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

Dear Ms Dennett

Mylan Inc. welcomes the opportunity to submit comments to the Inquiry by the Senate Standing Committees on Legal and Constitutional Affairs into the Patent Amendment (Human Genes and Biological Materials) Bill 2010. We understand the purpose of this private Senators' Bill is to amend the Patents Act 1990 to prevent the patenting of biological materials existing in nature, including human genes, and those which, though somehow modified, do not meet the requisite standard of "invention" because the modification does not change what the material is or what it does.

Mylan is the third largest generic and specialty pharmaceuticals company in the world. Mylan serves customers in more than 140 countries and territories. The company maintains one of the industry's broadest and highest quality product portfolios, which is regularly bolstered by an innovative and robust product pipeline. With more than 16,000 employees, Mylan has attained leading positions in key international markets through its wide array of dosage forms and delivery systems, significant manufacturing capacity, global commercial scale and a committed focus on quality and customer service. The company ranks among the top five generics companies in several international markets – including Australia - and is the largest U.S.-based generics manufacturer in the world.

Alphapharm is Mylan's wholly owned Australian affiliate. Alphapharm is the largest supplier of prescription medicines in Australia, with more than 550 employees locally and a state-of-the-art manufacturing facility in Queensland. Alphapharm's specialty is bringing patent-expired medicines to market. We manufacture more than 2.5 billion tablets and capsules a year, about half of which are exported to some 50 countries.

Mylan accepts that patents encourage and reward invention. Mylan respects the rights of patent holders in all jurisdictions in which it conducts business. But Mylan is also aware that many patents are mistakenly granted. Therefore, there are issued patents in existence which are not valid. In support of this contention, Mylan respectfully draws to the Committees' attention the fact that no granted Australian patent is guaranteed validity as a matter of patent law (Section 20, Patents Act 1990). The grant of an invalid patent is highly problematic because it provides patent holders with a patent monopoly when none is deserved. This patent monopoly can have drastic and unwarranted consequences on the Australian economy and, in the field of pharmaceuticals, on the cost of providing health care. Accordingly, if invalid patents are granted and are not tested in the Australian courts, it may be necessary, as it is in this instance, for the Australian Parliament to intervene. Mylan is interested in ensuring that government policies in Australia are balanced, fair and equitable to the interests of all parties participating in the pharmaceuticals sector.

Generic (small-molecule) medicines help the Australian government, taxpayers and consumers save money. Since the advent of substitution in 1995, generics have saved the Pharmaceutical Benefits Scheme (PBS) more than $3 billion by lowering the benchmark price of medicines. Recent PBS reforms will realise expanded and accelerated savings through their price-disclosure policy.

Unfortunately, the same PBS reforms are encouraging evergreening and brand aggression as "Big Pharma" companies fight to keep their medicines in the F1 category to avoid onerous price reductions. This aggression and assertive gaming of the patent system in an attempt to extend patent monopolies illegally and in ways that undermine the economic intent of the Australian patent system, is exacerbated by the drying up of the invention pipeline upon which producers of generic medicines rely. The aggression and gaming also are exacerbated by a large wave of patent expiries that will continue through 2015 in relation to large-value pharmaceuticals. Moreover, inappropriate patent claims are being sought by some originators to extend monopoly rights.

In the future, biologic (large-molecule) medicines will play an increasingly important role in providing cutting edge, efficacious treatments to Australians. However, the high cost of these medicines will severely challenge and threaten the sustainability of the PBS. The timely production and supply of biogeneric medicines – patent-expired alternatives – will be crucial to the provision of affordable health care.

Mylan expends considerable sums in patent litigation, either challenging the validity of patents or defending itself against allegations of patent infringement. The company is, therefore, well aware of how powerful patent monopolies are, particularly when the Australian courts, by readily granting interlocutory injunctions, prevent the timely supply of generic medicines to the Australian people pending the resolution of the patent challenge or infringement suit.

As the European Union noted in the Pharmaceutical Sector Inquiry, enforcing patent rights in courts is legitimate and constitutes a fundamental right. However, the

Inquiry's findings also show that, like in any other industry, litigation can also be an efficient means of creating obstacles in particular for smaller companies. In certain instances "Big Pharma" companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants.[1]

Each time access to the market is denied or delayed for a generic medicine, the government continues to pay more for prescription pharmaceuticals than is warranted.

