9 August 2019

Business Law Team
Ministry of Business, Innovation & Employment (MBIE)
Wellington

Re: Discussion Paper for Intellectual Property Laws Amendment Bill

Dear MBIE Business Law Team

We are providing a written submission on issues that may be included in the Intellectual Property Laws Amendment Bill (the IP Amendment Bill). We are responding to the Discussion Paper entitled *Intellectual Property Laws Amendment Bill- Patents Act 2013, Trade Marks Act 2002 & Designs Act 1953* produced by the Ministry of Business, Innovation and Employment (MBIE). We also provide comment on the review and specific issues that we believe have not been adequately covered off in the Discussion Paper.

Medicines New Zealand is the industry association representing companies engaged in the research development, manufacture and marketing of prescription medicines and vaccines, including patent-protected pharmaceuticals. As a result, we will limit our comments on issues as they relate to pharmaceutical products in the proposal regarding the Patents Act 2013. We will not make comment on the proposed amendments or actions on the Trade Marks Act 2002 or the Designs Act 1953.

Purposes and scope of the Discussion Paper:

Before responding directly to the questions raised in the Discussions Paper, and given the technical amendments being proposed by MBIE are to ensure that the Patents Act 2013 "…remain workable…", Medicines New Zealand notes it is extremely disappointed at the limited technical amendments being proposed to the Patents Act 2013 relating to patents on pharmaceutical products.

Medicines New Zealand's largest concern in this area is a lack of consideration for the introduction of amendments into the Patents Act 2013 relating to pharmaceutical patent term extension. Specifically, those resulting from either patent office (IPONZ) processing

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delays or regulatory market approval delays due to the pharmaceutical regulator (Medsafe). delays. In our view, in order for the Patent Act 2013 to both "…remain workable…" and better align with patent law best practice in other jurisdictions, pharmaceutical patent term extension provisions should be introduced in any Patents Act amendment processes being undertaken in New Zealand.

<u>Request for additional amendment to be added to the Patent Act 2013:</u>

As noted above, Medicines New Zealand is concerned that the matter of pharmaceutical patent term extension has not been included in the proposed amendments to the Patents Act 2013. This is an area where the current Act is silent, and where other territories such as Australia, Japan and other developed nations have well-constructed clauses enshrined in their legislation.

1. *The need for pharmaceutical patent extension and suitable definition of 'unreasonable curtailment'*

   Medicines New Zealand believe that New Zealand needs to make available patent term adjustment to compensate a pharmaceuticals patent owner for 'unreasonable curtailment' of the effective patent term as a result of the marketing approval process through the Regulator. From a practical perspective certain delays, even though they are not directly attributable to the regulator (currently Medsafe), are in fact necessary to obtain the marketing approval from Medsafe and are thus indeed the result of the marketing approval process.

   We recommend that New Zealand include a section on pharmaceutical patent term extension clauses in the Patent Act 2013. We further note that the approaches used in Japan and the United States provide, and below useful examples that are fully aligned with international best practice and could be adopted into New Zealand legislation.

   The pharmaceutical patent term extension in Japan takes into consideration the date of commencement of relevant clinical trials. In the United States the patent term extension period is based on the regulatory review period, which is in turn composed of a "testing phase" and a "review phase." For a drug approval in the United States the "testing phase" begins on the effective date of an Investigational New Drug ("IND") Application and ends on the date a New Drug Application (NDA) is submitted to the Food and Drug Administration (FDA). The "review phase" for a drug product is the period between the submission and the approval of the NDA. The patent term extension calculation in the United States is based on the sum of one-half of the time in the "testing phase" plus all of the time in the "review phase" minus any time during which the applicant did not act with due diligence.

The above approaches by Japan and the United States appropriately compensate pharmaceutical patent owners and encourage the rigorous clinical research and development necessary to ensure that the pharmaceutical product is effective and safe.

Assuming MBIE agree with need to have pharmaceutical patent term extension included in the legislation review, we strongly recommend that a suitable definition of "unreasonable curtailment" is also generated. As such, the definition needs to cover delays incurred through diligent efforts to complete the necessary clinical trials to secure marketing approval from Medsafe.

