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25 February 2011

The Secretary
Senate Legal and Constitutional Affairs Committee
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Secretary

PATENT AMENDMENT (HUMAN GENES AND BIOLOGICAL MATERIALS) BILL 2010

I write in support of Medicines Australia's submission (attached) in relation to the Patent Amendment Bill 2010, introduced into Parliament on 24 November 2010 by Senators Coonan, Heffernan, Siewert and Xenophon.

As a global biopharmaceutical company, Bristol-Myers Squibb (BMS) medicines help millions of people around the world in their fights against cancer, cardiovascular disease, diabetes, viral hepatitis, HIV/AIDS, rheumatoid arthritis and psychiatric disorders. The company has a long and proud history of developing and delivering innovative medicines to help Australian patients prevail over serious diseases. A significant number of medicines currently in research, including those invented by BMS scientists, are biologically based and are thus potentially affected by this Bill.

We note the historical context for this Bill and reiterate Medicines Australia's summation that previous reviews have not found Australia's patent laws to be wanting in those areas of concern expressed by proponents of this Bill.

BMS submits that the Bill ought to be rejected and, specifically, that biological materials not be excluded from patentable subject matter. BMS joins Medicines Australia in encouraging the Committee to investigate other more meaningful approaches to advance medical and scientific research.

Yours sincerely

James W. Cain
Managing Director

25 February 2011

The Secretary
Senate Legal and Constitutional Affairs Committee
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Secretary

RE: Patent Amendment (Human Genes and Biological Materials) Bill 2010

Thank you for the opportunity to comment on the Patent Amendment (Human Genes and Biological Materials) Bill 2010, which was introduced in Parliament on 24 November 2010.

This Bill was introduced in response to a concern about whether patenting of human genes and biological materials could restrict patient access to medicines and future medical research. While this concern is understandable, in fact the issues of concern are already dealt with by existing legislation and in a future Bill the Government plans to introduce shortly.

Medicines Australia assumes that it is not the intent of the Bill to prevent the development of new medicines, however this is what the effect of the Bill will be if it goes ahead. The changes proposed in this Bill, if they were implemented, would have far-reaching and extremely negative consequences for Australia's biopharmaceuticals industry and for Australian patients. Therefore, we strongly urge this Committee to recommend that the Bill be rejected and that Parliament investigate other, more meaningful ways to achieve the goals of the Bill's sponsors, which we share. These are:

- to improve Australian patients' access to new health technologies; and
- to ensure that Australian scientists are free to conduct research on patented inventions (so long as it is for the purpose of investigating the patented invention and not their intention to infringe valid patents by selling these inventions without the inventors' permission).

Medicines Australia represents the innovative pharmaceuticals industry in Australia, which brings new medicines, vaccines and health services to the Australian market, and which, in 2009, generated more than $4 billion in export earnings for the Australian economy. The pharmaceuticals industry is Australia's third largest investor in research and development – in 2009 alone, the industry invested more than $1 billion – and one of Australia's largest employers of medical researchers.

In this submission, we explain what the consequences would be of excluding biological materials from patentable subject matter and why taking this action would, contrary to the Bill's intention, harm Australian patients, destroy Australian jobs and stall medical research in Australia.

If you have any questions about statements in this submission, please do not hesitate to contact me on Medicines Australia would also welcome the opportunity to appear before the Committee to discuss its submission.

Yours sincerely

Dr Brendan Shaw
Chief Executive

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Background

1. Overview of the Australian Patent System

The Australian patent system is governed by the *Patents Act 1990*, which is administered by IP Australia, a Federal Government agency, on behalf of the Department of Innovation, Industry, Science and Research.

To obtain a patent in Australia, a formal application must be lodged with IP Australia. This application must contain a "specification", which describes in detail how an invention works. Specifications end in one or more statements called "claims" which carefully define the exact scope of the protection sought.

All patent applications in Australia are published approximately 18 months after they have been lodged with IP Australia, which gives third parties and actual or potential competitors an opportunity to challenge the grant of exclusive patent rights, before such rights are granted. IP Australia then examines each patent application, evaluating its validity against several criteria, such as novelty, inventiveness and utility. This evaluation is based on the information in the application and all other information in the field published anywhere in the world (prior art). If IP Australia considers that all relevant criteria have been met, it accepts and republishes the application. At this stage, third parties and actual or potential competitors can, once again, formally challenge the grant of a patent and they have three months to do so. If no opposition is received, IP Australia will grant the patent.

