GMiA Generic Medicines Industry Association Pty Ltd

ABN 19 096 009 540

PO Box 222
Pymble BC
NSW 2073

Generic Medicines Industry Association

GMiA submission regarding the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*

25 February 2011

Introduction

The Generic Medicines Industry Association (**GMiA**) represents the interests of suppliers of generic medicines in Australia. Members of GMiA account for more than 90% of generic prescriptions dispensed through the Commonwealth Pharmaceutical Benefits Scheme.

GMiA welcomes the opportunity to submit comments on the pending Patent Amendment (Human Genes and Biological Materials) Bill 2010 ("**Gene Patenting Bill**").

GMiA has commented elsewhere[1] on the developing concern from companies in industries such as ours that patent law in Australia has been growing increasingly out of step with trends in Australia's major trading partners on major patent issues. This is clearly affecting innovation and investment in research and development in Australia.

GMiA strongly believes that differences between patent laws in Australia and the trends in major patent regimes of the world discourages innovation in Australia and puts the Australian public at a disadvantage with respect to the rest of the world. These differences have led to a significant lowering of the threshold requirements for obtaining patent protection in Australia as compared to the rest of the world and has meant that it has become increasingly more difficult to challenge the validity of granted patents in Australia.

In the Australian pharmaceutical and biopharmaceutical industries, innovation, research, and market competition have been unnecessarily stymied because of the increasing reach of patent rights.

Patent monopolies regarding critical pharmaceuticals and biopharmaceuticals which have been invalidated elsewhere have either remained unchallenged in Australia (due to the relatively small size of the Australian market) or have been held to be valid in Australia (due to significant differences in Australian law). Australian industry and the Australian public have been disadvantaged and will continue to be disadvantaged if these issues are not rectified.

Correcting this imbalance will assist all of Australia – inventors, industry and the general public – by having a more level playing field with the global community in today's critical fields of innovation. Importantly, the current innovation environment is a global one with worldwide information becoming more and more accessible. The globalization of intellectual property is reflected in the push to change patent laws around the world. If Australia remains out of step with patent law trends of its major trading partners it risks compromising its enviable reputation as a country of innovation.

[1] Including in the GMiA submission to IP Australia regarding IP Australia's consultation paper "Getting the Balance Right" in May 2010.

GMiA applauds initiatives to correct this imbalance, and welcomes an ongoing dialogue regarding the Gene Patenting Bill, and other initiatives which seek to raise the bar for patentability of inventions in Australia.

GMiA submissions regarding the Gene Patenting Bill

GMiA makes the following submissions regarding the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* ("**Gene Patenting Bill**"):

1. GMiA is not anti-patent, and supports the patentability of all inventions which meet fair standards for patentability. GMiA supports the enforcement of valid and infringed patents relating to patentable inventions.

2. In many areas of patent law, Australia is out of step with global trends. Accordingly, patents in Australia are easier to obtain, and harder to revoke (overturn), than elsewhere.

- Much of Australia's "drift" away from global trends has occurred in the Courts, where similar standards for patentability have been implemented differently in Australia as compared with the rest of the world, resulting in patents being easier to obtain and harder to revoke than in Australia as compared with the rest of the world.
- The threshold for inventive step is easier to meet in Australia as compared with the rest of the world, and Australian patent examination processes are less robust than the rest of the world, so weaker patents are more likely to be granted in Australia as compared with the rest of the world. As a result, the Australian public is disadvantaged, and free competition is impeded.
- Competitors wishing to use such technology must, at great cost, obtain a Court ruling that the patent is not infringed or is not valid. In the generic pharmaceutical and biopharmaceutical industries, they will also likely be injuncted until the final Court decision on the matter

3. The GMiA is very concerned that patents in Australia are easier to obtain, and harder to revoke, than elsewhere.

4. The GMiA strongly supports changes which realign Australia's patent law with global trends regarding standards for patentability.

- Legislative intervention is required to correct Australia's standards for patentability as, to a significant degree, the Australian "drift" has occurred in the Courts.
- GMiA is very concerned about the current position in Australia where the threshold standard for patentability has been lowered to a point where almost everything is considered to be inventive.
- In many key areas of patent law, there is an urgent need for legislative intervention to correct this "drift". GMiA applauds initiatives seeking to provide clear statutory guidance to focus relevant triers of fact (Courts and/or patent office examiners) on higher, more appropriate threshold standards for patentability in Australia.

5. In light of (1) to (4), GMiA supports the intent of the Gene Patenting Bill which seeks to clarify and reign in the law regarding standards for patentability in Australia, in this case for biological materials.

