

GETTING THE DEAL THROUGH

# Pharmaceutical Antitrust

The application of competition regulation in 29 jurisdictions worldwide **2008**

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## Pharmaceutical regulatory law

- 1** Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products?

The Medicines Act 1991 (the Medicines Act) provides the framework for the regulation of medicines, including the authorisation to manufacture, import, prescribe, sell and supply medicines and medical devices in New Zealand. Generally, a medicine or a medical device may only be imported, sold and supplied in New Zealand if it is authorised under the Medicines Act. The Medicines Act does specify a minor number of exemptions to this, including where the medicine is being used in a clinical trial (in which case there are alternative authorisation requirements both for the medicine and the clinical trial before it can proceed), and where a medical practitioner has prescribed it for a named patient in particular circumstances. Any new medicines including hazardous substances or new organisms (which include most genetically modified organisms or new organisms not previously present in New Zealand) also require approval under the Hazardous Substances and New Organisms Act 1996 (the HSNO Act).

If a supplier is also manufacturing a medicine in New Zealand, it must apply for authorisation to do so in accordance with the Medicines Act, which includes obtaining certification of its Good Manufacturing Practice.

The Medicines Act also provides regulatory direction and specific obligations and restrictions on the advertising of medicines and medical devices. Further restrictions on the use, sale and control of medicines and medical devices, as well as labelling and advertising details can be found within the Medicines Regulations 1984 (the Medicines Regulations) with additional guidance set out in the Guidelines for Advertising Over-the-Counter Medicines Direct to Consumers (2005).

In December 2006, the Therapeutic Products and Medicines Bill 2006 was introduced. It proposes a joint Australia–New Zealand regulatory scheme for therapeutic products and, if passed, would replace the Medicines Act and the Medicines Regulations. Its scope is wider than that of the Medicines Act and Medicines Regulations in that it also introduces a regulatory framework for complementary (natural) medicines and dietary supplements alongside that for medicines and medical devices. The inclusion of complementary medicines in the Bill was met with significant debate and submissions at select committee stage. Progress on the Bill was deferred by the government in August 2007.

In New Zealand the pricing of pharmaceuticals has a unique regulatory framework.

A number of medicines in New Zealand are publicly funded. The New Zealand Public Health and Disability Act 2000 (the NZPHD Act) obliges the Pharmaceutical Management Agency

(PHARMAC), a Crown entity, to maintain and manage a pharmaceutical schedule, which specifies the medicines and medical devices that are publicly subsidised in the community, and those which are available in hospitals at a nationally consistent price payable by district health boards.

The subsidy (for community pharmaceuticals) and the price (for hospital pharmaceuticals) are not determined through any regulatory framework, but through contractual negotiations between PHARMAC and the relevant pharmaceutical supplier.

Provided a medicine or a medical device has the necessary authorisation (or is exempt from requiring such authorisation under the Medicines Act) it may be sold in New Zealand without being listed in the pharmaceutical schedule, although it will not be publicly funded and the relevant patient will be required to fund the full cost of the medicine.

Restrictions and obligations relating to competition and pricing practices, which apply to the sale and supply of medicines and medical devices, are found in the Commerce Act 1986 (the Commerce Act). PHARMAC, as the single ‘purchaser’ of pharmaceuticals on behalf of District Health Boards, has an exemption from the ‘restrictive trade practices’ provisions of the Commerce Act (see question 10).

The Dumping and Countervailing Duties Act 1988 may also impact on the price of a medicine or medical device. Any pharmaceutical supplier who imports or distributes pharmaceuticals in New Zealand is subject to this Act, which enables the Crown to impose duties on any person dumping goods in New Zealand or importing goods subsidised by an international entity.

Further restrictions on the marketing of medicines and medical devices (beyond those found in the Medicines Act and Medicines Regulations) can be found in the Fair Trading Act 1986, which prohibits misleading and deceptive conduct, false representations and unfair practices in trade.

