
“Human beings” as excluded subject matter for the purposes of the Patents Act 1990 (Cth)

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The purpose of this article is to review the meaning of “human beings” as it is used in the Patents Act 1990 (Cth). The analysis demonstrates that the meaning remains uncertain and that appeals to essential characters and taxonomic conceptions of “human beings” are not satisfactory. The article concludes that the existing qualitative test of what constitutes “essentially human characteristics” (that is not defeated by any technological means of how the “human being” is constituted or created), and the “unlikely to be ephemeral” standard in applying the “contrary to law” exclusion for post-patent grant exploitation limitations, are problematic.

INTRODUCTION

The *Patents Act 1990* (Cth) grants exclusivity¹ to certain dealings with some biological organisms.² The concern of this article is that the terminology of inclusion and exclusion used in the *Patents Act* for the grant of exclusivity fails to meaningfully conceptualise the biological organisms referred to as “human beings”.³ The purpose of the article is to examine the current state of interpretation by IP Australia, the potential for practice in other jurisdictions to assist in this interpretation and whether taxonomy (the classification of organisms) might assist interpretation. The analysis is timely as any discussion about including or excluding “human beings” as suitable subject matter for the *Patents Act* needs to ascertain the content of the likely inclusion or exclusion. The conclusion is significant as the analysis shows the existing approaches to interpreting the exclusion of “human beings” is problematic.

The article is structured as follows. The next part maps the statutory schemes in the *Patents Act* for the exclusion of subject matter as “contrary to law” and “[h]uman beings, and the biological processes for their generation, are not patentable inventions”.⁴ The following parts consider whether some assistance might be gained from the use of the “essentially” terminology in the *Convention on the Grant of European Patents (European Patent Convention)*,⁵ and then the likely application of taxonomy following on from the ordinary dictionary meaning of the phrase “human beings”. The article concludes that the meaning of “human beings” in the *Patents Act* remains uncertain with flaws in the current approach by IP Australia.

PATENTS ACT 1990 (CTH) SCHEME

Following an application for a “standard patent”,⁶ the Commissioner of Patents (in IP Australia) makes an assessment of the various threshold criteria on examination (including a “modified

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¹ See *Patents Act 1990* (Cth), s 13(1).

² *Patents Act 1990* (Cth), s 18(2) specifically excludes “human beings” from “standard patents” and “innovation patents”, s 18(3) specifically excludes “plants” and “animals” from “innovation patents”. Any other biological organisms that satisfy the requirements of the Act will be patentable.

³ See *Patents Act 1990* (Cth), s 18(2).

⁴ See *Patents Act 1990* (Cth), ss 18(2), 50(1)(a).

⁵ 5 October 1973 as amended by the Act revising Art 63 *Convention on the Grant of European Patents*, 17 December 1991, as affected by decisions of the Administrative Council of the European Patent Organisation, 21 December 1978, 13 December 1994, 20 October 1995, 5 December 1996, 10 December 1998, 27 October 2005 and the provisionally applicable provisions of 29 November 2000.

⁶ *Patents Act 1990* (Cth), Sch 1 “standard patent”.



examination”),⁷ opposition,⁸ and re-examination.⁹ Others can later seek the revocation of a granted patent in proceedings,¹⁰ including as a cross-claim to infringement.¹¹ A part of the assessment at each of these stages is whether the alleged invention is appropriate subject matter.¹² The exclusions set out in the *Patents Act* relate to inventions that are “generally inconvenient”,¹³ “contrary to law”,¹⁴ certain “food or medicine”,¹⁵ and “[h]uman beings, and the biological processes for their generation, are not patentable inventions”.¹⁶

Following an application for an “innovation patent”,¹⁷ the Commissioner must accept the “patent request”,¹⁸ and “complete specification”¹⁹ following a “formalities check”.²⁰ Subsequently, the Commissioner assesses the complete specification,²¹ assessing the various threshold criteria on examination²² and re-examination.²³ The Commissioner and others can seek the revocation of a granted innovation patent either by the Commissioner²⁴ or in proceedings,²⁵ including as a cross-claim to infringement.²⁶ A part of the assessment at examination, opposition and revocation is whether the alleged invention is appropriate subject matter.²⁷ The exclusions set out in the *Patents Act* relate to inventions that are “generally inconvenient”,²⁸ “contrary to law”,²⁹ to certain “food or medicine”,³⁰ to “[h]uman beings, and the biological processes for their generation, are not patentable inventions”,³¹ and “plants and animals” and “the biological processes for the generation of plants and animals”.³²

⁷ *Patents Act 1990* (Cth), s 45(1) “examination”, s 48(1) “modified examination”, s 3 and Sch 1 “examination”, “modified examination”.

⁸ *Patents Act 1990* (Cth), s 59.

⁹ *Patents Act 1990* (Cth), s 97(1), “pre-grant”, s 98(1) “post-grant”. Notably, this expressly does not apply to “innovation patents”: s 96A.

¹⁰ *Patents Act 1990* (Cth), s 138, “revocation in circumstances other than surrender”. Notably the patent holder can also seek revocation on surrender of the patent: s 137 “revocation on surrender”.

¹¹ *Patents Act 1990* (Cth), s 121(1) “cross-claim to infringement”.

¹² See *Patents Act 1990* (Cth), ss 45(1)(b), (c), “examination”, s 48(1)(a), (b), “modified examination”, s 59(b), “opposition”, s 98(1), “re-examination”, s 138(3)(b), “revocation in other circumstances”.

¹³ *Patents Act 1990* (Cth), ss 18(1), 18(1)(a) and Sch 1 “invention” (“s 6 of the *Statute of Monopolies*”).

¹⁴ *Patents Act 1990* (Cth), s 50(1)(a).

¹⁵ *Patents Act 1990* (Cth), s 50(1)(b).

¹⁶ *Patents Act 1990* (Cth), s 18(2).

¹⁷ *Patents Act 1990* (Cth), Sch 1 “innovation patent”.

¹⁸ *Patents Act 1990* (Cth), s 3 and Sch 1 “patent request”.

¹⁹ *Patents Act 1990* (Cth), s 3 and Sch 1 “complete specification”.

²⁰ See *Patents Act 1990* (Cth), s 3 and Sch 1 “formalities check”; s 52(1), (2); *Patents Regulations 1991* (Cth), reg 3.2B.

²¹ *Patents Act 1990* (Cth), ss 101A, 101B(1) “examination”, s 101G “re-examination”, s 101N(3) “opposition”.

²² *Patents Act 1990* (Cth), s 101B(1) “examination”.

²³ *Patents Act 1990* (Cth), s 101G(2) “re-examination”.

²⁴ *Patents Act 1990* (Cth), s 101F, after “examination”, s 101J, after “re-examination”, s 101N “opposition”.

²⁵ *Patents Act 1990* (Cth), s 138 “revocation in circumstances other than surrender”. Notably the patent holder can also seek revocation on surrender of the patent: s 137 “revocation on surrender”.