2. *Length of extensions for patent term arising from delays in the regulatory approvals process*

While Medicines New Zealand understand that it is the New Zealand Government's previously stated view that "…the complexity of biologics [and into the future, precision medicines and gene therapies] means that applications for marketing approval require more expert advice and consultation and will therefore take longer to process than those for small-molecule pharmaceuticals…", such delays do not in any way diminish the intent of an obligation to compensate the patent owners for the effective patent term lost due to the marketing approval process for any type of pharmaceutical. Loss of effective term would be at least as significant for patents directed to small molecule pharmaceuticals as it is for biologics and other modern therapies. Therefore, we submit that any definition of "unreasonable curtailment" for pharmaceutical products should not distinguish between small molecule and biologic or other complex pharmaceuticals as relates to the terms of time period and is best set at a quantum that aligned to more complex molecules review processes.

Medicines New Zealand submits that any method utilised for calculating the length of extensions for pharmaceutical patents should also include delays not directly attributable to the regulator (Medsafe) and include delays that are outside the direction or control of Medsafe.

Such an approach would take into account the expensive, high-risk, and time-consuming research and development necessary to obtain regulatory approval of new medicines. For example, before the regulatory review period can commence, new pharmaceutical candidates must undergo a lengthy, rigorous clinical "testing phase" to ensure the safety and efficacy of the drug. A suitable method must take in the need to provide robust incentives for companies to undertake research and development of new medicines.

Again, the approaches in Japan and the United States are informative and should be considered for adoption in New Zealand. The calculation of the length of pharmaceutical patent term extension in Japan also takes into consideration the date of commencement of relevant clinical trials. Further, as described, in the United States, the patent term extension period is based on the regulatory review period, which is in turn composed of a "testing phase" (clinical study phase) and a "review phase" (FDA review phase). The patent term extension calculation in the United States is the sum of one-half of the time in the "testing phase" plus all the time in the "review phase" minus any time during which the applicant did not act with due diligence. This means that in the US, the patent term extension cannot exceed 5 years.

We believe the above approaches by Japan and the United States more appropriately compensate the patent rights owners for time lost due to the lengthy clinical development and regulatory review processes and encourage development of new medicines.

3. *Patent term extension arising from delays in patent office processes*
   Medicines New Zealand also notes that if there is any unreasonable processing delay by IPONZ (New Zealand's patent office), it is only fair to fully compensate the rights holder for the loss of that time by granting an extension of the patent term. Our view is that the term should be *follow that* used in other jurisdictions where a formula is used to determine the patent term adjustment. This should also be included in any pharmaceutical patent term extension provisions introduced into the Patents Act 2013.

   Medicines New Zealand therefore believes that the best solution in this case is to have the ability for the awarding of a patent term extension due to delays in patent application and granting processes.

In summary on the topic of pharmaceutical patent term extension provisions, our view is that the Patent Act 2013 currently lacks alignment with developed country norms and good practice. While we have raised this issue before, to avoid this becoming a "lost opportunity" for New Zealand, we would hope that MBIE do consider Medicines New Zealand's proposed actions around pharmaceutical patent term extension and include them as part of the suite of amendments to the Patents Act 2013.

In the following sections, Medicines New Zealand has provided comments and views on some of the proposed actions/preferred options being proposed by MBIE around matters relating to amendment to the Patents Act 2013. Overall, there are a number of areas of concerns

which we highlight, and we hope that MBIE consider those when moving through the legislative review.

Question P1: Transition Provisions on Divisional Patent Applications

The discussion paper suggests that there is a problem in relation to the transitional provisions of the Patents Act 2013 relating to divisional patent applications. However, it is not clear from the information provided in the discussion paper that there is indeed a problem. In paragraph 46 the paper mentions that as of mid-February 2019 there were approximately 774 pending 1953 Act divisional applications, the majority of which were second generation divisionals. This seems to be a small number of divisional applications, and without information in relation to the total number of pending applications it is difficult to assess whether this number is problematic.

When the original parent applications were filed under the 1953 Act, there was an expectation that it would be possible to file divisional applications as required to pursue protection for different inventions disclosed in these applications, and accordingly it could be argued that the status quo should be maintained. There will also be a significant problem if divisionals filed from the 1953 Act parent applications are made subject to all aspects of the 2013 Act. Firstly, the pre-dating which applied to such New Zealand divisionals will give them an effective filing date prior to the commencement of the Patents ASct 2013, and will be inconsistent with making such divisional subject to a Patents Act that did not exist as of their effective filing date.