- 2** Which body or bodies are entrusted with enforcing these regulatory rules?

The minister of health is ultimately responsible for enforcing the rules set out in the Medicines Act and the Medicines Regulations, although in practice MedSafe, a business unit of the Ministry of Health, is primarily responsible for such enforcement, including the provision of relevant authorisations, and monitoring compliance with relevant marketing obligations. If the Therapeutic Products and Medicines Bill 2006 was passed and enacted, such responsibilities would fall to a new Australia New Zealand Therapeutic Products Authority.

Where approval is also required under the HSNO Act, the minister for the environment will govern the approval process.

As discussed above, PHARMAC, in accordance with the

NZPHD Act, determines which medicines and medical devices are publicly funded in New Zealand, and in that respect determines the applicable price or subsidy following contractual negotiation with the pharmaceutical supplier.

The Commerce Commission (the Commission) enforces the Commerce Act and the Fair Trading Act. The minister of commerce through the Ministry of Economic Development enforces the Dumping and Countervailing Duties Act 1988.

- 3** Which aspects of this legislation are most directly relevant to the application of competition law to the pharmaceutical sector?

The Commerce Act is the relevant competition law legislation that governs the pharmaceutical sector. Of the 'non-competition' legislation and regulations discussed in question 1, those relating to PHARMAC and product authorisation are the most relevant, as they dictate the extent to which incumbent pharmaceutical firms are constrained by PHARMAC's negotiating power and by the threat of new entry – both of which are important factors when assessing the impact of a merger or contractual arrangement on competition in a market.

- 4** Which laws govern the entry or approval of generic drugs?

The Medicines Act and the Medicines Regulations provide for the authorisation of medicines and medical devices in New Zealand, including generic medicines, but do not explicitly distinguish between generic medicines and medicines that are the original formulation of that chemical entity. Hence from a statutory perspective, generic medicines and the applicable original formulation are governed by the same rules.

However, the New Zealand Regulatory Guidelines for Medicines, volumes 1 to 4 provide greater guidance on the authorisation process, including the information required in an application for authorisation. The information requirements for generic medicines are explicitly addressed in the Guidelines, and rely heavily on bioequivalence data with the original formulation that has previously been approved in New Zealand. If MedSafe approves the generic as being bioequivalent and interchangeable with the original formulation already approved in New Zealand (the New Zealand reference product), then both the New Zealand reference product and the generic are added to the New Zealand Interchangeable Multi-source Medicine List.

However, this does not mean that such a generic is automatically publicly funded (even if the New Zealand reference product is publicly funded and the generic is listed as being interchangeable with the New Zealand reference product). It is simply approved as being interchangeable from a bioequivalence and supply perspective. In order to be publicly funded, PHARMAC must list the generic medicine or medical device on the pharmaceutical schedule.

Although MedSafe may consider and require information to be provided in relation to particular patents (particularly any patents still held by the innovator), it generally states that it is the supplier's obligation to ensure that its product and application to supply that product in relation to particular indications does not breach any patents. The relevant regulatory rules for patents are covered by the Patents Act 1953.

#### Competition legislation

- 5** Which legislation sets out competition law?

New Zealand's competition laws are set out in the Commerce

Act, which prohibits restrictive trade practices (including price fixing, anti-competitive arrangements, resale price maintenance and misuses of market power); and governs mergers and acquisitions that substantially lessen competition in a New Zealand market.

- 6** Are there guidelines on the application of competition law that are directly relevant to the pharmaceutical sector?

Yes, there are guidelines entitled 'The Commerce Act and the Health Sector – a General Guide', but their relevance is limited given their age and the fact that they were drafted prior to the 2001 Commerce Act amendments to the threshold test for a misuse of market power and that relating to mergers and acquisitions.

- 7** Which authorities investigate and decide upon pharmaceutical mergers and the anti-competitive effect of certain conduct in the pharmaceutical sector?