²⁶ *Patents Act 1990* (Cth), s 121(1) “cross-claim to infringement”.

²⁷ See *Patents Act 1990* (Cth), s 101B(2)(b) “examination”, s 101M(b) “opposition”, s 138(3)(b) “revocation in other circumstances”. Notably “re-examination” is confined to the thresholds of “novel” and “innovative step”: s 101G(3).

²⁸ *Patents Act 1990* (Cth), ss 18(1A), 18(1A)(a) and Sch 1, “invention” (“s 6 of the *Statute of Monopolies*”).

²⁹ *Patents Act 1990* (Cth), s 101B(2)(d). Notably, this only applies on “examination”: s 101B(1).

³⁰ *Patents Act 1990* (Cth), s 101B(4). Notably, this only applies on “examination”: s 101B(1).

³¹ *Patents Act 1990* (Cth), s 18(2).

³² *Patents Act 1990* (Cth), s 18(3).



Presumably, for "innovation patents" the standards of exclusion of "contrary to law", certain "food or medicine", and to "[h]uman beings, and the biological processes for their generation, are not patentable inventions" will be the same as those applying to "standard patents".³³ The exclusion of "plants and animals" and "the biological processes for the generation of plants and animals" is, however, confined to "innovation patents" and not considered further here. The following analysis addresses the exclusions "contrary to law", and "[h]uman beings, and the biological processes for their generation, are not patentable inventions".³⁴ These exclusions are considered because they directly address the exclusion of "human beings" as suitable subject matter under the *Patents Act*.

"Contrary to law"

The *Patents Act*, s 50(1)(a) applies only on examination and modified examination,³⁵ and provides:

The Commissioner *may* refuse to accept a request and specification relating to a standard patent, or to grant a standard patent: (a) for an invention the use of which would be contrary to law (emphasis added).³⁶

The exclusion of alleged inventions that are "contrary to law" is, in practice, a narrow exclusion exercised at the discretion of the Commissioner. It is "to be understood as covering broadly statute law, including regulations and ordinances, and case law" and addressing inventions that "either (1), one [of] the primary use of which would be a criminal act, punishable as a crime or misdemeanour, or, (2), one [of] the use of which would be an offence by reason of its being prohibited under by-laws or regulations made for police and administrative purposes", but only "where an unlawful use and no lawful use has been described".³⁷ As a consequence this is a discretion rarely exercised by the Commissioner. A recent example illustrates how this discretion might be exercised in respect of "human beings".

The alleged invention in *Woo-Suk Hwang's Application* [2004] APO 24 (9 September 2004) was a method of replacing cow embryo nucleus with a human nucleus to produce a hybrid embryo. The delegate of the Commissioner noted that the discretion to exclude alleged inventions as "contrary to law" was rarely exercised and that it "should only be applied in the clearest of circumstances" (at [12]). The *Prohibition of Human Cloning Act 2002* (Cth) provided that it was an offence if "the person intentionally creates a hybrid embryo", being "an animal egg into which the nucleus of a human cell has been introduced".³⁸

³³ Presumably "innovation patents" will also exclude "human beings". As a matter of interpretation the express exclusion of "animals" from "innovation patents" will also exclude those organisms also defined as "human beings" that are a part of the content of "animals". While arguable, there is no discourse asserting that the later inclusion of the express exclusion of "animals" from "innovation patents" (through *Patents Amendment (Innovation Patents) Act 2000* (Cth)) modified the earlier exclusion of "human beings" so that an "innovation patent" might be available for "human beings".

³⁴ Notably, in recent times the exclusion of "generally inconvenient" has been narrowly construed by the courts so that its application to particular subject matters other than methods of medical treatment is doubtful, and its application to methods of medical treatment has been rejected by a majority of the Federal Court: see *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1; 28 IPR 383 at 389 (Lockhart J), 423 (Wilcox J); *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (1998) 41 IPR 467 at 557-558 (Black CJ and Lehane J). See also *Pfizer Inc v Commissioner of Patents (NZ)* (2004) 60 IPR 624 at 626 (Anderson P), 636 (Glazebrook, William Young and O'Regan JJ). See generally Pila J, "Methods of Medical Treatment within Australian and United Kingdom Patents Law" (2001) 24 UNSWLJ 420. See also *Australian Patent Office: Manual of Practice and Procedures* (IP Australia, 2009) at [2.9.3]: "There is really no clear guidance as to when an invention may or may not be regarded as 'generally inconvenient'. Hence, examiners should refrain from taking this objection".

³⁵ *Patents Act 1990* (Cth), s 45(1)(d) "examination", s 48(1)(c) "modified examination"; *Patents Regulations 1991* (Cth), reg 3.18(2)(c).

³⁶ Notably, "contrary to law" is also an express limitation imposed by the *Patents Act 1990* (Cth) ss 18(1), 18(1)(a) threshold requirements of "invention" and "manner of manufacture within the meaning of s 6 of the *Statute of Monopolies*" where s 6 of the *Statute of Monopolies* provides "that any declaration before mentioned shall not extend to any letters patents and grants of privilege for the term of fourteen years or under, hereafter to be made, of the sole working or making of any manner of new manufactures within this realm, to the true and first inventor and inventors of such manufactures, which others at the time of making such letters patents and grants shall not use, so as also they be not contrary to the law".

³⁷ See *Manual of Practice and Procedures*, n 34, [2.9.6].

³⁸ *Prohibition of Human Cloning Act 2002* (Cth), s 8(1) "hybrid embryo", s 20(2).



The delegate reasoned that the alleged invention (addressed in more detail below) could *only* be applied to humans according to the description and claims set out in the application, and so was one that “the primary use of which would be a criminal act, punishable as a crime or misdemeanour” and so was excludable. In exercising the discretion, however, the delegate considered that “it seems to me that a relevant consideration is whether the relevant law is of an ephemeral nature – that is, whether it is reasonable to expect that what is illegal today will be illegal throughout the term of the patent”. As the prohibitions in the *Prohibition of Human Cloning Act 2002* (Cth)³⁹ were “unlikely to be ephemeral” then the discretion should be exercised excluding patentability (at [15]-[19]).⁴⁰

“Human beings”

The exclusion of “human beings, and the biological processes for their generation, are not patentable inventions” was a late amendment to the principal *Patents Act*.⁴¹ The outcome of these parliamentary debates was summarised in *Re Luminis Pty Ltd and Fertilitescentrum AB* (2004) 62 IPR 420 at [25] 427-428; [2004] APO 19:

several points can be gleaned from the parliamentary debates:

- Much of the debate was a contrary reaction to Senator Coulter’s amendment, which would have had the effect of excluding genetic material and life forms from patentability;
- There was a clear intention to continue to allow the patentability of life forms – with a recognition that research into medical issues was very important;
- There was unanimous agreement that human beings (whatever might be encompassed by the term) were not patentable;
- There was a clear intention to exclude not just human beings, but also of the “biological processes for their generation”; and
- While the scope of “biological processes for their generation” was queried by Senator Coulter, there was no detailed elaboration. Senator Harradine gave techniques for cloning at the four-cell stage as an “extreme example” which suggests the exclusion relates primarily to reproductive technologies of much lesser significance than cloning. The opposition thought the exclusion was “essentially” of in-vitro fertilisation and cloning for reproduction purposes. But they also thought that there should not be patenting of “any human production process for generation in any way, shape or form”. The government merely stated that the biological processes for their generation would not be patentable inventions – without any indication of scope, nor disagreement with the views of the opposition or Senator Harradine.⁴²

The delegate considered a claim to the substance granulocyte-macrophage colony-stimulating factor (GM-CSF) that was (at [1] 421):

effective at substantially increasing the proportion of early embryos that develop to blastocyst and increasing the proportion of those embryos that continue to expanded blastocyst and then hatched blastocyst stages of development.

