PHARMAC AND THE COMMERCE ACT

Competition Issues in New Zealand Pharmaceutical Markets

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CONTENTS

I INTRODUCTION

In New Zealand, around three-quarters of health and disability services are publicly funded.[1] The Government's primary objective in providing health and disability services is to "improve health status, improve, promote and protect the public health and to promote the independence of the people of New Zealand."[2] Over $6.2 billion of public funding has been allocated to health expenditure for the 1998/99 year to achieve this objective.[3] This money cannot buy all the health and disability services that New Zealanders need. Therefore important decisions must be made about which services will receive priority for Government funding. Ensuring that these services are provided in an efficient and appropriate manner is also crucial to prevent Government money from being wasted.

The Health Funding Authority (HFA) is the agency responsible for allocating Government health funding in New Zealand. One of the HFA's responsibilities is managing Government expenditure on pharmaceuticals and related therapeutic products. In 1993, PHARMAC[4] was established to fulfill this role through the operation of the Pharmaceutical Schedule, the list of subsidied pharmaceuticals. PHARMAC has the competing responsibilities of striving to attain the best health outcomes for New Zealanders whilst also curtailing increasing health spending on pharmaceuticals. Assisted by an independent expert body, the Pharmacology and Therapeutics Advice Committee, PHARMAC decides which drugs will receive subsidies and what the levels of the subsidies will be. PHARMAC uses a "Reference Pricing" system whereby drugs are classified into therapeutic groups and subgroups. All the drugs in a given subgroup are subsidised at the price of the lowest priced drug in that group.

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[1] Ministry of Health *Health Expenditure Trends in New Zealand 1980-97* (Wellington 1998) 10 [*Health Expenditure Trends*].
[2] Ministry of Health *Funding Agreement between the Minister of Health and the Health Funding Authority for the period 1 July 1998 to 30 June 1999* (Wellington, 1998) 5.
[3] The Crown *The Estimates of Appropriations for the Government of New Zealand for the Year Ending 30 June 1999 Volume II* (GP Print, Wellington) 273.
[4] PHARMAC's full legal title is the Pharmaceutical Management Agency Ltd. In this paper the organisation will be referred to as PHARMAC.

Although PHARMAC is not directly involved in the market for pharmaceuticals as a supplier or a consumer, its activities have a considerable impact on market participants. A decision not to list a drug on the Pharmaceutical Schedule can make it extremely difficult for that product to compete in the market for that type of therapy as, in the absence of a government subsidy, the consumer will have to pay the manufacturer's full price. PHARMAC also engages in negotiations and enters into deals with drug manufacturers concerning the prices and listings of pharmaceuticals. These activities may have a damaging effect on competition in various pharmaceutical markets.

New Zealand's anti-trust or competition law is contained in the Commerce Act 1986 (the Act) which is "[a]n Act to promote competition in markets within New Zealand".[5] Part II of the Act sets out prohibited practices. These practices essentially involve the substantial lessening of competition in a market and using a dominant position in a market. However in *RMI v PHARMAC,*[6] it was held by the High Court, and affirmed by the Court of Appeal, that PHARMAC's activities were exempt from Part II of the Commerce Act pursuant to section 2 of the Finance Act 1994.

This paper will examine potential claims which could arise against PHARMAC under the Act in the absence of the exemption upheld in *RMI v PHARMAC.* In particular, PHARMAC's ability to substantially lessen competition (section 27) and use its dominant position to restrict, prevent, deter or eliminate competitors from the pharmaceutical market (section 36) will be discussed. It is probable that claims against PHARMAC under section 27 would succeed, although section 36 claims would have to overcome difficulties defining the market in which PHARMAC is dominant before success is likely.

The final section of this paper will discuss whether PHARMAC's activities should be subject to competition law. Pharmaceutical expenditure management must be examined

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[5] Introduction to the Commerce Act 1986.

[6] *Researched Medicines Industry Association of NZ Inc and Independent Pharmaceutical Manufacturers Association v Pharmaceutical Management Agency Ltd and Transitional Health Authority* (22 October 1997) unreported, High Court, Wellington Registry, CP177/95; (4 May 1998) unreported, Court of Appeal, CA257/97 [*RMI v PHARMAC*].

in the context of competing Government objectives: maximising health benefits for New Zealanders; controlling public expenditure; and promoting competition in markets in New Zealand. The unique nature of pharmaceutical markets and the structure of the pharmaceutical industry will be discussed. Models of pharmaceutical management systems from other countries will be analysed, however it is found that all management schemes have potentially negative implications for competition law.

Overall, it is submitted that government fiscal and social objectives outweigh the desire to promote competition in pharmaceutical markets. It is therefore acceptable for PHARMAC to damage competition in drug markets. The extent to which PHARMAC may impair competition is constrained by the need to ensure that drug companies continue to supply pharmaceuticals to New Zealand. PHARMAC should continue to enjoy immunity from the Commerce Act.

II PHARMAC

A What is PHARMAC?

The Regional Health Authorities (RHAs) were established under the Health and Disability Services Act 1993 (the HDS Act) as part of reforms to the New Zealand public health service. Section 33 of the HDS Act prescribes the two functions of the RHAs to be monitoring the need for public and personal health and disability services, and purchasing public and personal health and disability services.

The Crown supplies money to the RHAs by means of a funding agreement which specifies the services which the RHAs must provide with the Government funding they receive.[7] The funding agreements are re-negotiated annually. The Crown provides the RHAs with written notice of its health objectives prior to negotiation of the terms of the agreement.[8]

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[7] Health and Disability Services Act 1993, s 21.
[8] Health and Disability Services Act 1993, s 8.

The HDS Act defines health services as including goods, which includes pharmaceuticals. The RHAs are "required to decide which medicines and related products receive subsidies...[and]...are also responsible for ensuring access to safe, cost effective quality medicines to meet reasonable health needs."[9] This is an important Crown objective that recognises both the significance of pharmacological therapy to the health of New Zealanders and the substantial level of health funding which is spent on pharmaceuticals.[10]

In 1993, the RHAs jointly established PHARMAC as the agency to undertake the RHA's responsibilities in relation to pharmaceuticals. PHARMAC is a wholly owned subsidiary of the RHAs. It has a small number of highly qualified staff.[11]

Since 1993 the public health service has undergone further reform. The RHAs were replaced by the Transitional Health Authority (THA) in 1997 that became the Health Funding Authority (HFA) in 1998. Health funding is now undertaken by this single central body, although HFA retains four regional offices (Southern, Central, Midland and Northern). These structural changes have not impacted on PHARMAC's operations.[12]

B What PHARMAC Does

PHARMAC's two principle objectives are:[13]

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[9] PHARMAC *PHARMAC, The First 20 Months* (Wellington, 1995) 6 [*The First 20 Months*]. The Funding Agreements between the RHAs and the Minister of Health set out objectives for the operation of pharmaceutical subsidies at length. This statement by PHARMAC succinctly summarises the principle provisions.

[10] In 1996/97 $754.1 million was spent on medicaments (largely pharmaceuticals). This represented 13.9% of health expenditure in New Zealand for that period. *Health Expenditure Trends in New Zealand*, above n 1, 13.

[11] In 1997, PHARMAC employed sixteen people who together possessed three medical degrees, two pharmacy degrees, three science degrees and ten other tertiary qualifications. PHARMAC *Annual Review for Year Ended 30 June 1997* (Wellington, 1997) 20 [*Annual Review 1997*].

[12] The RHAs, THA and HFA are considered to be the same body for the purposes of this paper. Reference will be made to RHA, THA or HFA depending on the organisational structure at the relevant period. PHARMAC is now owned by the HFA.

[13] PHARMAC *Statement of Intent for the Year Ending 30 June 1998* (Wellington, 1998) 2 [*Statement of Intent*].

(i) To optimise pharmaceutical's contribution to health status within THA's financial constraints.

(ii) To regularly promulgate accurate information about the listing of pharmaceuticals and the conditions under which they are subsided.

PHARMAC's Operating Policies and Procedures Manual, published in July 1993, was developed following extensive consultation with the industry.[14] The manual sets out how PHARMAC is to go about its activities in order to achieve its objectives. PHARMAC is responsible for the operation of the Pharmaceutical Schedule on behalf of the HFA.[15] This involves assessing new drugs, reviewing currently subsidised drugs, negotiating with drug suppliers, and providing information about the availability and terms of subsidies.[16] PHARMAC's performance is measured by the savings it achieves through lowering subsidy expenditure on drugs already listed, offset against costs generated by newly listed subsidised drugs.[17]

Every four months[18] PHARMAC publishes the Pharmaceutical Schedule, listing the medications and related products subsidised by the HFA. The primary objective of the Pharmaceutical Schedule is to "provide prescribers and dispensers with the list of subsidised pharmaceuticals that can be prescribed, and the conditions applying to them."[19] The manual contains 'decision criteria' to be used by PHARMAC when it is making decisions concerning the Pharmaceutical Schedule. These criteria are:[20]

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[14] *The First 20 Months*, above n 9, 8.

[15] PHARMAC took over the functions of the Drug Tariff Section of the Department of Health. Prior to the establishment of the *Pharmaceutical Schedule*, the list of government subsidised drugs was known as the Drug Tariff.

[16] *Statement of Intent*, above n 13, 3.

[17] *Statement of Intent*, above n 13, 4. PHARMAC achieves savings by working to lower subsidy levels, delist drugs and improve drug targeting.

[18] Updates are published monthly.

[19] *The First 20 Months*, above n 9, 12. Among other things, the *Pharmaceutical Schedule* specifies: the drugs to be subsidised; conditions of supply (for example, quantity and dispensing restrictions); patient charges; and prescribing restrictions.

[20] PHARMAC *Operating Policies and Procedures of Pharmaceutical Management Agency Limited* (Wellington, 1993) 7 [*Operating Policies and Procedures*].

- the health needs of New Zealanders,
- the availability and suitability of existing pharmaceutical and other therapies to meet these health needs,
- the clinical benefits, risks and costs of a pharmaceutical,
- the cost-effectiveness of meeting health needs by purchasing pharmaceutical services rather than by purchasing other health care and disability services,
- the overall budgetary impact of any changes to the Pharmaceutical Schedule,
- the direct cost of pharmaceuticals to users,
- any recommendations on core health and disability services made by the National Advisory Committee on Core Health and Disability Services,
- any other matters that PHARMAC sees fit.[21]

PHARMAC consider these criteria "reflect the natural tensions and conflicts of decision making in the health sector...[such as]...health needs of New Zealanders, the clinical benefits and risks of pharmaceuticals, as well as financial considerations."[22] It should be noted that impact on the pharmaceutical industry does not form part of the decision criteria.[23]

PHARMAC receives advice from the Pharmacology and Therapeutics Advisory Committee (PTAC). PTAC is a team of independent medical advisors made up of medical specialists and general practitioners. Committee members are nominated by professional bodies such as the New Zealand Medical Association and the Royal New Zealand College of General Practitioners.[24] It makes recommendations to PHARMAC concerning the medical, pharmacological and therapeutic consequences of amendments to the Pharmaceutical Schedule.[25]

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[21] PHARMAC "endeavours to ensure that suppliers are advised of any such 'other matters' and is given the opportunity to make submissions on those matters as they relate to a supplier's application to list a pharmaceutical on the Pharmaceutical Schedule or otherwise to the listing(s) of pharmaceutical(s) already on the Pharmaceutical Schedule." *Operating Policies and Procedures*, above n 20, 7.
[22] *The First 20 Months*, above n 9, 9.
[23] *Operating Policies and Procedures*, above n 20, 7.
[24] PHARMAC *Annual Review for Year Ended 30 June 1995* (Wellington, 1995) 5 [*Annual Review 1995*].
[25] *Annual Review 1995*, above n 24, 5.

C Listings on the Pharmaceutical Schedule

There are six ways in which a pharmaceutical may be listed on the Pharmaceutical Schedule:[26]

(i) *Listed.* The drug may be prescribed by any qualified medical practitioner (including midwives and dentists in limited cases). Most drugs are in this category.[27]

(ii) *Specialist prescription.* Prescriptions may only be written by specialists.[28]

(iii) *Specialist.* General practitioners (GPs) may prescribe the drug on a specialist's recommendation.

(iv) *Hospital pharmacy-specialist prescription.* Prescriptions may only be written by specialists and only dispensed by hospital pharmacies.

(v) *Hospital pharmacy-specialist.* GPs may prescribe the drug on a specialist's recommendation however only a hospital pharmacy may dispense it.

(vi) *Special Authority.* A prescription is subsidised after approval is obtained from Health Benefits Limited (HBL).[29] Patients must meet the criteria defined in the Pharmaceutical Schedule.

PHARMAC provides these listings to improve targeting of drug funding. This means that people's access to particular drugs is targeted towards those who would receive the most benefit. For example, some drugs may be more effective for certain people than

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[26] *Annual Review 1995*, above n 24, 4.
[27] Kyle Jones, Senior Analyst, PHARMAC. Telephone conversation, 21 September 1998.
[28] The Pharmaceutical Schedule contains a definition of "specialist". PHARMAC *Pharmaceutical Schedule* (August 1998) 15 [*Pharmaceutical Schedule*]. However the general understanding of what constitutes a specialist is fairly clear.
[29] Health Benefits Limited (HBL) is an HFA subsidiary responsible for administering subsidy payments to pharmacies.

the alternatives available,[30] however these drugs may also be more expensive. PHARMAC targets the drug at the people who need it by assigning the drug a restrictive listing (for example, specialist prescription). PHARMAC considers that a specialist has a greater level of knowledge and skill to determine whether the drug is necessary for the patient or if a cheaper alternative will suffice. GPs are not necessarily prevented from prescribing the drug but are discouraged from doing so as the consumer will have to pay the manufacturer's full price.

D PHARMAC's Decisions

Decisions concerning a drug's listing can become necessary for several reasons.[31] Pharmaceutical companies may apply to have a new drug listed on the Pharmaceutical Schedule once they have gained approval from the Ministry of Health to market the drug in New Zealand.[32] Alternatively, drug companies may apply to have an existing drug listed or apply to have a drug's listing reviewed.[33] In addition, as PHARMAC recognises that the pharmaceuticals industry is dynamic, it regularly undertakes Therapeutic Group Reviews.[34] PTAC may also initiative such a review.

E Reference Pricing

PHARMAC operates a Reference Pricing system. This is based on categorising pharmaceuticals into therapeutic groups and subgroups. Therapeutic groups are sets of pharmaceuticals that are used to treat the same or similar conditions. Therapeutic

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[30] For example, side effects profiles. *Annual Review 1997*, above n 11, 23.

[31] They key types of decisions which PHARMAC makes include: listing a new pharmaceutical; declining to list a new pharmaceutical; delisting a pharmaceutical; changing the listing, guidelines or restrictions on prescribing and dispensing a currently listed drug; changing the level of subsidy of a pharmaceutical; amending the Pharmaceutical Schedule therapeutic groups and subgroups. Katrina Groshinski "Judicial Review of Pharmac" (LLM Research Paper, Victoria University of Wellington, 1996), 14 [Judicial Review of Pharmac].