A valid patent provides the owner with "exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention".[1] However, patents may be re-examined at any time by IP Australia or challenged by third parties through the courts.

The rigorous process that underpins the Australian patent system ensures that patents are only granted when there is sufficient evidence that granting them will advance innovation and not undermine equitable public access to inventions.[2] This system has, for decades, ensured patient access in Australia to the latest and most effective treatments.

2. Scope of the Patent Amendment (Human Genes and Biological Materials) Bill 2010

The Bill proposes to prevent IP Australia granting patents on "biological materials including their components and derivatives, whether isolated or purified or not and

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[1] Section 13, *Patents Act 1990*

[2] For example, section 50 of the *Patents Act 1990* states:

(1) The Commissioner may refuse to accept a request and specification relating to a standard patent, or to grant a standard patent:

(a) for an invention the use of which would be contrary to law;

(b) on the ground that the specification claims as an invention:

(i) a substance that is capable of being used as food or medicine (whether for human beings or animals and whether for internal or external use) and is a mere mixture of known ingredients; or

(ii) a process producing such a substance by mere admixture.

however made, which are identical or substantially identical to such materials as they exist in nature". The Bill goes on to define "biological materials" as "DNA, RNA, proteins, cells and fluids".

The Bill's sponsors and supporters argue that its scope is narrow, and that it only aims to ban the practice of human gene patenting. The Bill has emerged out of a concern about whether patents could prevent patient access to treatments and medical research. While this is an understandable concern, the proposed Bill does not achieve this objective, but has a number of very serious unintended consequences that are likely to actually constrain or prevent the development of new medicines for patients. A plain reading of the Bill suggests that its provisions actually go much further than was intended and would cast doubt on the (patent) eligibility of a broad range of man-made products which are used in clinical medicine such as:

- recombinant proteins[3] (including monoclonal antibodies, biosynthetic hormones and protein-based vaccines);
- synthetic small molecules which are designed to mimic their natural counterparts (such as thyroxine); and
- complementary DNA sequences[4].

3. Previous Inquiries

The claims put in support of the Patent Amendment (Human Genes and Biological Materials) Bill 2010 as the basis for introducing the Bill in Parliament are that patents on genetic and biological materials pose a threat to public health and to scientific advancement and prevent medical and scientific research. The validity of these claims has been tested three times in the last decade, and on all occasions, the inquiries found no grounds for amending Australia's patent law to exclude genetic or biological materials from patentable subject matter.

In 2004, dealing specifically with the (patent) eligibility of genetic materials, the Australian Law Reform Commission found that there are no "fundamental flaws in patent law or practice as applied to genetic materials and technologies." In its final report, the Commission recommended that:

- patent applications relating to genetic materials and gene derivatives should be assessed according to the same legislative criteria for patentability that apply to patent applications relating to any other type of technology;
- the *Patents Act 1990* should not be amended to:
    - exclude genetic materials and technologies from patentable subject matter; or
    - exclude methods of diagnostic, therapeutic or surgical treatment from patentable subject matter;

  and

[3] A recombinant protein is a protein which is derived from recombinant DNA. Recombinant DNA is genetically engineered DNA made by recombining DNA sequences that would not occur together in nature.

[4] Complementary DNA (or cDNA) is a piece of single stranded DNA that is generated in the laboratory. Scientists use cDNA to artificially induce protein production in cells which normally would not produce these proteins.

- IP Australia should enhance training and develop revised guidelines, consistent with the *Patents Act 1990*, the *Patents Regulations 1991* and existing case law, to assist patent examiners in appropriately applying the patentability criteria to genetic technologies and gene derivatives.[5]

In November 2010, dealing more broadly with the (patent) eligibility of "genes and gene derivatives", the Senate Community Affairs Committee also found that there are no grounds for amending the *Patents Act 1990* to "include an express prohibition on human genes and genetic products".[6]

Finally, in February 2011, after a two year review of patentable subject matter[7], the Australian Government's Advisory Council on Intellectual Property recommended:

