New Zealand. Generics (UK) is a 100% subsidiary of Merck KgaA, a German pharmaceutical company. Merck KgaA owns 100% of Merck Generics Group BV which owns 100% of Pacific Pharmaceuticals Limited (Pacific). Brochures disclose that Merck Generics Group of companies is one of the worlds leading internationally based generic pharmaceutical groups specialising in development, production, marketing and distribution of generic drugs.

#### Base Prices

The sales from Generics (UK) to Pacific have been treated as arm’s length transactions. The companies are related but it is considered that the transactions have not been influenced by

this relationship and that the export prices have not been artificially inflated. This is explained in more detail below:

- Generics (UK) and Pacific are sister companies within the Merck Generic Group of companies. Both companies _____ and Merck KgaA is in a position legally to exercise restraint or direction over both Generics (UK) and Pacific. However, there is no evidence that Merck KgaA has any involvement in the day to day running of either company and does not have an influence on prices; and
- There is no evidence that Pacific, or a person or entity related to Pacific (including Merck KgaA and Merck Generics Group BV) will directly or indirectly, be reimbursed, be compensated, or otherwise receive a benefit for, or in respect of, the whole or any part of the price. The financial information showed that Pacific sold Genox in New Zealand at a profit therefore section 3(3) of the Act does not apply; and
- The Ministry in its investigations constructed an export price in accordance with section 4(1)(b) of the Act to test whether the prices had been affected by the relationship between companies. Deductions were made for all costs incurred between the point of resale in New Zealand back to the ex-factory level of sale in the United Kingdom. This analysis indicated that actual export prices had not been artificially inflated thereby hiding or decreasing any apparent margin of dumping.

Base prices are ___ prices charged to Pacific by Generics (UK).

#### Adjustments

Adjustments have been made to base prices for overseas insurance, airfreight, document-handling charge, delivery/pickup charge and fuel surcharge. Pacific and Generics (UK) sell to each other many pharmaceutical commodities and _____ and no cost of credit adjustment was needed.

### Export Prices

Export prices were established for each consignment to New Zealand, relative to the two different strengths of tamoxifen, during the period of investigation by deducting the adjustments described above from the base prices.

## 3.2 Normal Values

Normal values are determined in accordance with section 5 of the Act.

(1) Subject to this section, for the purposes of this Act, the normal value of any goods imported or intended to be imported into New Zealand shall be the price paid for like goods sold in the ordinary course of trade for home consumption in the country of export in sales that are arm's length transactions by the exporter or, if like goods are not so sold by the exporter, by other sellers of like goods.

(2) Where the [Chief Executive of the Ministry of Economic Development] is satisfied that the normal value of goods imported or intended to be imported into New Zealand cannot be determined under subsection (1) of this section because-

(a) There is an absence of sales that would be relevant for the purpose of determining a price under that subsection; or

(b) The situation in the relevant market is such that sales in that market that would otherwise be relevant for the purpose of determining a price under subsection (1) of this section are not suitable for use in determining such a price; or

(c) Like goods are not sold in the ordinary course of trade for home consumption in the country of export in sales that are arm's length transactions by the exporter and it is not practicable to obtain within a reasonable time information in relation to sales by other sellers of like goods that would be relevant for the purpose of determining a price under subsection (1) of this section, -

the [Chief Executive of the Ministry of Economic Development] may determine that the normal value, for the purposes of this Act, shall be either-

(d) The sum of -

(i) Such amount as is determined by the [Chief Executive of the Ministry of Economic Development] to be the cost of production or manufacture of the goods in the country of export; and

(ii) On the assumption that the goods, instead of being exported, had been sold for home consumption in the ordinary course of trade in the country of export,-

(A) Such amounts as the [Chief Executive of the Ministry of Economic Development] determines would be reasonable amounts for administrative and selling costs, delivery charges, and other charges incurred in the sale; and

(B) An amount calculated in accordance with such rate as the [Chief Executive of the Ministry of Economic Development] determines would be the rate of profit on that sale having regard to the rate of profit normally realised on sales of goods (where such sales exist) of the same general category in the domestic market of the country of export of the goods; or

(e) The price that is representative of the price paid for similar quantities of like goods sold at arm's length in the ordinary course of trade in the country of export for export to a third country.

(3) Where the normal value of goods imported or intended to be imported into New Zealand is the price paid for like goods, in order to effect a fair comparison for the purposes of this Act, the normal value and the export price shall be compared by the [Chief Executive of the Ministry of Economic Development] -

(a) At the same level of trade; and

(b) In respect of sales made at as nearly as possible the same time; and

(c) With due allowances made as appropriate for any differences in terms and conditions of sales, levels of trade, taxation, quantities, and physical characteristics, and any other differences that affect price comparability.

(4) Where the normal value of goods exported to New Zealand is to be ascertained in accordance with subsection (2) of this section, the [Chief Executive of the Ministry of Economic Development] shall make such adjustments as are necessary to ensure that the normal value so ascertained is properly comparable with the export price of those goods.

(5) Where -

(a) The actual country of export of goods imported or intended to be imported into New Zealand is not the country of origin of the goods; and

(b) The [Chief Executive of the Ministry of Economic Development] is of the opinion that the normal value of the goods should be ascertained for the purposes of this Act as if the country of origin were the country of export, -

the [Chief Executive of the Ministry of Economic Development] may direct that the normal value of the goods shall be so ascertained.

(6) Where the [Chief Executive of the Ministry of Economic Development] is satisfied, in relation to goods imported or intended to be imported into New Zealand, that -

(a) The price paid for like goods -

(i) Sold for home consumption in the country of export in sales that are arm's length transactions; or

(ii) Sold in the country of export to a third country in sales that are arm's length transactions,-

is, and has been for an extended period of time and in respect of a substantial quantity of like goods, less than the sum of -

(iii) Such amount as the [Chief Executive of the Ministry of Economic Development] determines to be the cost of production or manufacture of the like goods in the country of export; and

(iv) Such amounts as the [Chief Executive of the Ministry of Economic Development] determines to be reasonable amounts for administrative and selling costs, delivery charges, and other charges necessarily incurred in the sale of the like goods by the seller of the goods; and

(b) It is likely that the seller of those like goods will not be able to fully recover the amounts referred to in subparagraphs (iii) and (iv) of paragraph (a) of this subsection within a reasonable period of time,-

the price so paid for those like goods shall be deemed not to have been paid in the ordinary course of trade.

## Generics (UK) Limited

**Base Prices**

Generics (UK) sell generic medicines, including Tamoxifen Citrate, mainly to wholesalers (distributors) and a small proportion to hospitals under local contracts. Generics (UK) is not related to any of its domestic customers and transactions are considered to be at arm's length.

The investigating team selected a group of _____ wholesalers, the _____ as an appropriate group of domestic customers for purposes of comparison of domestic with export sales. This group of customers was selected on the basis that the group was a similar customer to Pacific in terms of the functions it carried out, the way it is treated by Generics (UK), the level of trade and volume of sales.

The investigating team was satisfied that sales on the domestic market were not made at a loss and were produced in sufficient quantities to be used to establish normal values. Base prices were determined by the investigating team from the verified information obtained during the overseas industry verification visit.

In response to the Essential Facts and Conclusions report, Blackburn Croft again queried whether normal values are reliable for purposes of establishing normal values. Blackburn Croft notes that, while the Ministry found that Tamoxifen was sold by Generics (UK) at a profit, profit obtained on other products would assist in ascertaining whether domestic prices are reliable. Blackburn Croft observes that profit obtained on other products is not necessarily relevant and the Ministry agrees, as it would expect that profit levels would differ between different pharmaceutical products. EBIT on Generics' domestic sales of Tamoxifen from

May to July varied, between ___ and ____ of selling prices. Generics (UK)'s operating profit over all products for the year to 31 August 2000 of ____ of sales revenue falls within this range.

Blackburn Croft also queried whether there was evidence of the significant price changes that occurred in the United Kingdom market during the period of investigation. The Ministry refers to attachments to Generics (UK)'s response to the Manufacturers Questionnaire relating to the disruption in supply of generics in general in the United Kingdom market and notes that company information sighted at the verification visit was not inconsistent with those reports. In summary, the combination of the following events resulted, in 1999, in a shortage of supply of generic medicines in the United Kingdom and consequent price increases:

- A major UK supplier, Regent GM Laboratories, suspended production at the end of 1998;
- Two other large manufacturers, APS and Norton, moved their operations offshore; and
- An EEC directive that medicines be dispensed in a tamper proof patient pack caused disruption.

Generics (UK) states that the supply problems of 1999 have now been resolved and this resolution "together with the introduction of Lord Hunt's maximum price scheme, which set ceiling wholesale prices, has meant that prices are now declining towards their 1998 levels".

For the period from _____, base prices for assessing normal values are ___ prices invoiced to _____ customers for sales at as nearly as possible the same time as the export sales, being the invoice dates.

Generics (UK) considered that comparison of export prices with normal values _____ and the time of the announcement of Pacific's successful tender bid were irrelevant. Generics (UK) did not provide domestic prices on a transaction basis. In the absence of that information, for the period _____, the Ministry used the normal values provided by Douglas in its application for the period _____

Bell Gully (acting for Pacific and Generics) submits that normal values provided by the applicant should not be used in a transaction-to-transaction comparison as such normal values do not represent transaction information but instead are derived from the pharmacist maximum prices listed in the United Kingdom Drug Tariff. In addition, Bell Gully advised that there is generally _____ and it considers, therefore, that monthly weighted average figures _____. The Ministry sought confirmation of this situation from Generics (UK)'s representatives.

In response to the Essential Facts and Conclusions report, Bell Gully notes that the Ministry's use of the applicant's normal values _____ results in normal values that are "artificially high" and "at the wrong level of trade".

Generics (UK) was given the opportunity to provide normal values for that period at the time of the verification and declined to do so. As indicated above, at a later stage Generics (UK) indicated that it would provide information for this period, however, this further information

had not been provided at the time this report was being finalised. The Ministry has used, therefore, the normal values provided by the applicant. The Ministry notes that the values it used were based on published information, but had been significantly reduced to be comparable with estimated export prices at the ex-factory level. The Ministry notes that export prices were _____ higher than assessed normal values in the period _____, and that no dumping margins were found during that period, even though the Ministry used the applicant's normal value information that was claimed to be artificially high.

**Submissions from Interested Parties**

**Situation in the United Kingdom Market**

PHARMAC considers that the situation in the United Kingdom market is such that sales in that market are not suitable for use in determining normal values in accordance with section 5(1) of the Act because of the situation in the UK market, namely "there is no buyer in the UK market offering sole supplier status for periods as long as in the PHARMAC contracts for similarly assured levels of sales". PHARMAC considers construction of normal values is not appropriate because allocation of overheads would be an arbitrary matter as fixed costs relating to manufacture and sale of a wide range of products of different values would need to be allocated to Tamoxifen Citrate.

PHARMAC considers that export prices should be compared with representative prices for sales to third countries. Factors that PHARMAC considers should be taken into account by the Ministry in order to ensure that the normal value is properly comparable with the export price involve identifying appropriate functional markets, which are as far as possible comparable with the PHARMAC tender market, identifying comparable prices and the relevant source market. PHARMAC suggests that "the closest relevant comparison would appear to be with similar term bulk supply contract prices throughout the European Union where quantities are predictable".

The Ministry considers that, if normal values could not be established using section 5(1) of the Act, it would be able to construct normal values from the costing information provided by Generics (UK). The problem of allocation of overhead costs to individual product lines is one that is common to many manufacturing enterprises producing more than one product line. In these circumstances, the Ministry assesses the reasonableness of methods used to allocate overhead costs to a particular product. The Ministry notes that it prefers not to use prices of sales to third countries, as the basis for normal values as it is possible that such sales may also be dumped.

Other parties to the investigation did not consider that a particular market situation existed that prevented the use of section 5(1) of the Act. Generics (UK) considered that sales to wholesalers in the United Kingdom were suitable for comparison with export prices to New Zealand. Generics (UK) did not argue that the situation in the United Kingdom market was such that domestic sales were not suitable for use in determining arm's length prices in the ordinary course of trade. Blackburn Croft on behalf of Douglas argued that prices in the United Kingdom market were competitive.

The Ministry considers that a competitive market situation exists in the United Kingdom in respect of sales of generic medicines and there is no reason for sales to be regarded as unsuitable due to a particular market situation in the United Kingdom. The Ministry notes

that while the exporter will have sole supply of the New Zealand market for two-and-a-half years it achieved this as a result of its customer's successful tender in a competitive situation. The Ministry notes that the New Zealand market size is limited and that for comparison purposes it selected a group of customers in the United Kingdom to whom sales of a similar volume had been made.

#### Level of Trade

PHARMAC indicated early in the investigation that prices for sales to hospitals were appropriate for comparison with export prices and in its submission provided prices to hospitals under local contracts.

Blackburn Croft considers that "the fact that Pacific won the business through a tender does not impact on the level of trade for the purposes of establishing a normal value in the country of export". Blackburn Croft considered the appropriate comparable level of trade in the UK to be "Generics selling to a wholesaler/distributor". Generics (UK) also considered this to be the appropriate level of trade.

When considering the appropriate domestic customer the Ministry considers the functions, distribution flows and place in the distribution chain and volume of sales of the New Zealand customer to establish the correct level of trade. In terms of place in the distribution chain, domestic wholesalers were considered to be at an equivalent level to Pacific.

Wholesalers in the United Kingdom were either _____ wholesalers or _____ wholesalers. The _____ wholesalers tended to dominate the distribution of _____ whereas _____ wholesalers distributed most of the _____ medicines. In terms of function the most appropriate customer type at the same level of trade as Pacific appeared to be _____ wholesalers. In terms of a _____ wholesaler's sales volume, the _____ was selected.

Hospitals source tamoxifen from manufacturers under local contracts or from wholesalers. The investigating team considered Pacific to be at a higher level of trade than hospitals as Pacific sells to hospitals, wholesalers and pharmacists and does not provide medicines direct to patients. In terms of volume of sales _____ were sold to __ hospitals in the United Kingdom, whereas sales to Pacific alone over the investigation period were several times higher at _____.

#### Comparison of Unbranded Domestic Sales with Branded Export Sales

The base prices for normal values selected by the Ministry are for UK sales of an unbranded product. Generics (UK) sells tamoxifen on its domestic market as a generic product "Tamoxifen Tablets BP" with the company name and logo.

Export prices are based on sales to New Zealand of a branded product. Tamoxifen Citrate exported by Generics (UK) and sold by Pacific on the New Zealand market is labelled 'Genox 20' (20mg) or 'Genox 10 ' (10mg).

### Submissions by Interested Parties

Submissions were received from representatives of the New Zealand industry arguing that export prices of a branded product should not be compared with domestic prices for an

unbranded product, and from representatives of the exporter arguing that branding did not affect the comparison.

**New Zealand Industry**

Blackburn Croft suggested to the Ministry, that to effect a fair comparison, it should start with the price of a branded product sold in the United Kingdom properly adjusted so that it can be compared with the export price of a branded product. Blackburn Croft argues that the fact that Generics (UK) does not sell a branded form of Tamoxifen Citrate in the UK "is not an acceptable reason for the Ministry to use the lower unbranded price as the starting point to establish a normal value".

