Submissions to Ministry of Foreign Affairs and Trade

Proposed free trade negotiations with UK – Issues for Douglas Pharmaceuticals Ltd

Executive summary

- Judging by recent experience, intellectual property law will be a live issue in any new free trade negotiation. Some specific issues in the pharmaceuticals space include the possible introduction of patent term extension (sometimes referred to as 'restoration"), patent 'linkage' (where the grant of marketing authorities for generics may be delayed by patents without going through the courts), and restrictions on the exemption of regulatory activities from infringement liability.
- Commercial development of generic pharmaceuticals in New Zealand for export is only internationally competitive because of the current settings of NZ IP law. Key settings include: a non-extendable 20-year patent term; no patent linkage; and exemptions from patent infringement for preparatory regulatory activities, including those required by overseas regulatory agencies for goods destined for export.
- Changes to those settings could render the pharmaceutical export industry in New Zealand much less viable, and potentially damage the commercial viability of export projects currently underway.
- The New Zealand based pharmaceutical generics industry would prefer to see IP settings around pharmaceuticals untouched.

- However, if change becomes inevitable, the worst effects of these changes may be avoided or mitigated by:
    - Retaining the regulatory exemption which allows regulatory activities for generic development, including importation of samples, before patent expiry, for export as well as domestic products.
    - Ensuring that any provision for patent term extension is clear and transparent, and the exception rather than the rule, and does not result in New Zealand based manufacturers being disadvantaged with respect to companies based elsewhere.
    - Only permitting patent term extension for patent applications which are lodged after the date of any new law, and not making it retrospectively available for existing patents.
    - Including an 'export exception' (as was proposed in the CA/EU CETA negotiation) permitting manufacture in New Zealand of stock for export, during the term or any extended term of a New Zealand patent.

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1. Introduction – The Douglas Companies

1.1. This submission is from Douglas Pharmaceuticals Limited ("DPL") of Central Park Drive, Henderson, Auckland, New Zealand and its associated companies (together "the Douglas Companies").

1.2. DPL is both a New Zealand owned and based company. The company was founded in 1967 and today is the largest New Zealand owned pharmaceutical company.

1.3. A key aspect of the Douglas Companies' activities in recent years has been its export business. The Companies embarked some years ago on a very aggressive strategy of exports. Projected sales for the year ended 31st March 2019 are NZ$245 million, around 65% of which is attributable to exports. Actual sales to the UK in the 12 months to 31 Dec 2018 exceeded NZ$4 million.

1.4. The Douglas Companies' manufacturing activities include the manufacture of generic medicines for the New Zealand and export markets and the manufacture of consumer ethicals (over-the-counter products).

1.5. The Douglas Companies have made considerable investment in New Zealand in product development laboratories and in specially designed containment suites for the manufacture of anticancer, immunosuppressant, steroid and retinoid medicines. DPL's research and development facilities and systems are US FDA inspected and approved. The Douglas Companies' manufacturing plants in New Zealand and Fiji are licensed by the Ministry of Health and the Australian Therapeutic Goods Administration, and the New Zealand plant is FDA audited.

1.6. The Douglas Companies employ about 750 people globally (including facilities in the USA and Fiji) – the majority in Auckland. A very substantial proportion of the staff are highly skilled science graduates with over 60% having tertiary qualifications from New Zealand and overseas universities.

1.7. The pharmaceutical industry is a heavy user of the patenting system. Production of generic pharmaceuticals is strongly dependent on a suitable balance being struck in patent law between protection as a reward for innovation, and freedom to compete.

2. Existing pharma patent law gives New Zealand a competitive advantage

2.1. The Douglas export business in patent-constrained generic pharmaceuticals relies on certain aspects of current NZ patent law: (i) New Zealand has a maximum 20-year patent term, with no extensions; (ii) regulatory activities, both for domestic and export markets, can be carried out before patent expiry (the "regulatory exemption" - see s145 Patents Act 2013 (NZ)); and (iii) there is no "patent linkage" system (which can cause lengthy delays in approval and launch of generic products).