- codifying the established principles of patentability – so that an invention must be an artificially created state of affairs in a field economic endeavour;[8] and
- maintaining the current exclusion from patentability of human beings and biological processes for their generation – **but not introducing any further specific exclusions**.[9]

4. Importance of Intellectual Property Rights

The process of bringing new medicines to the market involves an extraordinary degree of risk. Only a small portion of "promising research" yields safe and effective products, of which only a fraction are profitable enough to make the initial investment financially and materially worthwhile.[10] On average, the cost of bringing a new medicine to market is approximately US$1.2 billion, and it can take between 12 and 15 years to complete the process.[11]

By guaranteeing a clearly defined period of market exclusivity, patents (and other forms of intellectual property rights such as data exclusivity) act to mitigate the extraordinary risk of bringing new medicines to market, making it significantly more likely for private enterprises to continue to invest in research and development.

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[5] The Commission's full report, *Genes and Ingenuity: Gene Patenting and Human Health*, is available online at: www.alrc.gov.au/inquiries/gene-patenting.

[6] The Committee's full report, *Gene Patents*, is available online at: http://www.aph.gov.au/senate/committee/ clac_ctte/gene_patents_43/index.htm.

[7] The Council's full report, *Patentable Subject Matter – Final Report*, is available online at: http://www.acip.gov.au/library/ACIP%20PSM%20final%20report%204%20Feb%202011.pdf.

[8] With respect to the current test for patentable subject matter, the Council noted that "it has the flexibility to cope with a variety of concepts and to adapt to new technologies. It has been tested by users and refashioned by Parliament and the courts over a period of time that has seen unprecedented technological change."

[9] In one of its earlier reports, the Council also noted that the formulation of proscriptive categories of subject matter which are to be excluded from patentability is a crude on/off switch, which has the potential to stifle entire fields of innovation. Medicines Australia believes that this is particularly so for fields such as pharmaceuticals and other technologies which treat and prevent human diseases, where the risks of failure are high and huge investment of resources are required to understand and then address medical and scientific problems.

[10] Grabowski, Henry, *Follow-on biologics: data exclusivity and the balance between innovation and competition*, Nature Reviews Drug Discoveries (**2008**).

[11] DiMasi, Joseph, and Grabowski, Henry, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, Managerial and Decision Economics, (**2007**), 28:469-479.

Consequences of Implementing the Patent Amendment (Human Genes and Biological Materials) Bill 2010

1. Impact on Patients

Banning patents on biological materials could severely restrict Australian patients' access to an entire class of innovative medicines and diagnostic tools.

Between 1998 and 2008, at least 28 new medicines for diseases ranging from breast cancer to diabetes and heart disease were listed on the Pharmaceutical Benefits Scheme (see Table below) whose active ingredients may be defined as “biological materials”. In addition, 19 vaccines such as Prevenar® and Priorix®, to prevent a total of 16 communicable diseases such as pneumococcal infections and measles, have been made available through the National Immunisation Program which contain active ingredients that may be defined as "biological materials". Last year, some half a million Australians were treated using these medicines and vaccines.

Major Indications[12]	Generic Name	Brand Name
rheumatoid arthritis	Anakinra	Kineret®
rheumatoid arthritis	Adalimumab	Humira®
Diabetes mellitus	Insulin aspart	NovoRapid®
multiple sclerosis	Natalizumab	Tysabri®
rheumatoid arthritis	Abatacept	Orencia®
Anticoagulant	Bivalirudin	Angiomax®
fertility treatment	Choriogonadotropin α	Ovidrel®
Anaemia	Darbepoetin alfa	Aranesp®
severe sepsis	Drotrecogin alfa	Xigris®
osteoporosis	Teriparatide	Forteo®
anaemia	Epoetin beta	NeoRecormon®
cardiac ischemia	Eptifibatide	Integrilin®
rheumatoid arthritis	Etanercept	Enbrel®
prostate cancer	Triptorelin embonate	Diphereline®
multiple sclerosis	Glatiramer acetate	Copaxone®
Crohn's Disease	Infliximab	Remicade®
anaemia	Epoetin alfa	Eprex 2000®
colorectal cancer	Cetuximab	Erbitux®
fertility treatment	Follitropin alfa	Gonal-F 75®
macular degeneration	Ranibizumab	Lucentis®
neutropenia	Pegfilgrastim	Neulasta®
hepatitis C	Peginterferon alfa-2b	PEG-Intron®
HIV	Enfuvirtide	Fuzeon®
heart attack	Reteplase	Rapilysin 10 U®
leukaemia	Rituximab	Mabthera®
myocardial infraction	Tenecteplase	Metalyse®
thyroid cancer	Thyrotropin alfa	Thyrogen®
breast cancer	Trastuzumab	Herceptin®