Blackburn Croft observes that Genox is not recorded on the Intellectual Property Office of New Zealand (IPONZ) database, but notes that "the long established use of the trade name, will, presumably allow Generics (and/or its customers) to ensure the name is not used by any other party". Blackburn Croft advises that it appears that Genox is a trade name and that Generics (UK) would not manufacture Tamoxifen Citrate for an unrelated third party wanting to use its trade name. Blackburn Croft considers the export sale of Tamoxifen Citrate under the name Genox to other markets, for example Australia, demonstrates that the exported Tamoxifen Citrate is a brand name and cannot be correctly compared with an unbranded sale in the United Kingdom.

Blackburn Croft refers to the value of a brand and notes that, because the brand Genox appears to have been available for sale in New Zealand since December 1985 (10mg) and February 1987 (20mg), it would have achieved some value after this length of time in the market.

Blackburn Croft suggests that the relationship between Generics (UK) and Pacific distinguishes Generics (UK)’s sales of Genox from examples of transactions where an independent manufacturer sells to a brand holder, for example ‘Reebok’, which subsequently realises a price premium due to the brand.

Blackburn Croft considers Genox is, or was, prior to the de-listing of other products, sold in New Zealand as a branded form of Tamoxifen Citrate. Blackburn Croft considers it is incorrect for the Ministry to look at the market subsequent to the effects of the dumping and say it is an unbranded market. Blackburn Croft considers it is clear that, prior to de-listing of branded products, New Zealand was a branded market for Tamoxifen Citrate. Blackburn Croft also notes that for Generics (UK) to make a sale of Tamoxifen Citrate to New Zealand [that is eligible for subsidy], it had to have a branded product. It is Blackburn Croft ’s opinion that it is only because of the dumping and the resultant material injury that the Ministry can say that New Zealand is no longer a branded market because of the sole supplier status.

Blackburn Croft considers that, by not comparing the prices of a branded export product with a branded domestic product, "the Ministry is making an interpretation which is outside of its usual practice and interpretation of the Act and the Agreement".

Blackburn Croft considers that "the Ministry is effectively allowing an adjustment for general advertising and different margins by using an unbranded price as the basis of establishing a fair comparison to the export sale of a branded product". Blackburn Croft observes that "the

Ministry does not allow adjustments off the domestic price (in the country of export) for advertising that is not related to a particular sale".

Blackburn Croft also refers to a hypothetical example involving oil filters as follows. "Purolator is a branded oil filter exported to New Zealand. The promotion of the product in New Zealand is, for argument ’s sake, left to the importer. An export sale of the Purolator brand is, however, not compared with the sale of an unbranded filter in the USA because of the little, if any, brand support in New Zealand". Blackburn Croft extends the example so that ArvinMeritor Inc (Arvin), the exporter of branded oil filters, although having property rights in the brand name, has no interest in promotion of the brand and that the importer requested the name of Purolator. In Blackburn Croft’s example, Arvin argues that the proper comparison to establish a normal value is the sale of an unbranded filter in the United States. "Arvin goes on to claim that even though it sells the Purolator brand to other export markets this is purely coincidence as importers in those markets prefer the Purolator name".

Blackburn Croft considers this example illustrates the difficulty it has "accepting the argument put to the Ministry by Generics that Genox is merely a convenient term and which should be ignored as Genox is really no different from an unbranded form of Tamoxifen Citrate".

United Kingdom Exporter

Generics (UK) advise that the originator of a product secures branded prices. In the case of Tamoxifen, the originator brand was Nolvadex and that is still sold at the same price as when it was launched. Generics (UK) advises that it does not own the Genox brand and does not incur any costs in support of the Genox brand and the price at which it sells to Pacific is not affected by whether the product is branded.

Bell Gully advises that the right to use the name Genox "_____. It can in no way be compared with UK branded products."

Bell Gully, in its letter of 4 December 2000 advises that it has demonstrated that tamoxifen sold in the United Kingdom is identical and therefore a ‘like good’ to tamoxifen sold to Pacific. The fact that Pacific has instructed Generics (UK) to put the name ‘Genox’ on the packet does not disqualify the two products from being like goods in all respects.

Bell Gully notes that the intent of Blackburn Croft’s argument "seems to be to establish a normal value which is considerably higher than the price at which Generics (UK), the exporter, sells tamoxifen in the United Kingdom". Bell Gully considers that tamoxifen sold by Generics (UK) to Pacific is like in all respects to the tamoxifen it sells on the United Kingdom market. Bell Gully emphasises that:

The good allegedly dumped, and allegedly causing material injury, is Tamoxifen. It is not a carton with a name on it. That Pacific has chosen to instruct Generics UK to provide it with Tamoxifen in packaging which has the name "Genox" on it does not change in any way the characteristics of the good being Tamoxifen.

Generics (UK) states that "unlike New Zealand, an authorised pharmaceutical that is sold in the United Kingdom with a specific brand name has a different price arrangement than one that is sold with no such specific brand name".

**The Ministry's View**

The Ministry notes that the Act requires that export prices and normal values be compared to establish whether imported goods are being dumped. Section 5(1) of the Act requires that normal values "shall be the price paid for like goods sold in the ordinary course of trade for home consumption in the country of export in sales that are arm's length transactions by the exporter, or if like goods are not so sold by the exporter, by other sellers of like goods".

Only if normal values cannot be determined under section 5(1) because of reasons set out in section 5(2), relating to an absence of relevant sales, situation in the relevant market, or lack of information on relevant sales by other exporters, may the Ministry depart from section 5(1) and construct normal values or use representative prices for sales to a third country.

The Ministry established that the United Kingdom exporter, Generics (UK), made arm's length sales of like goods in the ordinary course of trade for the United Kingdom market. The Ministry considers that, although Tamoxifen Citrate sold by Generics (UK) is not exactly the same in all respects as the exported Genox, it has characteristics closely resembling the subject goods and is therefore like goods to the subject goods.

Generics (UK)'s domestic sales were of unbranded product. Two other sellers (Pharmacia & Upjohn and Zeneca) sold like goods in the United Kingdom market in the form of branded product, but prices of these branded products could only be used by the Ministry if the exporter, Generics (UK), was not selling like goods in arm's length transactions in the ordinary course of trade in the United Kingdom market. This was not the case since Generics (UK) was making such sales. The Ministry used Generics (UK)'s prices for domestic sales of like goods, in the form of unbranded tamoxifen, as the base prices for assessing normal values and then considered whether due allowance needed to be made to ensure a fair comparison between normal values and export prices.

The Ministry disagrees with Blackburn Croft's comment that "the Ministry is effectively allowing an adjustment for general advertising and different margins by using an unbranded price". The Ministry has selected comparable domestic sales, that is, those that are the most appropriate for comparison with the export sales.

Blackburn Croft's suggestions that the Ministry examine selling prices of either branded products by Generics (UK) or branded Tamoxifen Citrate by other sellers in the United Kingdom so that Generics (UK)'s unbranded prices could be adjusted "to reach an equivalent branded price for the Generics (UK)'s Tamoxifen Citrate sold in the United Kingdom" are not appropriate in view of the reasons outlined above.

The Ministry considers that branding identifies a product and differentiates it from other brands and unbranded products, but does not necessarily increase the value of a product over a period of time. The value of a brand, if any, is also dependent on conditions affecting competition and may vary from market to market.

The Ministry notes that Generics (UK) neither owns nor supports the Genox brand, _____ _____. Generics (UK) incurs no promotional or advertising costs in respect of sales of the Genox brand to New Zealand. Generics (UK) advised that its price to Pacific is not affected by whether the product is branded or unbranded. The Ministry considers that Generics (UK) does not receive any

price premium related to brand value from the sale of the branded product to Pacific in New Zealand. The Ministry considers that it is reasonable in these circumstances to compare the branded export product with sales of the unbranded domestic product.

Pacific instructed Generics (UK) to put the name of Genox on the packet of Tamoxifen Citrate. The decision by Generics (UK) to sell Tamoxifen Citrate labelled Genox to Australia does not necessarily demonstrate that there is any value in the name Genox. Those sales are into a different market and have no effect on transactions with Pacific and therefore sales to Australia have no relevance to this investigation.

Blackburn Croft & Co, in response to the Essential Facts and Conclusions report, notes that its reference to oil filters was a hypothetical example to demonstrate a possible argument that could be put by an exporter to lower normal values. An argument could be put by an exporter supplying an oil filter with a brand owned by the exporter that, because it left the promotion of the product in New Zealand to the importer, its export sale should be compared with the normal value of an unbranded filter in the United States. Blackburn Croft explains that "if the export sale of a branded product is compared with the domestic sale of an unbranded product the Ministry is allowing adjustments to the domestic price that it would not normally allow".

Should the Ministry encounter this hypothetical example, it would need to consider it on its merits and on the basis of the facts available. It is important that export price and normal value are comparable and that a fair comparison is made. If an exporter makes a sale of a product for export which is labelled with a brand name, but does not price that product any differently than it would price a sale of an unbranded product, then it appears appropriate that the price of a branded product can be compared with the price of an unbranded product. Any advertising and marketing costs incurred by the importer to support the brand in New Zealand would not normally form part of the export price, but nor would similar costs be included in the normal value for the unbranded product. There would, therefore, be no argument in support on any adjustment for fair comparison.

In relation to the actual oil filter investigation (Automotive Oil Filters, USA December 2000), the Ministry notes the Purolator brand is managed and supported for both domestic and export sales by the United States exporter. Purolator is a brand of ArvinMeritor Light Vehicle Aftermarket. This is not the same situation as in the tamoxifen investigation where the exporter neither manages nor supports the Genox brand used by the New Zealand importer.

The invitation to tender administered by PHARMAC for the New Zealand market requests tenders to supply certain forms and strengths of chemical entities. A brand name is required where there is more than one form and strength of a particular chemical entity for each tender item.

PHARMAC manages the Pharmaceutical Schedule for the New Zealand market and publicises that its aim is to "provide the New Zealand public with the best healthcare value from the New Zealand Government’s expenditure on pharmaceuticals. PHARMAC’s decisions incorporate a balanced view of the needs of both prescribers and patients. In addition, PHARMAC seeks to balance the needs of patients for equitable access to healthcare with the needs of taxpayers for responsible management of the costs they ultimately bear". The decision by PHARMAC in accepting a tender is based on whether the supplier can meet the conditions of the tender, including the ex-manufacturer list price. There is no reference in the invitation to tender that trade names are considered when the PHARMAC board makes its

decision on whether to accept a certain tender therefore the brand name appears to have no relevance other than differentiating the product. The Ministry notes that the system of sole subsidised supplier status of a product removes similar products from the marketplace and any price premium that might be associated with a brand or trademark no longer applies.

The Pharmaceutical Schedule's operating policies and procedures state that on pricing schedules "all pharmaceuticals are listed under their approved name. However, brand names are also listed and then cross-referenced to their approved name. To be eligible for subsidy brands must be listed on the Pricing Schedules" (emphasis added). The Ministry also understands that, prior to sole subsidised supply of Tamoxifen Citrate being granted to Pacific, the market consisted of a number of products that had brand names, but there was no distinction between a branded and unbranded market as there is in the United Kingdom. In addition, all of the listed brands of Tamoxifen Citrate were being sold at the same ex-supplier prices.

PHARMAC aims to get the best healthcare value from the New Zealand Government's expenditure on pharmaceuticals. Its insistence on brands appears to be for ease of identification in operating the Pharmaceutical Schedule, rather than to increase health expenditure by creating a branded market in which products are sold at a premium. In response to the Essential Facts and Conclusions report, PHARMAC concurs with the Ministry's approach and notes that "the brand name is not an evaluation criterion in the tender and is required for identification purposes only".

Prices of generics and branded medicines in the United Kingdom are separately regulated – generics, including Generics (UK)'s Tamoxifen Citrate, under the Health Services (Control of Specific Generic Medicines) Regulations 2000, and branded product under the Health Services (Control of Prices of Branded Medicines) Regulations 2000 and the Pharmaceutical Price Regulation Scheme (PPRS). The Ministry considers that, while pharmaceuticals are sold on the New Zealand market under brand names, this does not make the market a branded market in the sense that there is a branded market in the UK where products are sold at a premium.

The Ministry considers that it is appropriate to compare Genox with sales of unbranded product in the United Kingdom, rather than with sales of branded product.

**Sales at the Same Time**

In response to the Essential Facts and Conclusions report, PHARMAC argues, on the basis that its contract with Pacific was for prices to be reduced on 12 July 2000, that all pricing comparisons before 12 July should be based on pre-tender prices. PHARMAC notes that dumping was found to occur in May and June 2000 when compared to export prices resulting from the successful tender, but that there would be no dumping in those months if normal values had been compared with pre-tender export prices.

Generics (UK) reduced its prices to Pacific effective from _____. The Ministry is required to make a comparison of normal values and export prices in respect of sales made at as nearly as possible the same time. The Ministry, therefore, compared export sales made in May and June with domestic sales made in those months. The comparison was made between the exporter's export sales to New Zealand and those on its domestic market. The Ministry

considers that the date of any subsequent sales by the importer in New Zealand is not relevant.

## Level of Normal Values

In response to the Essential Facts and Conclusions report, Blackburn Croft claimed that "the normal values established by the investigators appear to be extremely low". Blackburn Croft supplied a July 2000 invoice _____ that showed prices for packs of 10mg and 20mg of £____ and £____ respectively. These prices were similar to published August 2000 prices of £____ and £____ shown in _____ _____ did note, however, that _____ A __ percent reduction would lower these prices to £____ and £____ respectively. Generics (UK)'s prices to _____ customers were _____ than these prices at £____ in May and £____ in July for 10mg tablets, and £____ in June for 20mg tablets. Blackburn Croft also referred to _____ showing retail prices for Tamoxifen in the United Kingdom, but these prices were for branded forms of Tamoxifen.

The Ministry notes that there are different types of wholesalers in the United Kingdom and that Generics (UK)'s prices differ between wholesalers. The Ministry's verification team considered that the _____, which is a group of _____ wholesalers, was an appropriate group of customers for comparison, after consideration of the functions, distribution flows, places in the distribution chain and volumes of sales of the New Zealand customer and UK customers.

Blackburn Croft also referred to a verification report comment that sales by Generics (UK) to another customer in the UK would be made at a loss. The prices to that customer were given as an indication that domestic prices were trending downwards and were lower than those to the group of customers selected for comparison purposes.

## Adjustments

### Terms and Conditions of Sale

#### Discounts

One of the companies within _____ received discounted sales over the investigation period. An adjustment was made on transactions with that company.

#### Rebates

Generics (UK) is offering an annual rebate of _____ for the financial year ended 31 December 2000. Sales to the _____ at the end of September had reached _____, which indicated to the investigating team that Generics (UK) was on track _____. The investigating team has received evidence that a _____ was granted to the _____ and an adjustment of this percentage has been made after any discounts.

#### Inland Freight

Sales to domestic customers were inclusive of delivery. An adjustment for delivery on the basis of _ percent of the net invoiced price was made.

#### Credit

Various credit terms were offered by Generics (UK) to companies in _____. From each of the selected domestic invoices, the investigating team made an adjustment for credit on the basis of the mid-range of days that credit is extended, using an interest rate of _____. This adjustment for cost of credit was calculated as a percentage of the price net of discounts, but not net of _____.

#### Level of Trade

The investigating team compared the sales to New Zealand at the level of sales to wholesalers in the United Kingdom as Pacific is considered to be at the same level of trade as domestic wholesalers. No adjustment was required.

