New Zealanders for HEALTH RESEARCH
Ngā Tāngata o Aotearoa mō te Rangahau Hauora

"New Zealand's peak body representing the entire health and medical research pipeline"

Submission on MBIE's discussion paper: Intellectual Property Laws Amendment Bill – Patents Act 2013, Trade Marks Act 2002, Designs Act 1953

Introduction

New Zealanders for Health Research (NZHR) was established in November 2015 to bring about increased investment in health research from government, industry and philanthropy. One of our areas of focus has been to increase industry investment in health and medical research in New Zealand, which typically occurs by way of investment in clinical trials.

NZHR's submission is that

- Clinical trials, including industry funded clinical trials, contribute significantly to New Zealanders' health and prosperity
- Incentives to encourage industry investment in clinical trials are significantly outweighed by systemic disincentives, resulting in industry being increasingly disinclined to lift investment in health and medical research in New Zealand
- Policy settings which impact on industry investment in health and medical research should wherever possible be adjusted to add to the suite of investment incentives
- The 2013 Patents Act be amended to allow EPC2000-type claims on the grounds that this would make it make it easier for pharmaceutical companies to invest in researching and developing of new medicinal uses of known drugs, both in New Zealand and elsewhere.

Clinical trials in New Zealand

NZHR's Roy Morgan 2019 public opinion poll report[1] found that:

- 11% of respondents reported that they had been asked to participate in a clinical trial
- 7% said that they had participated in a clinical trial
- 81% said that it is important for New Zealanders to be able to participate in clinical trials
- 67% said that participating in clinical trials is as important as giving blood
- 71% said that there should be more opportunities to participate in clinical trials for new medicines, and
- 87% said that they would be willing to participate in a clinical trial of a new medicine if they had a condition it might be able to treat

NZHR believes that there would have been a similar pattern of responses had the questions referred to participating in trials for repurposing of existing medicines.

The following graphs suggest a gap between New Zealander's beliefs about clinical trials and the declining pharmaceutical industry investment in the sector[2].

[1] New Zealand Speaks! 2019 Roy Morgan NZHR opinion poll. NZHR. July 2019.
[2] Clinical Trials in New Zealand: a discussion paper. NZHR. March 2019. https://www.nz4healthresearch.org.nz/wp-content/uploads/2019/02/Clinical-trials-in-New-Zealand-NZHR-op-ed-130319-V2.pdf

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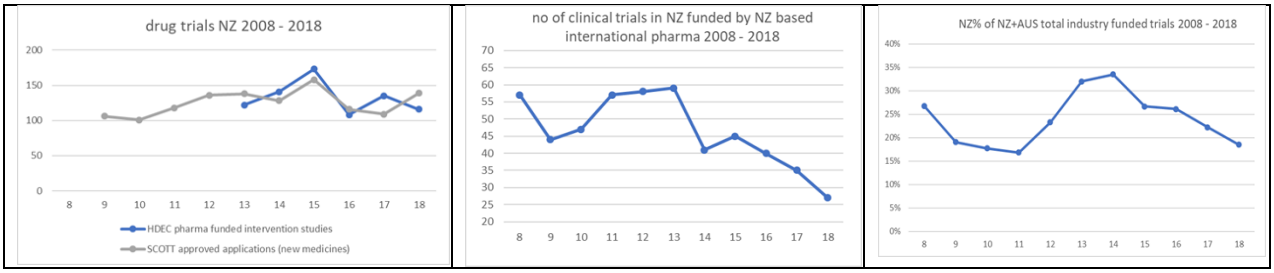

Swiss and EPC2000-type claims

We note the following from the MBIE discussion document[3]:

- The discussion document considers whether the 2013 Patents Act should be amended to allow EPC2000 type claims instead of Swiss-type claims (EPC 2000 refers to the revised version of the European Patent Convention adopted at a Diplomatic Conference in 2000)

- **A Swiss-type claim** is a claim in a patent specification for use of a specified substance for the manufacture of a pharmaceutical for the treatment of a specified medical condition in humans

- **An EPC 2000-type claim** is a claim in a patent specification for use of a specified substance for the treatment of a specified medical condition in humans.

