

Response to the Australian Government Advisory Council on Intellectual Property's Request for Written Comments on Patentable Subject Matter[†]

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SUMMARY

1. Any statutory definition of inherent patentability or other threshold exclusion from patentability should have a clear normative basis. In the case of inherent patentability, that basis should relate to the patent system's aim of encouraging and rewarding inventive activity for the benefit of society.
2. Consistent with this, the Australian requirement for inherent patentability should remain statutorily entrenched as a requirement for an invention, but 'invention' redefined using modern language. The definition should be neutral as to field of technology, and otherwise consistent with Australia's obligations under TRIPS and AUSFTA. It should emphasise the nature of inventions as technical artefacts, without adopting the European language of 'technical effect'. In particular, 'inventions' should be understood to mean any artificial combination of steps (method) or properties (product) that creates an effect in the physical world. It should be made clear for methods and products that the requisite effect must be the result of the combination of steps or properties constituting the relevant invention itself.
3. Australian law should not include a 'black list' of non-inventions as exists in Europe. If such a list is adopted, the Legislature should make the following things clear:
 - a. Whether the list is a deeming or definitional list;
 - b. Whether the list represents a codification or amendment of existing principles; and
 - c. The policy basis for each of the items included on the list, and how they relate to each other and the patent system's purpose.

Article 52(2) EPC should not be transplanted into Australian law, whether for the purpose of harmonisation or otherwise. The reason is that it has been the subject of conflicting interpretations among EPC States, and has been all but abandoned by the EPO in an interpretive approach described as 'the product of legal casuistry' by the European Economic and Social Committee and 'intellectually dishonest' by the UK Court of Appeal. If harmonisation with European law is sought, Australia would do better to redefine 'invention' as a technical artefact in the manner above.

4. Australian law should include a general public interest exclusion from patentability such as that contained in European law, covering inventions the commercial exploitation of which would be contrary to *ordre public* or morality, and including a non-exhaustive list of such subject matter. In addition to the subject matter contained in Article 6 of the European Biotech Directive (reproduced in Rule 28 of the EPC Implementing Regulations), that list should include:
 - a. Human beings and the biological processes for their generation, either in its existing (section 18(2)) form, or in the form of Article 5 of the European Biotech Directive (reproduced in Rule 29 of the EPC Implementing Regulations); and
 - b. Methods of treating the human or animal body, consistent with (the first clause of) Article 53(c) EPC 2000.

Such a provision would be TRIPS and AUSFTA compliant, and would facilitate harmonisation with European law; though it may challenge the vision of the Lockhart Review.

5. Australian law should not extend the existing exclusion covering ‘plants and animals, and the biological processes for the generation of plants and animals’ from innovation to standard patents. The only such subject matter for which a threshold exclusion from standard patentability is currently justified are those falling outside the definition of ‘invention’ above, those the commercial exploitation of which would be contrary to *ordre public* or morality, and those eligible for *sui generis* protection under a breeders’ rights or similar regime. However, Article 17.9 of AUSFTA would seem to permit exclusions on the first or second of these grounds only, which exclusions should be ensured by adoption of the proposals above.
6. If Australia does decide to adopt a plant/animal/biological process exclusion for standard patents, it should not model the exclusion on Article 53(b) EPC 1977/2000, nor Articles 2 and 4 of the European Biotech Directive. The authoritative interpretation of the varieties exclusion of Article 53(b) EPC 1977/2000 has been described by one EPO Technical Board of Appeal as not complying with the normal rules of logic, and the clarificatory provisions of Rules 26(6), 27(b) and 27(c) of the Implementing Regulations (reproducing Articles 4.2, 4.3 and 2 of the European Biotech Directive) are unnecessarily complex and lacking in a clear policy basis.
7. Harmonisation is not of itself an appropriate policy rationale for substantive patent law provisions. Having said that, it is a legitimate consideration in deciding how best to express a policy decision in statutory language. The laws of other jurisdictions are also important sources of instruction and possible solutions to the specific challenges of formulating threshold limits to patentability. Given the choice between harmonisation with European or US law, Australia should opt for the former on the basis that the values underpinning its intellectual property system are closer to those underpinning the European than the US intellectual property system.