#### Sales At As Nearly As Possible The Same Time

The investigating team has carried out a transaction to transaction comparison for the entire period of investigation. For the period _____ normal values for unbranded tamoxifen estimated by the applicant were used as base prices for assessment of normal values. From _____ invoices for domestic sales to _____ where the transaction was as close as possible to the dates of the export invoices were selected. The difference in days varied by up to a maximum of _ days.

#### Taxation

All transactions were net of VAT therefore no adjustment was required.

#### Quantities

Prices on the domestic market to the _____ were the same irrespective of the quantity ordered therefore no adjustment was made.

#### Physical Characteristics

There is no physical difference between the blister-packed tablets of tamoxifen exported to New Zealand and those sold on the domestic market. No adjustment was required.

### Other Differences Affecting Price Comparability

#### Packaging

Domestic cartons of tamoxifen contain _____. However, _____ in the export cartons. An adjustment was made. The cartons for the domestic market are ordered _____ than export therefore domestic costs were higher. The investigating team did not consider this difference affected price comparability and therefore no adjustment was made.

Generics (UK) sell unbranded Tamoxifen Citrate in its domestic market. Genox is the brand of the product manufactured by Generics (UK) but sold by Pacific in the New Zealand market. Generics (UK) do not own the brand of Genox nor does it incur costs of brand

support. As explained above, the Ministry made no adjustment on grounds that the comparison of a branded product for the New Zealand market with an unbranded product for the domestic market did not result in any difference affecting price comparability.

Compliance costs are incurred on domestic sales but not export sales. It was not clear to the investigating team whether some or all of these costs were not also incurred in respect of sales for exports. The quantum of any cost difference was not established. No adjustment was warranted.

Sales promotion costs for New Zealand are borne by Pacific in New Zealand. On the domestic market in the United Kingdom _____ in the Operations/Production division processes export orders. Generics (UK) did not demonstrate any differences in costs that affected price comparability. In response to the Ministry's verification report Generics (UK) requested that a selling adjustment should be made to allow a fair comparison between normal value and export price. Due allowance is made by the Ministry for any differences that affect the comparability of domestic and export prices. Such an allowance is made on the basis of costs related to the price difference. Before an allowance is given it must be demonstrated to the Ministry that the costs are directly related to the sales under consideration, the buyer is aware of the matter for which costs are incurred, and the costs affect market value and price comparability. Generics (UK) stated that almost all of its sales and distribution costs relate to sales in the United Kingdom, however, before the Ministry could give further consideration to where any adjustments should be made, further information was sought. At the time that this report was being finalised representatives of Generics (UK) advised that they are in the process of reviewing the Ministry requirements and intend on discussing these with their client. As of the date of this report no further information has been received.

**Normal values**

Normal values have been calculated by deducting from the base prices the verified adjustments noted above.

## 3.3 Comparison of Export Price and Normal Value

Dumping margins have been calculated for each strength of Genox exported to New Zealand over the period of investigation from 1 September 1999 to 31 August 2000. Based on the information available to the investigating team the comparison has revealed that prior to May 2000 no dumping occurred. There has been dumping on the New Zealand market of Genox from 12 May 2000 to 29 June 2000 ranging from 22 to 33 percent of export price. However, from late July 2000 to late September 2000 there has been no dumping as normal values have significantly dropped since July 2000.

The following table represents the range over the period of the investigation of dumping margins for each strength of tamoxifen:

Table 3.1 Range of Dumping Margins
(UK pounds per unit)

| | 10 mg | 20 mg |
|---|---|---|
| Normal Values | **CONFIDENTIAL** | **CONFIDENTIAL** |

| | | |
|---|---|---|
| Export Prices | CONFIDENTIAL | CONFIDENTIAL |
| Dumping Margins | CONFIDENTIAL | CONFIDENTIAL |
| Margins % of EP | Nil to 33 | Nil - 31 |

**Volume of Dumped Goods**

The volume of dumped goods has been calculated by applying the percentage of dumped goods during the investigation period to the volume of imports.

Over the period of investigation, _____ units of 10mg and _____ units of 20mg tamoxifen were dumped, representing 52 percent of 10mg imports and 40 percent of 20mg imports. Dumping occurred in the months of May and June 2000.

Table 3.2 Volume of Dumped Goods

| | 10 mg | 20 mg |
|---|---|---|
| % Dumped | 52 | 40 |
| Volume (30 tablet packs) | CONFIDENTIAL | CONFIDENTIAL |

Section 11(1) of the Act provides that where the Minister is satisfied in respect of some or all of the goods under investigation, that there is insufficient evidence of dumping or injury to justify proceeding with the investigation then it shall be terminated. Section 11(2) of the Act provides that evidence of dumping shall be regarded as insufficient if the volume of imports of dumped goods, expressed as a percentage of total imports of like goods into New Zealand, is negligible, having regard to New Zealand's obligations as a party to the WTO Agreement. The WTO Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994 ("the Anti-Dumping Agreement"), deals with the negligibility of dumped imports under Article 5:8 as follows:

5.8 An application under paragraph 1 shall be rejected and an investigation shall be terminated promptly as soon as the authorities concerned are satisfied that there is not sufficient evidence of either dumping or of injury to justify proceeding with the case. There shall be immediate termination in cases where the authorities determine that the margin of dumping is de minimis, or that the volume of dumped imports, actual or potential, or the injury, is negligible. The margin of dumping shall be considered to be de minimis if this margin is less than 2 per cent, expressed as a percentage of the export price. The volume of dumped imports shall normally be regarded as negligible if the volume of dumped imports from a particular country is found to account for less than 3 per cent of imports of the like product in the importing Member, unless countries which individually account for less than 3 per cent of the imports of the like product in the importing Member collectively account for more than 7 per cent of imports of the like product in the importing Member.

The following table shows the volume of imports of the dumped subject goods compiled from information provided by Generics (UK) for Genox and IMS data for other imported brands. Non-dumped Genox imports have been included in the figures for other imports. The calculations have been made for 20mg x 30 tablet pack equivalents, in relation to total imports in the year from 1 September 1999 to 31 August 2000 covering the period of investigation of dumping.

Table 3.3: Volume of Dumped Imports
(30 x 20mg equivalent packs)

| Year Ending August 2000 | % |
|---|---|

| | | |
|---|---|---|
| Dumped Imports | **CONFIDENTIAL** | 41% |
| Other Imports | **CONFIDENTIAL** | 59% |
| Total Imports | **CONFIDENTIAL** | 100% |

On the basis of this information, imports of the subject goods from individual countries are not negligible.

## 3.4 Conclusions Relating to Dumping

The investigation has established that of the _____ units of 10mg and _____ units of 20mg, of the subject goods, imported from the United Kingdom during the investigation period, _____ units of 10mg and _____ units of 20mg were dumped, with a dumped volume of 52 percent for 10mg and 40 percent for 20mg.

The investigation has established dumping margins of Nil to 33 percent for the 10 mg tablets and Nil to 31 percent for the 20 mg tablets.

# 4. Injury Investigation

The basis for considering material injury is set out in section 8(1) of the Act:

8. Material injury to industry—(1) In determining for the purposes of this Act whether or not any material injury to an industry has been or is being caused or is threatened or whether or not the establishment of an industry has been or is being materially retarded by means of the dumping or subsidisation of goods imported or intended to be imported into New Zealand from another country, the [Chief Executive of the Ministry of Economic Development] shall examine—

(a) The volume of imports of the dumped or subsidised goods; and

(b) The effect of the dumped or subsidised goods on prices in New Zealand for like goods; and

(c) The consequent impact of the dumped or subsidised goods on the relevant New Zealand industry.

## 4.1 Material Injury Caused By Dumping

Section 13 of the Dumping and Countervailing Duties Act 1988 provides:

> ... the Minister shall make a final determination as to whether or not, in relation to the importation or intended importation of goods into New Zealand,—
>
> (a) The goods are being dumped or subsidised; and
>
> (b) By reason thereof material injury to an industry has been or is being caused or is threatened or the establishment of an industry has been or is being materially retarded.

This means that the material injury must be caused by reason of the dumping of goods.

Section 8 of the Dumping and Countervailing Duties Act 1988 sets out the injury factors which must be examined by the Chief Executive . These are:

- the volume of dumped goods;
- the effect of the dumped goods on prices in the New Zealand market for like goods; and
- the consequent impact of the dumped goods on the relevant New Zealand industry.

The Ministry interprets this to mean that injury is to be considered in the context of the impact on the industry arising from the volume of the dumped goods and their effect on prices. This is consistent with Article 3 of the WTO Anti-Dumping Agreement.

The Act goes on to set out a number of factors and indices which the Chief Executive shall have regard to, although noting that this is without limitation as to the matters the Chief Executive may consider. These factors and indices include:

- the extent to which there has been or is likely to be a significant increase in the volume of dumped goods, either in absolute terms or relative to production or consumption;
- the extent to which the prices of dumped goods represent significant price undercutting in relation to prices in New Zealand;
- the extent to which the effect of the dumped goods is or is likely significantly to depress prices for like goods of New Zealand producers or significantly to prevent price increases for those goods that otherwise would have occurred;
- the economic impact of the dumped goods on the industry, including actual or potential decline in output, sales, market share, profits, productivity, return on investments, and utilisation of production capacity; factors affecting domestic prices; and actual and potential effects on cash flow, inventories, employment, wages, growth, ability to raise capital, and investments;

In addition, the Chief Executive must have regard to factors other than dumping which may be injuring the industry, since in accordance with Article 3 of the WTO Anti-Dumping Agreement, it must be demonstrated that the dumped imports are, through the effects of dumping (as set out in paragraphs 4.1.2 and 4.1.3 above) causing material injury. The demonstration of a causal relationship between the dumped imports and the injury to the domestic industry must be based on an examination of all relevant evidence before the authorities, who must 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. Factors which may be relevant in this respect include, inter alia, the volumes and prices of non-dumped imports of the product in question, 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.

Section 11(1) of the Act provides for the termination of an investigation where the Minister is satisfied in respect of some or all of the goods under investigation, that there is insufficient evidence that material injury to a New Zealand industry has been or is being caused or is threatened by means of the dumping of the goods.

# 4.2 Introduction

In considering whether material injury has been caused by dumping, the way in which the dumped goods may affect the market needs to be considered.

## PHARMAC

PHARMAC is responsible for the operation and development of the Pharmaceutical Schedule. The Pharmaceutical Schedule contains a list of all prescription medicines that are subsidised by the New Zealand government. In order for a pharmaceutical to be subsidised, a supplier must deal with PHARMAC. Tendering is one of the methods PHARMAC employs to facilitate the supply of subsidised pharmaceuticals to the New Zealand market.

### The Tender

In this case the tender was for the sole subsidised supply of Tamoxifen Citrate to the New Zealand market. The period of the contract was for three years with a transition period before and after the two and a half-year period of sole supply. The call for tenders was made on 24 December 1999 and closed on 6 March 2000. The winner of the tender was announced on 30 May 2000. PHARMAC announced that the new subsidised price would be effective from 1 August, but PHARMAC required that any current supplier should reduce its prices in the market by 12 July 2000 if it wanted to receive the new level of subsidy. These companies would be eligible to receive the subsidy during a transition period up until 1 December 2000 to allow, as PHARMAC has stated, an orderly transition to sole supply. After 1 December 2000, only the tender winner (Pacific) would be eligible for the subsidy. The supply period for the tender was until 30 June 2003.

PHARMAC has stated that "the tender does not preclude pharmaceutical suppliers from supplying their brands of tamoxifen via chemists on an unsubsidised basis for the private market, or through hospitals, which purchase pharmaceuticals, independently of PHARMAC. PHARMAC estimated 10 percent of the total tamoxifen sales occur in hospitals and in the private market (however this figure is based on limited data). Blackburn Croft provided IMS data, which is considered to be more accurate, showing that hospital sales of tamoxifen, both government and private, amount to around _ percent of the tamoxifen market. It is considered that private sales outside of hospitals would be negligible given the difficulty competing with the low subsidised price that is now in the market.

### Injury

PHARMAC has stated that "it is difficult to apply [let alone establish] the provisions of section 8 in a meaningful way to the current tendering scenario". It argues that dumping relates to an importer dumping significant volumes of low priced products on the domestic market at prices and volumes that make it difficult to compete, but that tendering involves an entirely different process where importers and producers have the opportunity to enter a competitive tender process to become a sole subsidised supplier. It is argued that it is "inherent in the competitive tender process itself" that only one supplier will remain" and that volume itself does not cause injury …" because other suppliers are required to exit the market before the tender winner supplies the entire volume. PHARMAC states that "price is necessarily a factor in determining the successful tenderer" although there are other important factors as well. PHARMAC further states that "producers and importers do not physically compete in the market at its lower price except during a short transition period before the sole supply arrangements come into force".

In addition, PHARMAC states that you cannot compare the prices prevailing in the market prior to the tender, with the prices of the tender winner. PHARMAC argue that therefore injury cannot be sensibly addressed by a comparison of the Pacific tender price and Douglas's pricing before the tender. It should be noted that the Ministry does not intend to do so and has addressed the price comparison under the section on price undercutting.

PHARMAC also stated that in order to "establish material injury, Douglas needs to show that its tender price was lower than the Pacific price adjusted upwards by the margin of dumping" (leaving aside the point that price is only one factor in the tender evaluation criteria). This is also discussed further under the section on price undercutting.

**The Concept of Tender Dumping**

Tender dumping occurs when a supplier wins a tender with dumped prices. The dumped goods may not have entered the market at the time of the tender and the tender may have been won some months or longer prior to the goods arriving in the market.

Material injury to an industry may occur as a result of the loss of the tender because of the accompanying loss of volume that the goods represent. In addition, the industry cannot necessarily reduce its prices in the market and win back the tender contract. The lowering of prices to a dumped level in the market may also affect further business.

A dumping application against a tender situation is usually taken against goods that are in the market or about to arrive in the market. (In this case an application of threat of material injury was taken where the goods had started to arrive but where injury was not yet apparent. It was considered that there was sufficient evidence, for purposes of initiation, of a threat of material injury.)

Even when dumping is found (assuming the dumping has caused the injury), an anti-dumping remedy may not prevent material injury, since the contract to supply has been lost, and remedying the injury caused to the industry may not be possible.

These are some of the main features of tender dumping. A further description of tender dumping can be found in an Australian Anti-Dumping Authority Report (No.77 June 1992, pages 3 to 5) which can also be found on the Public File for this investigation.

In response to the Essential Facts and Conclusions report, Blackburn Croft has stated that paragraph 4.2.11 equally applies to non-tender dumping situations. An example was given of "a supplier of imported canned peaches to the … [five] key grocery accounts in New Zealand, represent 80 percent of the purchases of canned peaches [which] could have an exclusive contract for six months [say] to supply canned peaches. As a result of a dumping investigation it is found that the canned peaches are dumped but the price of non-dumped canned peaches can still undercut the local producer. The contract has already been "lost" and the imposition of an anti-dumping duty will not result in the volumes lost to dumping reverting back to the local manufacturer. An anti-dumping duty would however, be applied in this situation even though it could be argued that "remedying the injury…may not be possible". A duty would remedy price undercutting caused by the dumping. The Act does not contemplate that an anti-dumping duty will guarantee the recovery of lost sales". Blackburn Croft considers that the reasoning in paragraph 4.2.11 of the report is wrong, and that "once there is dumping which has caused material injury the Act obligates the imposition of anti-

dumping duties at an appropriate level. It is unlawful and a clear error of law to interpret and apply the legislation in the way suggested by the Ministry."