[32] Medicines Act 1981.

[33] For example to change the drug's listing from hospital-specialist to general.

[34] Drugs on the subsidy list are appraised within the overall context of PHARMAC's objectives to provide cost effective and appropriate drugs for the population's health needs. *The First 20 Months*, above n 9, 9. In 1997, PHARMAC completed three therapeutic group reviews and started two more. Drug companies submitted 84 applications for listings or listing changes for PHARMAC's consideration. Fifty five of these resulted in a listing. *Annual Review 1997*, above n 11, 19.

subgroups are sets of pharmaceuticals that produce the same or similar therapeutic effects in treating the same or similar conditions.[35] All pharmaceuticals in a subgroup are subsidised at the level of the lowest priced pharmaceutical in that subgroup. Therefore, the lowest priced drug in a subgroup is fully subsidised and free to the consumer. However, the consumer must pay the difference between the subsidy and the manufacturer's price for the remaining drugs in the subgroup.[36]

Subsidies may differ between different subgroups within a therapeutic group. This "reflect[s] PHARMAC's willingness to pay for pharmaceuticals which do not produce the same or similar therapeutic effect."[37]

As the sole agency in New Zealand with the ability to grant subsidies on pharmaceuticals, PHARMAC is in a position to exert a significant influence over activities in drug markets. Part III of this paper discusses the impact of PHARMAC's decisions on competition in New Zealand pharmaceutical markets.

III PHARMAC AND COMPETITION ISSUES

Firstly, it is important to note that although the market for pharmaceuticals is often referred to as a singular market, it is in fact made up of numerous smaller markets. A person suffering from asthma is not in the same market for pharmaceutical therapies as a person suffering from arthritis. These two people fall into separate therapeutic groups. The markets for different drug therapies may be divided further. For example, some people require breath-activated asthma inhalers because they are unable to use manual inhalers.[38] It is arguable that the therapeutic subgroups, to use PHARMAC's terminology, of manual and breath-activated inhalers may be two distinct markets. A fuller discussion of market definitions within the pharmaceutical industry will be undertaken in Part V of this paper.

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[35] *The First 20 Months*, above n 9, 10.
[36] This is referred to as the "manufacturer's premium".
[37] *Operating Policies and Procedures*, above n 20, 9.
[38] In particular, children may have difficulty co-ordinating triggering the inhaler with taking a breath.

There are several ways in which PHARMAC conducts its activities which may impact on the competitiveness in pharmaceutical markets.

A The Reference Pricing System

It has been alleged that PHARMAC is able to "control the [pharmaceutical] market via its dominant position in being alone in deciding which drugs get subsidies."[39] Certainly PHARMAC's decision whether or not to list a pharmaceutical on the Pharmaceutical Schedule is pivotal to the drug's success in the New Zealand market.[40] Consumers prefer to receive the drugs and therapies they require at minimal personal cost. Therefore, the ability of the manufacturer of an unsubsidised drug to compete with the manufacturer of a subsidised drug is extremely limited. By refusing to grant a subsidy on a drug, PHARMAC may effectively eliminate that product from the market.

In addition, restrictive listings may interfere with a drug's ability to compete in the market. A drug that is available subsidised only on a special authority or hospital pharmacy-specialist prescription, for example, may be unable to compete effectively with alternative drugs that have a general listing and are fully subsidised.[41]

Reference Pricing may also give rise to competition concerns in respect of the classification of drugs. PHARMAC, as discussed above, categorises drugs into therapeutic groups and subgroups. However, there is not necessarily consensus that a drug has been grouped appropriately.[42] For example, SmithKline Beecham disagrees with PHARMAC's decision to classify its drug "Serzone" as an SSRI (selective serotonin re-uptake inhibitor), which is a type of mood altering drug or anti-depressant.[43] SmithKline Beecham claims Serzone is "from another technical drug

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[39] Alan Woodfield, John Fountain and Pim Borren *Money & Medicines* (Merck Sharp & Dohme, Auckland, 1997) 38 [Money & Medicines].
[40] Judicial Review of Pharmac, above n 31, 2.
[41] Around 2,500 drugs and therapeutic products are subsidised. The majority of these have a general listing. *Statement of Intent*, above n 13, 2.
[42] "For many conditions and patients there simply is no medical consensus about equivalence of medicines." "Too many bitters pills in Pharmac policy" *National Business Review*, Auckland, New Zealand, 15 May 1998, 38.
[43] Prozac is an SSRI.

group"[44] and is taking PHARMAC to court over the decision.[45] If a drug is incorrectly categorised by PHARMAC then it may be subsidised at a lower level than is appropriate because the drug against which it is reference priced may be an inferior, cheaper alternative.

B Negotiating with Drug Companies

PHARMAC frequently negotiates deals with drug companies concerning the listing of the companies' products. The most common arrangement is one where PHARMAC agrees to list a company's new drug on the condition that the company reduces the price of another, already-listed drug.[46] PHARMAC's intention is to reduce the reference price of the drug subgroup. The price decrease of the already-listed drug will drop below the current reference price so that the reference price is reduced. Consequently, the manufacturer's premium[47] increases for all other drugs in the subgroup. Unless the manufacturers of these drugs also reduce their prices, the ability of their products to compete against the reference price drug is inhibited.

These deals assist PHARMAC with achieving its financial objectives, as a lower reference price means that PHARMAC is paying a lower subsidy on every drug in that therapeutic subgroup. PHARMAC is now examining other ways of reducing costs, including sole supply arrangements, preferred supplier arrangements, pay-to-play contracts, average daily dose contracts, capped maximum annual contracts, and price/volume contracts.[48] The first three types of arrangement in this list are aimed at reducing drug prices and the last three are directed at risk sharing.

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[44] "New anti-depressant may force Prozac price down" *National Business Review*, Auckland, New Zealand, 15 May 1998, 5.

[45] Drug companies have taken to using judicial review as a means of challenging PHARMAC's decisions. However, a recent statement from the courts indicated that this tendency ought to be discouraged. *Annual Review 1997*, above n 11, 21. Whether judicial review is the appropriate forum for examining PHARMAC's decisions is beyond the scope of this paper.

[46] It was precisely this type of arrangement which was the subject of legal proceedings under the Commerce Act in *RMI v PHARMAC*, above n 6. See Part VI of this paper.

[47] The part of the drug's price the consumer must pay on partially subsidised drugs.

[48] *Annual Review 1997*, above n 11, 23.

1 Sole supply arrangements

Once a drug's patent expires, there may be several brands of the drug available on the market. PHARMAC invites the drug companies to tender for a sole supply agreement whereby the tender winner's product will be the only drug in the group on which PHARMAC will pay a subsidy. This contract is generally awarded to the lowest priced product, but price is not the only factor PHARMAC takes into account.[49] The arrangement is usually for a period of three years, thereby effectively preventing other drug manufacturers from competing in the relevant drug market for that length of time.

PHARMAC considers that these arrangements are positive for generic[50] manufacturers that would otherwise be discouraged from entering the market due to high entry costs.[51] In addition, generics entering the market face difficulties obtaining market share from branded suppliers that have been in the market for many years. PHARMAC may award a tender to a drug that is not yet registered, provided the manufacturer obtains Ministry of Health registration within a reasonable time.[52]

2 Preferred supplier arrangements

Preferred supplier arrangements are similar to sole supply contracts but do not have as radical an effect on market share. Where a prescription is written generically or there is a substitution order[53] in place, the pharmacist has a choice which drug to dispense. Preferred supplier arrangements oblige a pharmacist to dispense a particular brand

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[49] Kyle Jones, Senior Analyst, PHARMAC. Telephone conversation, 10 September 1998.
[50] Generics are copies of proprietary drugs on which the patent has expired.
[51] Obtaining registration from the Minister of Health is a costly exercise.
[52] This is also controversial as the term "reasonable" is open to interpretation. Branded drug manufacturers lack certainty about when the subsidy on their product will be withdrawn by PHARMAC, although once the tender winner's drug is registered there is generally a three month lead-in time before PHARMAC switches the subsidy. Kyle Jones, Senior Analyst, PHARMAC. Telephone conversation, 21 September 1998.
[53] A substitution order is a letter from a doctor to a pharmacist authorising the pharmacist to dispense any brand of the drug even though a particular brand is specified. These orders may be for a specific drug only or for all drugs.

where there is a choice. The result of the arrangement is that the market will generally reduce to two companies: the preferred supplier and the original brand supplier.[54]

The preferred supplier is determined through a competitive tender process in a similar manner as sole supply arrangements.[55] The preferred supplier receives a fixed subsidy on its product for a fixed period of time. PHARMAC is encouraging doctors to allow use of preferred suppliers by sending them a form which authorises pharmacists to substitute their prescriptions for a preferred supplier product where available.[56]

3 *Pay-to-play contracts*[57]

Some markets are unsuitable for sole supply or preferred supply arrangements. For example asthma products are not strictly generic, they are often 'me too' drugs.[58] However certain drugs have devices associated with them which differentiate the products, such as different types of asthma inhalers. PHARMAC recognises that, although the active chemical in the inhaler may be the same, it cannot force people to use a particular type of device, especially one that may be unsuitable for them. PHARMAC also recognises that entry into the market is very expensive and that the Ministry of Health imposes rigorous testing requirements for new devices. Without alternative products available, there is no incentive for the existing manufacturer to lower its prices.

In order to encourage other companies to enter the market, PHARMAC offers them a financial incentive. Two payments are made; a bulk payment[59] and a subsidy per unit.

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[54] Kyle Jones, Senior Analyst, PHARMAC. Telephone conversation, 10 September 1998.
[55] Originally, PHARMAC treated the process in a similar fashion to deciding on a new listing. However, this proved to be problematic (and time consuming) and the tender process is now the general practice.
[56] "Authority to Substitute" forms are also contained in the back of the *Pharmaceutical Schedule*, above n 28.
[57] Also known as "two part pricing".
[58] 'Me too' drugs are products where the molecular structure is altered sufficiently to enable a patent to be registered, however they are in fact replications of a patented drug already on the market. 'Me toos' may differ slightly from one another, for example in terms of side effect profiles, although their therapeutic effects are usually substantially the same.
[59] These payments are not insignificant and represent at least partial reimbursement to the manufacturer of the costs incurred obtaining entry to the New Zealand market. A bulk payment to a manufacturer may be

PHARMAC must be satisfied that it can subsidise the new product at, or lower than, the level of the existing product before it will enter a pay-to-play contract.

4 Average daily dose contracts

Drug companies promote higher dose levels because higher volume of sales equates to more revenue. These increases are known as "dosage creep".[60] To combat the risk of ever-increasing dosage levels, and therefore ever-higher subsidy payments, PHARMAC sets an average daily dose level. For example, if the 20mg capsule costs $1.00 and the 40mg capsule costs $2.00, PHARMAC may set the average daily dose level at $1.50. This limits PHARMAC's risk of volume growth "within" a prescription. That is, a person's increase in dosage will not result in a higher subsidy payment to the drug manufacturer.

5 Capped maximum annual contracts

These contracts aim to reduce PHARMAC's risk of volume growth both "within" a prescription and "among" prescriptions (the total number of prescriptions written). The drug company enters a contract with PHARMAC agreeing that if more than a particular amount is expended on a certain product, the company will reimburse PHARMAC the excess. These contracts alter the drug companies' incentive away from wanting to sell as much product as possible, therefore encouraging more responsible promotion of pharmaceutical products.

PHARMAC considers these arrangements to be crucial to minimising its risk of budgetary blowouts, particularly as new drugs are usually more expensive than their predecessors. For example, the new anti-depressants such as Prozac are eight to ten times more expensive than the old type of anti-depressants.[61]

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around $300,000. Kyle Jones, Senior Analyst, PHARMAC. Telephone conversation, 10 September 1998.

[60] Kyle Jones, Senior Analyst, PHARMAC. Telephone conversation, 10 September 1998.

[61] Kyle Jones, Senior Analyst, PHARMAC. Telephone conversation, 10 September 1998. Prozac carries a budget cap.

6 *Price/volume contracts*

PHARMAC observed that once a patent expired on a drug, the prices offered by generic manufacturers for the same active chemical were not significantly lower than the branded product. For example, generic drugs in New Zealand were only 10-15 per cent cheaper than the equivalent branded drug, compared to more often than 50 per cent in other countries.[62] Price/volume contracts offer drug companies higher volumes for lower prices, that is, once the volume reaches a pre-determined level, the price of the drug is reduced.

When these contracts were introduced, PHARMAC was not using sole supply or preferred supplier contracts and was therefore unable to deliver the high volumes required to fulfill the contracts' objectives. As a result, these contracts have had little value for PHARMAC and its use of them has diminished to the extent that they are no longer entered into.

As demonstrated by the above discussion, PHARMAC's activities raise concerns for competition in drug markets. In particular, the deals PHARMAC negotiates with drug companies may substantially damage competition in individual markets, and sole supply contracts effectively form a barrier against entry into a market by other manufacturers for three years. Restrictive trade practices such as these would ordinarily be subject to proceedings under the Commerce Act 1986. However, pursuant to a recent ruling in the Court of Appeal, PHARMAC is exempt from the provisions of Part II of the Act.

IV PHARMAC'S EXEMPTION FROM THE COMMERCE ACT

In 1995 and 1996, two pharmaceutical industry representative associations and several pharmaceutical supply companies initiated proceedings against PHARMAC.[63] The plaintiffs' claims included alleged breaches of sections 27 and 36 of the Commerce Act 1986, together with applications for judicial review. The issue which arose with regard

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[62] Kyle Jones, Senior Analyst, PHARMAC. Telephone conversation, 10 September 1998.
[63] *RMI v PHARMAC*, above n 6.

to the Commerce Act causes of action was whether PHARMAC was immune from all claims under the Commerce Act pursuant to section 2 of the Finance Act.[64] Section 2 broadly states that the restrictive trade practices provisions of the Commerce Act do not apply to the Funding Agreement between PHARMAC and the RHAs and PHARMAC's activities under this Agreement.

It is useful to examine PHARMAC's background with regard to the activities of its predecessor, the Drug Tariff Section of the Department of Health, and the Commerce Act. Before the 1993 health reforms, the Minister of Health had authority under section 99 of the Social Security Act 1964 to fix the prices of pharmaceuticals and determine which drugs would be included on the Drug Tariff.[65] That is, as PHARMAC does now, the Minister determined whether a drug would be subsidised and to what level.[66]

The leading case concerning the Drug Tariff and the Commerce Act is *Glaxo New Zealand Ltd v Attorney-General*[67] The plaintiff, Glaxo, manufactured an antibiotic which was included on the Drug Tariff with a "hospital pharmacy" classification. Glaxo's application for a full listing on the Drug Tariff was denied. The plaintiff alleged that the Minister was in a dominant position in the New Zealand market for general prescription antibiotics and that in exercising her powers under section 99 of the Social Security Act the Minister was in breach of section 36 of the Commerce Act.