³⁹ Notably this provision was amended by the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cth), s 3 and Sch 1 (item 7) and the equivalent prohibition is now set out as *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 18, providing: “A person commits an offence if the person intentionally develops a hybrid embryo for a period of more than 14 days, excluding any period when development is suspended” (emphasis added). The former provision: “A person commits an offence if the person intentionally creates a hybrid embryo” (formerly s 20(2)).

⁴⁰ It appears that *Woo-Suk Hwang’s Application* [2004] APO 24 (9 September 2004) might now be decided differently on this point on the basis that the alleged invention could now have been lawfully used for up to 14 days (excluding periods of suspended development): see *Manual of Practice and Procedures*, n 34, [2.9.6]: “Where the invention could be used both for lawful and for unlawful purposes, there is authority in *Pessers and Moody v Haydon & Co* (1909) 26 RPC 58, for saying that a patent in respect of it would not necessarily be bad”.

⁴¹ For an overview of these developments: see *Re Luminis Pty Ltd and Fertilitescentrum AB* (2004) 62 IPR 420 at 425-428; [2004] APO 19; Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Report 99 (2004) pp 168-191 (ALRC Report 99).

⁴² See also Agovic A, “Stem Cell Patents on a Knife Edge” (2008) 3 JIPLP 718 at 720-724; Rimmer M, *Intellectual Property and Biotechnology: Biological Inventions* (2008) pp 250-252; ALRC Report 99, n 41, pp 381-382; Rimmer M, “The Attack of the Clones: Patent Law and Stem Cell Research” (2003) 10 JLM 488 at 489-495.



The patent also claimed a method of growing pre-blastocyst human embryos that the examiner objected to as contrary to the exclusion of “human beings” and the “biological processes for their generation”. The independent claim provided (at [4] 421):

A method of growing pre-blastocyst human embryos, the method including the step of incubating the embryos in vitro in a culture medium containing an effective amount of human GM-CSF to increase the chance of implantation of the embryos, the amount of the GM-CSF being sufficient to increase the proportion of blastocysts formed from the pre-blastocyst embryos when compared to embryos incubated in a medium lacking GM-CSF.

The examiner contended that the claim was to “a step along the path of generating a human being”, while the applicant contended that as the method was applied *after* “the time the pro-nucleii of the fertilised ovum have coalesced so as to obtain mixing of the genetic materials from the respective parents”, thus *after* a human being was formed, and was therefore a treatment of a human being (at [5] 421-422).

In a challenge against the examiner’s contentions, the applicant made submissions as part of a process of amending the application.⁴³ The delegate considered that in interpreting the exclusion of “human beings” and the “biological processes for their generation” fixing on “some particular point in the reproductive process” would fail as there was “no way of reconciling the divergent views” about the appropriate point. He also rejected any interpretation fixed by the method, such as cloning, nuclear transfer, and so on. The delegate’s favoured approach was to recognise that “the generation of a human being (as distinct from a human life form) occurs over a substantial period of time” (at [31] 428-429).

This period of time was bounded by the start at “a human life form is created at fertilisation” (at [32]) and was completed at “the *full* status of human being is not acquired until birth” (at [35]), such that for “human beings” (at [37] 430):

The prohibition of “human beings” in my view is a prohibition of patenting of any entity that might reasonably claim the status of a human being. Clearly a person that has been born is covered by this exclusion. But to the extent that there is a process of generation of a human being that lasts from fertilisation to birth, I consider that a fertilised ovum and all its subsequent manifestations are covered by this exclusion.

And for “biological processes for their generation” (at [38] 430):

The prohibition of “biological processes for (the generation of human beings)” clearly covers all biological processes applied from fertilisation to birth – so long as the process is indeed one that directly relates to the generation of the human being. I also consider the exclusion of biological processes includes the processes of generating the entity that can first claim a status of human being. For example, processes for fertilising an ovum; processes for cloning at the four-cell stage by division; processes for cloning by replacing nuclear DNA.

The decision in this case was that the claim was within the exclusion of “biological processes for their generation”. This was because “it is a process involving the presence of a chemical such that the in vitro environment better simulates the natural fallopian tube environment” and as such “the process is one that directly relates to the generation of a human being” (at [40] 430).

Further insight into the meaning of “human beings” has been provided in the IP Australia decision of *Woo-Suk Hwang*, where the alleged invention was essentially a method to create a de-nucleated cow embryo shell (including the cow’s mitochondrial DNA) with human nuclear DNA, and claiming, in part:

- A method for producing chimeric embryos derived by nuclear transfer using human cells as nucleus donors and enucleated bovine oocytes as recipients, which comprises the steps of:
- (i) preparing non-totipotent, non-immortalised donor somatic human cell lines;
 - (ii) maturing oocytes collected from cow ovary in vitro;
 - (iii) removing cumulus cells surrounding the oocytes, cutting a portion of zona pellucida of the matured oocytes to make a slit, and squeezing out a portion of cytoplasm including the first polar body through the slit to give enucleated recipient oocytes;

⁴³ See *Patents Act 1990* (Cth), s 107.