It should be noted that the inference taken by Blackburn Croft in paragraph 4.2.11 that a remedy would not be considered if dumping were found to be causing material injury because a remedy is seen to be ineffective, is incorrect. The Ministry notes that if dumping were found to cause material injury, a remedy would be considered.

The Ministry also considers that while the material injury that has been incurred due to a lost contract may not be able to be remedied as outlined above, a remedy could still be considered to prevent further injury or a recurrence of injury. The question of the effectiveness of a remedy only arises if the investigation finds that the dumping of goods has caused or is causing or threatening material injury to the New Zealand industry.

## 4.3 Import Volumes

*Section 8(2)(a) of the Act provides that the [Chief Executive of the Ministry of Economic Development] shall have regard to the extent to which there has been or is likely to be a significant increase in the volume of imports of dumped or subsidised goods either in absolute terms or in relation to production or consumption in New Zealand.*

Imports of tamoxifen are not separately defined in the Tariff and all imports cannot be identified from Customs data. IMS data has been used to calculate import volumes. IMS data is collected from the supplier on a monthly basis when sales are made. Imports are reflected in the IMS data to the extent that imports must have been made to a level likely to be greater than the sales (taking into account some level of safety stock). Douglas has said that its production figures are similar to its sales figures. Douglas provides sales figures to IMS for that company's database at the end of each month. IMS collects sales data for tamoxifen from each supplier at the same point, therefore, IMS data has been used as an approximation of imports of tamoxifen. The data has been recorded as MAT March years and includes an MAT October 2000 year, which includes the effect of the new tender price.

Table: 4.1: Estimated Import Volumes
(30 x 20mg equivalent packs)

| | 1998 | 1999 | 2000 | MAT Oct 2000 |
|---|---|---|---|---|
| Dumped Goods | 0 | 0 | 0 | Increase |
| Undumped Subject Goods | | Decline | Increase | Decline |
| Other Imports | | Decline | Increase | Decline |
| Total Imports | | Decline | Increase | Increase |
| Industry Sales | | Increase | Decline | Decline |
| NZ Market | | Increase | Increase | Increase |
| Change on previous year: | | | | |
| Dumped Goods | | 0 | 0 | Increase |
| Undumped Subject Goods | | decline | Increase | Decline |
| Other Imports | | Decline | Increase | Decline |
| Total Imports | | Decline | Increase | Increase |

| | | | | |
|---|---|---|---|---|
| Industry Sales | | Increase | Decline | Decline |
| NZ Market | | Increase | increase | Increase |
| % Change: | | | | |
| Dumped Goods | | 0% | 0% | 100% |
| Undumped Subject Goods | | Decline | Increase | Decline |
| Other Imports | | Decline | Increase | Decline |
| Total Imports | | Decline | Increase | Increase |
| Industry Sales | | Increase | Decline | Decline |
| NZ Market | | Increase | Increase | Static |
| Dumped goods as % of: | | | | |
| - Industry Sales | | 0% | 0% | |
| - NZ Market | | 0% | 0% | |

The data for the years to March reflect sales by all brands competing with the same subsidised prices in the market. The table also shows the actual volume of the dumped goods found in the year to August 2000 since dumping was only found in May and June, and these figures have been recorded as the dumped volume in the MAT October 2000 figures. The new price of tamoxifen was actually in effect for most of July 2000, as Pacific dropped its price to the market in early July. Table 4.1 shows that in the year ended October 2000, the dumped goods have increased significantly in absolute terms and as a percentage of industry sales and as a percentage of the New Zealand market.

The following table shows the IMS data for the individual months of April to October 2000 combined with the actual import volumes for Genox in May and June.

Table 4.2: Imports of Tamoxifen
(Year 2000, 30 x 20mg Equivalent Packs)

| | Apr | May | Jun | Jul | Aug | Sep | Oct |
|---|---|---|---|---|---|---|---|
| Dumped Goods | 0 | | | 0 | 0 | 0 | 0 |
| Undumped Subject Goods | | | CONFIDENTIAL | | | | |
| Other Imports | | | CONFIDENTIAL | | | | |
| Total Imports | | | CONFIDENTIAL | | | | |
| Industry Sales | | | CONFIDENTIAL | | | | |
| NZ Market | | | CONFIDENTIAL | | | | |
| Dumped goods as % of: | | | CONFIDENTIAL | | | | |
| - Industry Sales | 0% | | | 0% | 0% | 0% | 0% |
| - NZ Market | 0% | | | 0% | 0% | 0% | 0% |

The data shows that there were dumped imports in May and June and that there was an increase in imports in those months which have sustained the increase in sales of Genox over the months of July to October. From 1 August there were no sales of Douglas's brand Tamofen. The subject goods (both dumped and undumped) as a percentage of the total market increased from __ percent in April to __ percent of the market in October. The dumped goods increased significantly in May and June. It should be noted that the volume increase of the subject goods since July is as a direct result of Pacific winning the tender.

Other imports of tamoxifen declined from __ percent in April to _ percent of the market in October, being replaced almost totally by the subject goods.

**Conclusion**

The Ministry concludes that the import volumes of dumped goods from the United Kingdom have increased significantly in absolute terms, and relative to production and consumption in New Zealand.

# 4.4 Price Effects

**Price Undercutting**

Section 8(2)(b) of the Act provides that the [Chief Executive of the Ministry of Economic Development] shall have regard to the extent to which the prices of the dumped or subsidised goods represent significant price undercutting in relation to prices in New Zealand (at the relevant level of trade) for like goods of New Zealand producers.

In considering price undercutting, the Ministry will normally seek to compare prices at the ex-factory and ex-importers store levels, to ensure that differences in distribution costs and margins do not confuse the impact of dumping. Accordingly, the Ministry's position is generally to compare importers' prices, including relevant selling and administration costs, which involve similar cost elements to those in the New Zealand manufacturer's ex-factory price, but not including cost elements relating to the distribution of goods.

The present situation can be distinguished from a normal situation due to the involvement of PHARMAC. PHARMAC, which at the time of the tender was funded by the Health Funding Authority, manages the New Zealand Pharmaceutical Schedule (the Schedule) which lists subsidised pharmaceuticals and sets out the reference prices at which drugs are subsidised. Products that are not subsidised are much less likely to be prescribed by medical practitioners or dispensed by pharmacies because of the higher cost to the patients.

The loss of the tamoxifen tender by Douglas and the other brands in the market, does not preclude the sale of these brands of tamoxifen, but directly affects their market share as they have not been subsidised from 1 December 2000 and have been removed from the Schedule.

The year 2000 was the first year in which PHARMAC tendered tamoxifen for sole subsidised supply, the period of the tender being two and a half years. From 1 December only Pacific will receive the subsidy.

As a result of the tender, suppliers of other brands of tamoxifen have limited choices, since the market is almost certain to choose the subsidised brand as soon as the new subsidised price is implemented in the market. This is borne out by the IMS sales data for the months of August to October 2000, which show few sales of any brand of tamoxifen other than Genox.

**Point of Comparison for Price Undercutting**

As sales of Tamofen by Douglas have all but ceased, the best measure of price undercutting is probably that taken as a comparison of the actual prices tendered. All brands of tamoxifen

have exactly the same active chemical ingredient and so can be compared directly with each other.

The Ministry considers that the appropriate point at which prices should be compared is the point at which the goods first compete in the New Zealand market. The level of the tender bids for sole subsidised supply were lodged as ex-manufacturer/distributor prices and this is considered to be the first point of competition and therefore the relevant point at which prices should be compared for the purposes of a price undercutting comparison.

The following table shows the tender prices submitted to PHARMAC by Douglas and Pacific.

Table 4.3: Comparison of Tender Prices per Pack

(NZ$)

| | Genox Tender Offer | Tamofen Tender Offer | Undercutting | % |
|---|---|---|---|---|
| From 1 August | | | | |
| 10mg x 30 | 2.60 | CONFIDENTIAL | | |
| 20mg x 30 | 2.99 | CONFIDENTIAL | | |

The table shows that the subject goods _____ undercut the industry's prices in the tender round.

Douglas submitted that the prices of its original proposal should be used in the price undercutting comparison which arose as a result of PHARMAC's request for offers in its price consultations of 23 November 1999 with Douglas. The prices submitted by Douglas for Tamoxifen Citrate were $4.40 (10mg x 30 per pack) and $8.35 (20mg x 30 per pack). Douglas stated that the offer prices were rejected by the PHARMAC board and were put up for sole subsidised tender on 24 December 1999. PHARMAC released these consultation offer prices to all pharmaceutical suppliers (as well as a range of offer prices for other pharmaceuticals). Douglas argues that by informing the industry of the offer prices it effectively set a ceiling for the various tenders, which followed. Douglas says it then had to reduce its offer price in the tender in an effort to win the tender. Douglas claimed that if PHARMAC had not released its original offer price, it would have had no cause to lower these prices _____ and so the original offers should be used in the price undercutting comparison.

PHARMAC submitted that it is not sensible to compare Pacific's tender price with Douglas' previous pricing. It states that the tender prices that were bid for sole subsidised supplier status assures a company of the market for a set period, and would be much lower than prices in multi-supplier market conditions (as in Douglas's first offer). PHARMAC also contends that to establish injury, Douglas needs to show that its tender price was lower than Pacific's price adjusted upward by the margin of dumping. PHARMAC states that if Douglas's price was higher than both Pacific's dumped and non-dumped prices, then there could be no material injury to the industry as a result of Pacific's pricing at a dumped level, since Pacific would have won the tender anyway.

The Ministry considers that the prices paid in the market prior to the tender are not likely to be relevant in the assessment of price undercutting, as the market conditions were different in that all brands were subsidised at a similar level and had equal access to the market. Neither are Douglas's initial prices for tamoxifen offered in the consultations held with PHARMAC in November 1999, which were not offered on the basis of being for sole subsidised supply. Douglas was, however, able to put in a lower offer in the subsequent tender round for sole subsidised supply. The tender bids were all made on the same basis, and would seem to be the correct level of comparison.

PHARMAC has argued that the magnitude of the margin of dumping is significant if Pacific could have won the tender at a non-dumped price and therefore could not have caused material injury caused to the industry. It is not known whether this would have occurred since there may have been other potential bidders in the market and price is not the only factor that PHARMAC takes into account when in awarding a tender.

PHARMAC considers that if Pacific's prices were lower than Douglas's at an undumped level, then no material injury has been caused to the industry. This raises the question that if Pacific could have won the tender with undumped prices, why did it not do so?

It is apparent that there is significant undercutting of Douglas' tender prices and that part of this is due to the dumping margin. It is also apparent also that Pacific might have won the tender if it had tendered an undumped price.

In response to the Essential Facts and Conclusions report, Blackburn Croft, responded to the question of why Pacific had not tendered a non-dumped price. Blackburn Croft stated that:

Pacific had a choice. It could have offered a dumped price or a non-dumped price. To ensure that it got the tender it presumably offered its lowest possible price, which was a dumped price. This dumped price was a material contribution to the inability of Douglas to compete. If Pacific had offered a non-dumped price, it may well have considered that the price might not be low enough and could therefore trigger another tender request. By offering a dumped price Pacific could have taken the view that the low price might remove any uncertainty in securing the tender. The resultant injury to Douglas was caused by this low tender price which was dumped.

In response to the Essential Facts and Conclusions report, PHARMAC has argued that the price in the market was at the pre-tender level when the dumping occurred in May and June, and that the price as a result of the contract formed, after the PHARMAC board agreement on 26 May 2000, required the tender price reduction on 12 July 2000. PHARMAC noted that it was of the view that "all pricing comparisons before 12 July 2000 should be made against the pre-tender prices."

The Ministry notes that the dumping comparison is made between the ex-factory export price to New Zealand and the ex-factory normal value (United Kingdom domestic price). This comparison is somewhat removed from the price undercutting comparison which is usually based on prices in the New Zealand market. In the dumping investigation "ACE Inhibitors from Germany and Switzerland" which was a pharmaceutical case involving reference pricing, the price undercutting comparison was made at the point of sale of national distributors to wholesalers. Pacific would be considered a national distributor in that instance and the reference prices (prior to the tender) were set at the point of the supplier to the

wholesaler. A price undercutting comparison of price prior to 12 July (or more correctly 7 July since that is when Pacific dropped its prices) would result in no price undercutting in the market, since all the reference prices for individual strengths from each supplier were the same. In addition this would not reflect the effect of the tender on prices. A price undercutting comparison after 7 July would be a comparison of a reference price with a tender price but these were not set on the same basis and do not take into account the level of the unsuccessful tenders.

Mr McPhail has noted that "the losing tender price may not be relevant as a point of comparison, since it is not a market price, and may not have reflected any actual sales. Also, in cases where the contract concerned is to buyer in a position such as that of Pharmac, comparison with prices of sales to other buyers may not be relevant, since they are not comparable. This suggests that in tender price situations, price undercutting may not be an appropriate element to consider in establishing the impact of the dumping of goods."

The Ministry considers that the most relevant prices in this case seem to be the tender prices, since all of the companies were bidding on the same basis for sole subsidised supply and since price is the substantial determinant of the winning tender. The facts available to the Ministry show that the subject goods tender prices undercut the industry's tender prices for tamoxifen. It is considered, therefore, that there is evidence of price undercutting, part of which was due to dumping.

**Price Depression**

*Section 8(2)(c) of the Act provides that the [Chief Executive of the Ministry of Economic Development] shall have regard to the extent to which the effect of the dumped or subsidised goods is or is likely significantly to depress prices for like goods of New Zealand producers.*

Price depression occurs when prices are lower than those in a market unaffected by dumping, usually in a previous period.

The following table shows Douglas's average prices in the market.

Table 4.4: Average Selling Prices of Tamoxifen
(Price per 30 x 20mg pack)

| | 1998 | 1999 | 2000 | 2001 |
|---|---|---|---|---|
| Douglas | | Decline | Decline | Increase |

Douglas has not claimed that there has been price depression. Average selling prices in the years prior to the tender from 1998 to 2000, although declining, do not indicate price depression in the sense that dumping has caused prices to decline. The decline of Douglas's average selling price to the year 2000 are a result of PHARMAC's negotiated reimbursement prices each year, which affected all brands subsidised by PHARMAC including the subject goods.

Any price depression as a result of the tender would only be apparent if Douglas dropped its selling price following the tender in order to receive the new level of subsidy available to it until December 2000. Douglas' contention that it would not change its selling prices from previous levels is borne out by the average selling price so far for the 30 x 20mg packs of

Tamofen _____. The table shows that this average price increased only slightly compared with the large reductions in the average selling price for 2000 compared with 1999. Pricing information from Douglas also confirmed that _____

In response to the Essential Facts and Conclusions report Blackburn Croft has argued that the market price is now permanently depressed to a dumped price level, and that to be able to compete in any future tender, it would have to bid at a depressed price level. If the goods were not retendered it would be permanently be locked out of the market. This issue is discussed further under "Causality".

It is concluded that there was no price depression in the investigation period in that Douglas did not reduce its prices.

**Price Suppression**

Section 8(2)(c) of the Act also provides that the [Chief Executive of the Ministry of Economic Development] shall have regard to the extent to which the effect of the dumped or subsidised goods is or is likely significantly to prevent price increases for those goods that otherwise would have been likely to have occurred.

