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25 February 2011

Committee Secretary
Senate Legal and Constitutional Committees
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

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

Dear Committee Secretary

GlaxoSmithKline (GSK) welcomes the opportunity to comment on the *Patent Amendment (Human Genes and Biological Materials) Bill 2010,* which was introduced in Parliament by Senators Coonan, Heffernan, Siewert and Xenophon and referred to the Senate Committee on 26 November 2010 for inquiry and report.

GSK is strongly opposed to the amendments to the *Patents Act 1990* outlined in this Bill and submits that the proposed changes would have far reaching, negative consequences for patient access to innovative medicines and the Australian pharmaceutical and biotechnology industries.

We support the views submitted by Medicines Australia on behalf of the research based pharmaceutical industry. We share the goals of the Bill's sponsors, which are:

- to improve patient access in Australia to new health technologies; and
- 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 or using these inventions without the inventors' permission).

However, we believe Parliament should investigate other, more meaningful ways to achieve these goals.

There is no coherent body of evidence establishing that patents have had a negative impact on access to healthcare or have impeded research to any significant degree in Australia or elsewhere. On the contrary, patents incentivise medical research by providing security to investors active in the area. The removal of this security would inhibit research and development and significantly reduce patient access to innovative medicines.

We therefore strongly urge the Senate Legal and Constitutional Affairs Legislation Committee to recommend that the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* be rejected.

If you have any questions about statements in this submission, please contact GSK's Senior Policy Adviser, on or by email at .

Yours faithfully

Tim Murphy
Head, Government Affairs and Policy
GlaxoSmithKline Australia

Submission to the Senate Legal and Constitutional Affairs Legislation Committee

Patent Amendment (Human Genes and Biological Materials) Bill 2010

25 February 2011

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GlaxoSmithKline Submission

Executive summary of GSK's position

GlaxoSmithKline (GSK) is strongly opposed to the amendments to the *Patents Act 1990* outlined in the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* and submits that the proposed changes would have far reaching, negative consequences for patient access to innovative medicines and the Australian pharmaceutical and biotechnology industries. There are also possible consequences for other biological-based industries, such as chemicals, food and agriculture.

GSK believes that the issues raised by the Bill's sponsors have been addressed previously by the Australian Law Reform Commission (ALRC) Report in 2004 and the Senate Community Affairs References Committee Report in 2010. However, GSK is pleased to continue to support public debate on this matter.

The patent system is a social good. The Australian Government, through the *Patents Act 1990* and IP Australia, has established a system which provides protection for innovators and investors so that society may benefit from the development of new knowledge, products and services. Central to the patent system is the disclosure of innovative ideas in exchange for patent protection. The proposed amendments to the *Patents Act 1990* go to the heart of this social contract – and would unravel it – to the detriment of Australian patients and industry.

Patents incentivise medical research by providing security to investors active in the area. The removal of this security would inhibit research and development and reduce patient access to innovative medicines.

There is no coherent body of evidence establishing that patents have had a negative impact on access to healthcare or have impeded research to any significant degree in Australia or elsewhere. Rigorous patent examination and stringent interpretation of patent law ensure that this remains the case. The patent system also has a number of effective remedies on the rare occasions that a third party believes an IP right is being abused.

The concerns raised by the Bill's sponsors will not be addressed by banning patents of biological materials. Instead, the efficient application of appropriate patenting standards should alleviate any justified concerns that there might be. The 2004 ALRC and 2010 Senate Community Affairs References Committee report came to this same conclusion when investigating this matter.

The introduction of the proposed amendment would not only fail to improve patient access and stimulate medical research, but it would in fact have the opposite affect and result in less medical research and consequently poorer patient access to innovative medicines.

Finally, any amendment to the *Patents Act 1990* resulting in the restricted patentability for a particular area of technology would conflict with Australia's obligations under the TRIPS Agreement and there may be other negative consequences to Australia's international commitments, including under the Australia/US Free Trade Agreement.

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

Introduction

GSK is a global, research-based pharmaceutical and healthcare company with a long, proud history in Australia. Since 1886, we have contributed to the Australian economy through agriculture, manufacturing and innovation, while also delivering the highest quality medicines, vaccines and over-the-counter products to the Australian community.

We have a challenging and inspiring mission to improve the quality of human life by enabling people to do more, feel better and live longer. Shareholder investments make our work possible. Success allows us to provide a return to shareholders, continue developing new medicines and invest in community programs. We do our work in a way that reflects our values - respect for people, patient focus, transparency and integrity.

We are proud to be an EOWA Employer of Choice for Women, and in Australia provide around 1600 skilled jobs across five sites, four involving manufacturing. Last year our exports totalled $943 million, almost a quarter of Australia's $4.12 billion pharmaceutical and medicinal exports.

