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Submission to the Senate Community Affairs Committee Inquiry into Gene Patents

Xenome Ltd is a privately held biopharmaceutical company with core expertise in the development of peptide drugs, primarily in the fields of pain and inflammation. A key asset is its venom peptide library, which forms the basis for drug discovery partnerships with corporate partners.

Xenome has a staff of 13 fulltime employees, spread across three locations: two members of its senior management team are based in Melbourne, the discovery team and corporate offices are based at Xenome's laboratory facilities outside Brisbane, Queensland, and its clinical team is based in San Diego, USA.

This submission has been made in response to the invitation to comment by the Senate Community Affairs Committee on the 'Inquiry into Gene Patents'.

The terms of reference for the submission are:

The impact of the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form, with particular reference to:

- (a) the impact which the granting of patent monopolies over such materials has had, is having, and may have had on:
 - (i) the provision and costs of healthcare,
 - (ii) the provision of training and accreditation for healthcare professionals,
 - (iii) the progress in medical research, and
 - (iv) the health and wellbeing of the Australian people;
- (b) identifying measures that would ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the *Patents Act 1990* should be amended, in light of the any matters identified by the inquiry; and

- (c) whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over such materials.

In the first instance we would like to comment on the scope of patentable material that is covered by the current Inquiry. The impetus for the Inquiry was the patenting of specific genes, such as BRCA1 and BRCA2. However, the scope of the Inquiry covers:

'human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form'

This is an exceptionally broad scope and , and encompasses facets of many industries within Australia – not only the medical and biotechnology fields but also the agricultural and brewing fields to name a few. Indeed, if the full spectrum of materials listed above were deemed to be non-patentable, it would have extremely negative effects on a large number of Australian companies and would drastically undermine emerging industries such as biotechnology.

In response to specific elements within the terms of reference:

- (a) *the impact which the granting of patent monopolies over such materials has had, is having, and may have had on:*
- (iii) *the progress in medical research, and*
 - (iv) *the health and wellbeing of the Australian people;*

There is a general perception, particularly amongst the academic community, that there will be great benefits to be gained by medical researchers if patent laws are changed to exclude patenting of genes. Putting aside any philosophical questions regarding the patenting of genes, the reality is that medical researchers in particular, and the community in general, benefit from the ability of individuals, institutions and companies to obtain patent protection for individual genes. The explosion of genetic information over the past twenty years was driven largely by companies which invested in gene sequencing technologies and infrastructure, driven by their ability to patent the outcomes from this investment. When a patent becomes public anyone is able to perform research in the area with limitations being enforced when outcomes of the research are to be

commercialized. Further research is therefore not hindered, but enhanced by the availability of information. If these items are prohibited from patent protection there is every chance that the technology and information will remain in house secrets – which researchers will not have the ability to access. Thus in reality research would be hindered in the areas of gene technology.

If gene patents (and the broader descriptor) were disallowed there would be a dramatic result on the health care industry with no investments being made in this area because of the inability to gain returns. For the advancement of research to the point of becoming profitable large amounts of investment is required – if there is no guarantee of recouping costs with the exclusivity of patent protection then investment in this area would cease and many Australian industries would be no longer viable.

In regards to the remaining terms of reference:

- (b) *identifying measures that would ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the Patents Act 1990 should be amended, in light of the any matters identified by the inquiry; and*
- (c) *whether the Patents Act 1990 should be amended so as to expressly prohibit the grant of patent monopolies over such materials.*

If the Patents Act 1990 was amended so as to expressly prohibit the grant of patent monopolies over genes and associated material then Australia would no longer be in line with International Patent Law and in fact be diverging from the push towards international harmonization of intellectual property laws. This would make Australia a country where the value of a patent is intangible and of little value, again heavily impacting on many sectors within Australia industry. It would also dramatically remove the incentive for non-Australian companies to develop and market new biotechnology-derived drugs in Australia due to the absence of protection, thereby negatively impacting the health and well-being of Australians.

Our very strong view is that amending the Patents Act 1990 to render genes (and the other entities listed) as being non-patentable would be a retrograde step. It would be negative for industry and negative for the general Australian population. While it might

appear to be a positive for medical research due to commonly held misperceptions regarding patents, the reality is that it would also have a negative impact on medical research in Australia because it would reduce the prospects for development and commercialization of that research.



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