The High Court found that the Minister's activities in regulating the prices and subsidies of pharmaceuticals pursuant to section 99 of the Social Security Act was not subject to the Commerce Act. Firstly, the Minister's activities were exempt from the Commerce Act pursuant to section 5 of the Act, which provides an exemption for the Crown

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[64] *RMI v PHARMAC* (HC), above n 6, 3.
[65] Section 99 is set out in full in Appendix 1.
[66] Subsidised pharmaceuticals could be given one of two listings; either a full listing where the subsidy is paid when the medication is prescribed by a general practitioner (GP) and dispensed by a pharmacist, or a "hospital pharmacy" listing where the subsidy is paid only when the medication is dispensed from a hospital pharmacy. *Glaxo New Zealand Ltd v Attorney-General* [1991] 3 NZLR 129 (HC and CA) 131 [*Glaxo*].
[67] *Glaxo*, above n 66.

provided it is not "engaging in trade". The Court held that although the Crown's activities were affecting trade, the Crown could not be said to be acting in trade.[68]

Although satisfied that the defendant's first submission was made out, Barker J went on to consider section 43 of the Act.[69] Section 43 provides that the Act does not apply to any activity specifically authorised by another Act. Barker J considered that the Minister's activities were "specifically authorised" by section 99 of the Social Security Act and so were exempt from the Act under this further point.[70]

The Court of Appeal upheld Barker J's decision. In respect of the "engaging in trade" matter argued by the appellant, Casey J noted that such a definition referred to activity of a commercial nature. Although the Minister's decisions may have commercial effects, "the activity itself is the exercise of regulatory functions…in order to achieve…social welfare purposes."[71] Casey J further agreed with the trial judge as regards section 43 of the Commerce Act. That is, even if the Minister was considered to be engaging in trade section 43 would make her activities exempt from the Act.[72]

Glaxo v Attorney-General established that the former regime for managing drug subsidies, the Drug Tariff Section of the Department of Health, enjoyed immunity from the Commerce Act. This issue arose again after the health reforms of 1993, when PHARMAC had taken over operation of the Pharmaceutical Schedule, in the case of *RMI v PHARMAC.*[73]

A RMI v PHARMAC (The High Court Decision)

The case involved three claims that were heard together.

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[68] *Glaxo* (HC), above n 66, 133.
[69] *Glaxo* (HC), above n 66, 133.
[70] *Glaxo* (HC), above n 66, 134-135.
[71] *Glaxo* (CA), above n 66, 139-140.
[72] *Glaxo* (CA), above n 66, 140.
[73] *RMI v PHARMAC*, above n 6.

(i) The RMI Claim

This claim essentially centred around PHARMAC's decisions not to list certain pharmaceuticals. The plaintiff claimed that PHARMAC (and the RHAs) had a dominant position in the market and had been using it to restrict the entry of the plaintiffs into and competing in the market (s36 Commerce Act).[74]

(ii) H_2 Antagonists Claim

PHARMAC entered an agreement with one manufacturer (the second defendant in this proceeding) that it would list a new H_2 Antagonist drug if the manufacturer reduced the price of its already-listed H_2 Antagonist by 40 per cent. The reduced price of this drug became the reference price for all H_2 Antagonists. The plaintiffs claimed that this agreement was in breach of section 36 of the Commerce Act.[75]

(iii) Calcium Channel Blockers (CCB) Claim

PHARMAC decided to negotiate with suppliers to reduce the price of CCB drugs. It advised the plaintiffs that the subsidy on CCBs was to be reduced and that if their prices were not adjusted accordingly, consumers would have to pay the difference. The plaintiffs alleged breaches of sections 27 and 36 of the Commerce Act.[76]

The issue in the proceeding was not whether these claims under the Commerce Act would succeed, but whether PHARMAC enjoys immunity from all claims under the Commerce Act.[77] Section 2 of the Finance Act 1994 provides immunity from the Commerce Act in limited circumstances. The relevant subsections are as follows:[78]

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[74] *RMI v Pharmac* (HC), above n 6, 15.
[75] *RMI v Pharmac* (HC), above n 6, 15.
[76] *RMI v Pharmac* (HC), above n 6, 16.
[77] *RMI v Pharmac* (HC), above n 6, 3.
[78] This section replaced s 29 of the Health Reforms (Transitional Provisions) Act 1993. Section 2 is set out in full in Appendix 2.

> (2) This subsection applies to an agreement (whether reached before or after the commencement of this Act) if, and only if, -
>
> (a) At least 1 party to it was a specified body at the time it was reached; and
>
> (b) It was reached after consultation between the Minister of Health and 1 or more of the parties to it; and
>
> (c) It relates to pharmaceuticals for which full or part payments may be made by 1 or more specified bodies.
>
> (3) It is hereby declared that nothing in Part II of the Commerce Act 1986 applies, or has ever applied, to -
>
> (a) Any agreement to which subsection (2) of this section applies; or
>
> (b) Any act, matter, or thing, done by any person to give effect to such an agreement.

It is interesting to compare section 2 of the Finance Act with section 99 of the Social Security Act which provided PHARMAC's predecessor, the Drug Tariff Section of the Department of Health, with immunity from the Commerce Act, as confirmed in the *Glaxo* case.[79] The provisions of section 99 of the Social Security Act are significantly more specific than section 2 of the Finance Act. Section 99 is entitled "fixing of prices for pharmaceutical requirements" and refers specifically to the activities involved in operating the Drug Tariff.[80] Section 2 of the Finance Act is a very general section, headed "application of Part II of the Commerce Act 1986 to regional health authorities, Public Health Commission, and certain subsidiaries". The majority of the section is devoted to setting out definitions of terms such as "agreement" and "specified bodies" to assist with interpretation. The only reference to pharmaceuticals is made in section 2(2)(c) and is still in broad terms: "it relates to pharmaceuticals for which full or part payments may be made by 1 or more specified bodies." Read in its entirety, the section is obviously intended to capture only government agreements relating to pharmaceuticals. However, if section 2 of the Finance Act was intended to reflect the same immunity from the Commerce Act for the reformed health bodies as section 99 of the Security Act provided for the Drug Tariff Section, it is difficult to understand why section 2 was drafted in such a convoluted manner. This point was noted by Ellis J in the first instance decision of the *RMI v PHARMAC* case.[81]

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[79] Section 99 and s 2 are set out in full in Appendices 1 and 2 respectively.

[80] For example s 99(1) concerns who is eligible to claim pharmaceutical benefits, terms and conditions the Department can impose, and payments. Subsection (2) provides for price fixing, special authorities and categorisation of classes of pharmaceuticals.

[81] "The argument before me has highlighted the unfortunate drafting of ss29 and 2,". *RMI v Pharmac* (HC), above n 6, 19.

In order to claim immunity under section 2 of the Finance Act, PHARMAC had to first show that its Agency Agreement[82] with the RHAs was an agreement for the purposes of section 2(2), and secondly show that decisions made in relation to the Pharmaceutical Schedule were acts, matters or things done to give effect to the Agency Agreement.

1 The Agency Agreement

The issue of whether section 2 of the Finance Act was applicable to the Agency Agreement relied principally on there being consultation with the Minister of Health concerning the Agency Agreement, a requirement of section 2(2)(b). Ellis J considered the intention of Parliament with regard to the section. He found that Parliament clearly had the agreements between the RHAs and PHARMAC in mind, and that it intended the Minister of Health's involvement to be a prerequisite to exemption.[83] In addition, Ellis J considered that Parliament must have also had in mind the exemption that PHARMAC's predecessor, the Drug Tariff Section of the Department of Health, had enjoyed pursuant to section 99 of the Social Security Act 1964 and confirmed in *Glaxo v Attorney-General*.[84] Ellis J held that there had been sufficient deliberations with the Minister of Health concerning the Agency Agreement to satisfy section 2 of the Finance Act.

2 PHARMAC's decisions under the Agency Agreement

Ellis J then had to consider whether each of PHARMAC's decisions in relation to the Pharmaceutical Schedule was exempt from the Commerce Act. The plaintiffs submitted that the Act required the Minister be consulted before each decision was made, particularly where the decision involved an agreement with someone else, such as a drug company.[85] Ellis J took the approach that the requirement of consultation existed to differentiate decisions of a political nature from those "with a merely commercial

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[82] The Agency Agreement is PHARMAC's founding document. It sets out the decision criteria, as discussed in Part II above, and PHARMAC's primary objective and obligations. *RMI v Pharmac* (HC), above n 6, 7-9.
[83] *RMI v Pharmac* (HC), above n 6, 13.
[84] *Glaxo*, above n 66.
[85] *RMI v Pharmac* (HC), above n 6, 16-17.

dimension."[86] He considered, after examination of Hansard, that "it is plain that Parliament intended that the implementation of major health reforms should not be impeded by the Commerce Act."[87] His Honour concluded that PHARMAC's decisions are clearly of a political nature and therefore these decisions are acts, matters or things done to give effect to the Agency Agreement, irrespective of whether a third party, such as a drug company, is involved.[88]

Ellis J held that section 2 of the Finance Act provided PHARMAC with a complete exemption from the Commerce Act 1986. The plaintiffs' claims failed.

B RMI v PHARMAC (The Court of Appeal Decision)

The plaintiffs appealed against the ruling of the High Court. Their primary argument in the Court of Appeal concerned the requirement of consultation contained in section 2 of the Finance Act. It was argued by the appellants that in order to qualify for an exemption, the "nature and object of the consultation...must be related to the circumstances which call for it".[89] The appellants submitted there was no evidence that the Minister of Health had been consulted specifically about the implications for competition law when granting an exemption.

Gault J, delivering the opinion of the Court, considered that even if the appellants' assertion was correct it was not possible to find that the Minister had not given the anti-competitive implications of the Agency Agreement full consideration. His Honour noted that under section 2 it is the Minister of Health who is to be consulted, not the Minister of Commerce or Chairman of the Commerce Commission who would be better equipped to assess anti-competitive effects.[90]

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[86] *RMI v Pharmac* (HC), above n 6, 18.
[87] *RMI v Pharmac* (HC), above n 6, 18.
[88] *RMI v Pharmac* (HC), above n 6, 19.
[89] *RMI v Pharmac* (CA), above n 6, 10.
[90] *RMI v Pharmac* (CA), above n 6, 13.

The Court of Appeal went further still, finding that the Funding Agreements between the RHAs and the Crown also satisfied the definitions contained within section 2 of the Finance Act. Therefore, the Agency Agreement itself could be viewed as an act, matter or thing done pursuant to the Funding Agreements and an exemption from the Commerce Act could be obtained in this manner.

The Court of Appeal therefore affirmed the decision of the High Court and dismissed the appellants' claim.

RMI v PHARMAC confirmed that section 2 of the Finance Act granted PHARMAC an exemption from the proceedings brought under the Commerce Act. Therefore, following *RMI v PHARMAC* it would appear that decisions made by PHARMAC concerning the Pharmaceutical Schedule are not subject to examination with respect to anti-competitive effects. Does the *RMI v PHARMAC* case in fact represent a blanket exemption or is it possible that PHARMAC may still be vulnerable to Commerce Act proceedings for some of its activities?

C A Total Exemption for PHARMAC?

As discussed above, PHARMAC had to prove two facts in order to be eligible for immunity under section 2 of the Finance Act 1994:

(i) that the Agency Agreement between PHARMAC and the RHAs was an agreement for the purposes of section 2(2) of the Finance Act; and

(ii) that the decisions PHARMAC made were acts, matters or things done to give effect to this Agreement.

Neither the High Court nor the Court of Appeal had difficulty establishing that the Agency Agreement satisfied the requirements of section 2 of the Finance Act. These requirements concerned consultation with the Minister of Health during the formulation of the Agreement, pursuant to section 2(2)(b). The issue which raises uncertainty about the full extent of the exemption is contained in section 2(3)(b), which provides an

exemption from Part II of the Commerce Act for any "act, matter or thing, done...to give effect to such an agreement." Therefore it is necessary to examine PHARMAC's conduct to ascertain whether it was consistent with its obligations under the Agency Agreement, the source of its immunity from the Commerce Act.

Gault J, in the Court of Appeal, stated:[91]

> ...the effect of the [Finance Act] provisions is to give a broad exemption where Pharmac is acting in accordance with the policies and procedures directed by the Minister and contained in the Funding Agreements and Agency Agreement.

It is useful to consider this passage having regard to the comments of Ellis J in the court below. His Honour stated that immunity from the Commerce Act was limited to activities that were political, rather than commercial, in content and that this proposition was supported by the Finance Act's requirement for ministerial consultation.[92] Ellis J cited the level of political activity between the drug companies and the Minister as evidence of the political nature of PHARMAC's decisions.[93]

In both courts, the nature of the "acts, matters or things, done" was considered to be relevant to their exemption. Both courts considered political content to be relevant; Ellis J referred directly to the "political arena"[94] and Gault J referred to "policies and procedures directed by the Minister".[95] Therefore if it could be proved that PHARMAC's activities were commercial rather than political in nature, its conduct may be open to examination under the Commerce Act.

The issue is then whether it is possible for PHARMAC to make a decision concerning the pharmaceutical subsidies which could be considered "commercial" rather than "political". The focus of the Agency Agreement is upon the achievement of political goals: the meeting of health needs and the most effective allocation of Government

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[91] *RMI v Pharmac* (CA), above n 6, 14.
[92] *RMI v Pharmac* (HC), above n 6, 18.
[93] *RMI v Pharmac* (HC), above n 6, 18.
[94] *RMI v Pharmac* (HC), above n 6, 18.
[95] *RMI v Pharmac* (CA), above n 6, 14.

funding to this purpose.[96] It is difficult to perceive how any decision PHARMAC makes with regard to the Pharmaceutical Schedule could be classified as falling outside these political objectives.

In conclusion it is submitted that, as the interpretation of the Finance Act exemption stands after *RMI v PHARMAC*, any activity that PHARMAC undertakes in relation to the Pharmaceutical Schedule is immune from Part II of the Commerce Act. However, any other commercial activities PHARMAC is involved with may be open to the provisions of the Act. For example, normal business activities such as leasing property could not be considered as being within the ambit of administering the Pharmaceutical Schedule. Therefore if PHARMAC was engaged in anti-competitive behaviour in aspects of its operations other than the Pharmaceutical Schedule, it is possible that PHARMAC could be successfully pursued under the Commerce Act. As the focus of this paper is on anti-competitive conduct in relation to the listing of pharmaceuticals, it is unnecessary to discuss any other activities in which PHARMAC may be involved.