1. THE PURPOSE OF THE AUSTRALIAN PATENT SYSTEM: TO ENCOURAGE AND REWARD INVENTIVE ACTIVITY FOR THE BENEFIT OF SOCIETY

The Issues Paper describes the role of the Australian patent system as being ‘to optimise innovation and public access to new technologies’.¹ I agree with the emphasis in this description, and believe that the primary aim of any reform to the Australian law of patentable subject matter ought to be to ensure that the system remains oriented around its original purpose of encouraging and rewarding inventive activity for the benefit of society.²

Having said that, it is not enough to say that the purpose of the patent system is to benefit society by encouraging and rewarding inventive activity, without an understanding also of how society benefits. Among other things, that understanding should indicate whether determinations of inherent patentability are best undertaken for individual subject matter or ‘entire fields of technology’.³

† Australian Government, *Advisory Council on Intellectual Property Issues Paper: Patentable Subject Matter* (July 2008) (‘Issues Paper’)

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¹ Issues Paper, 1.

² For an analysis of that purpose see Justine Pila, ‘The Common Law Invention in its Original Form’ [2001] IPQ 209-243. See also Paul A David, ‘Reflections on the Patent System and IPR Protection in the Past, Present and Future’ in *Interviews for the Future* (2006, European Patent Office) 115-140 (describing the patent system as having ‘acquired a life of its own, independent of the system’s original purpose, namely the encouragement of invention and the public revelation of novel and useful products and means of production’, and bemoaning ‘the retrograde drift into a policy that protects private (intellectual) property for its own sake, in the belief that assuring private profits for some segment of the economy must be a good thing for society as whole’).

³ Issues Paper, 63 (Question 1: ‘Should the subject matter of each individual invention be assessed to determine whether a patent is necessary to encourage innovation, or should such an assessment be done for entire fields of technology?’). An analogy might usefully be drawn with copyright. The copyright system is often described as existing to incentivize the creation and dissemination of expressive works for the benefit of the public. However, understandings of how the public benefits from such creation and dissemination vary, from greater democratic participation (through increased opportunities for and access to personal expression) to a strengthened market economy (through increased efficiency in the market for copyright works and the creation of a new market in copyright itself). Among other things, one’s choice between these understandings affects one’s view of how the copyright system ought to be structured. For example, a view of copyright as existing for democratic purposes

It is not my purpose to attempt a theory of the social benefits of encouraging and rewarding inventive activity. Suffice to say that in my view those benefits are not confined to specific fields of technology, and extend beyond the provision to the public of the democratic and other benefits of industrial development to the creation, also, of increased opportunities for individual human creativity. The implication is that determinations of inherent patentability ought not to discriminate between inventors or fields of technology, and that there ought to exist in law a general principle in favour of patentability for inventions with separate provision for public policy exclusions.⁴ This is also the approach required by Article 27.1 of TRIPS⁵ and Article 17.9 of AUSFTA.⁶

2. THE PURPOSE OF THE INHERENT PATENTABILITY REQUIREMENT: TO ESTABLISH A THRESHOLD REQUIREMENT FOR AN INVENTION

The question remains as to the purpose of the inherent patentability requirement, and how it helps the patent system fulfil its role.

According to the Issues Paper, ‘the current economic rationale for placing limits on patentable subject matter is to limit protection to those areas where it is known that free riding by competitors occurs and causes financial injury to inventors’.⁷ This statement however is vulnerable to criticism, for the fundamental threshold requirement of patentability is the requirement for an invention – ie, a subject matter regarded as *prima facie* suitable for the grant of a patent – and yet the statement assumes the existence of an invention,⁸ and is therefore an inappropriate basis for its definition. While the statement could be the basis for an exclusion from patentability, it sits uncomfortably alongside the other exclusions, which – with the possible exception of plants eligible for *sui generis* protection – have a public interest (*public ordre* or morality) foundation. By contrast, the criterion described in the statement above supports a market-based differentiation among inventors (and inventions) not furthering the aim of the patent system to encourage and reward inventive activity.