- (iv) transferring a nucleus into the recipient oocyte by injection of the whole donor cells into the enucleated recipient oocytes through the slit, followed by subsequent electrofusion and activation of the electrofused cells to give chimeric embryos; and
- (v) post-activating, culturing and differentiating the chimeric embryos in vitro.⁴⁴

The delegate of the Commissioner distinguished *Luminis* on the basis that in this application “there is no step of fertilisation per se” and “the embryo is a hybrid involving both human and bovine DNA”. In deciding that the alleged invention was excluded as a “method for the generation of a human being” the delegate articulated two significant propositions. First, that “an ovum that has been artificially activated is in principle no different to an ovum that has been fertilised by natural means”, and “post-activation of the ovum does not remove the process from the ambit of the [exclusion]”.⁴⁵ Secondly, that:

The embryo produced by the claimed process has both human and bovine DNA present. It is clear that the nuclear DNA is intended to be entirely human DNA. The mitochondrial DNA, which essentially is relevant to the energy use of the cell, is entirely bovine. The primary physical characteristics of mammals are governed by the nuclear DNA of the cells. In my view, the presence of the bovine mitochondrial DNA does not take away the *essentially human characteristic* of the embryo that is determined by the nuclear DNA. That is, the embryo that is produced by this method – while being hybrid – is properly described as human [emphasis added].⁴⁶

In short, this is a qualitative test of what constitutes “*essentially human characteristic[s]*” and is not defeated by any technological means of how the “human being” is constituted or created. These decisions have been interpreted by IP Australia to exclude from patentability “human beings” comprising “fertilised human ova and equivalents, zygotes, blastocysts, embryos, fetuses, and totipotent human cells including those cells that are the products of nuclear transfer procedures”.⁴⁷ The “biological processes for generating human beings” that might be excluded from patentability are:

methods of in vitro fertilisation, processes for intra-cytoplasm sperm injection, processes for cloning at the 4-cell stage, processes for cloning by replacing nuclear DNA, processes or methods of growing or culturing fertilised ova, zygotes or embryos, and so on, and processes or methods for introducing transgenes and donor genetic or donor cytoplasmic material into fertilised ova, zygotes or embryos, and so on.⁴⁸

As a proposition accepted by IP Australia, however, the benefit of any doubt is likely to favour the patent applicant:

To date there has been no judicial consideration of [*Patents Act 1990* (Cth)] s 18(2) and it remains unclear which inventions would be strictly caught by that provision. In the absence of any judicial consideration, IP Australia is required to give applicants the benefit of the doubt in relation to the patentability of inventions concerning human material. This follows from the decision of the High Court in the case of *Commissioner of Patents v Microcell* (1959) 102 CLR 232, which held that the Commissioner ought not to refuse acceptance of an application and specification unless it appears practically certain that a patent granted on a specification would be invalid.⁴⁹

More recently, IP Australia has stated:

Although IP Australia’s position will no doubt change as the technology evolves, the organisation’s current interpretation [of s 18(2)] is that anything which has an inherent capability to mature and become a human being should be excluded. According to this, the more complex the subject matter, the

⁴⁴ *Woo-Suk Hwang’s Application* [2004] APO 24 at [5].

⁴⁵ *Woo-Suk Hwang’s Application* [2004] APO 24 at [7]–[10].

⁴⁶ *Woo-Suk Hwang’s Application* [2004] APO 24 at [9].

⁴⁷ *Manual of Practice and Procedures*, n 34, [2.9.5].

⁴⁸ *Manual of Practice and Procedures*, n 34, [2.9.5].

⁴⁹ IP Australia, *Submission to the House of Representatives Standing Committee on Legal and Constitutional Affairs Inquiry into the Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research*, Submission 274 (2000) p 4, <http://www.aph.gov.au/house/committee/laca/humancloning/sub274.pdf> (viewed 21 October 2009). See also *Manual of Practice and Procedures*, n 34, [2.15.1].



more likely it is to be excluded ... complexities arise for subject matter such as fertilised ovum, stem cells, foetuses, genetically modified animals containing human genes, and humans treated with animal tissue.⁵⁰

The problem remains that the exact meaning of "human beings" continues to be uncertain, albeit there appears to be a standard of essentialism favoured by IP Australia. Some assistance might be gained from the use of the "essentially" terminology in the *European Patent Convention*, and the ordinary meaning of the phrase "human beings". These are considered in turn.

"ESSENTIALLY" UNDER THE EUROPEAN PATENT CONVENTION

The *European Patent Convention* prohibition from patenting some subject matters on the basis of an "essentially" standard (Art 53(b)) provides:

European patents shall not be granted in respect of ... plant or animal varieties or *essentially biological processes* for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof [emphasis added].

Subsequent decisions have provided some insight into the likely meaning of "essentially biological processes" and the reasoning demonstrates the difficulty in applying this subjective concept.

In *Novartis/Transgenic plant* G01/98 [2000] EPOR 303, the Enlarged Board of Appeal of the European Patent Office considered a claim to a "transgenic plant and the seed thereof comprising recombinant DNA sequences" and a "method of preparing a transgenic plant which is able to synthesise one or more" polypeptides from the DNA sequences "*and crossing said plants using conventional breeding techniques*" (emphasis added).⁵¹ The issue referred to the Enlarged Board of Appeal was, in part, the following question (at 305):

Does a plant variety, in which each individual plant of that variety contains at least one specific gene introduced into an ancestral plant by recombinant gene technology, fall outside the provision of Art 53(b) [*European Patent Convention*] that patents should not be granted in respect of plant varieties or essentially biological processes for the production of plants, which provision does not apply to microbiological processes or the products thereof?

The reasoning of the Enlarged Board of Appeal (at 314-317) was coloured by the particular interaction between the *European Patent Convention* progenitor provision in the *Convention on the Unification of Certain Points of Substantive Law on Patents for Invention (Strasbourg Patent Convention)*,⁵² and *International Convention for the Protection of New Varieties of Plants* [2000] ATS 6 (UPOV 1961),⁵³ that were being negotiated in parallel.⁵⁴

As a consequence, that subject matter protectable under UPOV 1961 was ineligible for patent protection was accepted in interpreting the *European Patent Convention*, and so (at 321):

the term "plant variety" is appropriate for defining the borderline between patent protection and plant breeders' rights protection irrespective of the origin of the variety ... Since plant varieties are excluded, the only question is the conditions under which they are excluded.

The Enlarged Board of Appeal then accepted the reasoning of the referring Board that it would have been unfair to allow a patent for a genetically engineered plant variety while excluding a traditionally obtained plant variety that would have been eligible under UPOV 1961 (at 321):

The Enlarged Board of Appeal supports the view of the referring Board ... that the mere fact of being obtained by means of genetic engineering does not give the producers of such plant varieties a privileged position relative to breeders of plant varieties resulting from traditional breeding only. Given the purpose of Article 53(b) [*European Patent Convention*], question ... has to be answered in the negative.

⁵⁰ ALRC Report 99, n 41, p 383 citing IP Australia, *Submission P56*, 4 November 2003.

⁵¹ See *Novartis/Transgenic plant* T1054/96 [1999] EPOR 123 at 125.

⁵² Signed 27 November 1963; entered into force 1 August 1980.

⁵³ Signed 2 December 1961, as revised 10 November 1972, 23 October 1978 and 19 March 1991.

⁵⁴ *Strasbourg Patent Convention*, Art 2(b) and UPOV 1987, Art 2(1) purportedly banned dual protection (although this was abandoned in UPOV 1991).