2.2. Overseas suppliers and customers realise the significance of the patent situation in NZ and this is a key competitive advantage for Douglas.

2.3. Maintenance of a New Zealand based generic pharmaceutical manufacturing industry is critically reliant on retention of these settings.

3. Regulatory exemption to infringement

3.1. Under s145 Patents Act 2013 (NZ), Douglas (and other companies operating in New Zealand) are permitted to conduct the necessary regulatory activities, in New Zealand, for pharmaceutical products to be sold in overseas markets such as Europe and the US, before the New Zealand patent expires, without liability for patent infringement. This includes being able to import samples for regulatory purposes (though not for commercial manufacture). These activities could otherwise amount to patent infringement.

3.2. This is in line with what is permitted in many other countries, including Europe.

3.3. These processes can be very lengthy, involving product trials and generation of data to show product equivalence, as well as answering questions posed by the regulatory authorities.

3.4. Once the New Zealand patent on a product expires, (after the full TRIPS-compliant 20-year term but without any additional extensions), Douglas can immediately begin commercial manufacture in New Zealand with regulatory approvals already in place. This enables competitive export to other countries with a 20-year term (e.g. Canada, South Africa, China, Hong Kong, Indonesia, Malaysia and the Middle East), and preparation of stock for a timely entry into major export markets such as Europe and the US (which have extendable patent terms for pharmaceuticals).

3.5. In order to be competitive as a generic entrant in these later markets, it is generally essential to be ready for immediate launch on patent expiry. This is only possible from a New Zealand manufacturing base, if there is a reasonable interval between NZ patent expiry and patent expiry in the target market, and if all regulatory work can be completed before patent expiry. New Zealand's distance from markets (and the consequent delay in movement of goods) makes this particularly critical.

3.6. The Douglas Companies strongly support the retention of the current regulatory exemption regime (s145 Patents Act 2013 (NZ)) including its applicability to overseas regulatory requirements.

4. Patent term extension

4.1. Patent term extension for pharmaceuticals increases costs to the New Zealand medical consumer and taxpayer (via Pharmac). While the patent is in force no generic competitor can enter the market. Generic entry inevitably results in significant price reductions, sometimes as much as 90%. **Therefore, any extension of patent term is costly to New Zealand.**

4.2. Introduction of any system of patent term extension for pharmaceutical patents in New Zealand has the potential to substantially disadvantage New Zealand based exporters – who are generators of jobs and revenue in this country. New Zealand based manufacturers cannot begin commercial production of a product, even if only for export, until the **New Zealand** patent expires. If this expiry occurs at the same date or later than expiry in an export market, then the product may not find customers.

4.3. Although it might be argued by other countries who already have such systems that an extension regime would merely be "levelling the playing field", the reality is that New Zealand manufacturers must already deal with disadvantages, in particular a very small local market and geographical distance from export markets.

4.4. DPL strongly opposes the introduction of any form of patent term extension for pharmaceutical patents in New Zealand.

5. Example – dutasteride soft gel

5.1. Dutasteride is a drug used to treat symptoms of prostate enlargement.

5.2. The constraining patent date for dutasteride was that of the compound patent for the dutasteride molecule. This patent was applied for internationally in 1994. Normal worldwide expiry (20-year patent term based on TRIPs) was therefore scheduled for 2014.

5.3. Under the regulatory exemption, preparatory formulation and regulatory work was able to be done in New Zealand before the New Zealand patent expired.

5.4. When the New Zealand patent for dutasteride did expire in Sep 2014 (no extension) commercial manufacture could begin immediately. Manufacture in New Zealand from that date enabled stock to be available for launch into overseas markets as the patents expired there.

5.5. Europe and Australia (also the US and some other countries) have forms of patent term extension. In Europe and Australia, these are based on the date at which a marketing authorisation for the product was granted in that territory.