The Commerce Commission, a national body, administers the Commerce Act and has jurisdiction over mergers and conduct in the pharmaceutical sector.

The Commission typically consists of five full commissioners, a specialist telecommunications commissioner, two cease-and-desist commissioners and two associate commissioners.

The Commission also employs economists, lawyers, industry experts and a team of investigating staff to support the commissioners. The staff collect information, receive submissions and undertake investigations in order to provide the commissioners with the information and recommendations necessary to make decisions.

- 8** What remedies can competition authorities impose for anti-competitive conduct or agreements by pharmaceutical companies?

The Commission must apply to the High Court to award an injunction restraining a person from engaging in allegedly anti-competitive conduct, or to impose pecuniary penalties. However, in appropriate cases, the Commission itself may issue a cease-and-desist order, which is a temporary administrative injunction that prevents the continuation of allegedly anti-competitive behaviour. Cease-and-desist orders can only be issued where it is necessary to act urgently in the interests of the public and to prevent serious loss or damage in respect of such behaviour.

If a breach of the Commerce Act is established in substantive Court proceedings, the Court may make an order for damages or impose a pecuniary penalty in respect of the breach. Pecuniary penalties can be up to:

- NZ\$500,000 for individuals; and
- for bodies corporate, the greater of:
  - NZ\$10,000,000; or
  - three times the value of the commercial gain resulting from the breach, or (if the commercial gain cannot be readily ascertained) 10 per cent of the New Zealand group turnover.

Further, the Court can also make an order varying or cancelling an agreement.

In April 1999, the High Court ordered two animal health firms to pay total penalties of NZ\$700,000 after both parties admitted price fixing in the supply of animal remedies for dairy cattle.

- 9** Do private parties have competition-related remedies if they suffer harm from anti-competitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and through which means can they be obtained?

While actions for pecuniary penalties can only be brought by the Commission, any other person can apply to the Court for the Court to award an injunction restraining allegedly anti-competitive conduct and damages. There is no notion of ‘treble damages’ in New Zealand.

- 10** Is the regulatory body for the pharmaceutical sector responsible for sector-specific regulation distinct from the general competition rules?

There is no sector-specific competition legislation applicable to the pharmaceutical sector.

However (as mentioned above), PHARMAC has an exemption from the restrictive trade practices provisions of the Commerce Act for certain conduct.

- 11** Can antitrust concerns be addressed with industrial-policy type arguments, such as strengthening the local or regional research and development activities?

The Commission has limited statutory authority to accept undertakings. In the merger context, it can only accept structural undertakings to dispose of assets or shares; it cannot accept behavioural undertakings. A firm’s behaviour (and indeed that of the wider industry) therefore tends only to be relevant where the Commission takes the view that it forms part of the market dynamic. (For completeness, if ‘authorisation’ is sought on public benefit grounds for a restrictive trade practice that would otherwise give rise to a breach, the Commission can impose a condition, which in practical terms is akin to a behavioural undertaking.)

- 12** Do non-government groups address antitrust concerns relating to the pharmaceutical sector?

No, although the countervailing negotiating power of PHARMAC is often a relevant consideration for the Commission in terms of whether a merger or acquisition substantially lessens competition in breach of the Commerce Act.

### Review of mergers

- 13** To what extent are the sector-specific features of the pharmaceutical industry taken into account when reviewing mergers between two pharmaceutical companies?

While there are no pharmaceutical-specific provisions in the Commerce Act, the Commission naturally takes into account the features of the industry when assessing an arrangement or a merger’s impact on competition, for instance. This is particularly so in terms of market definition.

In its *Johnson & Johnson/Pfizer Consumer Healthcare* decision, the Commission expressly observed that prescription and OTC products are not properly within the same ‘market’.

