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Senate Legal and Constitutional Affairs Legislation Committee

Inquiry into Patent Amendment (Human Genes and Biological Materials) Bill 2010

Submission by Professor Andrew Christie

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SUMMARY

1. The Bill in its current form runs the real risks of not achieving its stated aim, and of achieving outcomes neither sought nor desirable.

2. This is because the Bill applies the wrong test for distinguishing between a discovery and an invention.

3. Instead of amending the patents legislation in the way proposed in the Bill, the legislation should be amended so as to clearly codify the correct test for distinguishing between a discovery and an invention – namely, the requirement that material be an artificially created state of affairs.

MY QUALIFICATIONS

I make this submission in my individual professional capacity – that is, as an academic and professional lawyer with more than 25 years' experience in intellectual property matters, with a particular focus on patents.

Prior to my appointment to the Davies Collison Cave Chair of Intellectual Property in the Melbourne Law School in 2002, I held positions at law schools at the University of Cambridge, the University of Melbourne, the University of Toronto and Duke University. I am admitted to legal practice in Australia and the United Kingdom, and I worked for a number of years in the intellectual property departments of major law firms in Melbourne and London.

I was a member of the Advisory Committee on Genetics, Intellectual Property and Human Health, appointed by the President of the Australian Law Reform Commission (ALRC) to assist the ALRC with its inquiry into *Gene Patenting and Human Health*. From 2002 to 2010, I was a member of the Advisory Council on Intellectual Property (ACIP), a body appointed by the Minister for Innovation, Industry, Science and Research to advise him on intellectual property policy and administration. I chaired the working group of ACIP that conducted the review of *Patentable Subject Matter*, the final report of which was provided to the Minister in December 2010.

MY CONCERNS

My concerns with the Patent Amendment (Human Genes and Biological Materials) Bill 2010 are that it both does too little and does too much.

The Bill does too little in the sense that it does not achieve its primary stated aim. The Bill does too much in the sense that it is likely to have a practical effect beyond (and possibly inconsistent with) its stated aim – i.e. have unintended consequences.

The Bill does too little

As both the Explanatory Memorandum accompanying the Bill and Senator Heffernan's Second Reading Speech make clear, a primary aim of the Bill is to "reinforc[e] the applicability of the distinction between discovery and invention".

The main means by which the Bill seeks to achieve this aim is by excluding from patentability "biological materials … which are identical or substantially identical to such materials as they exist in nature". Unfortunately, this means does not achieve the aim. The distinction between a non-patentable discovery and a patentable invention is not determined by whether or not the material is identical or substantially identical to that which exists in nature. Rather, the distinction is determined by whether or not the material is an artificially created state of affairs. Thus, the Bill uses the wrong criterion for drawing the distinction that it seeks to reinforce.

The "artificially created state of affairs" criterion has been recognised as the appropriate test for distinguishing between a discovery and an invention since at least the 1959 decision of the Australian High Court in *National Research Development Corporation v. Commissioner of Patents* (1959) 102 CLR 252 ("*NRDC*"). In adopting this form of words, the High Court sought to make it clear that the key determinant of whether subject matter is an invention is the extent to which the alleged inventor has "created" (as distinct from "discovered") the material.

This determinant is, in essence, the same as the determinant used in the United States of America for distinguishing between discovery and invention. As the U.S. Supreme Court in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), confirmed, the test for inherent patentability is that the material is "made by man" – i.e. is human-made. The relevant issue, therefore, is not the extent of the similarity (or difference) between the claimed material and material which exists in nature. Rather, the relevant issue is the extent to which the claimed material can be said to be the result of a "transformation" (*American Fruit Growers, Inc. v. Brodgex Co.*, 283 U.S. 1, 12-13 (1931), citing *Anheuser-Busch Brewing Association v. United States*, 207 U.S. 556, 562 (1908), citing *Hartranft v. Wiegmann*, 121 U.S. 609). Naturally occurring material that has been transformed by human intervention in nature is human-made, and so is an invention rather than a discovery.

To focus, as the Bill does, on the extent to which claimed biological material is "identical or substantially identical to such materials as they exist in nature" is to apply the wrong test for distinguishing between a discovery and an invention. Thus, I believe the Bill will not achieve the stated aim of reinforcing the (correct) distinction between discovery and invention.

The Bill does too much

By applying the wrong test for distinguishing between a discovery and an invention the Bill not only fails to achieve the stated aim; it runs a real risk of achieving an outcome different from that sought. It seems to me quite possible for a patent application to claim biological material that is an artificially created state of affairs, but nevertheless is substantially identical to material existing in nature. In such a situation, the Bill would (wrongly) preclude the availability of a patent for that material.

(As an aside, I note that it may not be beyond the bounds of possibility for a patent application to claim biological material that is not substantially identical to material that exists in nature, but nevertheless is not an artificially created state of affairs. In such a situation, the availability of a patent for that material would be wrongly permitted, if the determinant of patentability were the material's substantial identity rather than its artificial creation.)

MY SUGGESTIONS

I share the aspiration of those behind the Bill, which I understand to be a desire to amend the patents legislation so as to make clear the distinction between a discovery and an invention, especially as it applies to biological materials. I believe that this would best be achieved by adopting the recommendations contained in the ACIP report of its review of *Patentable Subject Matter*. Those recommendations resulted from a detailed, consultative process undertaken by an independent, expert body.

The ACIP recommendation of most relevance to this Committee's inquiry is Recommendation 3, which reads as follows:

> Define patentable subject matter in the *Patents Act 1990* (Cth), for the purposes of both a standard patent and an innovation patent, using clear and contemporary language that embodies the principles of inherent patentability as developed by the High Court in the *NRDC* case and in subsequent Australian court decisions.

Some supporters of the Bill in its current form may say that this recommendation is insufficient to achieve the aspirations of those behind the Bill. They may say that a weakness of the recommendation is that it is not specially directed to biological materials, but rather applies to all subject matter. In my view, that is not a weakness but a strength of the recommendation. The patent legislation should, as a matter of principle and of necessity, strive to be technology-neutral and technology non-specific.

Some supporters of the Bill in its current form may say that the ACIP recommendation is insufficient because it does not give enough detail as to how to distinguish between a discovery and an invention – or, put another way, does not

"define" an invention in sufficient detail. While the desire for a detailed definition is understandable, it is not realistic. The concept of patentable subject matter, like many fundamental legal concepts, must be phrased at a relatively high level of generality. This fact was recognised by the Australian High Court in *NRDC*, when it said "any attempt to state the ambit of s. 6 of the *Statute of Monopolies* by precisely defining 'manufacture' is bound to fail". I believe that any attempt to precisely define which biological materials are discoveries rather than inventions is, likewise, bound to fail.

The better approach, in my view, is to insert into the patent legislation words that explain the distinction between a discovery and an invention, and leave for determination by patent examiners (and, if necessary, by courts) the application of that distinction to biological (and, for that matter, all other) materials on a case-by-case basis.