As noted above, it is accepted that *RMI v PHARMAC* provides PHARMAC with a blanket exemption from Part II of the Commerce Act 1986 in respect of the activities it undertakes concerning the Pharmaceutical Schedule. Were this exemption not in place, PHARMAC could face a number of proceedings under the Commerce Act, in particular, sections 27 and 36 of the Act. These will now be examined in depth.

V THE COMMERCE ACT

The Commerce Act is "[a]n act to promote competition in markets within New Zealand".[97] As discussed in Part III of this paper, PHARMAC's activities give rise to a number of concerns for competition in New Zealand pharmaceutical markets. Following is an analysis of how claims under the Commerce Act could be framed in the absence of the Finance Act exemption.

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[96] Key provisions of the Agency Agreement are contained in Appendix 3.
[97] Introduction to the Commerce Act 1986.

A Substantially Lessening Competition

PHARMAC frequently enters into negotiations with drug companies concerning pricing and listing of pharmaceuticals. The agreements which are reached as a result may breach section 27 of the Commerce Act (the Act) which prohibits contracts, arrangements and understandings that substantially lessen competition. Section 27 of the Act provides:

> 27(1) No person shall enter into a contract or arrangement, or arrive at an understanding, containing a provision that has the purpose, or has or is likely to have the effect, of substantially lessening competition in a market.

Following is a hypothetical fact situation which will be used to demonstrate how a proceeding against PHARMAC could be framed.[98]

Eli Pilly Ltd is a large multi-national drug company which manufactures a wide variety of drugs available in New Zealand and around the world. Eli Pilly has produced a new asthma drug, Flexibreath, and has applied to PHARMAC to have Flexibreath listed on the Pharmaceutical Schedule. PHARMAC has agreed to list Flexibreath on the Schedule, provided Eli Pilly reduces the price of its cholesterol-lowering drug, Savastatin, by 25%. This price decrease will mean that Savastatin is the lowest priced drug in the cholesterol-lowering "statin" therapeutic subgroup, therefore reducing the reference price of statins.[99]

Gallaxo Welldone Ltd's statin, Xpenstatin, was previously the reference price drug in this therapeutic group. Gallaxo Welldone claims that the reduced price of Savastatin will prevent Gallaxo Welldone from competing effectively in the market for statins.

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[98] This hypothetical fact situation is very similar to the second plaintiff's claim in *RMI v PHARMAC*, above n 6, that concerned the listing and reference pricing of a new H_2 Antagonist.

[99] It is important to note that the headings in the Pharmaceutical Schedule do not necessarily represent therapeutic subgroups. For example, the Ace inhibitors section lists eight different chemical groups, of which there are eleven brands. However, the Schedule does not show which drugs are reference priced against one another; there may be several therapeutic subgroups within the Ace inhibitors group. See *Pharmaceutical Schedule*, above n 28, 2. For simplicity, in this paper statins have been referred to as a therapeutic subgroup although in reality this may not be the case. Statins may be divided into two or more therapeutic subgroups depending on which statins have the same or similar therapeutic effect to each other.

Gallaxo Welldone initiates proceedings against PHARMAC and Eli Pilly under section 27 of the Act.

A section 27 claim may be broken down into four elements: contract, arrangement or understanding; purpose, effect or likely effect; substantially lessening competition; and market. It is important to note that it is not necessary for the parties to the contract, arrangement or understanding to be in competition with each other.[100]

1 Contract, arrangement or understanding

Gallaxo Welldone must prove that there was either a contract, arrangement or understanding (CAU) reached between PHARMAC and Eli Pilly. Even in the absence of a legally binding contract, given the negotiations that took place between PHARMAC and Eli Pilly it should not be difficult to establish the existence of an arrangement or understanding between the two parties. It is unlikely that this element would be contended by the defendants.

2 Purpose, effect or likely effect

Gallaxo Welldone must prove that that the CAU between PHARMAC and Eli Pilly had the "purpose, effect or likely effect" of substantially lessening competition. These are alternatives so only one of the three must be found. Each term will be examined in turn.

(a) Purpose

Section 2(5)(a)(ii) provides that the purpose need not be the sole purpose for the CAU but must be a "substantial purpose". Purpose refers to "object or aim".[101]

Gault J in *Port Nelson Ltd v Commerce Commission*[102] articulated two important factors concerning 'purpose'. Firstly, his Honour noted that it is the provision in the

[100] Brooker's *Gault on Commercial Law* (Brookers, Wellington, 1994), para CA27.05 [*Gault*].
[101] *Gault*, above n 100, para CA27.11.

arrangement, not the parties themselves, that must be shown to have the purpose.[103] Secondly, the purpose need not be shared by the parties.[104] Therefore it is sufficient that the anti-competitive provisions were included for the purposes of only one party to the CAU. In addition, although the issue has not been definitively determined, it is most likely that "purpose" has an objective meaning under section 27.[105]

PHARMAC's principle objective is to control and, where possible, reduce pharmaceutical expenditure. There would be little point in arguing that PHARMAC entered the CAU for the purpose of restricting competition between pharmaceutical manufacturers. A better argument can be made that Eli Pilly entered the CAU to diminish the ability of Eli Pilly's competitors to compete in the market for statins. The CAU provides that Eli Pilly's product, Savastatin, will be the reference price drug and, as such, the only statin available to consumers fully subsidised. In addition, as the reference price for statins has been reduced, the manufacturer's surcharge on statins will increase for all other statins on the pharmaceutical schedule. This will damage the capability of other statin manufacturers to compete in the market. Gallaxo Welldone can argue that Eli Pilly entered the CAU with a substantial purpose of decreasing competition in the market for statins.

This argument has some force, however Eli Pilly could rebuff the argument by claiming that its substantial purpose in entering the CAU was to ensure its asthma product, Flexibreath, was listed on the Pharmaceutical Schedule. Increasing the number of products available with Government subsidies serves to increase competition as consumers are given a greater choice of products at no or low personal cost. While such a submission has merit, as noted above, section 27 probably requires an objective approach to 'purpose'. It is dubious whether a court would accept that Eli Pilly did not have hindering its competitors as an aim when entering the CAU.

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[102] [1996] 3 NZLR 554 (CA) [Port Nelson].
[103] *Port Nelson*, above n 102, 563.
[104] *Port Nelson*, above n 102, 563.
[105] Yvonne van Roy *Guidebook to New Zealand Competition Laws* (2 ed, CCH, Wellington, 1990) para 452 [Guidebook to New Zealand Competition Laws].

Gallaxo Welldone would probably succeed in establishing that substantially lessening competition was a purpose of the CAU. However, as section 27 provides for the alternative options 'effect or likely effect' to be considered, it would be advisable for Gallaxo Welldone to also pursue their claim on these grounds.

(b) Effect or likely effect

A finding of 'effect or likely effect' is "a question of fact in each case".[106] 'Effect' requires proof of the results of the arrangement, whereas 'likely effect' is the consideration of results which may happen. Essentially, in order to prove effect, Gallaxo Welldone must show a "causal connection" between the CAU and the substantial lessening of competition in a market.[107] Gallaxo Welldone must prove that competition in the market for statins has been substantially lessened, and that this has occurred because of the CAU between PHARMAC and Eli Pilly. It is submitted that if Gallaxo Welldone can adduce evidence that competition in the statin market has been substantially lessened, it should be able to prove with little difficulty that this is due to the CAU.

In the absence of adequate evidence that competition in the statin market has been lessened, Gallaxo Welldone could argue that substantial lessening of competition was a 'likely effect' of the agreement. Therefore the degree of likelihood is "of primary importance".[108] There has been much discussion concerning what constitutes 'likelihood'. Gault J in *Port Nelson* defined 'likely' as "a real and substantial risk that the stated consequences will happen."[109] 'Likely' is therefore more than 'a mere possibility' and less than 'more likely than not'.

As discussed above, the price reduction of the reference price statin drug will result in a price increase to the consumer for the other drugs in the statin group. Gallaxo Welldone

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[106] *Gault*, above n 100, para CA27.12(1).
[107] *Gault*, above n 100, para CA27.12(3).
[108] *Gault*, above n 100, para CA27.13(1).
[109] *Port Nelson*, above n 102, 562.

can argue with some force that there is a real possibility that this will reduce the other drug companies' ability to compete in the statin market.

In conclusion, Gallaxo Welldone can make good arguments for establishing purpose, effect or likely effect. It is likely that it could successfully prove this element of section 27.

3 Market

Identifying the relevant market is critical to proving a section 27 claim as the market provides a context for the analysis of the allegedly anti-competitive behaviour. Section 3(1A) of the Act defines market as "a market in New Zealand for goods or services as well as other goods and services that, as a matter of fact and commercial common sense, are substitutable for them." The previous definition of market made no reference to substitutability and it appears the amendment was made to "make the relevance of economic substitutability explicit."[110] However, the High Court in *Telecom Corp of NZ Ltd v Commerce Commission* stated that "reliance upon substitution criteria in a contextual vacuum is not sufficient."[111] Therefore when determining the relevant market it is necessary to keep in mind the allegedly anti-competitive conduct.

A three stage test for delineating the relevant market was articulated in *Telecom*. Firstly, the area(s) of close competition are identified.[112] Secondly, demand and supply substitution is examined; that is, determine "how buyers and sellers would likely react to a notional small percentage increase in the price of the products of interest."[113] Lastly, analyse the product, space, functional and time dimensions of the market.[114]

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[110] *Telecom Corp of NZ Ltd v Commerce Commission* (1991) 3 NZBLC 102,341, 102,361 (HC) [*Telecom*].
[111] *Telecom*, above n 110, 102,360.
[112] *Telecom*, above n 110, 102,362.
[113] *Telecom*, above n 110, 102,362.
[114] *Telecom*, above n 110, 102,363. These last two elements are closely related. The Commerce Commission will use a 'ssnip' (small yet significant and non-transitory increase in price) test to determine substitutability between products. This test also assists with the determination of the product and geographic dimensions of the market. See Michael Pickford "The Economics of Competition Policy" in *Compliance* (New Zealand Commerce Commission, October 1997) 1-4.

In light of the above definition, it is immediately apparent that the market concerned in Gallaxo Welldone's claim is not what is generally referred to as the 'pharmaceutical market'. This blanket term covers all therapies, from insulin to contraceptives to heart drugs to anti-depressants. Defining the market this broadly violates the principle of substitutability, as different types of therapies cannot be interchanged.

To refine the market definition, it is convenient to use PHARMAC's pharmaceutical categories to express options for the relevant market. Arguments may be made for two relevant market definitions: therapeutic group or therapeutic subgroup.[115]

(i) Therapeutic Group[116]

"Lipid modifying agents" are a therapeutic drug group. These drugs work on controlling the patient's cholesterol levels.

(ii) Therapeutic Subgroup

"Statins" are one of several subgroups within the "lipid modifying agents" group. The drugs in these subgroups are considered by PHARMAC to have similar therapeutic effects to one another when treating cholesterol levels.[117]

These definitions facilitate an analysis of the substitutability of drugs. It is assumed for the purposes of this analysis that the drugs within a subgroup can be substituted for one another. Therefore, patients requiring the therapeutic effect of a statin are able to transfer reasonably freely between the statins available.[118]

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[115] It is acknowledged that this issue may be further complicated by arguments concerning therapeutic effect, for example, where there are arguments about PHARMAC's categorisation of a drug as belonging to a particular therapeutic subgroup. See discussion about SSRI drugs in Part III above. For the purposes of this analysis it will be assumed that PHARMAC's classification of drugs in the statin group is not in dispute by the pharmaceutical companies.

[116] It is possible to categorise a therapeutic group in several ways: by anatomical section (blood and blood forming organs); by therapeutic area (lipid modifying agents); by therapeutic type (statins). See *Pharmaceutical Schedule*, above n 28, 50. Therapeutic area has been selected for the purposes of this discussion because statins has been classified as the therapeutic subgroup.

[117] As noted in footnote 116 above, all the drugs classified in one therapeutic type will not necessarily be considered to have the same or similar therapeutic effects. Therefore, there is often more than one subgroup in a therapeutic type for the purposes of reference pricing. For the purposes of this analysis, statins have been considered to be one therapeutic group.

[118] This includes all statins available in New Zealand, not just those listed on the Pharmaceutical Schedule.

Under the three step *Telecom* analysis set out above, the statins therapeutic subgroup satisfies the definition of relevant market: all statins are in an area of close competition with each other; demand- and supply-side substitution is likely to occur with a nominal change in price; and product, space, functional and time dimensions are adequately defined.

An argument could be made that this definition of the market is too narrow and that the relevant market should be delineated by therapeutic group. It is possible that some substitution may occur between the different subgroups of lipid modifying agents. This position is difficult to accept if it is agreed that only drugs within the same subgroup have a similar therapeutic effect. While a patient may be in the market for a drug to control cholesterol levels, the effectiveness of the drug they use may be determined by a number of factors, for example, the cause of their condition. The drugs are grouped into subgroups for a particular reason; their active agents work on the body in different ways. Therefore, the product dimension of the drugs prevents drugs in different therapeutic groups from being substitutable.

In consideration of the above arguments, it is most likely that the court would accept the relevant market as being the market for statin drugs.

4 Substantially lessening competition

This element contains two distinct but interconnected concepts - competition and the substantial lessening thereof. Given that the concept of competition is economic it is important to resist straying into economic, rather than legal, definitions. Competition is defined in section 3(1) as "workable or effective competition." It is also important to note that competition refers to competition in a market and not the effect on individual competitors within that market.[119]

[119] *Auckland Regional Authority v Mutual Rental Cars (Auckland Airport) Ltd* [1987] 2 NZLR 647, 671 (HC).

A framework for undertaking an analysis of competition was expounded in *Re Queensland Co-op Milling Assn Ltd*[120] and approved in New Zealand in *Fisher & Paykel v Commerce Commission.*[121] The court stated in *Re Queensland Co-op Milling Assn Ltd*:[122]

> ...effective competition requires both that prices should be flexible reflecting the forces of demand and supply and that there should be independent rivalry in all dimensions of the price-product-services packages offered to consumers and customers.

Five elements of market structure were proposed, although barriers to entry could be considered the most important.[123]

Competition in the statin market will always be constrained to some degree by the level of Government subsidy paid on the product and Government requirements for registration of new medicines, which pose substantial barriers to market entry. However, even when these factors are taken into account, competition does exist in the statin market. Manufacturers are able to set their own prices, having consideration of the effect their price decisions will have on the cost of the product to consumers. Further, they may engage in promotional and branding activities to bolster market share and consumer loyalty.