However, should MBIE continue with its proposal to have all divisionals examined under the novelty, inventive step and support requirements under the 2013 Act, it will be very important that the priority test applied to the newly filed (and antedated) divisionals is the fair basis test that was applicable under the 1953 Act. Since different priority tests could result in different priority dates, there will be a danger that a new form of poisonous priority will arise in New Zealand if the priority test is not consistently applied across all members of a family related through parent/divisional relationships.

In order to avoid this complication, we prefer to retain the status quo in relation to the transitional provisions for divisional applications.

In addition, if the proposal proceeds it will be important to provide a period of notice, that is of at least 6 months, before the change in the examination requirements, should applicants wish to take the opportunity to file a further divisional under the 1953 Act.

Question P2: "Daisy-chaining" of divisional patent applications.

Medicines New Zealand does not agree with MBIE's assessment of so-called "daisy chaining" of divisional patent applications. Medicines New Zealand notes that the practice of filing divisional applications of divisional applications is allowed in many countries and regions, including Europe, United States, Australia and Japan. Accordingly, we do not believe that it is acceptable to prevent applicants from filing divisional applications of divisional applications in New Zealand.

We do not agree with either options (ii) or (iii) as described in the Discussion paper (paragraph 49, page 15) as being suitable solutions. In our view, there should be no limitations on filing divisional applications of other divisional applications, neither should there be a time limit placed on gaining acceptance of divisional applications.

On the latter point of having no time limits, we understand from our membership that there are already substantial delays in issuance of Directions to Request Examination (DREs) on pending applications occurring in New Zealand - for up to several years. In this regard, it is common to reach the deadline for requesting examination *without* issuance of a direction to request examination.

It would seem that New Zealand is currently unable to examine applications promptly and is not using DREs effectively to bring examination deadlines forward. If DREs are issued close to the 5 year deadline, our members have noted that, as applicants, they will be placed in position of having to make decisions regarding the filing of a first divisional application at the same time as they are requesting examination of the original parent application. At that point in time, not having any examination report, the applicant will be uncertain if any objection will be raised by IPONZ, or how many divisionals will be needed. In our view this is an unacceptable position for the applicant to be placed in.

We also note that the delay in the processing of applications within IPONZ is not solely attributable to the applicant but can often be the result of delays within IPONZ. For these reasons we are not supportive of the existing structure that effectively places a 5 year deadline on filing all divisional applications. We further note that this could in part be responsible for the issues identified by MBIE around so-called "daisy-chaining" itself.

Question P3: Options for dealing with "Daisy-chained" divisional patent applications.

As highlighted in answer to P2 above, our members have reported substantial delays before issuance of an examination report, after examination requests.

Medicines New Zealand is not supportive of MBIE's position and preferred option of requiring the outcome of all divisional patent applications to be determined by a specified date to be

desirable, particularly if that specified date is the 12 month acceptance date for the parent application. The rationale for our position is that we believe that limited time period will be insufficient to enable applicants to file divisional applications, request examination, receive examination reports, then respond to any objections and finally to gain acceptance of the applications. Our justification for this is based on situations, where the first report issues after the 5 year deadline, and experiences now of our members, where the current systems within MBIE are unable to accommodate the filing of divisional applications, in a suitable timeframe. Therefore, to have defined or specified date (option iii under section 93 of the Discussion Paper) seems both unrealistic and ill-suited to resolving the issue.

Medicines New Zealand believes that if MBIE were to adopt its preferred option, then the consequence of this would be that applicants would file a higher number of divisional applications as a cautionary strategy. Reducing the time to gain acceptance, would lead to more hearings being requested in order to provide an opportunity to get the divisional in a form for acceptance. In other words, the outcome of MBIE's action will likely be longer pendency times and a significant rise in the number of divisional filings.

Medicines New Zealand also believes that the best way to progress with divisional applications in New Zealand is to require all applicants to request examination at the time of filing, and for MBIE (IPONZ) to prioritise examination of divisionals.

