22 April 2010

Naomi Bleeser
Committee Secretary
Senate Community Affairs References Committee
Parliament House
Canberra ACT 2600

c/o Community.Affairs.Sen@aph.gov.au

Dear Ms Bleeser

Thank you for the opportunity to comment on Senator Heffernan's extensive submission to the Senate inquiry into gene patents. Please pass my comments on to the Committee as discussed.

On behalf of Cancer Council Australia, I support the findings and core recommendations in Senator Heffernan's submission.

As a medical oncologist, cancer researcher and bioethicist responsible for the nation's largest non-government cancer organisation, I believe the current gene patenting system poses a significant risk to the future of equitable cancer care in Australia, as articulated in Senator Heffernan's submission.

The examples in Senator Heffernan's submission of how the patents system has, or could have been, exploited by commercial interests at a significant cost to individual patients and the health system in Australia make a compelling case for gene patent reform.

In a cancer context, the most prominent gene patents discussed throughout the inquiry were those awarded for the genetic mutations BRCA1 and BRCA2, which a commercial entity tried to enforce in 2008 to monopolise life-saving breast and ovarian cancer risk tests. As Senator Heffernan's submission points out, there was nothing in the current system or laws to prevent this monopolisation occurring. Moreover, as a cancer scientist, I am deeply concerned that similar risks to publicly available familial cancer tests are likely to become commonplace unless patent law is amended before the technology evolves further.

The risks to competitive cancer research posed by gene patents and explored in Senator Heffernan's submission are also of great concern, particularly to non-profit medical researchers whose work over many years has built the foundations of evidence-based medical science. For example, the human genome was mapped to advance medical science without any profit motive; yet gene patents may restrict the progress of similar work in discovering how cancer develops at the genetic level.

Cancer genetics have long been a professional interest of mine. I can thus assert, in a scientific context, that the process of isolating or purifying biological materials such as genetic sequences is an act of discovery, not invention. This fundamental distinction underpins the gene patents debate. The widely agreed (apparently by all stakeholders except commercial interests) scientific view that genes and their products are discoveries is borne out accurately in the descriptions of inventive step and method of manufacture in Senator Heffernan's submission. Since the submission was published, a US court has ruled that the BRCA1 and BRCA2 patents are invalid – specifically on the basis that the gene mutations were "discovered" and not "invented".

In summary, Senator Heffernan's submission is a comprehensive exploration of the evidence that supports the urgent need for gene patent reform.

I understand some of the recommendations in Senator Heffernan's submission may be considered difficult to implement, particularly in a legal context. If so, it is in my view critical that the Committee nonetheless recommends that fundamental amendments to the Patent Act 1990 are required to ensure gene patents are not exploited at great cost to the community as genetic cancer technology evolves. Amending the Act to clarify that the isolation or purification of genetic material is not an inventive step, and that natural biological materials are thereby excluded from the definition of patentable subject matter, is the key.

I would welcome the opportunity to elaborate further, should any Committee members require additional information, particularly in relation to how gene patents can impact adversely on cancer care.

Yours sincerely

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