6. Global common law trends are away from the patentability of certain biological materials (eg EU and US), but no region has felt it necessary to legislate to facilitate that change.

In **Europe**, whilst the EU Biotech Directive confirms that biotech inventions are patentable in certain circumstances, a number of limitations to the patentability of biotech inventions and to the enforcement of such patents are clear. The European Patent Office (**EPO**) requires an invention to make a technical contribution to the field, and so no valid claim can be made to a biotech product or process which is in the same form as that found in nature. In the EPO, it is

not possible to patent sequences of DNA without being able to specify the function of the particular sequence.

Importantly, in June 2010, the Court of Justice of the EU issued its first decision under the EU Biotech Directive in the *Monsanto* case[2]. The effect of the Monsanto decision is that claims to DNA sequences will likely be limited to a particular function. Pursuant to *Monsanto*, it may not be sufficient that a function of the DNA is simply known and mentioned in the patent specification in order to enable the sequence to be validly patented; claims to the DNA sequence may be limited to the disclosed function, and there may be no protection for the DNA sequence per se. This is consistent with the (pre-existing) law of certain regions in Europe, including Germany and France.

Similarly in the **US**, recent patent office and Court decisions indicate a trend toward limiting the patentability of biotech inventions and to the enforcement of such patents. In March 2010, the District Court of the Southern District of New York recently held that "isolated DNA" was unpatentable subject matter. *Assoc'n for Molecular Pathology v. U.S. Patent & Trademark Office* ("Myriad") (March 29, 2010). According to the district court, the "isolated DNA" was not man-made (made by nature) and had not been transformed. As such, according to the district court, the claims were unpatentable.

Additionally, Judge Dyk in his concurrence/dissent in *Intervet v. Merial*[3] in August 2010, concludes that serious questions are raised concerning whether isolated nucleic acid claims represent patentable subject matter under 35 U.S.C. 101. He said:

> "it appears that in order for a product of nature to satisfy section 101, it must be qualitatively different from the product occurring in nature, with '*markedly different characteristics from any found in nature.*' It is far from clear that an 'isolated' DNA sequence is qualitatively different from the product occurring in nature."

Judge Dyk's analysis in *Intervet* is very similar to the district court judge's analysis in *Myriad*. Although Judge Dyk's opinion is dicta, it indicates that at least one member of the US Federal Circuit does not believe that "isolated DNA" claims represent patentable subject matter under U.S. law.

In addition to a tightening standard for patentable subject matter, the substantive requirements for patentability have also tightened for biotechnological inventions in recent years, for example

[2] *Monsanto Technology v Cefetra*, C - 428/08 ECJ judgment dated 6 July 2010, following the earlier Opinion of Advocate General Mengozzi (9 March 2010)

[3] *Intervet, Inc. v. Merial Limited*, 617 F.3d 1282 (Fed. Cir. 2010)

- A heightened written description standard was recently affirmed for claims generally directed to reducing NF-κB activity by the Federal Circuit in *Ariad Pharma v. Eli Lilly & Co.*[4]
- Moreover, in the context of obviousness, claims to specific nucleotide sequences were recently held unpatentable as obvious over a combination of art directed to the corresponding protein, a monoclonal antibody specific for the protein, and a laboratory cloning manual. *In re Kubin.*[5].

As indicated above, the trend away from patentability of such inventions in EU and in the US has been in the Courts. But GMiA strongly supports legislative intervention in Australia. The reason legislative intervention makes sense in Australia is:

- to date, there is little case law on patentability of biological materials in Australia; and
- it is necessary to prevent the common law "drift" we have seen in other areas of Australian patent law.

7. The GMiA acknowledges that Australia will be "ahead of the curve" if the Gene Patenting Bill is implemented without amendment, but supports Australia aligning its position with global trends, and taking the global lead in this important area.

8. The GMiA believes that the intent of the Gene Patenting Bill is worthy of detailed consideration, and supports discussion of the Gene Patenting Bill as part of a broader Australian patent reform initiative seeking to realign Australia's patent law with global trends.

[4] *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (*en banc*).

[5] *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (*en banc*).

[5] *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009).

9. The GMiA welcomes further dialogue on the detailed wording of Gene Patenting Bill (in particular, the definition of Biological Materials), and other initiatives which seek to raise the bar for patentability of inventions in Australia, particularly initiatives directed toward:
    - correcting the serious problems existing in the Australian standard for inventive step, and
    - correcting the dysfunctional provisions regarding declarations of non-infringement in Australia.

GMiA would be delighted to provide further information on these issues which are of great interest to GMiA member companies.