Another industry feature that has shaped the Commission’s view on market definition is its adoption of the Anatomical Therapeutic Chemical (ATC) classification system. As the Commission observed in relation to the *Glaxo Wellcome/SmithKline Beecham* merger proposal, the third level of the ATC system (ATC-3), which allows medicines to be grouped in terms of their therapeutic indications, is a useful starting point for market definition. However, the Commission’s approach (which is consistent with the approach of the EC Commission) is that ATC-3 will not

always be determinative in terms of market definition.

In *Johnson & Johnson/Pfizer Consumer Healthcare*, the Commission also commented on PHARMAC’s ability to exert countervailing power over the merged entity, given its role as a major ‘buyer’ of pharmaceutical products through its funding of subsidised products.

To some extent, although perhaps to a greater degree with respect to the animal health industry, the Commission has also recognised the constraint imposed by generic products, in particular because they face lower barriers to entry (although issues relating to brand loyalty may limit the constraint in particular circumstances).

- 14** How are product markets and geographic markets typically defined in the pharmaceutical sector?

As discussed, the Commission uses ATC-3 as a starting point for product market definition.

Geographically, the Commission has typically adopted national market definitions, citing nationwide supply and pricing uniformity. However, in a 2000 decision involving pharmaceutical distributors (rather than upstream suppliers), the Commission applied regional markets, on the basis that the relevant products required ‘same-day’ customer delivery, which was not considered possible on a national basis.

- 15** In what circumstances will a product and geographical overlap between two merging parties be considered problematic?

The Commerce Act prohibits the acquisition of shares or assets of a business if that acquisition would have the effect, or likely effect, of substantially lessening competition in any New Zealand market.

The Commission has published Mergers and Acquisitions Guidelines, which set out so-called ‘safe harbours’ for mergers and acquisitions. (The correct market definition is critical to applying these safe harbours.) The Commission typically uses these safe harbour guidelines as a screening device to determine which acquisitions it should investigate in more detail. In general, the Commission considers that an acquisition is unlikely to substantially lessen competition in a market where, after the proposed acquisition, either of the following situations exists:

- where the three-firm concentration ratio (with an individual firm’s market share including any interconnected or associated persons) in the relevant market is below 70 per cent, the combined entity (including any interconnected or associated persons) has less than in the order of a 40 per cent share; or
- where the three-firm concentration ratio (with an individual firm’s market share including any interconnected or associated persons) in the relevant market is above 70 per cent, the market share of the combined entity is less than in the order of 20 per cent.

However, while safe harbours are an appropriate starting point, further detailed analysis and investigation of competition conditions must occur before any conclusion can be drawn about a particular acquisition. Acquisitions resulting in market shares well outside the safe harbours frequently occur in New Zealand.

In addition to market shares and the level of market concentration, relevant factors in considering the competitive impact of a merger and an appropriate Commission strategy include:

- the existence and level of any barriers to entry and expansion;

- whether one of the merging parties is a ‘maverick’ (ie, a firm that affects market dynamics disproportionately to its market share);
- the ability of buyers and suppliers to exert countervailing power over a merged entity (eg, PHARMAC); and
- whether a merger might be said to facilitate coordination between the remaining participants in the market, post-merger.

In terms of barriers to entry and potential competition, the Commission’s Mergers and Acquisitions Guidelines note that an acquisition is unlikely to substantially lessen competition if the businesses in the relevant market continue to be subject to real constraints from the threat of market entry. However, for potential competition to be considered a sufficient threat on the incumbents, the Commission’s guideline is that entry must be feasible within a period of about two years from the point at which any market power is first exercised.

**16** When is an overlap with respect to pipeline products likely to be problematic?

A merger’s potential to adversely impact competition at a future date is relevant. Whether the potential overlap would in fact be problematic would depend on the likelihood and timing of a pipeline product coming to market, and the impact the ‘loss’ of such a constraint (due to the acquisition) would have on the level of competition in the market.