The Ministry has generally based its assessment of price suppression on positive evidence, in particular the extent to which cost increases have not been recovered in prices. Cost increases not recovered in prices will be reflected in declines in gross profit and EBIT expressed as a percentage of sales. Where cost savings have been made, the lack of any price increase will not normally be regarded as price suppression.

Douglas has not claimed it suffered price suppression prior to the tender. Douglas has claimed that there would be price suppression once the new tender price was in the market. The following table is based on the revised financial figures from Douglas.

Table 4.5: Price Suppression

(NZ$)

| | | | Forecast | |
|---|---|---|---|---|
| | 1998 | 1999 | 2000 | 2001 |
| Sales Revenue | CONFIDENTIAL | | | |
| Cost of Production | CONFIDENTIAL | | | |
| Gross Margin | CONFIDENTIAL | | | |
| Selling and Admin. | CONFIDENTIAL | | | |
| EBIT | CONFIDENTIAL | | | |
| GM as % of Sales | | Decline | Decline | Increase |
| EBIT as % of Sales | | Decline | Decline | Increase |

It should be noted that the decline in the reimbursement price which was the same for all brands of tamoxifen in the New Zealand market is shown in the years 1998 to 2000. Douglas had an accompanying decline in gross margin, but this is not claimed to be due to dumping. Any price suppression as a result of the alleged dumping would only be apparent in the year 2001 figures.

The forecast figures to 2001 include some actual data and show that the gross margin as a percentage of sales will increase, compared to the previous year. At the same time there is a forecast decline in sales to less than __ percent of the previous year's total, and production for the domestic market has now ceased. Gross margin actually increased slightly reflecting Douglas's managed exit from the market (since domestic production and sales have now ceased) rather than any improvement on the previous year. Given the actual loss of sales, had production continued, gross margin would no doubt have declined dramatically.

There is no evidence that there has been any injury caused to Douglas by price suppression.

**Conclusions on Price Effects**

The Ministry concludes that there is evidence of price undercutting which is partly due to dumping. There is no evidence of price depression or price suppression.

# 4.5 Economic Impact

*Section 8(2)(d) of the Act provides that the [Chief Executive of the Ministry of Economic Development] shall have regard to the economic impact of the dumped or subsidised goods on the industry, including—*

*(i) Actual and potential decline in output, sales, market share, profits, productivity, return on investments, and utilisation of production capacity; and*

*(ii) Factors affecting domestic prices; and*

*(iii) The magnitude of the margin of dumping; and*

*(iv) Actual and potential effects on cash flow, inventories, employment, wages, growth, ability to raise capital, and investments.*

Output and Sales

Movements in sales revenue reflect changes in volumes and prices of goods sold. Dumped imports can affect both of these factors through increased supply of goods to the market and through price competition.

Douglas did not provide details of its output but stated that its production volume is similar to its sales volume as recorded by the IMS data.

The price reduction for Genox came into effect on 1 August 2000 (although was in the market in early July). Douglas did not reduce its ex-manufacturer prices to the new subsidised price levels in July.

The following tables show the updated sales (output) and revenue figures for Tamofen which have been provided by Douglas from its financial data. They are in the form of the total number of 30 tablet packs, and so differ slightly from volume figures in some other tables, which give 20mg x 30 tablet pack equivalents.

Table 4.6: Volume of Sales
March Years, 30 Tablet Packs

| | 1998 | 1999 | 2000 | Forecast 2001 | Forecast 2002 |
|---|---|---|---|---|---|
| Industry | | Increase | Decline | Decline | 0 |
| Change on the previous Year: | | Increase | Decline | Decline | -100% |

Table 4.7: Sales Revenue
March Years, 30 Tablet Packs

| | 1998 | 1999 | 2000 | Forecast 2001 | Forecast 2002 |
|---|---|---|---|---|---|
| Industry | | Decline | Decline | Decline | 0 |
| Change on the previous Year: | | Decline | Decline | Decline | -100% |

The volume of sales forecast for 2001 shows an expected decline in sales of Tamofen. The actual sales volume figures for the year to date October 2000 from IMS data shows that a total of _____ 20mg x 30 tablet pack equivalents were sold. _____. It is likely that ____ 20mg x 30 tablet packs _____.

Previous years sales fluctuated, declining slightly overall in total, but these fluctuations occurred before the tender round, and so are not related to the allegedly dumped imports being investigated.

Regarding Douglas' sales revenue, the significant decline in sales revenue for Tamofen shown above from 1998 to 2000, reflects the declining level of the subsidised prices contracted with PHARMAC, while the corresponding volumes produced in those years fluctuated only slightly. The new subsidised prices were in the market in early July and at that point total sales revenues declined dramatically as sales almost ceased.

**Conclusion**

The Ministry concludes that the New Zealand industry's output (sales volume) and sales revenue have declined significantly.

## Market Share

The analysis of market share must take account of changes in the growth of the market as a whole. A decline in the share of the market held by the domestic industry in a situation where the market as a whole is growing will not necessarily indicate that injury is being caused to the domestic industry, particularly if the domestic industry's sales are also growing. There is no "entitlement" to a particular market share.

The following table shows the historic and current market share.

Table 4.8: Market Share
(30 x 20mg Equivalent Packs)

| | 1998 | 1999 | 2000 | MAT Oct 2000 |
|---|---|---|---|---|
| NZ Market | | Increase | Increase | Increase |
| Industry Sales | | Increase | Decline | Decline |
| Dumped Goods | 0 | 0 | 0 | Increase |
| Undumped Subject Goods | | Decline | Increase | Decline |
| Other Imports | | Decline | Increase | Decline |
| % Share Held By: | | | | |
| Industry Production | | Increase | Decline | Decline |
| Dumped Goods | 0% | 0% | 0% | Increase |
| Total Subject Goods | | Decline | Increase | Increase |
| Other Imports | | Decline | Increase | Decline |

Table 4.8 shows that in the years to March 1998, 1999 and 2000 the industry's share of the market fluctuated slightly when competing against imports of tamoxifen at the same subsidised price. The industry's fluctuations in market share over this period do not relate to any injury caused by the dumped goods that were found in this investigation, as the imports precede the tender. Table 4.8 shows that in the year ending October, sales by the industry declined significantly, being replaced in volume by imports of the dumped goods as the volume of other imports remained relatively stable.

The monthly sales covering the time that the new subsidised price entered the market in July are as follows:

Table 4.9: Industry Sales - Monthly
(Monthly, Year 2000, 20mg x 30 Equivalent Packs)

| | Apr | May | Jun | Jul | Aug | Sep | Oct |
|---|---|---|---|---|---|---|---|
| Sales Volume | CONFIDENTIAL | | | | | | |

The above table shows that the industry's market share has declined to zero and it is likely no further domestic sales will be made during the period of the tender.

**Conclusion**

The Ministry concludes that the New Zealand industry's share of the market has been adversely affected by the loss of the tender. While the industry has technically not lost access to the market, it is not eligible for the subsidy and cannot compete on price and so would appear to have lost 100 percent of its previous market share.

## Profits

Changes in net profit reflect changes in prices, sales volumes or costs. Dumped imports can impact on any or all of these. Normally, the extent of any decline in profit will be measured against the level achieved in the period immediately preceding the commencement of dumping.

The following table is based on Douglas's revised financial data.

Table 4.10: Profits

| | | | Forecast | |
|---|---|---|---|---|
| | 1998 | 1999 | 2000 | 2001 |
| EBIT | | Decline | Decline | Decline |
| EBIT per Tablet | | Decline | Decline | Increase |
| As % of Revenue | | Decline | Decline | Increase |

The figures show that EBIT declined each year to the year ending March 2000, but this decline is likely to be due to the decline in the reimbursement level for tamoxifen, rather than any injury from the dumped goods under investigation. Any decline in EBIT as a result of dumping would only be apparent in the year 2001 forecast figures. EBIT as a percentage of revenue has remained at a similar level during Douglas's managed exit from the market.

The forecast figures include some actual data for 2001, which shows that total EBIT will substantially decline in 2001 compared with 2000. EBIT as a percentage of revenue for the full year to 2001 will likely be maintained at a similar rate to the current level recorded. Douglas has now ceased to produce Tamofen for the domestic market.

**Conclusion**

The Ministry concludes that the New Zealand industry's profitability has been adversely affected resulting in a significant decline in total profits.

**Productivity**

Productivity is the relationship between the output of goods and the inputs of resources used to produce them. Changes in productivity are affected by output levels and by the level of capacity utilisation.

Douglas has not provided any figures relating to productivity, but noted that _____ were being made because customers did not want to _____. With the loss of the tamoxifen tender the company has ceased producing for the domestic market, reducing the overall productivity of the steroid suite.

**Return on Investments**

A decline in return on investments will result from a decline in returns with or without a relative increase in the investment factor being used. Movements in the return on investments affect the ability of the industry to retain and attract investment.

Douglas noted that production of Tamofen had required the use of a specialised steroid suite _____ and production of Tamofen was about __ percent of total usage. The company noted that although it would continue to produce for export, the reduction in margins and the consequent lower return on investment would be significant. The company has not provided any data to show the extent of the impact.

**Utilisation of Production Capacity**

The utilisation of production capacity reflects changes in the level of production, although in some cases it will arise from an increase or decrease in production capacity. In either case, a decline in the utilisation of production capacity will lead to an increase in the unit cost of production, and a consequent loss of profit.

Douglas stated that the company had reduced its shifts from _____. Douglas has stated that these changes are as a result of the loss of the tamoxifen tender, but has not provided any calculations showing the expected effect on capacity utilisation.

#### Other Price Effects

The investigating team is not aware of an adverse economic impact by the subject goods relating to other factors affecting domestic prices.

#### Magnitude of the Margin of Dumping

The magnitude of the margin of dumping can be a useful indicator of the extent to which injury can be attributed to dumping, particularly when it is compared with the level of price undercutting.

The margins of dumping are shown in Section 3.3. The margins of dumping were calculated separately for 10mg and 20mg 30 tablet packs and so can be directly compared with the level of price undercutting.

In the year ending August 2000 (the dumping investigation period) __ percent of the total volume of subject goods for the year were dumped in the two months that dumping occurred. For the product that was dumped, dumping margins as percentage of export price is Nil to 33 percent for the 10mg packs and Nil to 31 percent for the 20mg packs. Price undercutting based on the tender prices submitted at the level of __ percent for the 10mg packs and __ percent for the 20mg packs was found. The Ministry notes that the margins of dumping are less than the margins of price undercutting.

In the tender, when the outcome was essentially a win or lose situation, the magnitude of the dumping margin may only be of relevance in that the tender (and hence the market) has been lost. The magnitude of dumping will not cause any increase in the injury already caused to the industry.

### Other Adverse Effects

#### Cash Flow

The company stated the loss of profit for producing Tamofen for the domestic market and reduction in working capital would have a negative effect on cash flow. The company did not provide any projected figures to show the expected impact of this.

#### Inventories

Douglas has stated that the inventories had been run right down as Tamofen was effectively being phased out of the market. Douglas noted that there was a less efficient use of capital because of the reduced usage in the warehouse, and that there was a negative spin-off effect

for the reputation of the company concerning the inability to continue to supply patients with Tamofen. In addition there was a reduction in the presence of Douglas in the market in terms of contact with customers.

**Employment and Wages**

Douglas said that there would be an impact on employment. The current level of employment was approximately ___ in the manufacturing plant with another __ people employed in other areas, giving a total level of employment of ___. _____.

**Growth**

Douglas said that because the market environment was uncertain at the moment, any decision impacting on the growth of the company would be postponed.

**Ability to Raise Capital**

Douglas stated that the strength of their balance sheet is a determinant of the ability to raise capital and Tamofen was a contributing factor to the balance sheet.

**Investment**

The company stated that the loss of the tamoxifen tender to supply Tamofen on the domestic market would have a negative impact on the company's investment strategy, and in particular consideration of any further investment in New Zealand.

# 4.6 THREAT OF INJURY

Article 3.7 of the WTO Anti-Dumping Agreement states:

A determination of a threat of material injury shall be based on facts and not merely on allegation, conjecture or remote possibility. The change in circumstances which would create a situation in which the dumping would cause injury must be clearly foreseen and imminent[10]. In making a determination regarding the existence of a threat of material injury, the authorities should consider, inter alia, such factors as:

(i) a significant rate of increase of dumped imports into the domestic market indicating the likelihood of substantially increased importation;

(ii) sufficient freely disposable, or an imminent, substantial increase in, capacity of the exporter indicating the likelihood of substantially increased dumped exports to the importing Member's market, taking into account the availability of other export markets to absorb any additional exports;

(iii) whether imports are entering at prices that will have a significant depressing or suppressing effect on domestic prices, and would likely increase demand for further imports; and

(iv) inventories of the product being investigated.

No one of these factors by itself can necessarily give decisive guidance but the totality of the factors considered must lead to the conclusion that further dumped exports are imminent and that, unless protective action is taken, material injury would occur.

10 One example, though not an exclusive one, is that there is convincing reason to believe that there will be, in the near future, substantially increased importation of the product at dumped prices.

The application was made on the basis of a threat of injury arising from the contract price reduction of tamoxifen sold under the brand name Genox. Material injury would be incurred if patients switch to the fully subsidised Genox brand of tamoxifen.

The subject goods have been in the market at the new subsidised price level price level since 7 July and as at I December 2000 became the only brand of Tamoxifen Citrate listed in the Pharmaceutical Schedule and the only subsidised brand available in New Zealand. The sales statistics show that sales of Tamofen were ____ in the period August to October 2000. The investigation has changed from the threat of material injury claimed by the industry to one of actual material injury and the investigation has proceeded on that basis.

# 4.7 OTHER CAUSES OF INJURY

*Sections 8(2)(e) and (f) of the Act provide that the [Chief Executive of the Ministry of Economic Development] shall have regard to factors other than the dumped goods which have injured, or are injuring, the industry, including—*

*(i)The volume and prices of goods that are not sold at dumped prices; and*

*(ii)Contraction in demand or changes in the patterns of consumption; and*

*(iii)Restrictive trade practices of, and competition between, overseas and New Zealand producers; and*

*(iv)Developments in technology; and*

*(v)Export performance and productivity of the New Zealand producers; and*

*the nature and extent of importations of dumped or subsidised goods by New Zealand producers of like goods, including the value, quantity, frequency and purpose of any such importations.*

## Factors Other Than Dumping

The factors other than dumping that the [Chief Executive of the Ministry of Economic Development] must have regard to as set out in section 8(2)(e) of the Act, were considered by the investigating team. The following paragraphs summarise these considerations.

#### Volume and Prices of Goods Not Sold at Dumped Prices

##### Volume of Non-dumped Goods

According to Medsafe's letter dated 29 June 2000 there are three manufacturers other than Generics (UK), which import tamoxifen into New Zealand.

- Alpha Tamoxifen is registered with Medsafe but according to the data on sales recorded by IMS this product does not appear to be sold on the New Zealand market.
- Estrozyn is manufactured by Egis Pharmaceutical Limited, Hungary and packed in Western Australia.

- Nolvadex is manufactured and packed by Zeneca Pharmaceuticals Limited, United Kingdom.