Our scientists collaborate with Australian researchers and doctors to discover new ways of treating and preventing disease. We have over 30 discovery projects underway locally. Our Medicines Research Unit is the only Phase I facility supported by a pharmaceutical company in Australia. We invested around A$8.2 billion on research and development worldwide last year of which $45.2 million was in local R&D, making us one of Australia's top 15 investors.

Our medicines treat major disease areas such as asthma, virus control, infections, mental health, and diabetes. Our vaccines protect millions of Australians and we are the largest supplier of childhood vaccines to the National Immunisation Program. We are also pioneering new treatments for cancer and other complex diseases.

Developing medicines is difficult, costly, risky and time consuming. It generally takes between 8 to 12 years and many hundreds of millions of dollars to bring just one successful product to market from thousands of potentials. GSK is in a leading position in many new drug discovery technologies such as genomics and genetics. Due to the significant investment we make in R&D, protection of intellectual property is vitally important.

Equally, because GSK is a research-based company, we have an interest in ensuring that patents do not inhibit research to an unjustified extent. GSK is therefore interested in maintaining an appropriately balanced patent system and actively contributes to consultations and debates in this area. In particular GSK has been integrally involved in commenting on developments in gene patenting, primarily in Europe, for nearly 10 years. We hope to provide input based on experience of dealing with the practicalities of the patent system in many different countries, including Australia.

Summary of the Bill

The recently introduced *Patent Amendment (Human Genes and Biological Materials) Bill 2010* proposes to modify the *Patents Act 1990*. In particular, it proposes to repeal the current subsection 18(2) and replace it with the following:

"(2) The following are not patentable inventions:
(a) human beings, and the biological processes for their generation; and
(b) biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature."

Whilst adding a new subsection, 18(5):

"(5) In this section: biological materials, in section 18, includes DNA, RNA, proteins, cells and fluids."

GSK is strongly opposed to the proposed amendment which would have far reaching, negative consequences for medical research, overall patient well-being and the biotechnology and medicines industry in Australia. Our reasons are provided in more detail below.

Why patents are necessary

R&D programs are expensive ventures, coming at a cost of billions of dollars. In fact, a recent article published by the American government[1] suggested that:

"Finding new cures is an extremely expensive and risky proposition...Estimates about the cost of developing a new drug vary widely, from a low of US$800 million to nearly US$2 billion per drug. Even the high end of those estimates may soon be considered a bargain."

The patent system incentivises the development of new medicines and diagnostic tests through these research programs and in turn improves patient access to innovative and improved medicines[2]. It does so by providing the first entity to develop an invention with the reassurance that, once the invention is made, their investment will not be wasted, but will be protected by patent rights.

If patent protection were to be withheld from inventions made in the pursuit of new medicines, then there would be nothing to prevent a competitor, who does not undertake the cost and risk of investment, copying the invention as soon as it was made. Accordingly, without protection, there would be no incentive for an investor, public or private, to support research programs. As a consequence research would not take place and patient access to innovative medicines would be hindered.

Furthermore, the patent system requires that granted patents must clearly describe the invention. Accordingly society as a whole, including follow on innovators, benefit from disclosure of the invention and the academic literature surrounding it.

In summary, the patent system stimulates innovation by providing the security necessary for investment into medical research. The obligatory publication of patents and patent applications ensures that details of innovative ideas are made available to the community. Finally, patents allow inventions to be accurately defined, ensuring legal clarity for third parties wishing to work in the area.

[1] http://www.america.gov/st/business-english/2008/April/20080429230904myleen0.5233981.html
[2] David B Resnik, Science and Engineering Ethics (2001), 7, 29-62

The patent system works effectively

There is no coherent body of evidence establishing that biological patents have had a negative impact on access to healthcare or have impeded research to any significant degree in Australia or elsewhere. We note countries with some of the strongest patent laws related to healthcare have the most vibrant innovative industries and some of the best healthcare systems in the world. Whilst we would not argue that this is caused only by patent laws, it is evidence that patent laws are not creating significant problems in real world conditions.

The reason that the patent system is not adversely affecting patient access is because of the rigorous conditions which must be met before a patent is granted and enforced. These conditions have been carefully developed over many decades at both the local and international level.

For example, it is currently possible to have a patent granted in Australia that includes genes only if ALL of the following thresholds of patentability are met:

- the gene or gene fragment is artificially-generated or isolated from its naturally-occurring environment;
- the gene function is known and described in detail; and
- the requirements of novelty, inventive step and usefulness are demonstrated and clearly documented.

GSK stresses that isolated genes on their own, with no known utility, are not sufficient for a patent to be granted.

Not only have the basic conditions for patentability been carefully developed, but where these relate to specific technology areas, such as biological inventions, they have been applied in a stringent yet bespoke manner by many patent offices, without favour or prejudice, a position which we strongly support (see for example the European Patent Office Guidelines for Examination of biotechnological inventions[3], which are supported by the European Directive on the legal protection of biotechnological inventions[4]).