Had a ban on patents on biological materials been in place ten years ago, Australian patients today would likely not have access to many of the medicines and vaccines

[12] Nearly all of the medicines listed in this table are used to treat multiple conditions.

listed above. These medicines and vaccines would have been ineligible for patent protection, and the companies which developed them would, in many cases, not have sought to market them in Australia.

Passage of this Bill, or a variant of it, would lead to enormous uncertainty around the patent status of many current and future life-saving medicines. This would have serious effects on patient access to medicines in Australia.

2. Impact on Industry

Banning patents on biological materials would have devastating consequences for the Australian biotechnology and pharmaceutical industries.

A ban would invalidate patents on hundreds of products currently in development in Australia. Companies developing these products would no longer be able to use the promise of future returns to attract investment, without which they wouldn't be able to survive let alone continue their research and development activities.

A ban could also invalidate core patents on hundreds of existing products, exposing them to premature competition and costing companies that market these products hundreds of millions of dollars in lost revenue and potentially forcing them to cut thousands of Australian jobs.

Biological medicines represent the cutting edge of medicine. They have already revolutionised the field, and in time biological medicines are likely to deliver the most effective means of treating a variety of illnesses and disabilities. Over 250 innovative human-use biologics have been approved since 1990, and more than 400 are currently under development globally, targeting diseases such as cancer, AIDS, arthritis, Alzheimer's and Parkinson's. If Australians were denied access to biological medicines, they would, in many cases, have access only to older, less effective medicines.

Australia's Obligations Under International Treaties

Any discussion of proposed changes to Australia's intellectual property laws cannot occur without consideration of Australia's obligations under current international treaties. Two important treaties need to be considered – namely Australia's commitments to the World Trade Organisation and the Australia-US Free Trade Agreement. It is likely that if the Parliament were to pass the provisions contained in the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* that Australia may well be in breach of its international commitments and out of step with accepted intellectual property laws worldwide.

1. Agreement on Trade-Related Aspects of Intellectual Property Rights

As a member of the World Trade Organisation, Australia is required to implement the terms of the Agreement on Trade-Related Aspects of Intellectual Property Rights, including Article 27(1), which requires member countries such as Australia to make patents available to all fields of technology, without discrimination. Article 27(1) states:

"[...], patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. [...], patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."[13]

Banning patents on biological materials would be in clear violation of Australia's international obligations under the TRIPS Agreement.

2. Free Trade Agreement Between Australia and the United States

According to Article 17.9.1 of the Free Trade Agreement:

"Each Party shall make patents available for any invention, whether product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application. The Parties confirm that patents shall be available for any uses or methods of using a known product."[14]

As under the TRIPS Agreement, excluding biological materials from patentable subject matter would be in clear violation of Australia's obligations under its Free Trade Agreement with the United States.

Proposed and Existing Measures to Address the Impact of Patents

1. Research-Use Exemption

Claims put in support of the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* suggest that patents on genetic and biological materials stifle research. Despite the fact that numerous studies have found very little evidence to support this, Medicines Australia nevertheless strongly supports the introduction of an explicit research-use exemption clause in the Patents Act.

Once the information contained in a patent application has been published, it remains in the public domain. Members of the public, including researchers, are free to use the information and teachings available to them in a published patent application, provided they do not commercially exploit or supply the patented invention in a way that is an infringement under the Patents Act (i.e., without permission of the patent holder). However, the introduction of an appropriately-framed research-use exemption, would be extremely useful in providing clarity to researchers and the public as to their freedom to conduct research. The infringement exemption for experimental purposes included in the *Intellectual Property Laws Amendment (Raising the bar) Bill 2011*, which is close to being ready for introduction to the Parliament, would provide certainty for researchers. Medicines Australia strongly supports the amendment proposed in the Raising the Bar Bill.