- A Swiss-type claim is generally used when the substance is not new but the use of the substance to treat the specified condition is new and inventive, and is a way of claiming patent rights despite methods of medical treatment of humans not being patentable.

- In many countries, including New Zealand and members of the European Patent Convention (EPC), patents over methods of medical treatment of humans are not permitted. The main reason for this is the view that medical professionals should not be prevented by patents from choosing the best treatment for their patients.

- However, it often happens that new uses are found for existing pharmaceuticals. Because the substance is not new, it cannot be patented again. The method of using it cannot be patented in those countries which do not allow patents over methods of medical treatment of humans.

- However, pharmaceutical companies argue that developing new uses for known pharmaceuticals is costly, and that patent protection is required to provide an incentive to develop such uses. This eventually led to the Swiss courts developing the "Swiss-type" format in a bid to provide patent protection for new uses of known pharmaceuticals without breaching the ban on patents for methods of medical treatment of humans. Swiss-type claims are allowable in New Zealand.

- An EPC 2000-type claim is a claim to the specified substance itself, regardless of the use to which it is put. If the substance is known the claim would not be new, and under New Zealand law no patent could be granted.

[3] https://www.mbie.govt.nz/dmsdocument/5708-discussion-paper-intellectual-property-laws-amendment-bill-patents-act-2013-trade-marks-act-2002-designs-act-1953

- EPC members however have allowed such claims as a way of encouraging research into further medicinal uses of known drugs that would otherwise not be patentable. It was thought that disincentivising such research could reduce the range of medical treatments available, not just in EPC members, but in the rest of the world as well.

- The only way that EPC2000-type claims could be allowed in New Zealand would be if the 2013 Patents Act were to be amended to permit them

NZHR's submission

NZHR recommends that the 2013 Patents Act be amended to permit EPC2000-type claims in New Zealand, for the following reasons:

- It would be strongly supported by the New Zealand public and health service consumers

- It would incentivise the pharmaceutical industry to invest in clinical trials in New Zealand, thereby contributing to improvements in New Zealanders' health and prosperity. We note that when multinational pharmaceutical companies do include New Zealand in clinical trials it is typically as one of several participating countries globally, and it would be unfortunate if New Zealand's patents legislation became another reason for not investing. We disagree with the discussion paper's comment that allowing for EPC2000-type claims in New Zealand is unlikely to make any difference to the decisions of pharmaceutical companies to invest in the development of new medicinal uses of known drugs, either in New Zealand or anywhere else. Pharmaceutical companies already invest in the development of new drugs in New Zealand, despite only being about 1% of the world market, and it is not logical to suggest that this wouldn't be extended to existing medicines if the opportunity was to become available.

- The risks of flow on costs, although real, are not materially significant. Specifically, we do not accept the discussion paper's implication that allowing EPC2000-type claims significantly risks increasing costs to the public health system, PHARMAC and to consumers. We believe that the discussion paper overstates the risks, with a heavy reliance on unsubstantiated speculation. Even if the risks were as significant as the discussion paper suggests, however, NZHR believes that the benefits would be sufficient to offset any costs (and that PHARMAC would in any case be able to absorb such costs within its budget allocations).

- Not amending the Patents Act as recommended risks opportunity cost of not maximising our attractiveness for further investment. Protecting novel uses of existing drugs If anything widens the NZ market for pharmaceutical companies, and PHARMAC can negotiate advantageously on the basis of that larger market.

- There are positive health and economic reasons for adopting EPC2000-type claims. We specifically disagree with the discussion paper's assertion that "there do not appear to be any advantages or benefits to New Zealand in adopting EPC2000-type claims [and that the need to stimulate] research into new medicinal uses of known drugs….does not apply in New Zealand". This is an unverifiable assumption, and New Zealand cannot afford to forgo the health and economic benefits of industry investment in health research by arbitrarily closing off avenues and opportunities to do so. Furthermore, bringing clinical trials to NZ means that NZ patients have earlier access to drugs, and patients on trials are at zero cost to PHARMAC.

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In developing this submission we have consulted with our partners and members as set out below (and from whom we derive 100% of our funding).

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NZHR partners and members

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