If not to protect inventors from financial injury by free riding competitors, what is the rationale for the inherent patentability requirement? In my view, it is to support the aim above by establishing the *prima facie* availability of patents for objects of practical art, namely, technical artefacts.⁹

3. RE-DEFINING THE INVENTION: METHODS AND PRODUCTS PRODUCING AN EFFECT IN THE PHYSICAL WORLD

According to the High Court of Australia in *National Research Development Corporation v Commissioner of Patents (NRDC)* (1959) 102 CLR 252, an invention is a subject matter producing or representing an end of practical utility.¹⁰ By way of example, the Court offered an artificially created state of affairs having economic significance.¹¹ In doing so however it overreached its primary definition in a way that implied a different role for the patent system, oriented less around encouraging and rewarding inventive activity than granting property for ideas of commercial value.¹²

might require the supplementation of economic rights with moral rights and state support for long shelf-life works unlikely to be an attractive investment proposition for publishers, in recognition of the fact that democracy is served by diversity as much as quantity of expression.

⁴ Cf the ‘white list’ approach described by ACIP (Issues Paper, 68), consistent with that adopted in copyright law. Arguments in support of such an approach include: a. that it would provide the courts with greater policy guidance on issues of patentability and inventiveness (the latter of which requires the identification of the invention’s prior art base); and b. that it would be consistent with the idea of patents as ‘exception[s] to the rule of free competition’ (Issues Paper, 7).

⁵ The Agreement on Trade-Related Aspects of Intellectual Property Rights (1994) (‘TRIPS’).

⁶ The Australia-United States Free Trade Agreement (‘AUSFTA’).

⁷ Issues Paper, 63.

⁸ In its reference to ‘inventors’.

⁹ By ‘artefact’ here I mean ‘[a]n object made or modified by human workmanship, as opposed to one formed by natural processes’, consistent with the term’s common language meaning (see *Oxford English Dictionary*).

¹⁰ See (1959) 102 CLR 252, 276, discussed in Justine Pila, ‘Inherent Patentability in Anglo-Australian Law: A History’ (2003) 14 AIPJ 109, 146-148.

¹¹ See *ibid*.

¹² In this sense it represents ‘the retrograde drift’ described by David (see above n 2).

For this reason, the *NRDC* definition of inherent patentability is too wide. In addition, the statutory language on which it is based is opaque to all but those familiar with the history of the judicial development of section 6 of the Statute of Monopolies. For these reasons, the existing statutory definition of ‘invention’ ought to be replaced with a new definition that retains the adaptive capacities of the existing text while reorienting the system around the purpose above by restricting the availability of patents to technical artefacts, *viz*, artificial combinations of steps (methods) or properties (products) producing an effect in the physical world. It should be made clear that, in the case of both methods and products, the end of practical utility must be the result of the combination of steps or properties constitutive of the relevant invention itself.

While more restrictive than the *NRDC* definition above – and a distance from the extreme of US jurisprudence – this formulation finds support in the body of Australian cases involving business methods and other schemes, including *Re Cooper’s Application for a Patent (Cooper’s Application)* (1901) 19 RPC 53 (AG)¹³ and *Grant v Commissioner of Patents* [2006] FCAFC 120.¹⁴ It also balances the requirements of flexibility and certainty, by ensuring sufficient flexibility to enable the courts to resolve individual cases on their merits and respond to the demands of new technologies, sufficient certainty to facilitate social justice and economic efficiency, and sufficient judicial constraints and policy guidance to confer constitutional and democratic legitimacy. It is neutral as to field of technology, and consequently consistent with Article 27.1 of TRIPS and Article 17.9 of AUSFTA; and it represents a ‘best practice’ definition that conforms also to European jurisprudence while avoiding the obscurity of the language of ‘technical effect’. Indeed, it is informed by the pre-EPC German conception from which that jurisprudence is derived.¹⁵

One question that remains is whether the positive definition of ‘invention’ ought to be supplemented by a ‘black list’ of non-inventions?¹⁶ In my view it ought not to be, on the grounds that such a list would threaten the balance between flexibility and certainty above by entrenching a code with limited adaptive capacities. If however such a list is adopted, the Legislature might learn from the UK experience by making its intent with respect to the following matters clear:¹⁷

- a. Whether the list is a deeming or definitional list;
- b. Whether the list represents a codification or amendment of existing law; and

¹³ For a discussion see Pila, above n 10, 134-138.