Once competition in the market has been established, it is necessary to determine whether or not this competition has been or will be substantially lessened by the CAU. Section 2(1A) defines substantial as "real or of substance." It is likely that this meaning was adopted from the judgment of Deane J in *Tillermans Butcheries Pty Ltd v Australasian Meat Industry Employees' Union.*[124] In that case his Honour stated that "substantial...includes loss or damage that is, in the circumstances, real or of substance and not insubstantial or nominal."[125] The threshold of the test is therefore not

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[120] *Re Queensland Co-op Milling Assn Ltd* (1976) ATPR 17,223 [*QCMA*].
[121] [1990] 2 NZLR 731, 759 (HC) [*Fisher & Paykel*].
[122] *QCMA*, above n 120, 17,245, as quoted in *Gault,* above n 100, para CA3.
[123] *Gault,* above n 100, para CA3.16.
[124] (1979) ATPR 40-138 [*Tillermans Butcheries*].
[125] *Tillermans Butcheries*, above n 124, 18,500, as quoted in *Gault*, above n 100, para CA27.14.

significantly high and may be interpreted as a "desire on the part of Parliament to cast the net widely."[126] This position was endorsed by McGechan J in *CC v Port Nelson Ltd.*[127]

It should also be noted that while substantiality requires attention to relative effects, it is not a proportional test. Smithers J in *Dandy Power Equipment Pty Ltd v Mercury Marine Pty Ltd*[128] stated: "it is the degree to which competition has been lessened which is critical, not the proportion of that lessening to the whole of the competition which exists in the total market."[129]

The lack of precision in the definition of substantial gives the courts a wide discretion to determine whether competition has been substantially *lessened*. Section 3(2) of the Act provides that lessening of competition "includes references to the hindering or preventing of competition." The inclusion of hindrance in the definition of lessening "widens the ambit of section 27"[130] so that the section may capture behaviour that could not be strictly considered to be lessening competition, such as preventing competition.

Smithers J in *Dandy Power Equipment Pty Ltd v Mercury Marine Pty Ltd* provided a test for determining whether a substantial lessening of competition had occurred:[131]

> To my mind one must look at the relevant significant portion of the market, ask oneself how and to what extent there would have been competition therein but for the conduct, assess what is left and determine whether what has been lost in relation to what would have been, is seen to be a substantial lessening of competition... Has competitive trading in the market been substantially interfered with?

The CAU between PHARMAC and Eli Pilly has caused the reference price, and thus the Government subsidy, for statins to be lowered. Therefore, unless other manufacturers in

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[126] *Re Closure of Whakatu and Advanced Works* (1987) 2 TCLR 215; 1 NZLBC (Com) 104,200, as quoted in *Gault*, above n 100, para CA27.14.
[127] *Port Nelson,* above n 102, 563.
[128] (1982) ATPR 40-315 [*Dandy Power*].
[129] *Dandy Power*, above n 128, 43,888.
[130] *Gault,* above n 100, para CA27.15.
[131] *Dandy Power*, above n 128, 43,888.

the market reduce the prices of their statins the cost to the consumer of using these statins will increase. This puts pressure on these manufacturers to reduce their statin prices to prevent loss of market share. It is possible that some manufacturers would be forced to exit the market if they are unable to profitably market their statins at a lower price. It also follows that potential competitors would be prevented or deterred from entering the market for statins if they would have to price their product very low in order to compete with Savastatin.

Further, if Eli Pilly is cross-subsidising, or trading profits on Savastatin for market share for Flexibreath, the reference price and therefore the subsidy level would be below cost. While below cost pricing does not automatically contravene section 27, it can be used to show that the competitive process of the market is being interfered with.[132]

These results constitute effects that substantially lessen competition in the statin market. The last critical consideration for proving substantial lessening of competition is that section 27 requires a net approach. That is, if the conduct in question has both pro-competitive and anti-competitive effects on a market then these must be balanced against each other to determine whether the net effect promotes or damages competition in that market.[133] While dropping prices is usually considered to be pro-competitive behaviour, it is arguable that even if some price competition resulted from the lowering of the reference price this would be outweighed by the anti-competitive effects of increased difficulty in entering or competing in the statin market.

In conclusion, it is probable that Gallaxo Welldone would succeed with a section 27 claim against PHARMAC and Eli Pilly. When consideration is given to the other types of arrangements PHARMAC enters with drug companies, discussed in Part III of this paper, a breach of section 27 is also likely to be upheld in some cases. Sole supply arrangements deny subsidies to all drugs in a subgroup other than the tender winning product for three years, preventing effective competition in the relevant drug market for that period. Preferred supplier arrangements oblige pharmacists to dispense a particular

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[132] *Port Nelson*, above n 102, 571.
[133] *Guidebook to New Zealand Competition Laws*, above n 105, para 415.

brand of drug where they have a choice. Alternative brands are unable to compete at all in these circumstances. Preferred supplier agreements usually result in the market being reduced to two companies; the preferred supplier and the original brand supplier - other competitors are eliminated from the market.[134] Pay-to-play contracts, where PHARMAC makes a bulk payment to a manufacturer to encourage it to enter the market, may encourage competition in a market by mitigating a barrier to entry.[135] However, if a condition of the deal is that the new manufacturer must undercut the existing reference price it is possible that a section 27 claim could be made out.

The risk sharing types of arrangements used by PHARMAC, average daily dose contracts and capped maximum annual contracts, may also form grounds for a successful section 27 claim. Average daily dose contracts set reimbursement for a prescription at a particular level and may discourage drug companies from promoting the dispensing of higher dosage preparations. This could dampen competition between companies for this range of products. Capped maximum annual contracts provide that once PHARMAC has expended a particular amount on a drug within a twelve month period, the drug company must reimburse PHARMAC any further expenditure until the year has expired. This prevents the drug company from competing in the market for that drug for the remainder of the year after the limit has been passed. It is possible that these types of agreements would only affect the competitiveness of one competitor and not the market as a whole, however substantial lessening of competition must be established on the facts of each case and therefore cannot be precluded.

In summary, the agreements entered into between PHARMAC and drug companies are likely to provide a basis for claims under section 27 as they all potentially have the purpose, effect or likely effect of substantially lessening competition in a market.

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[134] See discussion in Part III of this paper.
[135] Ministry of Health testing requirements are costly in terms of both time and money.

B Use of Dominant Position in a Market

Section 36 of the Act prohibits the use of a dominant position in a market for proscribed purposes. Section 36 provides:

> 36(1) No person who has a dominant position is a market shall use that position for the purposes of -
>
> (a) Restricting the entry of any person into that or any other market; or
> (b) Preventing or deterring any person from engaging in competitive conduct in that or in any other market; or
> (c) Eliminating any person from that or any other market.

The fact situation used above to analyse a claim under section 27 would also provide Gallaxo Welldone with grounds for a claim under section 36 of the Act on the basis that PHARMAC has used its dominant position to prevent or deter competition in the statin market. However, as PHARMAC's principle activity, making decisions with regard to listings on the Pharmaceutical Schedule, has potentially anti-competitive effects it is interesting to analyse section 36 of the Act in this regard. Once again, a hypothetical fact situation is set out below and will be used to demonstrate how a section 36 proceeding against PHARMAC could be framed.[136]

Dugleast Pharmaceuticals Ltd developed a new "Ace inhibitor"[137] drug named Nuopril. Nuopril was duly registered for sale in New Zealand under the Medicines Act 1981 and Dugleast applied to PHARMAC to have the new drug listed on the Pharmaceutical Schedule. PHARMAC decided not to list Nuopril. Without a subsidy on the drug, sales of Nuopril will be severely restricted. Nuopril initiates a proceeding against PHARMAC under section 36, claiming that PHARMAC is using its dominant position to prevent or deter competitive conduct.

Section 36 can be broken down into three elements: dominant position; the use of that position; for one of the proscribed purposes contained in subsections (a)-(c).

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[136] This hypothetical fact situation is similar in essence to the *Glaxo* case, above n 66.

[137] Angiotensin Converting Enzyme (ACE) Inhibitors are cardiovascular system drugs taken to control blood pressure. As noted in footnote 117 above, there may be several therapeutic subgroups within the Ace inhibitors therapeutic type for the purposes of reference pricing.

1 Dominant position

A person in a dominant position is in a position to exercise a dominant influence over the market.[138] Dominant influence is considered to mean "an absence of effective competition, or an ability to act independently."[139] Before this can be determined it is necessary to clearly define the market in which the person is dominant.

Firstly, it is important to note that section 36 does not require the person to be deterring competitive conduct in the market in which it is dominant. Section 36 prohibits a dominant person from using its dominant position for anti-competitive purposes in *any* market.

What is the market in which PHARMAC is dominant? It is not a specific therapeutic drug market because PHARMAC is not directly involved in any drug markets. PHARMAC makes decisions about subsidies and subsidy levels of drugs in drug markets. It has a great deal of influence over activity in these markets, but it is not a supplier or a consumer in any drug market.

PHARMAC administers the Pharmaceutical Schedule. Can the supply and demand for Government drug subsidies be considered a market?[140]

The starting point for identifying a market is substitutability,[141] which is an economic concept.[142] Substitution encompasses both demand side and supply side decisions and examines how buyers and sellers would react to a change in the price of a product.[143] Given a sufficient price incentive, would buyers switch to another brand (demand-side

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[138] A lengthy definition of 'dominant influence is contained in s 3(8) of the Act.
[139] *Guidebook to New Zealand Competition Laws*, above n 105, para 722. The statutory definition of 'dominant influence' is contained in s 3(9) of the Act.
[140] Section 2(1) of the Act defines 'supply' in relation to services as including "provide, grant, or confer". Therefore it is not necessary for there to be consideration in the traditional contract law sense.
[141] The concept of substitutability is articulated in the Act's definition of 'market' in s 3(1A). Note that a discussion of market definition is also contained in Part V(A) above in the section 27 discussion.
[142] Maureen Brunt "'Market Definition' Issues in Australian and New Zealand Trade Practices Litigation" in Rex J Ahdar (ed) *Competition Law and Policy in New Zealand* (Law Book Co, Sydney, 1991), 122 [Market Definition].
[143] "Market Definition", above n 142, 129.

substitution) or would other suppliers enter the market for a product (supply-side substitution)? In this analysis, it is useful to consider the substitutability of product, space, function and time dimensions.[144] Product substitutability determines the products between which customers and suppliers will switch. Geographic space is the area in which sellers will sell and buyers will "shop".[145] Function refers to whether the emphasis is on the selling or buying aspect of the market, or on the functional level of a market (manufacturing, wholesaling or retailing).[146] In this respect, markets are usually confined to only one function although this is not always the case.[147] The time dimension concerns "how much time is needed for customers and suppliers to make their adjustments in response to economic incentives".[148]

When this analysis is applied to PHARMAC's activities it is not possible to conclude that the supply and demand for Government drug subsidies constitutes a market. The substitutability test is centered around delineating a market where either other products are produced or may potentially be produced. Intrinsic within the substitutability test is the element of choice - suppliers can choose to enter or exit a market, customers can choose between different products. The emphasis of substitutability is on the level of incentive suppliers and customers require in order to undertake the substitution process.

The product is a Government drug subsidy. Demand or supply side substitution is impossible within the product dimension. A subsidy is the only method by which drug manufacturers can ensure that their products are either free or cheap to the consumer. They cannot switch to another 'product' (subsidy) because there is not one available. Therefore there is no demand-side product substitution.

PHARMAC is the sole supplier of Government drug subsidies. Given that PHARMAC was established by the Government's health funding body specifically to fulfill the role of administering drug subsidies, it is extremely unlikely that the authority to grant drug

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[144] "Market Definition", above n 142, 130. Also see *Guidebook to New Zealand Competition Laws*, above n 105, para 405; and the discussion of relevant market in *Telecom*, above n 110, 102,363.
[145] *Guidebook to New Zealand Competition Laws*, above n 105, para 405.
[146] "Market Definition", above n 142, 130.
[147] *Guidebook to New Zealand Competition Laws*, above n 105, para 405.
[148] "Market Definition", above n 142, 130.

subsidies would be delegated to more than one body. Therefore, there is no potential for another supplier to enter the market (supply-side product substitution).

Further, the aim of managing drug subsidies is to reduce the Government's drug expenditure, not to make a profit. Thus it is difficult to see what incentive there would be for another supplier to enter the market for drug subsidies. This factor alone removes PHARMAC's activities from the realm of economics, the foundation of the substitutability test.

This analysis renders the other dimensions null. PHARMAC is the sole supplier of the product in New Zealand so there are no other geographic markets. The product has only one functional level. Analysing the time taken for market participants to adjust their behaviour is not relevant as it is not possible for any such adjustments to be made.

In conclusion, utilising the above economic approach taken by the Commerce Commission and the courts[149] it is not possible to consider that transactions concerning drug subsidies constitute a market.

However, it is possible the court would not feel constrained to use this analysis to determine the existence of a market. It is arguable that the substitution approach is necessary only to delineate the parameters of a market where there are substitute goods and services available. As there is clearly no substitute for Government drug subsidies, an analysis of substitutability is arguably inappropriate.

In addition, drug subsidies may be distinguished from most other products on the basis of their unique nature. Drug subsidies are a political mechanism implemented to achieve the social policy objective of enabling consumers to have reasonable access to expensive drug therapies. It is arguably artificial and irrelevant to subject the market for these subsidies to the strict economic test set out above.

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[149] *Guidebook to New Zealand Competition Laws*, above n 105, para 405.

Is it possible to frame an argument that there is a market for drug subsidies based on a common sense approach to the facts? Supply and demand for subsidies exists, even in the absence of traditional economic mechanisms such as price. The subsidies have an obvious value to all parties concerned. PHARMAC values the subsidies in terms of minimising Government payments so fiscal objectives can be achieved. Drug companies value the subsidies as they are crucial to the success of companies' products in the drug markets. These parties negotiate with each other over the granting of subsidies and subsidy levels in order to achieve their respective financial objectives.

The absence of competition forms a stumbling block for this argument. The market concept is "designed to assist in the analysis of processes of competition and sources of market power."[150] Certainly in the context of a section 36 analysis, the potentially anti-competitive effects of market power lie at the heart of the provision. As the political nature of PHARMAC's authority to grant subsidies precludes PHARMAC from having competitors, the argument that there is a market for subsidies is tenuous.

Whether the courts would follow the economic approach to market definition or adopt a more liberal approach is uncertain. However, arguments against the existence of a market for Government drug subsidies are persuasive. Obviously if the courts found that there was no market for drug subsidies, Dugleast's section 36 claim would be frustrated at this point. Conversely, if a market for drug subsidies was recognised, Dugleast would have no difficulty proving PHARMAC, as the sole supplier of subsidies, was in a dominant position in that market.

2 Use that position

Dugleast must establish that PHARMAC has used its dominant position for a proscribed purpose. In *Port Nelson*, Gault J adopted the Privy Council's test from *Telecom Corp of New Zealand v Clear Communications Ltd*[151] for establishing use:[152]

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[150] "Market Definition", above n 142, 122.
[151] *Telecom*, above n 110.
[152] *Port Nelson*, above n 102, 577.

> ...it cannot be said that a person in a dominant market position 'uses' that position for the purposes of s 36 unless [sic sc 'if'] he acts in a way which a person not in a dominant position but otherwise in the same circumstances would have acted.

