Douglas Pharmaceuticals Limited

Submissions on MBIE Consultation document: *Divisional Patent Applications: Possible Changes to the Transitional Provisions in Section 258 of the Patents Act 2013*

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1. **Background**

1.1. Douglas Pharmaceuticals Ltd (DPL) is an Auckland based, privately New Zealand owned pharmaceutical and nutraceutical business, employing 470 staff and exporting to around 35 countries. Approximately 65% of the company's revenue is derived from exports.

1.2. The pharmaceutical industry is highly patent-focused and DPL has long experience in navigating intellectual property rights in order to bring its generic products to market in a legal and timely manner both in New Zealand and overseas.

2. **Question 1:** ***Under section 258 of the 2013 Act, applications divided from patent applications made before the entry into force of the 2013 Act are examined under the 1953 Act. The Ministry considers that this approach may be adversely affecting third parties, including local businesses.***

2.1. DPL agrees with the Ministry that this provision has the potential to cause significant on-going harm to NZ businesses. In particular, DPL would like to draw attention to the on-going difficulties caused to exporters by 1953 Act patents.

2.2. The grant of New Zealand patents under the 1953 Act without examination for obviousness/lack of inventive step has put NZ patents out of step with patents granted in most other countries, including our major trading partners, for many years.

2.3. NZ patents have frequently been granted with broader – sometimes much broader - claims than those granted in other territories but covering the same product.

2.4. This can and does become a significant issue for businesses which wish to manufacture in New Zealand for export. If a New Zealand-based manufacturer wishes to make product in New Zealand (employing New Zealand labour) but sell it overseas, it must take into account any granted patents <u>both</u> in New Zealand and in the intended market country. Patents are potentially infringed by both or either of manufacture and sale.

2.5. If the NZ patent claims relevant to a particular product are significantly broader than the equivalent claims covering the same product elsewhere, then a product may not be able to be <u>manufactured</u> in New Zealand, even though it can legitimately be <u>sold</u> (or indeed, <u>manufactured</u>) in the overseas market. In this situation, New Zealand based manufacturers

are competitively disadvantaged, or potentially even excluded from the export market while the NZ patent remains in force.

2.6. Although it is true that the New Zealand patent may be opposed or revocation sought on grounds of obviousness/lack of inventive step, this involves significant extra costs, delay and uncertainty, which again reduce the competitiveness of the New Zealand manufacturer/exporter.

2.7. DPL has had a number of projects in which this has been a factor – that is, because of the existence of excessively broad NZ patent claims (broader than in the overseas market), DPL has had greater difficulty in achieving a non-infringing product than overseas competitors, has had to engage in protracted negotiations and/or litigation in order to clear or restrict the NZ claims to parity with the overseas equivalents (a cost not borne by our competitors) and/or has had to contemplate utilising an overseas manufacturing facility to supply export markets.

2.8. Therefore it is highly desirable that NZ patents are examined and granted in a manner which is at least reasonably consistent with the scope of patents for the same product granted elsewhere.

2.9. The 2013 Act was intended to bring NZ patents into line with international norms in this respect. However, as outlined by the consultation paper, the continued filing and daisy-chaining of divisional applications which must then be examined according to the 1953 Act, perpetuates the problem of NZ patents which are out of kilter with the rest of the world - potentially for almost 20 years.

Therefore the answer to Question 1 is yes.

3. **Question 2:** ***The Ministry has identified three options (including no change) for dealing with the potential problems identified in relation to section 258 of the 2013 Act. Are there any other options you think should be considered?***

3.1. Other possible options could be:

(i) to limit the <u>number</u> (rather than timing) of divisionals which could be 'daisy-chained' from a single original parent;

(ii) to impose a maximum time limit (for example, from original priority date, or from the date of first examination of the parent application) within which divisionals can be filed from <u>any</u> (not just 1953 Act) applications;

(iii) to impose extremely high fees for filing of divisionals.

3.2 Some of these methods have previously been tried in the UK/EPO. However, we do not consider that they offer particular advantages over and above Option 3.

4. Additional comments arising from consultation paper

4.1. Assessment of the options

4.1.1. **Para 37** of the consultation paper lists 4 factors as being most relevant to deciding on the most suitable option.

4.1.2. DPL proposes a 5th factor. This is the importance of reasonable consistency between the scope of claims granted in New Zealand in respect of a particular product, when compared to patent claims for the same product granted in our major trading partners.

4.2. Option 3

4.2.1. **Para 48** states that applicants with 1953 Act divisionals would, under this option, obtain patent protection which may be narrower than they might have obtained under the status quo. While this is technically correct, we point out that any such divisional application would not obtain narrower validly enforceable protection – only that the claims would be appropriately assessed and if necessary narrowed at the examination stage rather than requiring the intervention (and expense) of third parties via an opposition or revocation proceeding.

4.2.2. **Para 51:** Options 2 or 3, but not 1, satisfy the proposed additional 5th factor of reasonable consistency in claim scope when compared with equivalent patents granted by major international trading partners.

5. Question 3: *Do you agree that Option 3 is the best option?*

5.1. Yes, for the reasons already discussed and set out in the consultation paper.

6. Question 4: *What should the specified date be?*

6.1. Given the harm and uncertainty arising from the current provisions, and the ability of patent holders to continue to take advantage of the situation via daisy-chaining, DPL urges that the amendment be made as soon as possible and with a relatively narrow time frame for coming into effect. The suggested 3 months appears more than adequate, particularly since divisionals will still be permitted, and all that is being restricted is the grant of excessively broad, and ultimately invalid/unenforceable claims. The grant of such claims is in any case highly undesirable and should be discouraged, not further facilitated.

Thank you for the opportunity to contribute to this consultation.

Douglas Pharmaceuticals Ltd

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