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[13] The full text of the Agreement on Trade-Related Aspects of Intellectual Property Rights is available at: http:// www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm.

[14] The full text of the Free Trade Agreement Between Australia and the United States is available at: http:// www.dfat.gov.au/fta/ausfta/final-text/index.html.

2. Improvement threshold test for granting a patent

The Government's forthcoming *Intellectual Property Laws Amendment (Raising the bar) Bill 2011* is also likely to clarify and strengthen the conditions required to be met in order for a technology to become patented. This will help ensure the distinction between 'discovery' and 'invention' is clear and thereby also addresses many of the concerns that led to the introduction of the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*.

The Government's alternative forthcoming Bill will in all likelihood raise the threshold for granting a patent without the adverse unintended consequences that would come from the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*. Again, for this reason Medicines Australia recommends that the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* be rejected in expectation of the Government's alternative forthcoming *Intellectual Property Laws Amendment (Raising the bar) Bill 2011*.

3. Crown Use & Compulsory Licensing

The *Patents Act 1990* already contains safeguards to deal with rare situations where individual patents may cause gross market distortions or may lead to severe and unusual access-to-technology issues. These existing safeguards eliminate the need for technology-specific changes to the Patents Act, as recommended in the Patent Amendment (Human Genes and Biological Materials) Bill 2010.

The Crown Use provisions of the Patents Act permit certain Government entities to use, and to authorise others to use, patented inventions, without permission from the patent owner in some circumstances. The use is only permissible where such use is for the services of the Commonwealth, the State or a Territory. The Government would have to pay the patent owner or exclusive licensee remuneration for that use, in accordance with the Patents Act.

These provisions exist to assist government bodies where they can establish that such use is necessary for the proper provision of government services within Australia.

Compulsory licensing provisions under the Patents Act exist to require a patent holder to grant a licence to another to work their patented invention in certain circumstances. Such a licence would only be granted upon application to the court, and where the reasonable requirements of the public are not being met in accordance with the Patents Act. Examples of where public needs are not being met include where a trade or industry is unfairly prejudiced or demand for the product is not reasonably met because of the applicant's failure to adequately supply the patented product on reasonable terms or grant licenses on reasonable terms.

Conclusion

There is a strong and enduring rationale for making sure that no new laws are implemented that would, in any way, undermine the ability of patent owners to defend their legitimate rights and protect the fruits of their labour. Patents allow companies to invest in R&D, with the expectation that they will have a fair opportunity to recoup this investment before others, who did not bear the initial risk, are permitted to profit from new and improved products. It is important to understand that patents are not a barrier to access to medicines. Indeed, patents underpin the process of innovation in the pharmaceuticals industry and this process is what drives the invention and development of new medicines for previously incurable or unmanageable diseases.

Medicines Australia acknowledges that some stakeholders hold concerns about the impact of patents on the ability of scientists to conduct research on biological materials without having to determine whether doing so would infringe a patent. Supporters of the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* have indicated a concern to ensure that medical research and patient access to new therapies can continue in the future.

However, this could be achieved not by banning patents on biological materials altogether which as explained in this submission would have far-reaching, unintended and devastating consequences. Rather this could be achieved without the unintended consequences by implementing measures such as an explicit research-use exemption and strengthening the requirements to grant a patent, as recommended by various official reviews since 2004. This would clarify that scientists are free to conduct research on patented inventions, so long as it is not their intention to infringe a valid patent by selling the invention without the inventor's permission.

Ironically, the Patent Amendment (Human Genes and Biological Materials) Bill 2010 would not achieve this objective, nor would it ensure greater access for Australian patients to new health technologies. In fact, it would do the exact opposite. In addition, Medicines Australia has been informed that the Government will shortly be introducing the *Intellectual Property Laws Amendment (Raising the bar) Bill 2011* that will provide a research-use exemption and strengthen the requirements for granting a patent. This alternate bill, which Medicines Australia supports, responds to the issues raised in various reports prepared by the Australian Law Reform Commission, the Advisory Council on Intellectual Property and the Senate Community Affairs Committee.

For these reasons, Medicines Australia strongly urges the Senate Legal and Constitutional Affairs Committee to recommend that the Patent Amendment (Human Genes and Biological Materials) Bill 2010 be rejected.