**17** Which remedies will typically be required to resolve any issues that have been identified?

The Commerce Act provides that in giving a clearance or authorisation, the Commission may accept an undertaking to ‘dispose’ of such assets or shares as specified in the undertaking. (It cannot accept behavioural undertakings.) The divestment must be sufficient to remove the substantial lessening of competition that would otherwise occur. It may be that a divestment of one product in one given country will be sufficient to alleviate any competition concerns in respect of competition in a New Zealand market, and if so, that will be acceptable.

In 2007, Schering-Plough Corporation applied for clearance to acquire Organon BioSciences NV (as part of a wider global transaction). Prior to the acquisition, the parties were the only suppliers of a particular type of vaccine. To alleviate any concerns the Commission might have had in that market, Schering-Plough undertook to divest one of the vaccines, and clearance for the acquisition was granted on that basis.

A licensing arrangement may form part of a divestment undertaking (as may a transitional toll-manufacturing arrangement). However, as a general rule, a licensing arrangement alone is unlikely to be accepted as a ‘disposal’ of assets or shares, as contemplated by the legislation.

**18** Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

The Commerce Act defines ‘assets’ to include intangible assets, which would mean that the acquisition of a patent or a licence would be subject to the Commerce Act considerations (as set out in question 15). New Zealand adopts a voluntary notification regime.

### Anti-competitive agreements

**19** What is the general framework for assessing whether an agreement or practice can be considered anti-competitive?

There is an overriding prohibition in the Commerce Act against any provision of a contract, arrangement or understanding that has the purpose, effect or likely effect, of substantially lessening competition in any market.

As a general rule, New Zealand has fewer per se offences than many other jurisdictions. However, the Commerce Act does prohibit absolutely:

- price fixing, which is deemed to substantially lessen competition in a market;
- exclusionary provisions (although there is a defence if it is proved that the provision does not have the purpose, or does not have or is not likely to have the effect, of substantially lessening competition in a market);
- resale price maintenance; and
- a firm with a substantial degree of power in a market taking advantage of that power for a proscribed (anti-competitive) purpose.

As with mergers, the Commission can grant authorisation for certain practices that might otherwise breach the Commerce Act (although not for a misuse of market power) if it is satisfied that the economic benefits to New Zealand as a whole flowing from the practice would outweigh any anti-competitive detriment.

**20** Have there been cartel investigations into the pharmaceutical sector?

In 2004, the Commission issued a warning to the Pharmacy Guild of New Zealand that its Premiums Guide, a monthly publication detailing ‘premiums’ for pharmacists to charge patients on partially subsidised medicine, placed the Guild at risk of contravening the price-fixing provisions of the Commerce Act. Changes were made by the Premiums Guide at the start of the Commission’s investigation and no further action was taken.

In 2001, the Commission warned the New Zealand subsidiaries of three multinational vitamin companies in respect of alleged market sharing and price fixing agreements. The Commission’s investigation and warning followed a prosecution by the US Department of Justice in 1999, and investigations by regulatory authorities in other jurisdictions.

The Commission told the New Zealand companies they would have faced charges of price fixing, if it were not for the three-year limitation period in the Commerce Act (which has since been amended). The Commission also said that it was prevented from taking court action in New Zealand in respect of meetings it said occurred overseas during the limitation period for jurisdictional reasons. Despite there being no charges laid, the Commission advised the companies that it would continue to monitor the vitamin industry.

**21** To what extent are technology licensing agreements considered to be anti-competitive?

Licensing arrangements are subject to the restrictive trade practices provisions of the Commerce Act. While again there are limited specific prohibitions in the law, the overriding prohibition in the Commerce Act against provisions of contracts, arrangements and understandings that substantially lessening competition in a market is likely to be the most relevant provision.