The referring Board had provided:

In favour of coming to such a conclusion is the fact that this would meet the interests of the inventors and firms active in this field. Apart from the provision of Article 53(b) EPC, the European Patent Convention is already suited to deal with genetic engineering as applied to plant varieties. But, for the Board, there appears no reason why the mere fact of being derived by genetic engineering should give the producers of such plant varieties a privileged position relative to breeders of plant varieties which meet all the requirements of Article 52(1) EPC but have not been arrived at by genetic engineering.⁵⁵

The significance of the Enlarged Board of Appeal's decision was to decide the matter on the basis that a plant with added DNA sequences was still a "plant variety" (at 321). This did not consider the Board's approach to the question of "essentially biological processes for the production of plants or animals" because the applicant intended to amend its claims making the factual basis for any finding uncertain (at 307).⁵⁶ The Board, however, had considered three approaches, albeit they did not state a preference (at 308). Thus in *Novartis/Transgenic plant* T1054/96 [1999] EPOR 123 at 134 the Board had framed the issues as:

To decide whether a process can be defined as an "essentially biological process" requires a value judgment of the extent to which it should be non-biological before it loses the status of "essentially biological process", which value judgment can be arrived at by different approaches.

The various approaches were:

- (a) That the production of the plant (or animal) be only by "clearly identified non-biological process steps and no 'essentially biological' steps (whatever uncertainties may be attached to the term)" (at 134).⁵⁷ As an example, the Board suggested that crossing the allegedly invented plants using conventional breeding techniques would be impermissible.
- (b) That the "essentially biological" threshold be "judged on the basis of the essence of the invention, taking into account the totality of human intervention and its impact on the result achieved" (at 134).⁵⁸ Potentially a single *significant* human intervention would be enough to avoid the "essentially biological" threshold (at 134-135).⁵⁹
- (c) That the production of the plant includes "at least one clearly identified 'non-biological' process step" (at 135). This approach was consistent with the then European Community's *Draft Directive on the Legal Protection of Biotechnological Inventions in the European Union*, Art 2(2) approach that "[a] process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection" (at 135).⁶⁰

More recently, the Directive of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions was formalised and addressed the issue in an attempt to harmonise and clarify any uncertainty.⁶¹ There the Directive provided (Art 2): "A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection", and (Art 4(2)): "Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety."

These measures were incorporated into the *European Patent Convention* through the *Implementing Regulations of the Convention on the Grant of European Patents* (2000), rr 26(5) and

⁵⁵ *Novartis/Transgenic plant* T1054/96 [1999] EPOR 123 at 147-148.

⁵⁶ See also *Plant Bioscience/Broccoli* T0083/05 (2007) 12 *Official Journal of the European Patent Office* 644 at 658.

⁵⁷ Citing an analogous approach to *European Patent Convention*, Art 52(4) set out in *General Hospital/Contraceptive Method* [1995] EPOR 446.

⁵⁸ Citing the approach in *Lubrizol/Hybrid plants* T320/87 [1990] EPOR 173 at 177-179. See also *State of Israel/Tomatoes* T1242/06 (2008) 11 *Official Journal of the European Patent Office* 523 at 534; *Plant Bioscience/Broccoli* T0083/05 (2007) 12 *Official Journal of the European Patent Office* 644 at 656; *Harvard/Oncomouse* T19/90 [1990] EPOR 501.

⁵⁹ Citing the commentary in *Plant Genetic Systems/Glutamine synthetase inhibitors* T356/93 [1995] EPOR 357 at 376.

⁶⁰ See also *Plant Bioscience/Broccoli* T0083/05 (2007) 12 *Official Journal of the European Patent Office* 644 at 657-658.

⁶¹ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions (1998) *Official Journal of the European Communities* L 213/13, Recitals 9, 32, 33.



27(b).⁶² Appeals to the Enlarged Board of Appeal remain on foot addressing the exact operation of these provisions. In the first, in *Plant Bioscience/Broccoli* T0083/05 (2007) 12 *Official Journal of the European Patent Office* 644 at 645-647, the appellants challenged an opposition decision accepting as patentable an alleged invention that claimed a method of crossing *Brassica oleracea* plants and selecting for elevated levels of 4-methylsulfinylbutyl glucosinolates or 3-methylsulfinylpropyl glucosinolates using molecular markers.

The appellants contended that the subject-matter of the claims was an essentially biological process for the production of plants, and that the use of molecular markers in the selection step was not sufficient to escape the exclusion (at 649). The respondent asserted that the claimed method included one non-natural step and that was enough to remove the method from the exclusion as the claimed methods did not consist entirely of natural phenomena (at 650). The Board decided (at 651) to refer the matter to the Enlarged Board of Appeal, albeit setting out its particular perspective on the (conflicting) issues:

- (a) That the progenitor provisions of the *European Patent Convention* were drafted with the intention that term “biological” was used in opposition to “technical”, that the term “essentially” replaced the narrower term “purely”, and that for “plant breeding processes based on selection and hybridisation ... fall under the exclusionary provision even if secondary features of the processes were characterised by the use of technical devices” (at 655).
- (b) That the later Directive meant that “a process which, apart from ‘natural phenomena’ (which appear to cover crossing and selection by way of a legal fiction), contains an additional feature of a technical nature would be outside the ambit of the process exclusion” (at 661).

As a consequence of these conflicting propositions the Board considered that the effect of the Directive on interpreting the earlier decisions was difficult to reconcile and created an ambiguity (at 661-664). The Board posited the “correct approach”, referring (at 664-665) to the decision in *Novartis/Transgenic plant* T1054/96 [2000] EPOR 303 and *Harvard/Transgenic animal* T315/03 [2005] EPOR 31, suggesting that a step involving genetic manipulation was not “entirely of natural phenomena” and so taking the alleged invention outside the bounds of the exclusion. From the Board’s perspective the present matter required further Enlarged Board of Appeal consideration because there were clear steps of human technical intervention (at 666-667), but these would not have been sufficient in the light of the earlier decisions in *Lubrizol/Hybrid plants* T320/87 [1990] EPOR 173 and *Plant Genetic Systems/Glutamine synthetase inhibitors* T356/93 [1995] EPOR 357.⁶³

The question referred to the Enlarged Board of Appeal was, in part (in *Plant Bioscience/Broccoli* T0083/05 (2007) 12 *Official Journal of the European Patent Office* 644 at 669):

Does a non-microbiological process for the production of plants which contains the steps of crossing and selecting plants escape the exclusion of Art 53(b) [*European Patent Convention*] merely because it contains, as a further step or as part of any of the steps of crossing and selection, an additional feature of a technical nature?

Then in the second, in *State of Israel/Tomatoes* T1242/06 (2008) 11 *Official Journal of the European Patent Office* 523 the application claimed a method of crossing *Lycopersicon esculentum* plants with *Lycopersicon* species to produce hybrids and then re-crossing and selecting for reduced

⁶² Formerly *Implementing Regulations of the Convention on the Grant of European Patents* (1973), rr 23b(5), 23c. See also *Plant Bioscience/Broccoli* T0083/05 (2007) 12 *Official Journal of the European Patent Office* 644 at 658-660.

