Murdoch Childrens Research Institute Submission-

Patent Amendment (Human Genes and Biological Materials) Bill 2010

The Murdoch Childrens Research Institute (MCRI) is a large, independent medical research institute with over 1,000 staff. Our mission is to increase knowledge through laboratory, clinical and public health research to improve the health of children. MCRI is one of the top three Medical Research Institutes in Australia awarded NHMRC funding and incorporates as a wholly owned subsidiary the Victorian Clinical Genetics Service which provides a genetic clinical and diagnostic service to Victoria and Tasmania. We welcome the opportunity to respond to the Consultation Paper.

We agree in principle with the spirit and intention of the amendment; however the following examples are presented to highlight the difficulties for Medical Research Institutes if the changes were to be made to the Bill. An inability to patent naturally occurring gene sequences and biological materials would have a direct effect on two of our current patent applications. These applications have not yet been examined and would therefore be subject to the changes suggested in the amendment. The applications refer to the patenting of a neonatal vaccine for rotavirus and a diagnostic test for the genetic condition Fragile X syndrome. In both cases the base claim for the patent applications relies on patenting the biological materials which are the rotavirus strain found occurring in nature and the specific DNA sequence in the Fragile X syndrome gene related to the diagnostic test. We have included information below to support this argument that the inability to patent biological material would deter large biotechnology companies from investing money to develop and commercialise unprotected biological products.

RV3- Rotavirus neonatal vaccine

Rotavirus is the leading cause of severe diarrhoea among infants and young children. Each year more than 500,000 children die from diarrhoeal disease caused by rotavirus, and another two million are hospitalised. Nearly every child in the world will suffer an episode of diarrhoea caused by rotavirus before age five.

The RV3 Rotavirus Vaccine Program builds on 40 years of internationally recognized contribution to the understanding of rotavirus infection and the development of rotavirus vaccines, led by the group that initially discovered rotavirus in 1973.

RV3 was initially prepared as a vaccine from a naturally occurring asymptomatic strain found circulating in a neonatal ward in Melbourne. This vaccine was demonstrated to be safe and well tolerated in children in the 1990s but the immunogenicity was sub-optimal. The chief laboratory scientist selected from the virus pool another naturally occurring strain of the virus which had improved growth characteristics as well the ability to grow in a vaccine approved cell line. It

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is this naturally attenuated live rotavirus which is the basis of the vaccine and the “composition of matter” claim in the patent application.
The vaccine is at the end of Phase I trials in Australia with Phase IIa and Phase IIb clinical trials in New Zealand and Indonesia to commence in the second half of 2011. The clinical trial in Indonesia is in association with BioFarma. Bio Farma is the largest vaccine company in the ASEAN countries with a 120 year history of producing sera and vaccines. We have also have had discussions with large Pharma that are very interested in the outcomes of the clinical trials. These discussions have focused on intellectual property and our patent in this area.

Fragile X Syndrome (FXS) Diagnostics
Fragile X is the most common cause of inherited mental impairment. This impairment can range from learning disabilities to more severe cognitive or intellectual disabilities. FXS is the most common known cause of autism or "autistic-like" behaviours. Fragile X is a family of genetic conditions, which can impact individuals and families in various ways. These genetic conditions are related in that they are all caused by gene changes in the same gene, called the FMR1 gene.
An MCRI researcher has identified new regions of the human genome that are essential for expression of the FMR1 gene. The naturally occurring modification to these regions (referred to as methylation) can alter the expression of the gene and the severity of the disease. These regions can be used in the diagnosis of this common genetic condition. We have a series of patent applications that claim this region and its use for the diagnosis of FXS and related diseases. We are in negotiation with a large pharmaceutical/diagnostic company regarding these patents and have also been successful in acquiring an NHMRC development grant and a US-based philanthropic grant to further develop the work.

In conclusion we are unable to support the proposed amendment.

Yours sincerely,

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