Therefore, a dominant party acting in the same manner as a non-dominant party cannot be said to be using its dominant position.[153] This test may be expressed as a 'but for' test. The relevant question is: but for the dominant position, would the person have acted in the same way? Unfortunately this test requires the court to guess how a non-dominant firm would have conducted itself.[154] It is also difficult to separate use from purpose when applying the test.

PHARMAC's political nature strains the construction of this test. It is difficult to conceive how PHARMAC would behave if there was another agency with the authority to grant Government subsidies on drugs. However, it is intuitively appealing to say that PHARMAC has used its dominant position. PHARMAC has the power to deny a Government drug subsidy to any applicant; that is the very nature of its dominant position. In this context, PHARMAC *must* have used its dominant position. Interestingly it is the *Port Nelson* case which provides a way for a strict use test to be avoided, and for the courts to "use the means they consider best to make the causal connection between the conduct and the dominant position."[155]

PHARMAC's unique character may incline the courts to use a more flexible approach to establishing use and it is possible that PHARMAC may be found to have used its dominant position to deny Dugleast a subsidy. It is submitted that in this case, the element of use is not critical as the primary focus is on satisfying one of the proscribed purposes.

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[153] *Gault*, above n 100, para CA36.11.
[154] *Gault*, above n 100, para CA36.12.
[155] *Gault*, above n 100, para CA 36.12. "While it is not easy to see why use of a dominant position should not be determined simply as a question of fact without the need to postulate artificial scenarios, we are content in this case to adopt that approach, as did the High Court." *Port Nelson*, above n 102, 577.

3 *Purpose*

Whether use or purpose is the dominant requirement of section 36 has been discussed in several cases. Upon the construction of section 36 there is a strong argument to be made that use should be viewed as merely a link between dominant position and purpose, meaning that the purpose of the conduct is the important issue. This position has support in an Australian case concerning section 46 of the Trade Practices Act 1974, the Australian equivalent to section 36, *Queensland Wire Industries Pty Ltd v BHP Co Ltd*[156] and the New Zealand case, *Electricity Corporation Ltd v Geotherm Energy Ltd.*[157]

However, the Privy Council has expressed the opposite view and emphasised use to be the pivotal issue, with purpose following on. In *Telecom Corporation of New Zealand Ltd v Clear Communications Ltd*, the Lord Browne-Wilkinson stated:[158]

> If a person has used his dominant position it is *hard to imagine* a case in which he would have done so otherwise than for the purpose of producing an anticompetitive effect; there will be no need to use the dominant position in the process of ordinary competition. Therefore, it will frequently be legitimate for a court to *infer* from the defendant's use of his dominant position that his purpose was to produce the effect in fact produced.

The Privy Council's use of the terms "hard to imagine" and "infer" indicates that the purpose follows use approach to section 36 is not absolute. Dugleast's claim against PHARMAC is in fact a case where this inference may not be supported. PHARMAC's reasons for engaging in the allegedly anti-competitive conduct have no correlation to the proscribed purposes set out in section 36 (discussed below). It is submitted that it is PHARMAC's unique position as a tool for pursuing Government health policy and fiscal objectives which destroys the inference that purpose follows use. Certainly such an inference sits rather more comfortably in ordinary market situations where a

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[156] (1989) ATPR 40-925, 50,010. [*Queensland Wire*]. "It is these purpose provisions which define what uses of market power constitute misuse."
[157] [1992] 2 NZLR 641, 649 [*Geotherm*] as quoted in *Gault*, above n 100, para CA36.08.
[158] (1994) 5 NZBLC 103,552, 103,565 (PC) [*Telecom v Clear*]. Emphasis added.

dominant party seeks to maximise revenue to itself by undermining the competitiveness of its rivals.

Therefore, even if the use element is satisfied, it is still necessary for Dugleast to establish that PHARMAC's purpose for its conduct was one of the proscribed purposes contained in section 36(1) of the Act. These purposes are:[159]

(a) restricting entry into a market;
(b) preventing or deterring competitive conduct in a market; and
(c) eliminating any person from a market.

Firstly it is important to note that the relevant market in which to consider anti-competitive purpose is the market for Dugleast's new drug, Nuopril, not the drug subsidy market in which PHARMAC is dominant.

Secondly, the effect of PHARMAC's action is not a relevant consideration.[160] Therefore, Dugleast must argue that PHARMAC declined to subsidise Nuopril for the purpose of damaging competition in the ACE inhibitors market. As PHARMAC's principal objectives are to "optimise pharmaceutical's contribution to health status" within fiscal constraints,[161] it is these objectives that determine PHARMAC's conduct. An argument that the direct and immediate purpose of PHARMAC's decision not to list Nuopril was to damage competition in the ACE inhibitor market is not sustainable.

However, Dugleast may still be able to prove purpose because of the effect of PHARMAC's decision. While oblique intention, the intention to do an act known to have anti-competitive results, is insufficient to establish anti-competitive purpose,[162] consideration may be given to circumstances where the effect of anti-competitive

[159] Section 36(1) of the Act.
[160] *Gault*, above n 100, para CA36.14.
[161] *Statement of Intent,* above n 13, 2.
[162] *Gault*, above n 100, para CA36.15.

conduct was inseparable from the aim of the conduct.[163] This was considered by Cooke P in *NZ Apple & Pear Marketing Board v Apple Fields:*[164]

> By achieving some degree of fairness [the consequence which was the aim or object of the conduct] the levy at the same time inevitably carries out a policy or purpose of restricting new production [the inseparable anticompetitive consequence].

Dugleast may therefore be able to raise the anti-competitive effect of PHARMAC's conduct and argue that this effect cannot be isolated from PHARMAC's purpose. While PHARMAC's objective was to, say, minimise subsidy payments and control the public pharmaceutical spending budget, the hindering of competitors entering the ACE inhibitor market was an anti-competitive consequence inseparable from this objective. There is some force in this argument and it is probable that Dugleast could successfully argue that PHARMAC had the requisite proscribed purpose on this basis.

Overall, Dugleast may not be so successful with a section 36 claim. It is possible that use and purpose may be found, however establishing the existence of a market in which PHARMAC is dominant is a difficult obstacle for Dugleast to overcome. While Dugleast may be able to frame an arguable case, it does not have a high chance of success with a section 36 claim. Moreover, as the same issue relating to market definition will arise in any section 36 claim against PHARMAC, it is possible that even without an exemption from the Commerce Act PHARMAC would never face liability under section 36 of the Act.

The above discussion demonstrates two things. Firstly, that PHARMAC's activities with respect to operating the Pharmaceutical Schedule give rise to genuine concerns for competition in pharmaceutical markets. Secondly, if not for the exemption contained in section 2 of the Finance Act 1994, PHARMAC could probably be found to be breaching the Commerce Act. Whether or not PHARMAC should enjoy such an exemption is discussed in the following section.

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[163] *Gault*, above n 100, para CA36.15.
[164] [1989] 3 NZLR 158, 162, as quoted *Gault*, above n 100, para CA36.15(3).

VI SHOULD PHARMAC BE EXEMPT FROM THE COMMERCE ACT?

PHARMAC operates in a complex political environment. The role of government fiscal and social policy objectives are central to PHARMAC's activities. In addition, PHARMAC's conduct must be viewed in the context of a powerful drug industry and a unique market structure. These factors all have influence over whether or not PHARMAC should be subject to the restrictive trade practices provisions of the Commerce Act.

A Government Policy

The role of Government policy making is to balance competing interests for finite resources. Containing and, where possible, reducing expenditure on funding priorities is desirable as funds will made available for use in other areas. Pharmaceutical expenditure is an obvious target for Government cost control initiatives as it represents an ever-increasing proportion of Government expenditure on health.[165] Prior to the establishment of PHARMAC, the portion of Government spending used to subsidise pharmaceuticals was increasing at a rate that would double every seven years. PHARMAC claims it has slowed this growth to the point where doubling of expenditure will occur only every 10-12 years.[166]

Containing pharmaceutical expenditure is a significant public policy issue.[167] Unnecessarily high expenditure and wastage due to over-prescribing or unnecessary prescribing diverts Government money from other areas.[168]

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[165] Internationally, there has been massive growth in drugs expenditure since the end of World War II. World production has doubled since 1975 and reached [1980]US$150 billion in 1990. Robert Ballance, Janos Pogany and Helmut Forstner *The World's Pharmaceutical Industries* (Edward Elgar Publishing Ltd, England, 1992) 3 [*The World's Pharmaceutical Industries*]. In New Zealand during this period, the percentage of GNP spent on pharmaceuticals increased from 0.4% to 0.5%. *The World's Pharmaceutical Industries*, above, 227. A summary of the causes of this growth is contained in Appendix 4.

[166] PHARMAC *Annual Review for Year Ending 30 June 1996* (Wellington, 1996) 11 [*Annual Review 1996*].

[167] Peter Davis *Managing Medicines* (Open University Press, Buckingham, 1997) 97 [*Managing Medicines*].

[168] Helen Clark, MP "Pharmaceutical Costs and Regulation: From the Minister's Desk" in Peter Davis (ed) *For Health or Profit* (Oxford University Press, Auckland, 1992) 53 ["Costs and Regulation"].

However, there are two further issues that form the background over which the Government goal of cost containment must be laid. First is the nature of the product itself. There is a wider public interest in drugs than most products and access to pharmaceuticals is critical to promoting public health. The value of the product itself is the quality and prolonging of life, rather than personal utility.[169] It would be unethical for a Government to deny people access to drugs as there is a social benefit in improving the health of the general population. Further, there is a public expectation that the public health system "must provide regardless of cost wherever there is need."[170] The public's desire for "free" pharmaceuticals provides a further drive for the Government to apply downward pressure to the price of pharmaceuticals.[171] An additional market characteristic that distinguishes pharmaceuticals from other products is the complex nature of pharmaceuticals which means that the product is selected by a third party, a doctor, on behalf of the consumer.[172]

The second issue is the unique nature of the pharmaceuticals market. The specific character of the product as outlined above means that many of the factors which make other product markets price competitive are absent.[173] Market mechanisms which determine factors such as product range, price and promotional activities for most other manufacturers are markedly different for the pharmaceutical industry. In other markets, competition tends to contain or force down prices. Innovation usually reduces the price of technology in other markets, for example electronics, although it has the opposite effect in the pharmaceutical market.[174] These features of the pharmaceutical industry will be discussed in more depth below.

As the pharmaceuticals market does not operate and react in the same manner as most markets, the Government cannot rely on market forces to deliver budgetary stability.[175] Therefore, if the Government wishes to contain the costs of pharmaceuticals and deliver

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[169] *Managing Medicines*, above n 167, 97.
[170] "Costs and Regulation", above n 168, 69.
[171] "Costs and Regulation", above n 168, 54.
[172] Peter Davis "Pharmaceuticals and Public Policy" in Peter Davis (ed) *For Health or Profit?* (Oxford University Press, Auckland 1992) 3 [Pharmaceuticals and Public Policy].
[173] "Pharmaceuticals and Public Policy", above n 172, 3.
[174] *Managing Medicines*, above n 167, 97.

maximum health outcomes to the public, intervention in the pharmaceutical market is essential. The Government imperative to control the pharmaceutical budget results in a conflict with its role to encourage competition. In order to pursue Government policy objectives, it is necessary for PHARMAC to be exempt from the Commerce Act.

B The Drug Industry

The international pharmaceutical industry is dominated by a few, very powerful multi-national firms. Around fifty multi-nationals account for two-thirds of world production each year.[176] The financial strength of these multi-nationals often exceeds that of many governments.[177] In relation to the worldwide pharmaceutical market, New Zealand is minuscule. New Zealand accounts for about 0.2 per cent of international drug sales, which overall total around $300 billion per annum - about three times the output of New Zealand's economy.[178]

While there are many manufacturers in the industry, the pharmaceutical market is highly fragmented.[179] Therefore, competition in individual drug markets is not very vigorous. Each market is dominated by a few, efficient, patented drugs that, due to strong product branding, tend to remain dominant even after the patent has expired.[180] Although it may appear at first glance that there are many drug companies involved in competition with one another, when the market is analysed in terms of many distinct products and markets it can be seen that competition is in fact limited and that market power clearly exists.[181]

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[175] *Managing Medicines*, above n 167, 14-15.
[176] *The World's Pharmaceutical Industries*, above n 165, 4.
[177] Alan Klass *There's gold in them thar pills* (Penguin Books, Middlesex, 1975), 43.
[178] *Annual Review 1997*, above n 11, 11.
[179] On average, 21 per cent of the top 25 multi-national companies' earnings come from sales of a single product. *The World's Pharmaceutical Industries*, above n 165, 110. In each market for a particular type of drug, generally there will be one or two dominant firms which hold the majority of the market share. *The World's Pharmaceutical Industries*, above n 165, 114.
[180] *The World's Pharmaceutical Industries*, above n 165, 114.
[181] *The World's Pharmaceutical Industries*, above n 165, 118.

The Australian Pharmaceutical Industry Commission describes four categories of drugs and the varying degrees of competition which exist in the markets for them:[182]

1. unique, breakthrough drugs that are the only effective form of treatment and where there is no direct substitute;
2. drugs that are first in a new therapeutic class with equivalent efficacy to other drugs but with quality of life and/or safety improvements;
3. me-too drugs in the same chemical family with no additional benefits;
4. out of patent products.

The price effects for each of these categories differs. Breakthrough drugs have a monopoly over the market and are able to reap monopoly profits. However, competition from other drugs is quick to emerge so companies do not remain in a monopoly position for long.

Drugs in the second category have a more limited monopoly as there is competition from drugs with similar therapeutic effects. The third category, 'me too' drugs, by their nature are close substitutes for one another. Companies promote these products through branding.

The final category represents generic markets, which are highly competitive. However, prices may be maintained at a high level in order to promote brand image and preserve consumer perceptions of quality.[183]

The key feature of competition in individual drug markets is that competitive conduct usually involves innovation and branding, not product price.[184] What is distinctive about the pharmaceutical industry is "the extent to which innovation and promotion

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[182] The Pharmaceutical Industry Commission Australia *Report No. 51*, 3 May 1996, 191 [PICA]. These drug 'types' may also be considered as different stages in the lifecycle of a drug as it moves from 'breakthrough' (if that is the case, it may begin its life as a 'me too' or a copy of an existing available drug) to generic. See *The World's Pharmaceutical Industries,* above n 165, 206-207, in particular figure 8.2.

[183] For a full discussion see PICA, above n 182, 192.