⁶³ *Lubrizol/Hybrid Plants* T320/87 [1990] EPOR 173 at 179 providing: “[the invented process] multiplies the parent plants by cloning and then crosses the cloned, and thus derived, parent lines on a large scale repeatable to provide the desired resulting hybrid population. This arrangement of steps is decisive for the invention and permits the desired control of the special result in spite of the fact that at least one of the parents is heterozygous. The facts of the present case ... clearly indicate that the claimed processes for the preparation of hybrid plants represent an essential modification of known biological and classical breeders processes, and the efficiency and high yield associated with the product in the present case show important technological character”; *Plant Genetic Systems/Glutamine synthetase inhibitors* T356/93 [1995] EPOR 357 at 376 providing: “a process for the production of plants comprising at least one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the final result ... does not fall under the exceptions to patentability under Art 53(b) [*European Patent Convention*], first half-sentence”.



fruit water content by screening “ripe fruit and wrinkling of the fruit skin” on the vine (at 524-525). The significance of this application was the nature (“what kind”) and consequence of the human intervention (at 529-530, 534-538):

- that interspecies crossing required “special intervention in order to reach a reliably fertile offspring and would not occur in nature since individuals belonging to separate species are generally not capable of interbreeding” (at 529);
- that on the vine screening after ripening was not a normal or natural criteria (at 529-530);
- that leaving the fruit on the vine “prepared the tomato fruit for being susceptible for selection” (at 529); and
- selecting for an increased dry weight required the technical intervention of weighing (at 530).

Recognising that there was already a referral to the Enlarged Board of Appeal in *Plant Bioscience/Broccoli*, the Board considered a range of further questions that might be referred (at 526-528). The Board considered that interspecies crossing and weighing did satisfy the threshold of human intervention to avoid the exclusion (at 536-537). The question referred to the Enlarged Board of Appeal was, in part (at 539-540):

Does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants fall under the exclusion of Art 53(b) [*European Patent Convention*] only if these steps reflect and correspond to phenomena which could occur in nature without human intervention?

If question 1 is answered in the negative, does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants escape the exclusion of Art 53(b) [*European Patent Convention*] merely because it contains, as part of any of the steps of crossing and selection, an additional feature of a technical nature?

If question 2 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Art 53(b) [*European Patent Convention*] from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?

Undoubtedly, the decision of the Enlarged Board of Appeal in *Plant Bioscience/Broccoli* and *State of Israel/Tomatoes* will provide some clarification to the phrase “essentially biological processes for the production of plants or animals”.⁶⁴ The usefulness of this outcome for the *Patents Act 1990* (Cth) is not so certain as the term “essentially” is coloured by the evolution of the *European Patent Convention* exclusion and its relationship with *Strasbourg Patent Convention*, UPOV 1961 and the Directive.⁶⁵ Further, and perhaps more importantly, the context of the exclusions are very different. Under the *European Patent Convention* the exclusion is assessed according to how different the process is to that occurring “in nature”,⁶⁶ while under the *Patents Act* this exclusion was assessed by how similar the alleged invention is to a natural “human being”.⁶⁷

Thus, in Australia in *Woo-Suk Hwang* the alleged invention was unpatentable because the resulting embryo retained essentially human characteristics,⁶⁸ and was expressly not excluded because of the highly technological interventions by humans.⁶⁹ In short, the European jurisprudence about

⁶⁴ Appeals: *Plant Bioscience/Broccoli* T0083/05 (pending as G2/07); *State of Israel/Tomatoes* T1242/06 (pending as G1/08).

⁶⁵ Notably, the patent application has been sealed in Australia: see Schaffer A, *Method for Breeding Tomatoes Having Reduced Water Content and Product of the Method*, Standard Patent 55622/00 (2000).

⁶⁶ See the summary of propositions in *Novartis/Transgenic plant* T1054/96 [1999] EPOR 123 at 134-135.

⁶⁷ *Woo-Suk Hwang's Application* [2004] APO 24 at [9]. Notably, however, this distinction has not always been adopted in Australia with IP Australia distinguishing the patentability of some human cell lines potentially capable of developing into humans as suitable patent subject matter: “A human cell line is different from naturally occurring cells in the human body. It is capable of continuous propagation in an artificial environment by continual division of the cells, unlike naturally occurring cells which die after a limited number of divisions”: IP Australia, n 49, p 4.

⁶⁸ *Woo-Suk Hwang's Application* [2004] APO 24 at [9].

⁶⁹ *Woo-Suk Hwang's Application* [2004] APO 24 at [8]. Notably and similarly, in *Harvard/Oncomouse* T19/90 [1990] EPOR 501 the incorporation of an oncogene sequence into a transgenic mouse by highly technological means was sufficient to avoid the *European Patent Convention*, Art 53(b).



“essentially biological processes” is of limited use in resolving how an essential requirement might be conceived, other than to confirm that identifying the quantum of human intervention necessary to attract the exclusion remains contested.⁷⁰

TAXONOMIC CONCEPTIONS OF “HUMAN BEINGS”

The analysis in this article so far shows that for a “standard patents” under the *Patents Act* the threshold for being a “human being” is a qualitative test of what constitutes “*essentially human characteristic[s]*”,⁷¹ with the only practical guidance so far being that “the presence of the bovine mitochondrial DNA does not take away the essentially human characteristic of the embryo that is determined by the nuclear DNA”.⁷²

The question addressed now is whether taxonomy (the classification of organisms) might provide some guidance about what constitutes “*essentially human characteristics*”. Taxonomy is a suitable consideration because a dictionary definition suggests the term “human being” means “a member of the human race, *Homo sapiens*”.⁷³ This is a reference to taxonomic nomenclature of the genera (*Homo*) and an epithet (*sapiens*) consistent with the naming codes for animals set out in the *International Code of Zoological Nomenclature*.⁷⁴

The classification consistent with the taxonomic nomenclature addresses the characteristics of the genera and the species compared to similar organisms with shared and contrasting characters – this is a question of whether the biological organism shares sufficient distinguishing characters at the relevant taxa to fall within the category (box within a box) classified and named as “*Homo sapiens*”. Unfortunately the taxonomic detail of the family Hominidae (great apes) remains hotly contested with disputed character analysis of structural, behavioural, and physiological features and arguably contrasting with molecular features.⁷⁵ The taxonomically significant differences that characterise modern *Homo sapiens* are derived from differences at the taxon genera between the living *Homo*, *Pan* (chimpanzee and bonobos), *Gorilla* and *Pongo* (orangutan).⁷⁶

While the genera appear robustly certain, their relationship with the other genera remains contested – essentially whether *Pan* or *Pongo* is more closely related to *Homo*.⁷⁷ Resolving lower taxon characters often depends on distinguishing variation apparent as changes of size and shape

⁷⁰ Perhaps significantly, the opportunity in *Novartis/Transgenic plant* G01/98 [2000] EPOR 303 at 307 to address the quantum was avoided by relying on the applicant intending to amend its claims and making the factual basis for any finding uncertain, albeit this question might be expected to be addressed by the Enlarged Board of Appeal in *Plant Bioscience/Broccoli* T0083/05 (pending as G2/07) and *State of Israel/Tomatoes* T1242/06 (pending as G1/08).