We also believe the deadline for requesting examination of divisionals, being 5 years from filing of the parent application, should be removed.

However, if this 5 year deadline was to be kept, then new divisionals must at least be allowed in circumstances where a unity objection is raised in a report issued after the five year examination request deadline. Medicines New Zealand notes that an MBIE/IPONZ action that leads to a failure to provide an opportunity to file a divisional in these circumstances could potentially bring New Zealand into breach of Article 4G(1) of the Paris Convention.

Specifically: "*If the examination reveals that an application for a patent contains more than one invention, the applicant may divide the application into a certain number of divisional applications and preserve as the date of each the date of the initial application and the benefit of the right of priority, if any.*"

Question P5: Proposed Amendments to provisions relating to requests for examination and the proposed transitional provision.

Medicines New Zealand concurs with the MBIE view that it is appropriate to introduce provisions to ensure that applications for which a request for examination was not filed within the required time, and therefore can never proceed to grant, are deemed to be abandoned.

Question P6: Poisonous priorities

Medicines New Zealand believes that problems described in section 1.3 of the discussion paper arise solely because the Patents Act 2013 does not fully recognise multiple and partial priorities in a single claim. Rather, the Patents Act 2013 provides that a claim can only have a single priority date, even where subject matter included within the scope of the claim should be entitled to different priority dates in accordance with Article 4F of the Paris Convention.

Question P7: Solution for poisonous divisionals

Medicines New Zealand believes that the problems described in section 1.3 of the discussion paper could be addressed by amending the Patents Act 2013 to fully recognise multiple and partial priorities within a single claim, for example by allowing a single claim to enjoy more than one priority date.

In summary, we disagree with MBIE's preferred solution to dealing with poisonous priority solely by addressing affected divisional applications, and strongly recommend that MBIE consider our proposed solution, as the best and most viable option instead.

Question P8: Multiple priority dates for claims

Medicines New Zealand does not agree with MBIE's assessment that the 2013 Patents Act does not require amendment to recognise multiple priority dates in single claims.

Our reasons for holding this position were stated in previous sections. Medicines New Zealand holds a view that it is critical to change the Patents Act 2013 to fully recognise multiple and partial priorities within a single claim, and that the most practical manner to achieve this is via the introduction of a provision that allows a patent claim to have more than one priority date. Medicines New Zealand understands that this approach would be in alignment with the legislative approach taken in both the EU and Australia. It seems therefore, logical that adopting this solution should be possible in New Zealand as regards allowing multiple priority dates for claims.

Question P9 & P10: Extensions of time when hearing is requested

Medicines New Zealand agrees that the Patents Act 2013 and/or the 2014 Regulations should be amended to provide extensions of time for gaining acceptance when hearings are requested, and that such extensions should expire no earlier than 6 months period after the hearing decision is issued.

Our view is that this would provide greater certainty to applicants than the current system whereby an applicant must rely on a retrospective extension of time under Section 230 for delays caused by the Commissioner.

Question P11: Usefulness requirement

Medicines New Zealand's believes that the existing provisions around usefulness requirements are clear as written in the Patents Act 2013.

Question P12: EPC2000-type Claims

Medicines New Zealand strongly disagrees with MBIE's view on EPC2000-type claims and believes that the Patents Act 2013 should be amended to allow them.

We point out that since a number of EPC countries do indeed allow such claims to be made, that New Zealand in keeping up with good international patent law standards, will benefit from providing a more stimulatory environment for research activities into drug repurposing studies.

Furthermore, we note that MBIE has used flawed analysis to justify its proposed position and action of not allowing EPC200-type claims to be allowed under the Patents Act 2013 Act.

While MBIE correctly states, in paragraph 234 of the discussion paper, that EPC2000-type claims were adopted in EPC countries to stimulate research into new medical uses for known drugs (i.e. 'drug repurposing'), the statement that "…this does not apply in New Zealand" is incorrect. This latter statement infers that both little or no drug repurposing activity is undertaken or funded here in New Zealand, and that as such, there is no likelihood of a need to stimulate it further by allowing EPC2000-type claims to be considered for patent filing by organisations here.