[184] "Pharmaceuticals and Public Policy", above n 172, 4.

actually substitute for price competition."[185] In dynamic markets, research and innovation are crucial to success.[186] Mature markets rely on promotion and brand loyalty.[187]

1 Research and development

As discussed above, research and development (R&D) is crucial to the drug industry and is comparable in this respect to aerospace, electronics and chemical industries.[188] However, product development has actually slowed down[189] while money spent on research by the drug companies continues to increase.[190]

The R&D undertaken by the drug companies has been criticised as being generally focused on producing 'me too' drugs, which are then marketed as superior to (and therefore more expensive than) the existing drug on the market.[191] This claim is often dubious although not necessarily untrue.[192] The search for new drugs may be fueled by stagnating demand for some products. However, as many new drugs fall into the 'me too' category, drug companies have relied on increasing prices to raise the total value of sales.[193]

The motivation for drug companies to innovate is problematic for health funders because there are constantly new products available, some of which are better although most of which are not, and almost all are more expensive. However, it cannot be denied

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[185] *Managing Medicines*, above n 167, 96.
[186] "Product development rather than low prices has been the major determinant of market leadership...in industrialised countries." *The World's Pharmaceutical Industries*, above n 165, 60.
[187] *The World's Pharmaceutical Industries*, above n 165, 119.
[188] *The World's Pharmaceutical Industries*, above n 165, 85.
[189] In the period 1961-70, 844 new molecular entities (NMEs) were developed, compared to 665 between 1971-80, and 506 between 1981-90. *The World's Pharmaceutical Industries*, above n 165, 86.
[190] *Managing Medicines*, above n 167, 89.
[191] The Food and Drug Administration in the United States undertook a study of 348 new drugs introduced between 1981-88. It found that only 3 per cent of these drugs had an important potential contribution. Thirteen per cent had a most contribution, and a remarkable 84 per cent had little or no potential contribution. Ichiro Kawachi and Joel Lexchin "Doctors and the Drug Industry: Therapeutic Information or Pharmaceutical Promotion?" in Peter Davis (ed) *For Health or Profit* (Oxford University Press, Auckland, 1992) 245 [Doctors and the Drug Industry].
[192] *The World's Pharmaceutical Industries*, above n 165, 157.
[193] *The World's Pharmaceutical Industries*, above n 165, 29.

that drug companies' R&D activities are highly valuable, particularly in light of Government objectives for improved health outcomes in the population.

R&D is often cited by pharmaceutical companies as justification for highly priced products. The companies claim that Government policies constraining prices and encouraging price competition have the effect of decreasing funds available for R&D.[194] Therefore not only is the companies' profitability reduced, but the development of new breakthrough pharmaceutical treatments is hindered to the detriment of the population.

While it is agreed that R&D is critical to market success and that it also fulfills a valuable social benefit role, it is not necessary to abandon attempts to constrain drug prices on these grounds. Even if R&D and marketing is accounted for, drug companies' rates of profit are higher than the average for manufacturing industries.[195] It is worth noting that in almost all industrialised countries, Government funding for bio-medical research exceeds company-financed expenditure.[196]

While it is recognised that innovation is important to both manufacturers and consumers, it should not be used by drug companies as a mechanism through which to ensure prices continue to spiral upwards. Were PHARMAC not exempt from the Commerce Act, its ability to curtail excessive price increases for drugs would be severely inhibited.

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[194] *Managing Medicines*, above n 167, 89.

[195] *The World's Pharmaceutical Industries*, above n 165, 155. A study of the US drugs market undertaken between 1981-83 by the Office of Technology Assessment in Washington, US, concluded that "the long term persistence in the industry as a whole of dollar earnings that are higher than the amount required to justify costs and the R&D risk is proof of the unnecessary power of price fixing for ethical pharmaceutical products." World Health Organisation Task Force on Health Economics *Health Economics, The Uruguay Round and Drugs* (February 1997) 25.

[196] *The World's Pharmaceutical Industries*, above n 165, 90. These countries are Ireland, Japan, Switzerland and the UK. New Zealand generally produces only finished products, usually from imported inputs. However, it has limited research capabilities and has invented one NME in total.

2 *Promotion*

Drug companies spend around 20 per cent of the wholesale price of a drug on marketing, the second largest expense after manufacturing.[197] In addition, drug companies sponsor events such as conferences for doctors and undertake "indirect" promotion, that is the giving of gifts and merchandise to doctors.

Drug companies claim that their promotional materials and activities provide "essential information to physicians and other choice-makers."[198] However, critics claim that the objective of promotion is to support higher prices and increased market power for the drug companies. Certainly, the drug companies spend excessive amounts of their revenue on promotional activities.[199]

The role of marketing and promotion is to differentiate products and maintain the loyalty of the choice-maker.[200] The emphasis is on "product differentiation backed up by scientific claims of efficacy, and the target is the prescribing clinician."[201] Fierce promotion may be associated with the launch of a 'me too' product which differs very little from already available products.[202] The manufacturer will promote the brand of their product to encourage doctors to prescribe it over other, virtually identical, products.

Promotional activities do indeed have a significant impact on doctors' prescribing habits. The most obvious indication of this is the level of promotion which takes place; drug companies would soon abandon such expensive operations if they were not effective.

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[197] *Managing Medicines*, above n 167, 94.
[198] *The World's Pharmaceutical Industries*, above n 165, 159.
[199] A 1991 study undertaken in New Zealand showed that "drug companies spent over $500,000 in postage alone to send out 30 tons of print advertising to doctors." *Annual Review 1997*, above n 11, 7. In the US, promotional expenditure is equal to total sales of the new product in its first year, 50% in the second year and 25% in the third year. *The World's Pharmaceutical Industries*, above n 165, 160.
[200] *Managing Medicines*, above n 167, 92.
[201] *Managing Medicines*, above n 167, 94.
[202] "Doctors and the Drug Industry", above n 191, 245.

The major implication of promotional activities for Government drug expenditure is that doctors may be encouraged to prescribe more expensive drugs over equivalents that may be cheaper yet the same or similar in effect. In addition, excessive promotional activity may lead to over-prescribing of drugs, increasing Government spending. PHARMAC's exemption from the Commerce Act enables PHARMAC to curtail expensive or over-prescribing by selecting which drugs will be subsidised and limiting total expenditure on a particular drug.

C Government Alternatives

The above discussion has highlighted the unique nature of pharmaceutical products and the pharmaceutical industry, and the problems a government faces in seeking to minimise its health spending on pharmaceuticals. Given the competition law issues arising from PHARMAC's operation of a reference pricing system, what policy alternatives are available? Are any of these alternatives acceptable under the provisions of the Commerce Act?

One option is to allow natural price competition to bring down the prices of drugs once patents have expired and generics have entered the market. [203] Obviously this requires Governments to endure substantial periods where patent protection is available[204] and price competition is virtually absent from the market. A further difficulty is that, as noted above, there is no guarantee that price competition will occur once a patent has expired and generics are available. This is due to the intense branding and promotional activities undertaken by the branded drug manufacturers. Also, as market entry is difficult, sufficient generics may not be available to provide a truly competitive environment. In light of the Government's objective of controlling an escalating drugs bill, this option is unsatisfactory.

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[203] *The World's Pharmaceutical Industries*, above n 165, 207.
[204] A period of 16 years in New Zealand.

It is accepted that the Government must undertake some form of regulation of the drug industry in order to protect its fiscal interests. What are governments in other countries doing, and what implications do these schemes have for competition?

1 Drug market regulation overseas

Although methods differ, almost all Governments regulate drug prices.[205] In its 1996 Annual Review, PHARMAC discussed measures other countries had undertaken in the previous year to reduce their expenditure on pharmaceuticals.[206] For example, Denmark reduced antibiotic subsidies and negotiated price agreements with drug companies. France set a price ceiling on growth in expenditure generated by non-hospital doctors. Holland cut drug prices to the average of Belgium, France, Germany and the UK. Italy implemented a reference pricing system. Kenya introduced generic substitution.

There are three ways a Government can set about containing the cost of pharmaceuticals. It can put a ceiling on drug expenditure, make the drug products cheaper, or avoid excessive and unnecessary use.[207] The methods of containing pharmaceutical costs vary greatly in different countries and often employ a combination of all three methods noted above. One commentator identifies seven schemes used by various Governments to regulate pharmaceutical prices.[208]

(i) Direct Price Regulation

a) Italy has used international prices as a basis for setting domestic prices since 1991.[209]

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[205] *The World's Pharmaceutical Industries*, above n 165, 141.
[206] *Annual Review 1996*, above n 166, 11-12.
[207] F M Haaijer-Ruskamp, NMG Dukes *Drugs and Money: The problem of Cost Containment* (6 ed, Styx Publications, Groningen, 1991) 15 [*Drugs and Money*].
[208] Patricia M Danzon *Pharmaceutical Price Regulation* (AEI Press, Washington DC, 1997) 16-29 [*Pharmaceutical Price Regulation*]. Danzon also discusses the US model, however the US system is fundamentally different from most other countries as Government spending accounts for only around 2 per cent of expenditure on pharmaceuticals (*The World's Pharmaceutical Industries*, above n 165, 149). Therefore the US system has not been discussed.
[209] Comparisons with prices in other countries have problems which must be kept in mind. Using drug expenditure as a percentage of total health expenditure is coloured by costs and availability of other forms of medical care in each country. Drug expenditure as a percentage of GNP takes no account of different

b) France uses several criteria for setting prices (international comparisons with existing products; therapeutic merit; contribution to the domestic economy). In 1994 France added revenue limits to its scheme.

c) Canada benchmarks innovative products against their prices in nine other countries. Prices for non-innovative products are "tied" to their existing levels.

(ii) Revenue Limits

The Government sets the budget for drug expenditure and then negotiates a "firm-specific limit" on each manufacturer's sales. If this budget is exceeded, the firm must reduce its prices. This is incorporated into France's scheme.

(iii) Reference Pricing

German, the Netherlands, Denmark, New Zealand and British Columbia.[210] Although this commentator does not specifically identify Australia, Australia's Pharmaceutical Benefits Scheme is based on reference pricing principles.

(iv) Rate of Return

The UK operates a Pharmaceutical Price Registration Scheme (PPRS) which regulates profits instead of prices. Companies are free to set their own prices for new products, provided their rate of return on capital from subsidised products does not exceed a limit set by the National Health Service. While this system addresses concerns about R&D investments not being adequately accounted for with other systems (such as reference pricing), it has the unfortunate effect of stimulating creative accounting practices. As a result, regulations have become increasingly complex.

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standards of living among countries, and drug expenditure per inhabitant is distorted by exchange rate fluctuations. See discussion in *Drugs and Money*, above n 207, 7-9.

[210] Other Canadian states operate different schemes, however these are quite closely related to reference pricing. For example, Ontario uses a Best Available Price (BAP) system. See *Money and Medicines*, above n 39, 194-197, for full discussion.

(v) Physician Drug Budgets

In Germany, the first 280 million deutsche marks over the drug budget is taken from the physician budget for the next year and the next 280 million deutsche marks are charged to the drug manufacturers. The scheme is intended to discourage doctors from using the writing of prescriptions or repeat prescriptions as a way of increasing patient visits (to bolster their revenue).

(vi) The Japanese System

In Japan, most doctors also dispense drugs. Therefore, as they receive the Government reimbursement paid on the drug, any difference between the reimbursement and the manufacturer's price is theirs. Manufacturers seek to reduce their prices below the reimbursement level so that doctors have more incentive to subscribe the company's product. The Government surveys and reviews drug reimbursement levels every two years.

(vii) Patient Copayments

Cost sharing mechanisms are common in many European countries. They have historically been of little significance, mainly due to numerous exemptions available. Italy and Germany have recently increased copayment levels in an effort to make them a more effective deterrent to over-prescribing. Theoretically the copayments should be proportional to the drug's cost, and have an upper limit which is adjusted according to the income of the patient.

What are the competition implications of these alternatives schemes? Arguably wherever there is some Government intervention into the natural mechanisms of the marketplace there is an impact on competition, even if the intervention is not directly on prices.

Methods of price control, price regulation and revenue limits,[211] remove the ability of companies to set their own prices, affecting price competition in drug markets.

[211] Revenue limits are a price control mechanism as they force firms to lower their prices once a predetermined threshold is reached.

Therefore the use of direct price controls in New Zealand would be likely to have implications for competition law.

Alternative methods which seek to avoid excessive use of pharmaceuticals, such as Germany's physician drug budget, the Japanese scheme, and patient copayment schemes, arguably have less impact on competition in pharmaceutical markets. Drug companies are free to set their prices and undertake promotional activities, although they are motivated to keep prices down in order to encourage doctors to prescribe their products. The German and Japanese schemes both revolve around the unique character of their respective public health systems. In Germany, the disincentive for doctors to over-prescribe is based on a potential reduction of the physician budget. As doctor's visits are not subsidised in New Zealand, the Government is unable to apply pressure on doctors in this manner.[212] The Japanese system is fundamentally different from New Zealand because in Japan doctors, rather than pharmacists, dispense drugs. This scheme cannot be easily translated into the New Zealand situation. In any case, it is likely that both these schemes would also have implications for competition law in a similar fashion to PHARMAC's risk-reducing contracts discussed in Part III above.

Patient copayment schemes give drug companies the freedom to determine their prices and promotional activities, and rely on consumer demand for low cost drugs to control government pharmaceutical expenditure. However, these schemes arguably do not go far enough towards controlling the government drug budget. The proportional reimbursement mechanism means that expensive drugs are proportionately dearer to the consumer. Depending on the price differentials between alternative products, there may not be sufficient incentive for consumers, and doctors, to select the cheaper drug. In addition proportionality means that the subsidy levels on more expensive drugs are higher also, which increases the cost to the government. It is no doubt for these reasons

[212] In New Zealand, people on low incomes or who must visit a doctor frequently may qualify for a Government subsidy on GP visits. However, no subsidies are generally available.

that patient copayment schemes are usually operated in conjunction with other methods of budgetary control.[213]

The United Kingdom's rate of return scheme allows drug manufacturers to have a great deal of control over their operations. By determining the rate of return that is acceptable for drug companies, the scheme targets companies that are overpricing their products by focusing on excessive profits reaped in the industry. The R&D investments made by the drug companies are also recognised. This scheme enables the Government to foster price competition in drug markets. However, as noted above, administering the scheme is highly complex. Further, a small and relatively insignificant consumer such as New Zealand would be likely to encounter difficulties operating a rate of return scheme with the co-operation of powerful multi-national drug companies.

Finally, there is reference pricing. In principle, reference pricing may encourage competition between drugs priced above the reference price because drug companies have an incentive to compete on price.[214] There is also a disincentive for drug companies to saturate the market with 'me toos' as these are unlikely to be granted subsidies. However, as the discussion in Part V of this paper demonstrates, PHARMAC's operation of reference pricing in New Zealand would be the basis of claims under the Commerce Act were it not for the exemption contained in section 2 of the Finance Act.

2 *Reference pricing and competition*

It is accepted that the Government's fiscal objective to contain public expenditure on pharmaceuticals has precedence over its desire to promote competition in New Zealand markets. The above discussion indicates that alternatives to reference pricing feasible for New Zealand would also have implications for competition law. Reference pricing has been selected as the mechanism for controlling Government expenditure on

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[213] Many European countries, including the United Kingdom, operate patient copayment schemes in addition to other methods of pharmaceutical budget control. See "Pharmaceutical Price Regulation" above n 208, 27-28.