⁷¹ *Woo-Suk Hwang's Application* [2004] APO 24 at [9].

⁷² *Woo-Suk Hwang's Application* [2004] APO 24 at [9].

⁷³ Macquarie Library, *Macquarie: Australia's National Dictionary* (2006) p 582, “human being”.

⁷⁴ See Ride W, Cogger H, Dupuis C, Kraus O, Minelli A, Thompson F and Tubbs P, *International Code of Zoological Nomenclature* (4th ed, International Trust for Zoological Nomenclature, 1999), Art 5.1.

⁷⁵ For a recent overview of the controversy: see eg Schwartz J and Maresca B, “Do Molecular Clocks Run at All? A Critique of Molecular Systematics” (2006) 1 *Biological Theory* 357; Grehan J, “Mona Lisa Smile: The Morphological Enigma of Human and Great Ape Evolution” (2006) 289B *The Anatomical Record Part B: The New Anatomist* 139; Steiper M and Young N, “Primate Molecular Divergence Dates” (2006) 41 *Molecular Phylogenetics and Evolution* 384. See also Groves C, “The What, Why and How of Primate Taxonomy” (2004) 25 *International Journal of Primatology* 1105 (also addressing the biological species concept); Wood B and Collard M, “The Human Genus” (1999) 284 *Science* 65; Leakey L, Tobias P and Napier J, “A New Species of the Genus *Homo* from Olduvai Gorge” (1964) 202 *Nature* 7. A closely related debate is about the biogeographic origins of hominids according to the “Out-of-Africa” and “multiregionalists” theories: see eg, Wilson A and Cann R, “The recent African Genesis of Humans” (1992) 266 *Scientific American* 68; Thorne A and Wolpoff M, “The Multiregional Evolution of Humans” (1992) 266 *Scientific American* 76.

⁷⁶ The taxonomy being reviewed in Wood B and Loneragan N, “The Hominin Fossil Record: Taxa, Grades and Clades” (2008) 212 *Journal of Anatomy* 354 at 364-373 (genera (ape-human) differences), 373 (species (within *Homo*) differences) and the references therein; Wood B and Richmond B, “Human Evolution: Taxonomy and Paleobiology” (2000) 196 *Journal of Anatomy* 19 at 21-23 (genera (ape-human) differences), 38-50 (species (within *Homo*) differences) and the references therein.

⁷⁷ See eg, Grehan J and Schwartz J, “Evolution of the Second Orangutan: Phylogeny and Biogeography of Hominid Origins” (2009) 36 *Journal of Biogeography* 1823 and the references therein.



rather than discrete identifiable structures or molecular information.⁷⁸ The result is that there is no consensus about the specific taxonomic characters distinguishing *Homo sapiens*, although endocranial volumes, teeth, possession of language, the manufacture of stone tools and human-like precision grip with the opposable digits appear to be significant characteristics.⁷⁹ In short, taxonomy does not provide a useful framework of determining whether or not a biological organism is or is not patentable subject matter for the purposes of the *Patents Act*.

CONCLUSIONS

This article demonstrates that the likely conception of “human beings” excluded from patentability is uncertain, and that notions of “essentially” under the *European Patent Convention* and significant characteristics from taxonomy do not provide much assistance. The significance of the analysis of the *European Patent Convention* cases is to illustrate that appeals to essential characteristics do not resolve definitional problems, and that determining what is an “essentially biological processes” is not easily addressed. The significance of the analysis of taxonomy is to illustrate that fine and contested distinctions about the classification of “human beings” also remain, and that the kinds of distinctive characters applied in taxonomy might be of little usefulness in the context of the *Patents Act 1990* (Cth).

The analysis also demonstrates the dangers in IP Australia’s application of the “contrary to law” exclusion. The conclusion in *Woo-Suk Hwang* that the prohibitions in the *Prohibition of Human Cloning Act 2002* (Cth) were “unlikely to be ephemeral” so that the discretion should be exercised excluding patentability would not appear to be a good basis for determining the exercise of the discretion.⁸⁰ The later amendment by the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cth), contrary to the delegate’s decision, proves the failings and dangers in IP Australia attempting to make assessments about future legislative intentions.⁸¹ Clearly, basing a test of exclusion on predicting the future intentions of the legislature is problematic (and probably inappropriate).

That the patenting of “human beings” has *not* been highly contentious,⁸² or an issue in recent inquires, suggests that the uncertain conception of “human beings” for the purposes of the *Patents Act*

⁷⁸ See eg, González-José R, Escapa I, Neves W et al, “Cladistic Analysis of Continuous Modularized Traits Provides Phylogenetic Signals in Homo Evolution” (2008) 453 *Nature* 775; Goodman M, Portera C, Czelusniak J et al, “Toward a Phylogenetic Classification of Primates Based on DNA Evidence Complemented by Fossil Evidence” (1998) 9 *Molecular Phylogenetics and Evolution* 585. See generally Wood and Lonergan, n 76. Notably, there are comprehensive morphological taxonomic descriptions associated with naming publications: see eg, Brown P, Sutikna T, Morwood M et al, “A New Small-bodied Hominin from the Late Pleistocene of Flores, Indonesia” (2004) 431 *Nature* 1055 (*Homo floresiensis*); Leakey et al, n 75 (*Homo habilis*). See also Seiffert E, Perry J, Simons E and Boyer D, “Convergent Evolution of Anthropoid-like Adaptations in Eocene Adapiform Primates” (2009) 461 *Nature* 1118 (to illustrate the fine structural disputes in classifying fossil primates).

⁷⁹ See Wood and Lonergan, n 76 and the references therein; Straita D, Grineb F and Monizc M, “A Reappraisal of Early Hominid Phylogeny” (1997) 32 *Journal of Human Evolution* 17. See also Wood B and Collard M, “The Meaning of Homo” (2001) 9 *Ludus Vitalis* 63; Wood B and Collard M, “The Changing Face of Homo” (2000) 8 *Evolutionary Anthropology* 195 at 199-204 and the references therein.

⁸⁰ *Woo-Suk Hwang’s Application* [2004] APO 24 at [18]-[19]. It appears that *Woo-Suk Hwang* might now be decided differently on this point on the basis that the alleged invention could now have been lawfully used for up to 14 days, see *Manual of Practice and Procedures*, n 34, [2.9.6]: “Where the invention could be used both for lawful and for unlawful purposes, there is authority in *Pessers and Moody v Haydon & Co* (1909) 26 RPC 58, for saying that a patent in respect of it would not necessarily be bad”.