Because of the stringent interpretation of patentability criteria in the field of biotechnology, relatively few human gene patents have been granted and often those that have been granted (mostly in the US) have claims that are significantly limited compared with the claims as filed with the original application. Many published patent applications have been withdrawn or abandoned by the applicant or rejected by Patent Offices.

Checks and balances in the system

There are sufficient remedies available to challenge a granted patent should it be felt that it does not meet one or more of the patentability criteria. These options were highlighted in the ALRC's "Genes and Ingenuity" 2004 report[5], in relation to Myriad's European patent on the BRCA1 gene:

[3] http://www.epo.org/patents/law/legal-texts/html/guiex/e/c_iv_3_2.htm
[4] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML
[5] http://www.alrc.gov.au/publications/report-99

> *"Shortly before the Inquiry concluded, the European Patent Office ruled, in opposition proceedings, that Myriad's patent on the BRCA1 gene in Europe was not valid because it lacked an inventive step. It is not always appreciated that, in granting a patent, a patent office is not making a final determination about the validity of the patent. Such a determination is for the courts, if and when a patent is challenged. One of the key recommendations of this Report is that health departments should consider more actively and strategically whether to exercise any existing legal options—including challenging patents—in order to facilitate access to particular genetic inventions where gene patent applications, granted patents or patent licensing practices are considered to have an adverse impact on medical research or the cost-effective provision of healthcare" (p.14).*

In addition, in the rare cases where patents are abused there are remedies provided for in the form of compulsory licences and competition law to rectify such abuses.

The concerns raised by the Bill's sponsors will not be addressed by banning patents of biological materials. Instead, the efficient application of appropriate patenting standards should alleviate any justified concerns that there might be. The 2004 ALRC and 2010 Senate Community Affairs References Committee report came to this same conclusion when investigating this matter.

Furthermore, we note that the Government is currently advancing a number of amendments to the *Patents Act 1990*, which includes introducing a research use exemption and strengthening requirements for granting a patent.

The proposed Bill would strike at the heart of the development of new medicines, vaccines and diagnostic tests

One of the major arguments put forward by stakeholders in support of the proposed Bill is that the existence of gene patents restricts patient access to tests and new medicines. There is no coherent body of evidence to suggest that such consequences are occurring, inevitable or even likely on a wide scale basis.

On the contrary, it is the removal of patent protection as proposed in amended section 18(2)(b) which would bring about a restriction of patient access to tests and new medicines. By removing the incentive and security relied upon by investors into scientific research programs, there would be a consequential reduction in the number of new medicines made available.

In order to put this reduction in research programs into perspective, it is useful, as an example, to examine the Australian Immunisation Handbook as produced by the Australian Government. [6] It is particularly useful to consider part 3 of the Handbook which lists vaccines, made available by dedicated research programs, to a host of different diseases. There are over twenty diseases listed, including many which prove fatal in both children and adults alike.

The way a vaccine works is to present a biological molecule to the body. In order to cause the body to raise an immune response to the virus or bacteria which is being vaccinated against, the biological molecule must comprise an area (an epitope) which is identical or substantially identical to part of said virus or bacteria.

[6] http://immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook-home

As the proposed amendment intends to prohibit the patenting of *"biological materials...which are identical or substantially identical to such materials as they exist in nature*" vaccines would not be given patent protection. Consequently, research programs to develop vaccines would not be conducted.

Taking the argument to its natural conclusion, if the proposed amendment had been present since the inception of the patents system there would have been no incentive to develop the vaccines listed in the Australian Immunisation Handbook, which would have had dire consequences for medical science and indeed, society.

The same argument is true for the vast majority of biopharmaceuticals. For examples, therapeutic antibodies have a relatively small region which is specific for their target molecule and differs between antibodies. However, the remainder of the molecule must mimic naturally occurring antibodies as closely as possible in order to prevent adverse reactions in the patient. As a therapeutic antibody would fall within the definition: *"biological materials...which are identical or substantially identical to such materials as they exist in nature*", they too would not receive patent protection. Consequently, drugs such as Herceptin™, Avastin™ and many others may never have come to be.

It is clear, therefore, that the acceptance of the proposed amendment would drastically restrict patient access and inhibit medical research to the detriment of society. Australia, as a developed country with a burgeoning biotechnology industry would suffer greatly from such an amendment.

Breach of International Obligations

Finally, any amendment of the *Patents Act 1990* resulting in the restricted patentability for a particular area of technology would conflict with Australia's obligations under the TRIPS Agreement, which relies on the principle that patent law is technology-neutral (Art 27(1)). Applying different criteria by excluding classes of inventions from patentability would be discriminatory and contrary to TRIPS.

There may be other negative implications to Australia's international commitments, including under the Australia/US Free Trade Agreement.

Recommendation

GSK strongly urges the Senate Legal and Constitutional Affairs Legislation Committee to recommend that the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* be rejected.