[214] "Pharmaceutical Price Regulation", above n 208, 19.

pharmaceuticals. The issue is therefore to what extent the fiscal priority should have precedence over competition concerns. It is necessary, with the provisions of the Commerce Act aside, to analyse what is the true effect of PHARMAC's reference pricing scheme on the competitiveness of drug companies.

PHARMAC's position, unsurprisingly, is that reference pricing actually enhances competition in the markets for drugs. It states:[215]

> Reference pricing...reduces the excessive market segmentation based on brand marketing that allowed suppliers to establish markets that were free from price competition. Reference pricing brings price competition back into the pharmaceutical market.

The position that reference pricing type schemes are not damaging to competition is supported by the Pharmaceutical Industry Commission of Australia. The Commission found that the pharmaceutical markets in Australia are competitive, despite the operation of the Australia's Pharmaceutical Benefits Scheme.[216]

The drug industry perspective is that reference pricing type systems suppress prices.[217] The Researched Medicines Industry of New Zealand (RMI) considers that reference pricing enables PHARMAC to coerce drug companies into agreements they would otherwise not consider.[218] In addition, PHARMAC effectively controls entry to the New Zealand market.[219] This raises the concern that the availability of some drugs may be reduced if manufacturers choose not to market their drugs in a price-suppressed

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[215] *The First 20 Months*, above n 9, 10.

[216] The Pharmaceutical Industry Commission Australia noted that in competitive markets, revenue and costs are closely related. If sales revenue is reduced by, for example, the operation of the Pharmaceutical Benefits Scheme, production costs may not be covered and the companies' operations will become unsustainable leading to a loss of efficient activity in the market. In contrast, in markets where companies have significant market power, revenue will be sufficiently higher than costs and the effect of lowering revenue (within limits) will be to reduce profits, not production. Therefore there will be little effect on efficient activity in the market. Efficient activity evident in the Australian market led the Pharmaceutical Industry Commission to conclude that the market was competitive. PICA, above n 182, 322.

[217] PICA, above n 182, 192. In a Bureau of Industry Economics (Australia) survey of company perceptions undertaken in 1991 and again in 1995, 80 per cent of drug companies indicated that they thought their drug prices would be higher in a deregulated environment.

[218] Terence Aschoff, Manager, of the Researched Medicines Industry Association (RMI). Telephone conversation, 16 September 1998.

[219] Terence Aschoff, Manager, of the Researched Medicines Industry Association (RMI). Telephone conversation, 16 September 1998.

market.[220] The argument is that if a country's price regulations are too restrictive, drug companies will simply exit the market, leaving the population without a supply of pharmaceuticals it may need.

The counter-argument is that the selection of drugs available is so broad that considerable limitations can be imposed on this range without any real threat to the patients' therapeutic interests.[221] To what extent is this proposition is supportable is dubious. In a market the size of New Zealand, one drug company's decision to withdraw supply is a possibility that could have a potentially disastrous impact on achieving health objectives through pharmaceutical therapy.

In light of New Zealand's position as a very small player in a very large market, it is doubtful that PHARMAC is able to wield excessive power over the drug companies. There are certainly examples of drug companies withdrawing products from the New Zealand market, although whether the loss of particular products has an unduly adverse effect on the population's health requirements is uncertain.[222] Whether the therapeutic benefit of a particular drug should be differentiated from other similar drugs will always be a contentious medical issue relevant to the adequacy of the range of drugs available, as well as to reference pricing.

When the New Zealand market is examined in scale to the international drug industry it may be concluded that PHARMAC's activities are self-regulating. If a decision in relation to the Pharmaceutical Schedule is crippling to a drug manufacturer, that manufacturer may simply elect to cease supply to the New Zealand market. While

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[220] PICA, above n 182, 217.

[221] *Drugs and Money*, above n 207, 35.

[222] The patent on Zovirax, an anti-viral drug used to treat genital herpes, has expired and as a result its price has been reduced by 50 per cent. The reference price for this therapeutic subgroup will decrease accordingly on 1 October 1998. Valtrex is another anti-viral drug in the same subgroup as Zovirax and the lower subsidy level will result in consumers having to pay a manufacturer's surcharge of between $30 and $60 per prescription. Valtrex (and Zovirax) manufacturer, Glaxo Wellcome, said this would effectively stop people from using the drug and has withdrawn Valtrex from the New Zealand market. "Pharmac blamed over drug move" *Dominion*, Wellington, New Zealand, 14 September 1998. The material difference between the two drugs is that Valtrex need only be taken twice a day whereas Zovirax must be taken five times daily at regular intervals. PHARMAC considers this small advantage is outweighed by the $7.5 million in savings PHARMAC will achieve through the reduced subsidy level on these drugs. Kyle Jones, Senior Analyst, PHARMAC. Telephone conversation, 21 September 1998.

PHARMAC's decision criteria do not include impact on the pharmaceutical industry as a consideration, the availability and suitability of pharmaceuticals to meet New Zealander's health needs *is* a specific decision criterion. Therefore if the result of a PHARMAC decision was likely to be that New Zealanders would lose access to an important drug therapy, PHARMAC would have to take this matter into account.

VII CONCLUSION

Providing publicly funded pharmaceutical therapies is a task for Government that involves three competing objectives: maximising health benefits for New Zealanders; controlling public expenditure; and promoting competition in markets in New Zealand. PHARMAC is able to assert broad powers over drug companies and their ability to compete in New Zealand markets. In the absence of an exemption from the Commerce Act pursuant to section 2 of the Finance Act, PHARMAC would face claims of restrictive trade practices under the Act.

It is accepted that, against the public policy background of pharmaceutical markets, the Government's priority is cost effective provision of pharmaceuticals to meet the population's health needs. In this context, some negative impact on competition in pharmaceutical markets is acceptable.

Ultimately, PHARMAC's anti-competitive behaviour is self-regulating because it cannot allow suppliers of essential pharmaceutical therapies to exit the New Zealand market. In the event that drug companies were ceasing to supply such pharmaceuticals, this proposition would have to be reassessed. However even with regard to anti-competitive conduct which, but for PHARMAC's exemption, would be captured by the Commerce Act, competition in New Zealand drug markets is not being damaged to the extent that manufacturers are withdrawing supply and the Government's health objectives are being compromised.

PHARMAC's exemption from the Commerce Act must be preserved to enable the Government's fiscal and health policy objectives to be pursued.

APPENDIX ONE

SECTION 99 SOCIAL SECURITY ACT 1964[223]

99. Fixing of prices for pharmaceutical requirements - (1) The Minister may from time to time, by direction, specify all or any of the following matters:

(a) The medicines, drugs, appliances, and things in respect of which the Department will make payments to persons who supply them to -

(i) Persons entitled to claim and claiming pharmaceutical benefits; or

(ii) Any other persons for supply in the course of the rendering of a service by those other persons that is the subject of any other benefit provided for by the Part of this Act to persons so entitled and so claiming:

(b) Any terms and conditions that must be complied with before the Department will make payments in respect of pharmaceutical requirements, or make payments at a particular rate in respect of pharmaceutical requirements, as aforesaid:

(c) The payments to be made as aforesaid for pharmaceutical requirements.

(2) Any direction under subsection (1) of this section may -

(a) Fix the prices to be paid by the Department directly, or by reference to prices outside the control of the Minister, or in any other manner that the Minister sees fit, or by a combination of any 2 or more of such methods of calculation:

...

(c) In the case of pharmaceutical requirements supplied to persons for the purpose of enabling them to supply those requirements to other persons, specify or describe the persons to whom any such payment shall be made:

(d) Be a general direction, relating to pharmaceutical requirements supplied to any person claiming pharmaceutical benefits, or a special direction relating to specified pharmaceutical requirements or a specified class of pharmaceutical requirements supplied to a specified person or to a specified class of person:

(e) Make, in the case of a general direction, different provision for different pharmaceutical requirements or classes of pharmaceutical requirements, or for different classes of person supplying pharmaceutical requirements, or for different classes of person for whom pharmaceutical requirements are supplied.

(3) Nothing in this section shall limit or affect the provisions of sections 117, 118, 123, or 132 of this Act.

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[223] Section 99 appears as reproduced in *Glaxo*, above n 66, 131, as s 99 was repealed by s 24(1) of the Health Reforms Act 1993.

APPENDIX TWO

SECTION 2 FINANCE ACT 1994

2. Application of Part II of Commerce Act 1986 to regional health authorities, Public Health Commission, and certain subsidiaries - (1) In this section, unless the context otherwise requires, -

"Agreement" -

(a) Includes any agreement, arrangement, contract, covenant, deed, or understanding, whether oral or written, whether express or implied, and whether or not enforceable at law; and

(b) Without limiting the generality of paragraph (a) of this definition, includes any contract of service and any agreement, arrangement, contract, covenant, or deed, creating or evidencing a trust:

"Authority" means a regional health authority established by Order in Council in accordance with section 32 of the Health and Disability Services Act 1993:

"The commission" means the Public Health Commission established by section 27 of the Health and Disability Services Act 1993:

"Pharmaceuticals" manes substances or things that are medicines, therapeutic medical devices, or products or things related to pharmaceuticals:

"Reached" includes entered into, granted, and made; and "reaching" has a corresponding meaning:

"Specified body" means a body that is an authority, the commission, or any person wholly owned by a specified body or 2 or more specified bodies:

"Subsidiary" has the meaning given to that term by section 158 of the Companies Act 1995 or, as the case may require, sections 5 and 6 of the Companies Act 1993.

(2) This subsection applies to an agreement (whether reached before or after the commencement of this Act) if, and only if, -

(a) At least 1 party to it was a specified body at the time it was reached; and

(b) It was reached after consultation between the Minister of Health and 1 or more of the parties to it; and

(c) It relates to pharmaceuticals for which full or part payments may be made by 1 or more specified bodies.

(3) It is hereby declared that nothing in Part II of the Commerce Act 1986 applies, or has ever applied, to -

(a) Any agreement to which subsection (2) of this section applies; or

(b) Any act, matter, or thing, done by any person to give effect to such an agreement.

(4) For the purposes of section 2(7) of the Commerce Act 1986 (which relates to interconnected bodies corporate), neither the commission nor any authority or Crown health enterprise (within the meaning of section 2 of the Health and Disability Services Act 1993) shall be regarded as, or as having ever been, a subsidiary of the Crown.

(5) No person other than the Commerce Commission may commence any proceedings against an authority under section 81 or section 82 of the Commerce Act 1986 in respect of any act, matter, or thing, that has been done or will be done before the 1st day of July 1994.

(6) Section 29 of the Health Reforms (Transitional Provisions) Act 1993 is hereby consequentially repealed.

APPENDIX THREE

KEY CLAUSES OF THE AGENCY AGREEMENT BETWEEN THE RHAs AND PHARMAC[224]

2. APPOINTMENT

The RHAs jointly appoint Pharmac and Pharmac agrees to act as their agent with effect from and including 1 July 1993 for the purposes of operating and developing the common national Pharmaceutical schedule in accordance with the terms and conditions of this Agreement.

3. PRIMARY OBJECTIVE

Pharmac acknowledges that the primary objective of the Crown and the RHAs in relation to the operation and development of the common, national Pharmaceutical Schedule is to obtain access by the Eligible People to safe and cost-effective quality medicines, therapeutic medical devices and related products or things so as to meet, within the amount of funding provided to the RHAs, the reasonable health needs of the Eligible People in accordance with the requirements of the Act and agrees that, at all times, it will operate and develop the common, national Pharmaceutical Schedule in such a manner as to meet that primary objective in accordance with the terms of the Funding Agreements and this Agreement.

7. OBLIGATIONS OF PHARMAC

Pharmac undertakes and agrees with the RHAs that, as their agent, it will:

(a) at all times operate and develop the common, national Pharmaceutical Schedule in accordance with the provisions of the Funding Agreements entered into by the RHAs and in that regard will perform and carry out such activities and functions as it considers necessary for the operation and development of that Schedule including such consultation with such parties or persons as it deems appropriate;

(b) comply with any directions issued by the RHAs in relation to the operation and development of the Pharmaceutical Schedule;

(c) consider and, where reasonably necessary or desirable, incorporate in the Pharmaceutical Schedule restrictions on the prescription, or dispensing, of Pharmaceuticals;

(d) publish and will use its reasonable endeavours to ensure that all parties involved in the prescribing and dispensing of Pharmaceuticals have reasonable access to copies of the Pharmaceutical Schedule and any changes to that Schedule;

(e) not without the consent of all the RHAs undertake any business, operation or activity other than the operation and development of the Pharmaceutical Schedule in accordance with the terms of the Agreement;

(f) not describe itself as the agent or representative of the RHAs except as expressly authorised in this Agreement; and

(g) not pledge the credit of the RHAs, or any RHA, in any way whatsoever and will not commit itself to any expenditure beyond the budget approved by the RHAs.

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[224] These clauses are as reproduced in the *RMI v PHARMAC* case, above n 6, 8 (HC).

APPENDIX FOUR

WHY THE DRUGS BILL KEEPS GROWING

There are two principle causes for steady growth in pharmaceutical expenditure. Firstly, the range and cost of new drugs introduced to the market has increased steadily over the decades.[225] For example, the new style anti-depressants, like Prozac, cost around eight to 10 times more than the old style anti-depressants.[226]

Secondly, most industrialised countries, such as New Zealand, have aging populations that require higher volumes and generally more expensive pharmaceuticals. There is a strong relationship between age and drug consumption. Older people are more likely to need medication for chronic and degenerative illnesses associated with age, such as heart and circulatory diseases.[227] These drugs tend to be expensive, especially in comparison to the types of drugs most commonly used by younger people (for example painkillers and cold preparations, which are often generics or over-the-counter drugs).[228] The frequency with which drugs are taken also tends to increase with age.[229]

The increasing cost of pharmaceuticals for older people is of concern for Government spending as New Zealand has an aging population. In the 1996 census, 11.7 per cent of the population were aged 65 and over. This proportion is forecasted to increase to 13.3 per cent by 2011, 21.4 per cent by 2031, and 24.9 per cent by 2051.[230]

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[225] *The World's Pharmaceutical Industries*, above n 165, 43.
[226] Kyle Jones, Senior Analyst, PHARMAC. Telephone conversation, 10 September 1998.
[227] *The World's Pharmaceutical Industries*, above n 165, 41.
[228] *The World's Pharmaceutical Industries*, above n 165, 43.
[229] For example, a German study revealed that 55% of people over 45 take drugs more than once per week, compared to only 15% of people aged between 14 and 44. *The World's Pharmaceutical Industries*, above n 165, 43.
[230] Statistics New Zealand *Aging and Retirement in New Zealand* (August 1997) 40.

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