There is an exemption in the Commerce Act in relation

to intellectual property rights, which provides that the Act's restrictive trade practices provisions do not apply to contracts, arrangements or understandings to the extent that they contain a provision authorising any act that would otherwise be prohibited by reason of the existence of a statutory intellectual property right. While the scope of the exemption is limited (eg, it does not cover resale price maintenance or a taking advantage of market power), commentators suggest that it is intended to cover situations such as the assignment of rights owned under copyright. Whether the exemption would extend to a particular technology licensing agreement would depend on the facts of that case.

Further, the intellectual property exemption is not an 'over-arching' exemption for all intellectual property matters: it is limited to statutory intellectual property rights under the Patents Act 1953, the Designs Act 1953, the Trade Marks Act 1953, the Copyright Act 1962, the Plant Variety Rights Act 1987 and the Layout Designs Act 1994.

**22** To what extent are co-promotion and co-marketing agreements considered to be anti-competitive?

Whether such agreements breach the Commerce Act will depend on the facts of each case. To the extent that an agreement is between competitors and relates to price, discounts, rebates, etc, there is likely to be a price-fixing issue, unless the parties can bring themselves within one of the few, relatively narrow, exemptions.

One of the price-fixing exemptions relates to joint ventures, although it is generally considered that the exemption will not apply in respect of mere marketing joint ventures. There is also a price-fixing exemption in relation to the advertising of goods collectively acquired, although that exemption is also narrowly drafted. All agreements, including those pursuant to a joint venture or in relation to collective acquisitions, are subject to the general substantial lessening of competition prohibition.

**23** When is an agreement with a competitor (actual or potential) likely to be an issue? Can these issues be resolved by appropriate confidentiality provisions?

An agreement or understanding with an actual or potential competitor, or indeed any person, that gives rise to a substantial lessening of competition in a market will be an issue. An agreement or understanding with a competitor that interferes with the competitive determination of price, discounts, etc, will be an issue, regardless of whether that agreement or understanding in fact affects competition in any way (as price fixing is a per se offence).

In certain circumstances, it may be that confidentiality provisions provide sufficient protection against a possible breach, but those circumstances are often likely to be the exception, rather than the rule. For example, an agreement to provide historical sales data to an industry body for consolidation and distribution to contributing firms will often not give rise to a breach of the Commerce Act where each firm's individual data is maintained as confidential by the organisation consolidating the data.

**24** Which aspects of vertical agreements are most likely to raise antitrust concerns?

The general prohibition on provisions of contracts, arrangements or understandings that substantially lessen competition is most likely to be the relevant Commerce Act provision. The Commission would be concerned in respect of a vertical agreement that had the potential to foreclose a firm's access to a market at one level of the supply chain.

For example, a long-term exclusive supply contract between a supplier and a retailer might give rise to an issue if competing retailers had no other realistic sources of supply.

Obviously, a vertical arrangement amounting to resale price maintenance would be prohibited outright.

#### Anti-competitive unilateral conduct

**25** In what circumstances is conduct considered to be anti-competitive if carried out by a firm with monopoly or market power?

The Commerce Act prohibits a firm with a substantial degree of market power from taking advantage of that market power for a proscribed anti-competitive purpose. For there to be a breach of the Commerce Act, all three elements of the prohibition must be present, ie:

- it must be established that the firm has a substantial degree of power in a market;
- the firm must be taking advantage of that market power. This requires a causal connection between the firm's market power and the relevant conduct; and
- the conduct must be for one of the three proscribed anti-competitive purposes. In general terms, the proscribed purposes refer to restricting a person's entry to, preventing or deterring competitive conduct in, or eliminating a person from, any market.

The requirement that a 'taking advantage' of market power is necessary for a breach to occur means that, as a general rule, where the firm with market power acts in the same manner as a firm without market power would act in the same circumstances, a breach is unlikely. Misuse of market power cases frequently turn on this point.

In addition to the misuse of market power prohibition, firms with monopoly or market power are also subject to the various other prohibitions in the Commerce Act.