Our understanding is that MBIE itself has and continues to be funding drug repurposing studies, furthermore information provided by the Health Research Council (HRC), shows that the HRC has also invested almost $100 million ($99.4 million) in 61 studies relating to drug repurposing since 2012. Over the past 3 years alone, over $43. million has been invested by HRC into "drug re-purposing" studies. This level of government investment is clearly significant and would surely benefit from the potential for the New Zealand researchers to be able to patent their research outcomes from repurposing studies in New Zealand with more robust claims.

By allowing EPC2000-type claims to be part of patent applications, New Zealand may find that this action further catalyses researchers activity both now and into the future. Indeed, by allowing this claim type, MBIE may well also assist in strengthening justifications for existing and future government-funded activity in biomedical and pharmaceutical translational research. At the very least, by having MBIE, via amendment of the Patents Act 2013, providing a more conducive patenting environment would warrant and support the significant multimillion-dollar public investment to date in repurposing studies.

Furthermore, in paragraph 235, MBIE asserts that because New Zealand is a small market for pharmaceuticals that allowing EPC2000 type claims in New Zealand "…will have no impact on companies' decisions to invest in R&D in New Zealand… ". This is incorrect, we understand that private sector research funds in the past have been invested into such studies and the area of pharmaceutical research. We note that $21 million total basic research investment activity has been invested in New Zealand over a four year period by Medicines New Zealand members alone and over $171 million into clinical trials some involving drug repurposing. Logically, should New Zealand and MBIE adopt EPC2000-type claims then there is every possibility that New Zealand may obtain even more private sector investment into pharmaceutical related R&D activities into the future.

We would also point out a number of studies have indicated that the strength of the IP environment in a country have significant impacts on a private sector's willingness to undertake pharmaceuticals research. In one OECD study it was found that for every 1% change in the strength of a national IP environment there was a 2.8% increase in inflows of foreign direct investment (FDI)[1]. Therefore, it would hold that by enhancing claims on pharmaceutical patents to allow EPC2000-type claims that further FDI may well be generated in New Zealand. We also note that allowing such claims would see us better align with European patent law, which may also aid FDI into the future.

Medicines New Zealand notes that MBIE states in paragraph 236 that allowing EPC2000-type claims could make patented pharmaceuticals more expensive. However, nowhere in the Discussion document or elsewhere, does MBIE provide any robust evidence to justify such a bold claim. If MBIE is unable to provide robust evidential statements on this pricing matter then in our view, this point cannot be used this as a justification for not allowing EPC2000-type claims.

In summary Medicines New Zealand believes the case is much stronger for amending the Patents Act 2013 to allow EPC 2000-type claims to be made, than to not allow them.

Questions P13 and P14: Patent Rights Exhaustion

We do not have any comments on these questions on patent exhaustion.

Questions P15 & P16: Attorney-General's right to intervene in patent proceedings

We do not have any comments on these questions raised on this matter.

[1] Cavazos, R. et al, (2010), Policy Complements to the Strengthening of IPRS in Developing Countries, OECD Trade Policy Working Papers, No. 104, OECD Publishing.

Question P17: Availability of documents relating to 1953 Act applications
Medicines New Zealand concur with MBIE. The transitional provisions of the Patents Act 2013 should be amended to make it clear that the provisions of Section 91 within the Patents Act 1953 continue to apply to all 1953 Act cases. It is our view that applicants who filed patent applications under the Patents Act 1953, with the belief that the prosecution history would be confidential, should continue to be able to rely on that confidentiality into the future.

Question P18: Abstracts and Interpretation of Scope of the Invention
Medicines New Zealand's position is that the Patents Act 2013 should be amended to deliver an outcome where the Abstract must *not* be used to interpret the scope of the invention described, or claimed, in a complete patent specification.

It is critical that any New Zealand interpretation of the scope of an invention is consistent with corresponding provision applicable to patents in Australia and the similar provision present in PCT Article 3.3.

In conclusion, Medicines New Zealand would be pleased to have further dialogue with MBIE on any aspect of the responses we have made. We are also happy to be contacted should there be a need for clarification on any of our positions as regards the MBIE discussion paper.

We would welcome the opportunity to make both written and oral presentations at the Select Committee stage of the parliamentary process on amendments to the Patents Act 2013.

Yours sincerely,

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