The following is a table of the dumped and non-dumped goods:

Table 4.11: Volume of Non-Dumped Goods
(Monthly, Year 2000, 20mg x 30 tablet packs)

| | Apr | May | Jun | Jul | Aug | Sep | Oct |
|---|---|---|---|---|---|---|---|
| Genox | | Decline | Increase | Increase | Increase | Decline | Increase |
| Tamofen | | Increase | Decline | Decline | Decline | Static | Static |
| Nolvadex | | Decline | Decline | Decline | Decline | Decline | Increase |
| Estroxyn | | Static | Static | Static | Static | Static | Static |
| Total | | Decline | Increase | Increase | Increase | Decline | Increase |

The table shows that the volume of non-dumped imported brands, other than Genox, have declined. The volume of Tamofen has also declined. The volume of non-dumped Genox has increased since Pacific secured the tender. Imports from sources other than Generics (UK) have not caused injury to the New Zealand industry.

The sources of supply of tamoxifen in the New Zealand market have been changed as a consequence of the tender. PHARMAC advised that the tender does not preclude pharmaceutical suppliers from supplying their brands of tamoxifen via chemists on an unsubsidised basis for the private market, or through hospitals, which purchase pharmaceuticals independently of PHARMAC. PHARMAC has stated that the hospitals and private market make up about 10 percent of the New Zealand market. This is probably an overall figure for pharmaceuticals and not specific to tamoxifen, since Blackburn Croft have provided the IMS figures for government and private hospitals which show that tamoxifen totalled approximately _ percent of the market. It is not clear what percentage of sales would be made privately outside of hospitals however it is likely to be insignificant for tamoxifen, as it would be very difficult to compete with the new low tender price and not receive a subsidy. The tender has effectively resulted in no supplier other than Pacific being left in the New Zealand market.

#### Prices of Non-dumped Goods

The following are prices of non-dumped goods in the market.

Table 4.12: Prices of Non-Dumped Goods
(Year 2000, NZD)

| 10mg | April | July |
|---|---|---|
| Genox | 6.28 | 2.6 |
| Tamofen | 6.28 | 6.28 |
| Nolvadex | 6.28 | 6.28 |
| Estroxyn | NA | 6.28 |
| 20mg | | |
| Genox | 11.93 | 2.99 |

| | | |
|---|---|---|
| Tamofen | 11.93 | 11.93 |
| Nolvadex | 11.93 | 11.93 |
| Estroxyn | 11.93 | 11.93 |

The table shows that the only price change as a result of the tender was that for Genox. The other goods remained at the same price after the tender round.

**Contraction in demand or changes in the patterns of consumption**

All brands of tamoxifen can continue to be sold in New Zealand up to 1 December 2000, but subsequent to this date Pacific will be the only subsidised supplier and the other suppliers/manufacturer will be delisted from the Pharmaceutical Schedule. Market size for tamoxifen will remain fairly constant if tamoxifen continues to be the drug of choice for prescriptions and Genox will effectively be the only subsidised brand available to patients.

**Restrictive trade practices of, and competition between, overseas and New Zealand producers**

Douglas advised that there were no restrictive trade practices in the market in terms of the Commerce Act 1986, and that there were no barriers of entry into the market.

**Developments in Technology**

Douglas was not aware of any new developments in technology and stated that the worldwide use of tamoxifen was increasing rather than decreasing.

Generics (UK) advised that tamoxifen has had some recent bad press as a possible cause of other cancers.

In response to the Essential Facts and Conclusions report Blackburn Croft stated that no reference was made to any written reports that would substantiate such a comment. The Ministry notes that Generics did not provide any references in support of that contention. However, the Ministry is aware of a small amount of evidence of adverse effects, as evidenced by part of an article in the attachments to document 212 on the Public File which noted tamoxifen toxicity and drug resistance, but that by far the majority of the information about tamoxifen had been positive.

Various news items have been sighted in relation to developments concerning tamoxifen and they are as follows:

- *Chemist & Druggist* released information saying that Anastrozole is set to challenge tamoxifen as the gold standard treatment in women with advanced post-menopausal breast cancer. Data presented at the European Cancer Conference in Vienna reported that Anastrozole was well tolerated and at least as effective as tamoxifen and, in one study more effective than tamoxifen. AstraZeneca now plans to submit the data to the regulatory authorities to allow its first-line use in postmenopausal women with advanced disease.

- *Dow Jones Newswires* reported that Aromasin as an alternative as a standard breast cancer drug to tamoxifen should be studied further as possible initial therapy for women with advanced disease. The small study of 97 women was presented at the

American Society of Clinical Oncology meeting. In Aromasin patients, the median time before their tumours grew was 8.9 months compared to 5.2 months for those on tamoxifen. "Although the results were encouraging no claims can be made that Aromasin is better than Tamoxifen" said the lead investigator, Dr Robert J Paridaens, Professor and head of the Oncology clinic, University Hospital Gasthuisberg in Leuven, Belgium.

- *The Guardian,* UK reported that new clinical findings from two pivotal studies, presented for the first time at the European Breast Cancer Conference in Brussels, show the aromatase inhibitor Femara (Letrozole, 2.5mg) to be more effective than tamoxifen (20 mg) as first–line treatment and pre-operative therapy for breast cancer in postmenopausal women. tamoxifen, the drug used to treat breast cancer, looks set to lose its wonder status, following the announcement that a new medicine out-performed it in trials on women with advanced tumours. The trials, involving more than 900 post-menopausal women compared Letrozole with tamoxifen. The results showed that more women who took a course of the new drug were able to avoid having mastectomies – 45% compared with 35% on tamoxifen.

The above list is not exhaustive but does give an indication that alternatives to tamoxifen are being considered but are in trial stages only.

**Export Performance of the New Zealand Producer**

Douglas advised the Ministry that "it will continue to manufacture tamoxifen in New Zealand for its export markets". Douglas advised that the financial details included in the application into the dumping investigation are not affected by the export business.

The investigating team requested financial information from Douglas at the time of verification on export performance. This information was not provided on the basis that information pertaining to Douglas's exports had been removed from all data given to the Ministry and any effect that they might have had, had also been removed.

In response to the Essential Facts and Conclusions report, Blackburn Croft noted the fact that during the verification of the industry, some information on Douglas's sales to Australia was provided.

**Productivity of New Zealand Producers**

The investigating team noted that _____. On the other hand, Generics (UK) manufacture tamoxifen in four different strengths _____. Without more detail, the investigating team was not able to determine from these differences whether the New Zealand industry was more or less productive than other producers.

The investigating team did note, however, that the yield rate for Tamofen is __% and the yield rate for Genox is __%, and while this may indicate that Douglas achieves a _____ productivity than Generics (UK), the Ministry would need more information on all aspects of productivity before it could draw a conclusion.

#### Imports by the Industry

At the verification visit Douglas advised that they had not imported Tamofen to supply the domestic market and that the brand Tamofen was Douglas's own brand registered in New Zealand. Information obtained from Customs New Zealand verifies that Douglas has not imported Tamofen for supply to the domestic market.

### Other

Douglas manufactures to an international standard of good manufacturing process. The Ministry noted that Douglas recalled 10mg tablets in late 1999 due to the product's failure of a dissolution test over time. While ___ batches were affected, only _____ packs or _ percent of the total tablets potentially affected were returned. While this problem is significant, there is no indication that it contributed to Douglas's lack of success in the PHARMAC tender.

#### Cost Comparison

As a result of a comparison of the costs of the active ingredient Tamoxifen Citrate it was found that Generics (UK)'s costs were _____ Douglas on a per kilogram basis. The volume bought by Generics (UK) in _____ bought by _____ Douglas (over the period of approximately a year). It is not clear how long it would take Generics (UK) to use the volume bought, _____.

In addition, Generics costs to make and sell for the New Zealand market at £___ and £___ (or NZ$___ and NZ$____ (at an average exchange rate for the _____ of 0.32761) are _____ than Douglas's estimated ____ costs of goods sold of $___ and $___, and also its fully recovered costs to make and sell of $___ and $___.

### Conclusion on Other Causes of Injury

The investigating team concludes that factors other than dumping may have been a cause of injury to Douglas.

## 4.8 Causality

### Essential Facts and Conclusions

In the Essential Facts and Conclusions report released to interested parties, the Ministry expressed the following views about whether there is a causal link between material injury and the dumping of the goods.

#### Ministry's View

The Ministry noted that the system of tendering for sole subsidised supply of the New Zealand market may result in injury to New Zealand producers that are not successful in such tenders. The cause of the injury is not the system of tendering itself, but the factors that make the New Zealand producer's bid less attractive than the successful bid.

In a situation, such as in this case, where a tender has been won at dumped prices, the Ministry needs to consider whether injury has been caused by the dumping. Dumping does not need to be the only cause of injury or even the major cause of injury, but must be a cause of material injury of itself. In a situation where a New Zealand producer loses a tender to another New Zealand producer or to an importer of undumped goods, the cause of any injury would of course be due to factors other than dumping.

In the tender situation under consideration, there are evaluation criteria other than price, namely: savings to the Health Funding Authority; ability to supply, regulatory approval to market; interchangeability with leading market brand, and pack size and type of packaging. The Ministry is unaware of any significant differences between Pacific and Douglas in respect of factors other than price. In this situation price appears to provide the only differentiation between bids by the two companies. Analysis of price undercutting, therefore, may be determinative in this situation in deciding whether dumping is a cause of material injury to the New Zealand industry.

**Analysis of Price Undercutting**

If dumping were the sole cause of price undercutting, it would be clear that, in terms of price effects, dumping was the only cause of any injury to the New Zealand industry. In the current case, the importer's undercutting of the New Zealand producer's price is due partly to dumping and partly to other factors that allow Pacific to price lower than Douglas, even in the absence of dumping.

The Ministry has added back the margin of dumping to Pacific's price to estimate an undumped price. The following table compares price undercutting of dumped prices with price undercutting of undumped prices.

Table 4.13: Price Undercutting Comparison
($NZ per 30 pack)

| May - June 2000 | 10mg[1] | 20mg |
|---|---|---|
| Douglas tender price | CONFIDENTIAL | CONFIDENTIAL |
| Pacific Dumped Price | 2.60 | 2.99 |
| Price Undercutting - Dumped | CONFIDENTIAL | CONFIDENTIAL |
| Est. Pacific Undumped Price | CONFIDENTIAL | CONFIDENTIAL |
| Price Undercutting - Undumped | CONFIDENTIAL | CONFIDENTIAL |
| Undercutting due to Dumping | CONFIDENTIAL | CONFIDENTIAL |
| % Undercutting due to Dumping | CONFIDENTIAL | CONFIDENTIAL |

[1] A calculation error in the Essential Facts and Conclusions report has been corrected.

The table shows that dumping has contributed significantly to price undercutting, but that most of the undercutting is not due to dumping.

The Ministry notes that it is likely there were other tenderers, but PHARMAC would not release this information to the Ministry. The prices that any other tenderers bid, therefore, are not known.

**Douglas's Bid Uncompetitive Against Undumped Price**

In view of the large margins of price undercutting due to factors other than dumping, and the lack of any indication that other criteria would have significantly differentiated the bids, the Ministry considers it likely that Douglas would not have won the tender if Pacific had tendered at an undumped price.

**Past Investigations**

The Ministry notes that in many dumping investigations which do not involve a sole tender situation, price undercutting has been found to be greater than the margin of dumping. In those cases, the Ministry has recognised that dumping has contributed to price undercutting and has concluded that dumping has been a cause of material injury. The Ministry notes that in those situations, dumping as well as other factors are usually causing injury, but dumping, while not the only cause of injury, has been found to be a cause of material injury. Duties have been applied in those circumstances and the purpose of the Act, to protect New Zealand industry from unfair competition, is maintained.

**Sole Tender Factors**

The current investigation involves consideration of a tender for sole subsidised supply of the New Zealand market, and differs from the situation where the importer and New Zealand producers continue to compete in the same market. The tender involves a one-off situation, where only the successful tenderer will remain in the market. In a dumping investigation, the Ministry considers, therefore, the factors that have caused the New Zealand industry to lose the tender.

In this case, the tender has been lost due to price undercutting which is due to both dumping and to other factors. The Ministry notes that dumping is one of the factors contributing to price undercutting and that it could be argued, therefore, that dumping is one of the causes of injury and a cause of material injury. On balance, however, the Ministry considers that the stronger argument is that significant price undercutting would still exist in the absence of dumping, and that such price undercutting resulting in a successful tender would still be responsible for the total loss of the New Zealand industry's sales, output, market share and profits. In these circumstances, the Ministry considers that it is more likely that the price undercutting due to other factors, rather than the dumping, is the cause of injury.

**Conclusion**

The Ministry's view on causal link arises from the fact that the tender situation in this case involved an all or nothing outcome for the parties involved. In this situation where most of the price undercutting was not due to dumping and Douglas offered its tender price _____ above the price at which Pacific's price would be considered to be undumped, the Ministry has difficulty determining that there is a causal link between dumping and material injury.

The Ministry noted in the Essential Facts and Conclusions that it was likely to conclude that material injury had not been caused by dumping of imports of tamoxifen from the United Kingdom. The Ministry noted the complexity of the matter and its awareness that other administrations have had to consider cases of tender dumping and that New Zealand has also considered cases involving tenders. The Ministry observed that the cases considered,

however, have been of limited assistance, as the circumstances of the current case are different. The Ministry stated that if parties were aware, however, of relevant cases showing approaches taken by other administrations, the Ministry would be willing to further consider whether there is a causal link between the dumping and material injury in this case.

**McPhail Submission**

The Ministry sought the advice of Hugh McPhail, former Manager of the Trade Remedies Group. Mr McPhail was involved in negotiating the Anti-dumping Agreement in the Uruguay Round of Multilateral Trade Negotiations.

**Volume Effects**

Mr McPhail states, in relation to volume effects of the dumping (and in the absence of an appropriate price undercutting analysis), that "the loss of the totality of the contract would appear to be a persuasive indicator that dumping has had some effect".

**Margins Analysis**

Mr McPhail notes that the extent of the margin of dumping is relevant in considering causality.

However, it should be noted that in New Zealand experience, in most cases where duties at the full margin of dumping have been applied, the price differential in favour of the imported goods was significantly higher than the margin of dumping, suggesting that there were other causes of injury additional to the dumping. Nevertheless, the objective of the trade remedy legislation is to remove the injurious impact of dumping, irrespective of whether other causes of injury exist and are more significant.

Mr McPhail comments that price undercutting may not be an appropriate element to consider in establishing the impact of dumping in a tender situation.

. . . the losing tender price may not be relevant as a point of comparison, since it is not a market price, and may not have reflected any actual sales. Also, in cases where the contract concerned is to a buyer in a position such as that of Pharmac, comparison with prices of sales to other buyers may not be relevant, since they are not comparable. This suggests that in tender price situations, price undercutting may not be an appropriate element to consider in establishing the impact of the dumping of goods.

In cases where price undercutting analysis is appropriate, however, Mr McPhail concludes:

In case of tender dumping, price comparisons based on tender prices may not be appropriate, and consequently price undercutting comparisons may not be a relevant consideration in the assessment of injury.

In any event, the fact that price differentials may exceed the margin of dumping has not, in the past, prevented the imposition of anti-dumping duties to the extent of the margin of dumping, provided that material injury can be attributed to the dumping.

**Submissions by Interested Parties**

#### PHARMAC

Other Factors Have Caused Injury

PHARMAC submits that "factors other than dumping are the cause of any injury sustained by Douglas". PHARMAC claims that "it is the use of the tendering arrangements resulting in there being a sole supplier in the relevant market and other suppliers necessarily exiting that market which has the impact on Douglas, rather than any alleged dumping of goods". PHARMAC states that "Douglas would need to show that if dumping had not occurred, it would have won the tender for sole supply".