⁸¹ The relevant provision was amended by the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cth), s 3 and Sch 1 (item 7) so that the prohibition on using a hybrid embryo can be used up to 14 days: see *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), s 18.

⁸² For a notable exception in the context of stem cell patenting see Rimmer M, *Intellectual Property and Biotechnology: Biological Inventions* (Edward Elgar, 2008) pp 248-279.



is of little practical consequence.⁸³ Further, IP Australia practice now appears to have developed an internal consultation process in determining potentially contentious applications,⁸⁴ and a working principle has been applied:

Although IP Australia's position will no doubt change as the technology evolves, the organisation's current interpretation [of s 18(2)] is that anything which has an inherent capability to mature and become a human being should be excluded. According to this, the more complex the subject matter, the more likely it is to be excluded ... complexities arise for subject matter such as fertilised ovum, stem cells, fetuses, genetically modified animals containing human genes, and humans treated with animal tissue.⁸⁵

This approach of IP Australia does not, however, resolve the uncertainties and clearly leaves open the possibility that some patent applications may be rejected. IP Australia certainly accepts this as a problem, and has consistently asserted that the *Patents Act* is not the place for resolving matters of ethic and social policy.⁸⁶

IP Australia believes the Parliament should be responsible for placing limits on any patents dealing with ethical issues by incorporating these exclusions into the [*Patents Act 1990* (Cth)]. As an Australian Government Agency, it is not appropriate for IP Australia to be making these decisions administratively. Moreover, it should be noted that excluding particular subject matter from patentability does not restrict the public from using inventions of that nature. If restrictions are to be placed on these activities, IP Australia believes that this should be done under other laws rather than the [*Patents Act 1990* (Cth)].⁸⁷

To address some of these concerns in the context of patenting stem cell technologies, the Australian Law Reform Commission⁸⁸ recommended IP Australia develop "clear examination guidelines" identifying patentable stem cell inventions and "the basis on which patent protection may not be available".⁸⁹ Further guidance is now provided by IP Australia, albeit the uncertainty remains.⁹⁰ The Australian Law Reform Commission also recommended that "social and ethical concerns [about granting patents] should be addressed primarily through direct regulation of the use or exploitation of a patented invention" and not by the *Patents Act*.⁹¹

⁸³ See eg, Advisory Council on Intellectual Property, *Patentable Subject Matter*, Issues Paper (IP Australia, 2008) (ACIP Issues Paper); Advisory Council on Intellectual Property, *Should Plant and Animal Subject Matter be Excluded from Protection by the Innovation Patent?* (2004); ALRC Report 99, n 41; Australian Law Reform Commission, *Gene Patenting and Human Health*, Discussion Paper (SOS Printing Group, 2004); House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (Senate Printing, 2001); and so on. Perhaps most significantly, IP Australia did not address the exclusion of "human beings" in its submission to Advisory Council on Intellectual Property's *Patentable Subject Matter*: IP Australia, *Advisory Council on Intellectual Property – Patentable Subject Matter Issues Paper* at <http://www.acip.gov.au/reviewpatentable/IP34%20IP%20Australia.pdf> (viewed 22 October 2009). Further, the issue was not addressed in the Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (IP Australia, 2000).

⁸⁴ *Manual of Practice and Procedures*, n 34, [2.9.5]. See also ALRC Report 99, n 41, pp 382-383.

⁸⁵ ALRC Report 99, n 41, p 383 citing IP Australia, Submission P56, 4 November 2003.

⁸⁶ See IP Australia, n 49, p 5; ALRC Report 99, n 41, pp 186-187 citing IP Australia, Submission P86, 16 April 2004 and IP Australia, Submission P56, 4 November 2003. See also House of Representatives Standing Committee on Industry, Science and Technology, *Genetic Manipulation: The Threat of the Glory?* (AGPS, 1992) p 243.

⁸⁷ IP Australia, n 83.

⁸⁸ The ALRC undertakes review of matters referred by the Attorney-General under the *Australian Law Reform Commission Act 1996* (Cth), s 20, within the Attorney-General's Portfolio: see Department of Finance and Administration, *List of Australian Government Bodies*, Financial Management Reference Material No 1 (2004) p 59.

⁸⁹ ALRC Report 99, n 41, pp 389, 391. See also Rimmer M, "The Last Taboo: Patenting Human Beings" (2004) 14 *Expert Opinion on Therapeutic Patents* 1061.

⁹⁰ See *Manual of Practice and Procedures*, n 34, [2.9.5.1].

⁹¹ See also ALRC Report 99, n 41, p 191.



More recently, the Advisory Council on Intellectual Property⁹² has started to “inquire, report and make recommendations to the Australian Government on patentable subject matter”.⁹³ This inquiry has sought submissions about the exclusion for “human beings”⁹⁴ and the response was a variety of submissions that might be broadly characterised as those for, and those against, a specific social policy exclusion that addresses, in part, “human beings”.⁹⁵ Significantly, the Advisory Council has framed the exclusion of “human beings” as a “social policy” matter.⁹⁶ As a likely indication of the Advisory Council’s perspective:

We are not persuaded by submissions that the patent system is or should be ethically agnostic. The patent system is often referred to as a social contract between the innovator and the state. It seems incongruous that an innovator be awarded a patent for an invention that is socially unacceptable. Social and ethical considerations have always been a part of Australian patent law.⁹⁷

If the Advisory Council eventually advises the Minister to retain the exclusion of “human beings”, there remains the problem of certainly defining the content of what constitutes a “human being” for the purposes of the *Patents Act 1990* (Cth). The significance of the analysis in this article is to show that a certain meaning of “human beings” is unlikely and that some kind of subjective assessment of the alleged invention will be required.

The conclusion from the analysis in this article, however, is that (1) the existing qualitative test of what constitutes “*essentially human characteristic[s]*” (that is not defeated by any technological means of how the “human being” is constituted or created); and (2) the “unlikely to be ephemeral” standard in *Woo-Suk Hwang*⁹⁸ for assessing the “contrary to law” exclusion, are problematic. Further, whatever the outcome of the Advisory Council inquiry, any discussions and policy consideration about the exclusion of “human beings” also needs to address the conception of what it is that is a human being and how that assessment is to be made.

⁹² The Advisory Council on Intellectual Property is an “advisory body” within the Industry, Tourism and Resources Portfolio appointed by the Minister for Industry, Tourism and Resources and funded through IP Australia and its allocations: see Department of Finance and Administration, n 88, p 310.

⁹³ ACIP Issues Paper, n 83, p 5.

⁹⁴ See ACIP Issues Paper, n 83, p 64.

⁹⁵ See Advisory Council on Intellectual Property, *Patentable Subject Matter*, Options Paper (2009) pp 44-46 (ACIP Options Paper).

⁹⁶ See ACIP Options Paper, n 95, p 44.

⁹⁷ ACIP Options Paper, n 95, p 46.

⁹⁸ *Woo-Suk Hwang’s Application* [2004] APO 24 at [18]-[19].