5.6. The earliest marketing authorisation for dutasteride in Europe was granted in Sweden in Feb 2002, 7.5 years after the date of the patent. Supplementary Protection Certificates were granted in most European countries, extending the patent monopoly by 7.5-5=2.5 years, resulting in expiry in July 2017. Product manufactured in New Zealand could be exported and sold in Europe after that date.

5.7. In Australia, the first marketing authorization was granted in Nov 2002 – the Australian patent was consequently extended by 3 years, to Nov 2017. Australian generic manufacturers were only able to export dutasteride to Europe after Nov 2017 – 4 months after the patent monopoly had expired in the market and other generic products manufactured in non-extension countries had already been launched.

5.8. However, the New Zealand marketing authorization was granted much later, in Sep 2004. This is not especially unusual. Given New Zealand's small size and controlled market, new medicines often appear here later than in larger markets.

5.9. If New Zealand had had a system of patent term extension along the same lines as in Australia, the delay in the NZ MA would have meant that the New Zealand dutasteride patent would have been eligible for a full 5 years of extension, to 2019, making it the last patent for this product to expire, worldwide.

5.10. Likewise, had there been no regulatory exemption, the registration process could only have started at New Zealand patent expiry. Again, this would have resulted in a New Zealand manufactured product only being available years after products from generic competitors based elsewhere, making it commercially unviable.

5.11. Any New Zealand based generic manufacturer, such as DPL, would have been unable to supply dutasteride on time for overseas markets.

6. Recommendations should introduction of some form of patent term extension system prove to be an inevitable outcome of the overall FTA negotiation

6.1. The Douglas Companies recognise that an FTA negotiation is a complex process. If some form of patent term extension becomes an inevitable outcome, we propose the following potential mitigations.

6.2. Proposed Mitigation 1: retain the regulatory exemption for export

6.2.1. If the regulatory exemption was removed suddenly in relation to existing patents, projects which are well underway would have to be halted mid stream. On the other hand, if the regulatory exemption for exports is retained, then New Zealand manufacturers would at least be able to compete with overseas manufacturers on products not subject to extensions of patent term.

6.2.2. The regulatory exemption for export must be retained.

6.3. Proposed mitigation 2: Method of calculation of any patent term extension

6.3.1. Various forms of extension calculation can be envisaged. Typically, these are calculated as a form of “compensation” for delays beyond some “reasonable” timeframe, either in the grant of the patent or grant of marketing authorisation. While New Zealand authorities are relatively efficient in comparison to some overseas authorities, this may vary in the future. Therefore, a calculation which is dependent on raw delays, although rarely resulting in extensions in the present environment, may have unintended future consequences in the form of more frequent and longer extensions.

6.3.2. One way to avoid this would be to define a lengthy “reasonable” timeframe. Another option would be to initiate any calculation based on the first MA grant in any of a listed set of countries,

rather than locally (this could also have the effect of encouraging innovator companies to register their drugs in New Zealand at an early date, to the benefit of New Zealand patients). Finally, a short cap could be imposed on extensions. A further option could be to legislate that any extension could not extend later than the comparable extension in a specified list of potential markets (or preferably, earlier, to allow for manufacture and transport of exported generics prior to launch).

6.3.3. **Any contemplated extension system needs to calculate extensions in such a way that extensions remain the exception not the rule and/or that New Zealand patent expiry is not later than in major markets.**

6.4. Proposed Mitigation 3: Timing of implementation of law change

6.4.1. Worldwide, there has been considerable variation in the timing of introduction of patent extension schemes.

6.4.2. For example, when Singapore (as a result of its US FTA) introduced patent term extension, **it was only available to patents <u>applied for</u> after the date the new law came into effect.** This means that the first extensions could not take effect for 20 years. No project already in any pipeline based on a known expiry date was affected and there was ample time for businesses to take account of the new law in planning.