**26** When is a party likely to be considered dominant or jointly dominant?

Until 2001, the Commerce Act referred to a person having a 'dominant position in a market'. In 2001, the test was amended to refer to a person with 'a substantial degree of power in a market'. The substantial market power test is considered to be a lower threshold test than dominance.

Substantial market power is concerned with power which enables a firm to behave independently of competitive forces in a market. While there are no market share guidelines in New Zealand to indicate when a firm has substantial market power, factors to be taken into account include:

- the ability of a firm to raise price above the supply cost without rivals taking away customers in due course;
- the extent to which conduct within the relevant market is constrained by the conduct of competitors or potential competitors;
- the market share of each party (although this alone is not determinative of market power); and
- the presence of vertical integration (although its presence does not necessarily mean that a substantial degree of market power exists).

**27** Can a patent holder be dominant simply on account of the patent that it holds?

As discussed in question 21, there is an exemption in the Commerce Act in respect of intellectual property rights. However,

**Update and trends**

Although progress of the Therapeutic Products and Medicines Bill 2006 (see question 1) and associated negotiations were deferred by the government in August 2007, the agreement between the governments of Australia and New Zealand for the establishment of a joint scheme for the regulation of therapeutic products remains in place. The New Zealand government has not abandoned the prospects of establishing a joint Australia–New Zealand Therapeutic Products Agency, which would replace Australia’s Therapeutic Goods

Administration (TGA) and New Zealand’s MedSafe and report directly to both governments.

The proposed benefits of the Bill (if it progressed through parliament) include the creation of harmonised regulatory requirements for therapeutic products, which arguably would facilitate trade and reduce compliance costs. Supporters of the Bill argue that it would ensure consumers have early access to new products entering the market, while maintaining confidence in public health and safety.

this does not extend to the prohibition against misuse of market power. Thus, a person could be dominant in a market in New Zealand (ie, have ‘a substantial degree of power in a market’, which is the relevant statutory threshold) simply on account of ownership of a certain patent, although this would obviously be a question of fact. However, again, a breach also requires the presence of both a taking advantage and a prohibited purpose.

**28** To what extent can the application for the acquisition of a patent expose the patent owner to liability for an antitrust violation?

The Commerce Act extends the application of the intellectual property exemption to a person who has applied for a patent but has not yet been granted that patent.

However, in each case (and regardless of whether a person actually holds or has applied for a patent), it will be a question of fact as to whether any particular conduct will give rise to Commerce Act implications. If the Commerce Act is relevant, it will be a further factual question whether the person’s conduct falls within the intellectual property exemption in the Act.

**29** To what extent can the enforcement of a patent expose the patent owner to liability for an antitrust violation?

Enforcing a patent will not necessarily expose its owner to liability – whether such conduct amounted to a breach of the Commerce Act would be a factual question. In the event of a prima facie breach, it would be relevant to consider whether the conduct could be brought within the limited exemption in the Commerce Act.

**30** To what extent can the settlement of a patent dispute expose the parties concerned to liability for an antitrust violation?

Settling a patent dispute would not necessarily preclude any liability that parties might have under the Commerce Act. It will depend on the facts of each case.

**31** To what extent can certain life-cycle management strategies expose the patent owner to liability for an antitrust violation?

Again, exposure to liability would depend on the factual situation surrounding a particular strategy. For example, a life-cycle management strategy could expose a firm to liability under the Commerce Act where the firm attempted to maximise its brand investment by insisting a retailer stock only that particular brand, if such conduct substantially lessened competition in a market or amounted to a misuse of market power.

**32** Does the practice of authorised generics raise issues under the competition law?

Whether any conduct gave rise to a Commerce Act issue would depend in each case on the particular facts.

**33** To what extent can the specific features of the pharmaceutical sector provide an objective justification for conduct that would otherwise be infringing antitrust rules?

While there are no specific competition laws that apply to the pharmaceutical sector, a potentially relevant factor is the PHARMAC exemption, discussed in respect of earlier questions.

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