The Patent Amendment (Human Genes and Biological Materials) Bill 2010 aims to redress the imbalance in the patent framework in Australia by raising the bar for what is considered to be patentable material. Patentable material is only one of four prerequisites for the granting of a patent in Australia, the others being inventive step, novelty and utility. The Bill merely seeks to clarify and apply the true intent of patent law and amend that part of the Patents Act that provides the patentability criteria for the grant of a valid patent monopoly.

Biological materials that are identical or substantially identical to any that exist in nature should not be patentable because they are a product of nature and have not been transformed into a product of humankind, historically regarded as a prerequisite for patentability. Simply put, they are not "inventions." Just as a cotton ball removed from a cotton plant is not an invention, neither is a human gene mutation linked to, say, breast or ovarian cancer.

As established in Article 27.1 TRIPs, "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" (emphasis added). Allowing for the patenting of biological materials is, in effect, permitting the patenting of something that does not meet the patentability standard set in the TRIPs Agreement.

The patenting of naturally occurring biological materials is stifling medical and scientific research as well as the diagnosis, treatment and cure of human illness and disease. Such patenting prevents doctors, clinicians and medical and scientific researchers from gaining free and unfettered access to these materials, however made, that are identical or substantially identical to such materials as they exist in nature. The development of biogeneric medicines is being hampered by these patents, not because they claim a patent monopoly for an "invention," but because they claim a patent monopoly for a "discovery." These broad and unwarranted patent monopolies may prevent companies, such as Mylan, from even producing the exact same human protein. As such, these monopolies go well beyond the traditional scope of patent protection and are unfairly hampering free competition in the development of biogeneric medicines.

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[1] European Commission, Competition DG -- Pharmaceutical Sector Inquiry – Final Report – July 8, 2009

Banning the patenting of genes is fully consistent with the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) which Australia has signed. Indeed, Article 27.3 of TRIPs says:

> *2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.*
>
> *3. Members may also exclude from patentability:*
>
> *(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;*
>
> *(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement. (Emphasis added)*

Furthermore, a 2010 document commissioned by the World Intellectual Property Organization on biotechnology and exclusions from patentable subject matter and exceptions and limitations to the rights[2] stated that with regards to inventions concerning human beings (including genes and cells), "[s]uch inventions concerning directly the human beings are [sic] products may be generally prevented base on the morality or order public issue, with some important particularities. On the other hand, humans are animals, therefore under the possible exclusion mentioned in TRIPs art. 27.3."

In addition, as quoted in the Annex I of the same document, in 2003, the UK's premier scientific society, the Royal Society stated:

> *It is of particular importance to the scientific community that modifications to these exclusions from patentability do not lead to a greater risk of scientific knowledge being monopolised. We agree with the view of many scientists that pure knowledge about the physical world should not be patentable under any circumstances. That it should be freely available to all is one of the fundamental principles of the culture of science. Only by having knowledge unencumbered by property rights can the scientific community disseminate information and take science forward.*

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[2] World Intellectual Property Organization – Standing Committee on the Law of Patents - SCP/15/3 – Annex III – Biotechology -- Denis Borges and Karin Grau-Kuntz - September 2, 2010

This sentiment explains why various lobbyists and interest groups call for the per se exclusion of the patentability of genes: because they want it to be absolutely clear that scientists can utilize genes in various ways without worrying about the complexities of patent law. Although some have denied that patenting inhibits the free flow of knowledge in the way that these critics suggest (for example, emphasizing the existence of research exemptions), what is of interest here is not the merits of the specific positions, so much as the legal expression of the policy as an exclusion from patentability."[3]

Late last year, during a White House briefing, the U.S. government announced an administration-wide position regarding isolated biological materials and stated that they are not patentable subject matter under U.S. patent law. We strongly agree with this position.

We respectfully urge the Committees to recommend that the Bill be passed in its current form to ensure the advance of medical and scientific research and the availability to all Australians of quality, safe and efficacious medicines at a sustainable cost that the nation can afford.

Sincerely,

Heather M. Bresch
President
Mylan Inc.

[3] World Intellectual Property Organization – Standing Committee on the Law of Patents - SCP/15/3 – Annex I – Prof. Lionel Bently, Center for Intellectual Property and Information Law, Cambridge University, United Kingdom –September 2, 2010