6.4.3. Implementation in this way in New Zealand would likewise allow businesses such as the Douglas Companies to re-direct their business models and projects in a practical time frame.

6.4.4. The worst-case alternative would be that any patent which was **current** at the time of the new law immediately became eligible for extension. This would be commercially disastrous, not only for the Douglas Companies but for the whole generic supply stream in New Zealand, including Pharmac tender arrangements.

6.4.5. The Douglas Companies have projects in mid-pipeline now, with considerable investment in them, based on known New Zealand patent expiry. Abrupt extension of a **New Zealand** expiry to, the same or a later date than market expiry, would mean likely commercial failure of these projects, with very significant sunk costs.

6.4.6. Also, the Douglas Companies receive advance requests for contract manufacture to commence at a date determined by NZ patent expiry. Uncertainty about whether patents expiring in that time frame could possibly be extended in the interim, could block such export contracts coming to New Zealand for years.

6.4.7. **Any PTE system must be implemented with as much commercial lead time as possible.**

6.5. Proposed mitigation 4: Export exception

6.5.1. A simple way to mitigate the effect of patent term extension for exporters, is to permit an exception to patent infringement, similar to the existing regulatory review exception, but related to manufacture for export. Such a legislated exception would permit exporters to commercially manufacture stock during the term (or any extended term) of a New Zealand patent, provided that such stock was purely for export and eventual sale in a territory in which the equivalent patent had expired.

7. Patent linkage – what is it and why should New Zealand avoid it?

7.1. Patent linkage refers to a system or process by which a country links the process of granting marketing approval for a generic medicine to the status of patent(s) which are alleged by the innovator company to relate to the original drug product.

7.2. Patent linkage can be deployed very effectively by the holder of a patent to delay the entry of generic medicines to a market, without the patent holder having to demonstrate the level of legal entitlement which would be needed for a court to grant an injunction. In effect, patent linkage requires drug regulatory authorities (such as Medsafe) to take on the role of policing patents, effectively issuing an injunction against a generic application but without many of the checks and balances which would take place if the matter came before the court.

7.3. In some countries such as the US, patent linkage is incorporated into a system of incentives (such as periods of market exclusivity for successful patent challenges) to encourage early entry of generic products (the “Hatch-Waxman” legislation).

7.4. However, an incentive system is unlikely to be possible in the New Zealand market because: (i) the control of the market via the Pharmac tendering system means market exclusivity could not be promised; and (ii) the small size of the domestic market means that the cost of patent challenging litigation is unlikely to be justifiable.

7.5. Also, New Zealand patents (especially those granted under the 1953 Patents Act) often include broader claims than the equivalent overseas patents, as NZ patents were not examined to the same standard as in foreign markets. Therefore, patent linkage could be used to delay generic products being launched in NZ, even though those products would not be restricted elsewhere.

7.6. A system of patent linkage which included automatic delays to grant of generic marketing approvals pending litigation is highly likely to

reduce/delay entry of generic products (which means the prices paid by consumers/taxpayers stay higher for longer), rather than encourage attempts at early entry.

7.7. The Douglas Companies oppose the introduction of patent linkage in New Zealand.

7.8. Possible patent linkage mitigation: A patent linkage system could require the innovator to list patents it considered potentially relevant, but also require that any hold on marketing approval could only be granted via an application to the court for an injunction. The marketing authority would therefore not be put in the position of granting de facto injunctions. The court system would provide proper scrutiny of the arguability of the case for infringement, the potential for alternative remedies such as damages and consideration of the balance of convenience. The court can also require the patent holder to make an undertaking to pay damages in the event of the patent not being upheld – in other words all the usual legal checks and balances accompanying a commercial injunction.

8. Thank you for the opportunity to make submissions on this matter. The Douglas Companies would appreciate being kept informed of further developments. Any questions arising from this submission should be directed to our IP Counsel – see below.

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