PHARMAC points out that price is only one consideration when evaluating tenders. However PHARMAC considers that, on the basis of the price criterion alone, if Douglas's tender bid was higher than Pacific's non-dumped price, then Pacific's pricing could not have caused material injury to Douglas.

If one takes the price criterion alone, Douglas would not have won the tender if the price at which it bid was still higher than Pacific's "non-dumped" price. If Douglas' price was higher than both Pacific's "dumped" and "non-dumped" prices, then there could be no material injury to Douglas as a result of Pacific pricing at a "dumped" level.

PHARMAC notes that its tender evaluation committee is required to take account of the following matters in addition to price:

- savings to the Health Funding Authority;
- supplier's ability to ensure continued availability of tamoxifen throughout the tender period;
- regulatory approval to market tamoxifen;
- interchangeability of tamoxifen with the leading brand at the time of the tender; and
- pack size and type of packaging.

PHARMAC notes that "the tender documentation provides that PHARMAC is not bound to accept the lowest priced bid".

In response to the Essential Facts and Conclusions report, PHARMAC re-emphasises that there are other relevant decision criteria than just price. It states that the actual evaluation is confidential, but notes that in Douglas's submission to the Ministry, no reason was provided as to "why it [Douglas] could be selected even with a higher price than Pacific".

#### Generics (UK) and Pacific

Submissions were made on behalf of the exporter and importer of Tamoxifen by Bell Gully.

#### Tender Not Won by Dumped Imports

In response to the Essential Facts and Conclusions report, Bell Gully disagrees with the Ministry's conclusion that the PHARMAC tender was won by bidding at a dumped price. Bell Gully notes that "dumping was only found by the Ministry for the months of May and June 2000 over the whole investigation period". In response to the Essential Facts and Conclusions report, Bell Gully agrees that there was an increase in the volume of imports into New Zealand in May and June 2000, but considers that "this was not due to the product being

available at a dumped price, but rather as a consequence of Pacific having to build up the necessary inventory to supply 100% of the Tamoxifen market following the winning of the tender".

Bell Gully argues that "the contract was won on the basis of _____ _____ . . .". Bell Gully points out that the level of dumping would have been considerably different if the PHARMAC contract _____.

#### Analysis of Effects of Dumping

In response to the Essential Facts and Conclusions report, Bell Gully expresses concern about the period of investigation used to assess the effects of dumping. Bell Gully accepts that while "the pre-PHARMAC price period is not relevant in assessing the effect of Pacific's tender price bid on the New Zealand market, this effectively means that the Ministry's period of investigation has been reduced to only 4 months out of the original 12 month period". Bell Gully notes further that the Ministry has assessed price undercutting for only the two months in which dumping was found. Bell Gully considers that the _____ "must be taken into account in assessing the effect of any dumping".

Bell Gully argues that, "if the Ministry does not assess dumping over the whole period of investigation because of a change in circumstances", the Ministry should include the latest verified information in its assessment of the effects of dumping, namely September information requested by and provided to the Ministry's verification team. Bell Gully argues that this would extend the period of investigation to five months, rather than the two months shown in the price undercutting table 4.13.

Bell Gully also argues that, even though there were no export sales to New Zealand of ____ Tamoxifen in _____ ____, the Ministry should take account of its view that if there had been export sales in those months, they would have been undumped.

#### Tender Won by Competitive Advantage

Bell Gully considers that Pacific was able to win the tender, even at an undumped price, because its supplier Generics is a low cost producer of generic pharmaceuticals and has a competitive cost advantage.

The fact that a so-called dumped price won the tender is immaterial as Douglas was still unable to compete at the higher undumped price. This lower price simply meant an extra benefit to Pharmac and loss of profits to Pacific but no loss at all to Douglas as it was already out of the picture.

Bell Gully considers that "the result of the McPhail approach where a tender is won at a dumped price is a conclusion that dumping has had some effect, but this does not measure the impact or amount of the effect. The real cause of the injury remains unknown".

### Douglas

Submissions were made on behalf of Douglas by Blackburn Croft & Co and Robert Fardell.

#### Tender Dumping Causes Injury

Douglas advises that it was not competitive tendering per se that was the problem, but the inability to compete against dumped prices and that an overseas company could effectively secure the market for this or another product for 3 years. Douglas cites the WECO (Whangarei Engineering and Construction Ltd) case, which went to the Court of Appeal in December 1991. Douglas argues that it demonstrated that a tendered price can cause material injury independent of the process by which the dumped price was offered by the exporter and importer.

In response to the Essential Facts and Conclusions report, Robert Fardell, on behalf of Douglas, refers to Auckland Harbour Board v Comptroller of Customs (Unreported CP 423/87 High Court Auckland 20/12/89 Jeffries J (HC) and [1992] 3 NZLR 392 CA). Mr Fardell noted that in that case the Court rejected an argument that since the tender was already lost by the New Zealand industry due to dumped imports any duty would not provide a remedy. Mr Fardell observed that there was a significant price difference between the two tenders in that case, and that remedies had been provided in tender situations in the past.

#### Speculation About Successful Tenderer Misplaced

Blackburn Croft refers to the Ministry's statement that it "considers it likely that Douglas would not have won the tender if Pacific had tendered at an undumped price". Blackburn Croft objects strongly "to this statement being used to influence the outcome of the investigation. Blackburn Croft considers that "the Ministry should only be interested in price undercutting due to dumping and should not be influenced when assessing a causal link by speculating about the undercutting which is not due to dumping". Blackburn Croft considers "this speculation is misplaced and contradicts the intent of the dumping legislation".

Blackburn Croft cites an Auckland Harbour Board Court of Appeal decision which noted that "the injury as to causation . . . is not concerned with the motives of the importer but with the consequences of the importation at the contract price". Blackburn Croft considers the Ministry should not ask "what might have happened", but rather look at the evidence before it. Blackburn Croft considers that Pacific "had a genuine commercial reason for using a dumped price" and "chose to offer a dumped price" and the exporter "is not excused from the ramifications of dumping by the investigating authorities undertaking a speculative view of what might have happened". The company considers that "certainly a 'what might have happened' view is not a recognised threshold for a causal link.

#### No Distinction Between One-off Tender and Other Cases

Blackburn Croft comments that "the attempt to distinguish between a one-off tender and non-sole tender dumping allegation is unconvincing". Blackburn Croft observes that "there are many sole tender (exclusive supply) situations in dumping investigations" and notes that "if the imported product plus the dumping margin can still undercut the New Zealand industry price then this does not mean that there is no causal link between the dumping and material injury". Blackburn Croft considers that the Ministry's argument could lead to importers, who are supplying goods that are currently subject to anti-dumping duties to the majority of the New Zealand market, claiming that there is no causal link between the dumping and material injury.

Blackburn Croft considers the Ministry is often faced with transactions being all or nothing outcomes, for example long-term contracts for sugar, but that this did not lead to causal link being queried due to "different circumstances".

#### Factors Influencing Tender

Blackburn Croft suggests that while Douglas was unaware of the price at which it needed to win the tender, other parties were provided by PHARMAC with Douglas's reduced prices and Pacific "consequently "pitched" its price at a level that would guarantee success and minimise any likelihood that PHARMAC would reject Pacific's bid". Blackburn Croft considers that "this clearly assists in establishing causal link."

Blackburn Croft notes that Douglas _____. Cost of goods sold was $___ for 10mg (compared to Pacific's $2.60 bid) and $___ for 20mg (compared to Pacific's bid of $2.99).

#### Approach Inconsistent with Past Practice

Blackburn Croft argues that "the creation of an argument that the magnitude of the price undercutting has nullified the causal link is contrived particularly given the Ministry's past practice . . . [which] has created a legitimate expectation" that a remedy will be imposed. Reference is made to the plasterboard reassessment and investigation concluded last year, which Blackburn Croft considers "clearly established that even if only part of the injury caused by price undercutting is attributable to dumping the Ministry will still reach a positive finding and impose a remedy." Blackburn Croft notes that the Ministry "was not prepared to speculate on what Sigma would do in the future and therefore imposed a remedy . . ."

Blackburn Croft considers the Ministry is "developing a policy quite different from that applied in past dumping situations" where the differential between the dumping margin and the price undercutting has not been used to destroy the causal link.

Blackburn Croft notes that the Ministry considered that an importer of plasterboard would still not be undercutting the price of the New Zealand industry even if anti-dumping duty was removed, yet the Ministry still imposed an anti-dumping duty.

Blackburn Croft & Co states that:

The Ministry's conclusion that because price undercutting is greater than the margin of dumping that, in this case, there is therefore no causal link is wrong and if applied will have unintended consequences for the application of anti-dumping duties currently in place and for future investigations.

#### Effectiveness of a Remedy

Blackburn Croft refers to paragraph 4.2.11 of the Essential Facts and Conclusions report, which observed, in relation to tender dumping, that "an anti-dumping remedy may not prevent injury, since the contract to supply has been lost, and remedying the injury caused to the industry may not be possible".

Blackburn Croft considers that there is little value in the argument that a remedy should not be imposed because the tender has been lost. Blackburn Croft states:

This argument would inevitably lead to a view that a remedy cannot be applied if volume sales cannot be recovered. A remedy cannot be expected to deliver such a result particularly when there are inevitably other factors dictating the successful outcome of a sale. . . . A remedy can, however, address the other injurious elements, which are clearly present in this case.

Blackburn Croft notes that it is difficult to forecast the effect of an anti-dumping duty, and points to Pacific's submission and comments made by PHARMAC in The Independent which indicate there is some uncertainty about the effect of a duty. Pacific stated that:

The likely effect on the New Zealand market of the imposition of an anti-dumping duty on Genox is complex. Pacific Pharmaceuticals Limited has a contract with PHARMAC for the sole supply of Genox required in the New Zealand market at the current price.

Because Pacific Pharmaceuticals Limited is contractually committed PHARMAC's position is critical in terms of the consequences. Any alteration of the price would contravene this contract.

Blackburn Croft notes that PHARMAC general manager Wayne McNee was quoted in The Independent of 15 November 2000 saying that "it may be that Pacific would lose sole supply status" [if an anti-dumping duty was imposed]. Blackburn Croft considers that it is not for officials or the Minister to predict the effect that anti-dumping duties might have on a market. "Such speculation assumes an unrealistic knowledge of the market and of future events. . . there was no certainty of what might happen if anti-dumping duties were imposed on Genox."

**Impact on Industry's Access to Market**

Blackburn Croft considers that the Ministry has considered the consequent impact on one transaction, rather than on the relevant New Zealand industry as required by section 8 of the Act. Blackburn Croft argues that the margin of dumping has not only contributed significantly to the price undercutting, "but has significantly lowered the price of Tamoxifen such that re-entry into the New Zealand market at the end of this tender has been materially impacted" and it will be "extremely difficult for Douglas to re-enter the market when the period of sole supply ends".

Blackburn Croft advises that "PHARMAC has informed Douglas _____. Blackburn Croft notes that the contribution of dumping to price undercutting is significant and that "the price undercutting effects of the dumping margin are able to be linked to the extremely low prices of Tamoxifen which have the potential to forever exclude Douglas from obtaining orders for Tamoxifen for the domestic market". Blackburn Croft argues for a remedy to remove the price effects of the dumped price and allow Douglas the opportunity to re-enter the market.

PHARMAC _____.

**Ministry's Approach Challenged**

Blackburn Croft notes that the Ministry has concluded that there is no causal link because of the level of price undercutting. Blackburn Croft considers that by arguing that an anti-dumping duty may not prevent injury, because the contract to supply has already been lost the Ministry faces three fundamental problems.

a. This interpretation is inconsistent with its own past practice.
b. This reasoning does not fit with McPhail's opinion.
c. Why accept a case for initiation when the tender has been lost? Does this mean that an applicant has to show that a tender would have been won before an investigation is initiated? If a tender could not have been won is this grounds for termination?

Blackburn Croft states that Mr McPhail's paper provides no reason to conclude that there is no causal link between the dumping and material injury. Blackburn Croft states:

At the time the dumped price was offered the contract was won. The dumped price, which won the contract resulted in Douglas ceasing production of Tamoxifen Citrate for the domestic market. Put simply, the timing of the contract and the presence of dumping is a strong causal link.

**Ministry's Comments**

The Ministry makes the following comments in relation to the above submissions, before explaining its approach to causality in more detail. These comments will answer some particular points made by interested parties, while the Ministry hopes to cover other issues by a more complete discussion of its approach which will follow these comments.

**Was the Tender Won by Dumped Prices?**

In response to Bell Gully's concerns about the Ministry's finding of dumping and whether Pacific bid at a dumped price, the Ministry notes that in deciding whether material injury has been caused or is threatened by material injury, the Ministry examines the existence and extent of any dumping during the period of investigation and its impact on the New Zealand industry.

The Ministry has established dumping on the basis of the facts presented over a twelve-month period. In relation to anticipated prices, the Ministry notes that the Act does not require it to examine whether the exporter intended to dump, but to establish whether the exporter dumped and the extent of dumping. If the tender had been called for prices _____ _____. The Ministry observes that imports in those months were found not to be dumped. However, the facts are that the tender did call for prices to be reduced earlier than this and dumping was found in respect of imports meeting that price reduction.

The investigation has found that the PHARMAC tender was won by tender bids at prices which reflected the fact that dumping was occurring.

**Analysis of Effects of Dumping**

In response to Bell Gully's concerns about the period of assessment of price undercutting, the Ministry replies that, since dumping was only found in the months of May and June 2000, it

was only necessary to consider price undercutting due to dumping during those two months. The sales of 10mg Tamoxifen in July were not dumped and could not, therefore, contribute to price undercutting due to dumping.

The Ministry notes that there were no imports of ____ Tamoxifen in _____ and, therefore, there was no dumping in those months.

The Ministry uses a period of investigation of 12 months to assess whether, and the extent to which, dumping has occurred. The investigation has established that there was no dumping in the first eight months and the last two months of the period of investigation, while there was dumping in two months. The Ministry has then examined the volume and price effects of the two months dumping on the New Zealand industry, and considered whether there are causes of injury other than dumping.

#### Competitive Advantage

Douglas based its tender offer _____ of $__ for 10mg tablets and $___ for 20mg tablets. On this basis, Douglas's offer prices of $___ and $___ represented earnings before interest and tax of __% to __% of the offer price. Following the verification visit, Douglas recalculated costs of goods sold on a full recovery basis as $___ for 10mg tablets and $___ for 20mg tablets.

Based on its successful offer prices of $2.60 and $2.99 respectively for 10mg and 20mg tablets, Pacific's net profit as percentages of the offer prices are estimated at __% and _% respectively, while Generics (UK)'s net profit percentages on export sales to New Zealand were __% and __%. Generics costs to make and sell for the New Zealand market at £___ and £___ (or NZ$___ and NZ$___ (at an average exchange rate for the _____ of 0.32761) are _____ than Douglas's _____ _____ of $___ and $___ and also its fully recovered costs to make and sell of $___ and $___. A comparison of the prices paid for the active ingredient Tamoxifen Citrate, which accounts for the majority of the total cost of the raw materials, shows that _____.

The cost comparison _____.

#### Tender Dumping and Injury

The Ministry notes that the current case differs from other investigations in that it involves an all or nothing outcome in respect of supply of virtually the total New Zealand market and price is the determinative factor in deciding who will supply the market. The decisions have been taken by Pacific to tender at dumped prices and by Douglas to tender at prices that were ____ higher _____ undumped prices. The Ministry considers that the question is whether the New Zealand industry failed to gain the contract to supply because of dumping or because of some other reason, for example a bid by a more competitive supplier or an uncompetitive bid by the local industry.

If Pacific had presented undumped prices of $___ and $___ in the tender, on the basis of its ____ cost estimates Douglas could have won the tender at profit levels of up to __% and __% of contract prices, if it had chosen to bid at lower prices.

The Ministry notes that, on the basis of fully recovered costs, Douglas's cost of goods sold in ____ was actually $____ and $____ respectively. On the basis of fully recovered costs, Douglas _____
_____.

Blackburn Croft considers Douglas would have had to lower its prices by __% and __% to equal Pacific's undumped prices, but the Ministry's revised calculations show that Douglas would have had to lower prices by greater percentages, namely __% and __%.

In relation to Mr Fardell's reference to the Auckland Harbour Board case, the Ministry notes that the issue in the Court of Appeal was whether, in view of an Australian Government "grace and favour bounty", the case should have been dealt with as a dumping or a countervailing duties case. The Court of Appeal decided that the case should have been dealt with under the countervailing duties regime and struck down the anti-dumping duty, making the discussion of anti-dumping duties in the High Court irrelevant.

The Auckland Harbour Board argued that the tender had been awarded on a range of grounds as well as price, so the dumping did not cause injury to the New Zealand industry. The Court rejected this argument and held that the motives or intention of the importer were irrelevant. In doing so, the Court held that the conclusion that the goods were dumped was a sufficient basis for imposing anti-dumping duties. The Ministry notes, however, that in this case the amount of the margin of dumping was greater than the price difference between the bids. If this had been the case in the current Tamoxifen investigation, the Ministry would have seriously considered recommending a remedy.

#### Distinction Between One-off Tender and Other Cases

The Ministry considers that a three-year sole tender situation differs markedly from situations where imported and domestic goods continue to compete with each other on a daily basis. In the current case, the evaluation criteria for supply are known at a particular point in time at which a decision on supply for the next three years is made. In the case of Tamoxifen, on the basis of the information available, price was the overriding consideration and it was clear that the importer could have secured the contract whether the price was dumped or not. In other cases, where dumped and domestic goods continue to compete, there are a number of factors that affect buyers' decisions at different points in time, such as quality, service, and delivery, such that dumping and other factors may each be causes of injury in their own right.

#### Past Practice

In relation to its past practice, the Ministry comments that it has not previously dealt with a case that involves a tender for sole supply of the New Zealand market. The Ministry approaches each investigation on the basis of the facts that pertain to that particular case, and an approach that may be relevant in one case will not necessarily be appropriate in another case. The Ministry is however prepared to consider the appropriateness of adopting approaches used in previous cases.

The Ministry notes that it examines the extent to which dumping is causing price undercutting as part of its analysis of whether the dumping is causing injury. The fact that dumping contributes to price undercutting, does not mean that a causal link has been established as of right.

The Ministry considers the facts of each investigation and asks whether the dumping is a cause of the injury, and whether it is a cause of material injury. In the current case, the Ministry is not convinced that there is a causal link between the dumping and injury.

The Ministry notes that Blackburn Croft refers to a reassessment of anti-dumping duty on plasterboard, which followed a review that concluded that the removal of anti-dumping duties was likely to lead to a recurrence of material injury to the New Zealand industry. Anti-dumping duties had been in place on plasterboard for some years and export prices in some cases were designed by exporters to be above the threshold level for payment of anti-dumping duty. The threshold price was reassessed to ensure that a remedy was in place should export prices move below the non-injurious price.

#### Effectiveness of a Remedy

The Ministry notes the views of Blackburn Croft in relation to whether anti-dumping duties would remedy injury in this case. The Ministry also received submissions from other parties on whether remedies would be effective. In the material it has released on this case to date, the Ministry has not considered the question of whether a remedy would be effective. This is because the need to consider a remedy has not arisen as the Ministry considers there is no causal link between injury and the dumping. The Ministry does note, however, that, if a causal link had been established, cogent arguments could be put forward in favour of recommending an anti-dumping duty.

#### Impact on Industry's Access to NZ Market

In relation to Blackburn Croft's submissions on this matter, the Ministry replies that, before a remedy may be considered, injury must be either caused or threatened by the dumped imports, through the effects of dumping. The Ministry has already concluded that the injury suffered by Douglas was not due to the effects of dumping. Whether any injury will be caused by dumping once the sole tender period ends, depends on whether dumping occurs at that time and whether there is a causal link with the dumping of the goods. The Ministry cannot assume that prices at that time will be the same as those that apply during the current tender period, nor can it assume that, even if prices remain at the same level, that those prices will be dumped at that time.

#### Ministry's Approach to Causality

The Ministry notes that Blackburn Croft considers that the Ministry's conclusions are flawed. The Ministry considers that it should give as full an explanation as possible of its approach to causality. After careful consideration of all the arguments, the Ministry considers that, rather than being flawed, its approach is consistent with both domestic legislation and the WTO Anti-dumping Agreement.

Article VI.1 of GATT 1994 states that "the contracting parties recognize that dumping . . . is to be condemned if it causes or threatens to cause material injury" to a domestic industry.

Article 3.5 of the WTO Anti-Dumping Agreement states:

> It must be demonstrated that the dumped imports are, through the effects of dumping, as set forth in paragraphs 2 and 4, causing injury within the meaning of this Agreement. The demonstration of a causal relationship between the dumped imports and the injury to the domestic industry shall be based on an examination of all relevant evidence before the authorities. The 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. . . .

The matters to be considered in determining whether there is material injury are set out in section 8 of the Act, namely the volume of dumped goods, their effect on prices in the New Zealand market for like goods, and the consequent impact of the dumped goods on the relevant New Zealand industry and the factors required to be considered when examining these. Those factors and the injury analysis are contained earlier in Section 4 of this report, as is the Ministry's consideration of factors other than dumping which may be injuring the industry.

It is accepted that Douglas suffered material injury, because it is no longer producing tamoxifen for the New Zealand market. The question is what were the causes of material injury.

The Ministry considers that the dumping of goods must be a cause of material injury in its own right, or put another way, the injury attributable to the dumping of goods must be material.

Dumping does not need to be the only cause of material injury, but it must be a cause of material injury to the domestic industry, regardless of the intent of exporters. Injury arising from other factors or causes should not be attributed to dumping.

Section 8 of the Act refers to determining whether material injury has been or is being caused by "the dumping of goods". Section 13(1) of the Act refers to a final determination of whether "goods are being dumped" and "by reason thereof material injury has been or is being caused to an industry". The "by reason thereof" refers to by reason of the goods being dumped.

The Act requires, therefore, a causal link between the material injury and "the dumping of goods" or "the dumped goods". The Agreement also requires a causal link between the material injury and "the dumped imports . . . , through the effects of dumping", as set forth in paragraphs 2 and 4 of Article 3. Paragraphs 2 and 4 are essentially the same factors set out in section 8 of the Act in relation to volumes of dumped goods, their effect on prices in the New Zealand market for like goods, and the consequent impact of the dumped goods.

The Ministry's research has revealed that there are two basic approaches as to how the causal link should be examined. As set out below, the Act and the Agreement are not determinative on which approach should be pursued.

#### The "Dumped Imports" Approach

The first interpretation is that the causal link is implicit if there is dumping and material injury is shown, that is that there are "dumped imports" and material injury. Most of the factors in section 8 relate to the effect of the dumped goods and it could be inferred that the material injury is caused by the dumping of the goods. Similarly, the same inference could be drawn from the factors contained in the Agreement.

The implication that a causal link may be inferred from the dumping and material injury is supported by the adopted GATT Panel Report ADP/87 concerning the imposition by the United States of anti-dumping duties on imports of fresh and chilled Atlantic salmon from

Norway. The Panel held that the criteria in (now) paragraphs 2 and 4 were not only indicia of the existence of material injury, but they were also indicia of the necessary causal relationship.

This is not the only interpretation of how the question of causal link may be approached and different interpretations have been debated internationally for many years. The Act refers not only to injury caused by "the dumped imports", but also to "the dumping of goods". The different interpretations relate to whether "the dumped imports" caused material injury, or whether "the dumping" caused material injury.

#### The "Dumping" Approach

In this approach, while the dumped imports may have caused material injury, the question is whether the dumping aspect of the imports has caused material injury.

Whether the causal link should relate to "dumping" or "the dumped imports" has been subject to some discussion over the years. Edwin Vermulst, in a 1990 comparative study[1] states:

An issue that has raised considerable controversy in the United States, but has been largely ignored in the other jurisdictions concerns the question of whether the causal link should relate to the dumping margins (margins analysis) or to the dumped imports (imports analysis). Proponents of the margins analysis argue that the size of the dumping margin should play a certain role in the causation analysis. Thus, for example, if the dumping margin is 5%, but the margin of price undercutting is 45%, this might be an indication that any injury caused by the dumped imports is not caused by the dumping.

Vermulst notes that the US Court of International Trade ruled that there is no obligation to take into account the size of the dumping margins. Vermulst's opinion, however, was that "the size of the dumping margin should logically be a factor in the analysis of causation" and that this should be explicit in the Anti-Dumping Code. Vermulst noted, in relation to the then GATT Anti-Dumping Code:

The wording of the . . . Code would seem to contemplate a margins analysis in that it requires . . . that it must be demonstrated that the dumped imports are, through the effects of dumping, causing injury.

Magnitude of the margin of dumping is now included in the Agreement, but under Article 3.4 relating to examination of the impact of the dumped imports on the domestic industry, rather than under the causality provision in Article 3.5.

#### Dual Test Approach

Muller, Khan and Neumann, in EC Anti-Dumping Law[2] explain the EC approach to the causal link issue. The EC applies two causal link tests sequentially.

The first test focuses on the dumped imports and asks whether there has been material injury from the dumped goods. The first test involves essentially the application of the criteria in section 8(1) and (2)(a) – (d) of the Act and this test accepts that there is an inference that material injury is caused by dumping.

The second test examines whether there are any known factors apart from the dumped imports which are also injuring the industry. If there are such other factors, it must be established whether the injury caused by the other factors breaks the inferred "causal link" established under the first test. If there is no manifest cause of material injury apart from the dumped goods, then the causal link under the first test is confirmed.

The Ministry considers that the dual test approach is consistent with Article 3.5 of the Agreement and section 8 of the Act. The first test includes an assessment of the effects of the dumped imports under sections 8(1) and 8(2)(a) – (d) of the Act. Section 8(2)(e) requires the Ministry to have regard to factors other than the dumped goods that have injured the industry. This is the second test. In effect, the Ministry has carried out this test in its investigations through consideration of the circumstances of the tender.

The Ministry considers it appropriate to conduct the dual causation test. The matters that are taken into account are summarised below, as they have been dealt with earlier in this report.

References:

[1] Vermulst, Edwin A (1990) *The Antidumping Systems of Australia, Canada, the EEC and the USA: Have Antidumping Laws Become a Problem in International Trade* in Jackson, John J and Vermulst, Edwin A, Antidumping Law and Practice; A Comparative Study, Harvester Wheatsheaf, Hemel Hempstead, Hertfordshire, UK, p. 458

[2] Muller, Dr Wolfgang, Khan, Nicholas, Neumann, Dr Hans-Adolf (1998) EC Anti-Dumping Law – A Commentary on Regulation 384/96, John Wiley & Sons, Chichester, UK, p.209ff

**First Causal Link Test**

The investigation found that imports in May and June 2000, immediately following announcement of Pacific's success in the tender, were dumped. There was a significant increase in dumped imports in absolute terms and relative to New Zealand production and consumption.

The increased volumes of dumped imports are the result of the importer undercutting the offer price of the New Zealand industry and have resulted in declines in the industry's market share, output, sales and profits. The injury to the New Zealand industry is clearly material.

The Ministry concludes that there is a prima facie inference that dumped imports have caused material injury.

**Second Causal Link Test**

Have factors other than the dumped goods injured the industry? The list of factors referred to in section 8(2)(e) of the Act, while not exhaustive, includes (iii) "competition between, overseas and New Zealand producers" and (v) "productivity of the New Zealand producers". The Ministry has found that, in respect of Tamoxifen, _____.

The Ministry considers that the comparison of offer prices made by Douglas and dumped and undumped Pacific offer prices can be used as indicative of the extent to which dumping and other factors were factors in winning the tender.

The Ministry has compared Douglas's offer prices with Pacific's successful offer prices and found that Pacific's offer prices undercut Douglas's offer prices, for 10mg and 20mg tablets respectively, by __% and __% or $____ and $___. Dumping contributed __ cents and __ cents of the undercutting, representing __% and __% of the undercutting. The percentage of price undercutting not due to dumping was predominant at __% for 10mg tablets and __% for 20mg tablets. While dumping contributed significantly to the undercutting, most of the undercutting was not due to dumping.

Dumping was a significant factor in lowering Pacific's offer price, but even at undumped levels there was _____ gap between the two sets of offer prices that the Ministry concludes that Douglas's bid, in the absence of dumping, would not have been successful. The Ministry considers that the _____ that caused material injury, to the extent that breaks the inference from the existence of dumping and material injury that dumping is a cause of material injury to the New Zealand industry.

The Ministry notes that, if Douglas's tendered price had been relatively close to the undumped tendered price, such that factors other than price could have affected the outcome, the Ministry may have concluded that the inference there was a causal link between the dumping and injury was confirmed.

The Ministry also observes that, if it merely had to conclude that the imports were dumped and by that fact it was inferred that any loss of a tender by the New Zealand industry was caused by the dumped imports, the Ministry would in all investigations merely have to establish volume effects from dumped imports. This would appear to the Ministry to depart from the Act and the Agreement which require other causes of injury to be examined for a causal link to be drawn between dumping and material injury in light of that analysis.

The Ministry does however need to consider price effects and, in this case, has concluded that the price undercutting, due to factors other than dumping, was determinative in winning the tender.

## 4.9 CONCLUSIONS RELATING TO INJURY

The following is a summary of the conclusions reached during the investigation of injury:

a. import volumes of the subject goods have increased in absolute terms and as a percentage of production and consumption;
b. the tender prices of the subject goods undercut the industry's tender prices;
c. there is no price depression or price suppression attributable to dumped imports of the subject goods;
d. there is evidence of declines in market share, output, sales and profits;

injury has been caused by factors other than dumping.

# 5. Conclusions

On the basis of the information available, it is concluded that:

(a) some of the goods under investigation have been dumped; and

(b) material injury to an industry has been or is occurring; but

(c) it has not been demonstrated that dumping is a cause of material injury.

# 6. Recommendations

It is recommended on the basis of the information obtained during the course of the investigation into the dumping of Tamoxifen from the United Kingdom:

1. That the Minister determine pursuant to section 13 of the Act that in relation to the importation or intended importation of Tamoxifen from the United Kingdom into New Zealand:

   a. some of the goods were being dumped; but
   b. material injury to the New Zealand industry has not been caused by reason of the subject goods being dumped.
2. That the Minister sign the attached Gazette notice, and give notice of the final determination to interested parties in accordance with sections 9 and 13 of the Act.

*[Signed by the Minister of Commerce on 21 February 2001]*