¹⁴ According to the Court in *Grant*, for a method to produce an artificial state of affairs within the meaning of *NRDC* it must ‘produce an[] artificial state of affairs, in the sense of a concrete, tangible, physical, or observable effect’: ‘[A]n abstract, intangible situation, namely that a hypothetical unsecured creditor who recovered judgment against a user of the method could not levy against the user’s assets to the extent they were subject to the charge’ is not enough. ‘A physical effect in the sense of a concrete effect or phenomenon or manifestation or transformation is required.’ [2006] FCAFC 120, [30]-[32].)

¹⁵ See for example the following statement of that law by the German delegation to the Council of Europe’s Committee of Experts on Patents in 1953: ‘[T]he patent law is only concerned with technical creations. As a consequence, in default of a technical result, the simple concentrations of the human spirit, purely scientific doctrines, and theories or problems are not patentable. The “Reichsgericht” has decided as follows about the content of the notions of “technique” and “lack of technical” - the invention must be technical in its very essence, that is to say that it must put into practice natural means to produce an effect pertaining to this domain of human activity. Technology does not belong to the world of the intellect but to the world of the senses; it works according to physico-chemical principles. Ideas and methods which only concern an activity of the human spirit and which have no other object than that are not patentable. It would be thus, for example, with methods of teaching, of education, of work, of commerce, of consumer research, of counting, or of calculation (decision of the Reichsgericht published in the periodical “Gewerblicher Rechtsschutz und Urheberrecht, 1933, S. 289). It would be the same for the creation of an aesthetic novelty which was not supported with technical information. The patentability of methods of cultivating and rearing plants and animals can be admitted provided that all the other conditions are fulfilled, because action on living nature is considered as an enrichment of technology. ... For a technical effect to be present it is further necessary that the inventor should have found a technical problem and have given a solution to it. But it is necessary to distinguish, carefully from the question of the object of the invention, which is to put something of practical utility at the disposition of the public.’ (Committee of Experts on Patents, *Reply to the Questionnaire drawn up by the Bureau of the Committee of Experts of the Council of Europe, from the point of view of the German legislation* (12 January 1953), Council of Europe Doc EXP/Brev (53) 1.)

¹⁶ See Issues Paper, 69.

¹⁷ See generally Justine Pila, ‘Article 52(2) of the Convention on the Grant on European Patents: What did the Framers Intend? A Study of the *Travaux Préparatoires*’ (2005) 36 IIC 755-787, especially Part IV.

- c. The policy basis for each of the items included on the list, and how they relate to each other and the purpose of the patent system overall.

The Legislature should not adopt the list of non-inventions contained in Article 52(2) EPC 1977/2000, whether in the interests of harmonisation with European law or otherwise, for that list is the subject of conflicting interpretations among EPC States, and has been all but abandoned by the EPO in an interpretive approach described as ‘the product of legal casuistry’ by the European Economic and Social Committee¹⁸ and intellectually dishonest by the UK Court of Appeal.¹⁹ According to that approach, rather than denoting a series of discrete exclusions from European patentability, Article 52(2) denotes a positive requirement for a subject matter having technical character.²⁰ For this reason, it is something of a misnomer to describe it as a list at all, with the result that any aim of harmonisation with European law would be better pursued by redefining ‘invention’ as a technical artefact in the manner above.

4. PUBLIC POLICY EXCEPTIONS TO PATENTABILITY

Any threshold exclusion from patentability based on ethical or other public policy grounds should be separate from the requirement for an invention in recognition of their different normative bases. Three stand-alone policy exclusions might be considered for Australia:

- A general *ordre public*/morality exclusion, incorporating the existing exclusion of human beings and the biological processes for their generation,²¹ and supplementing the Commissioner’s existing discretionary power to refuse to accept an application for a standard patent or grant a standard patent ‘for an invention the use of which would be contrary to law’;²²
- An exclusion (from standard patentability) covering plants and animals, varieties of plants and animals, and/or biological processes for the production of plants and animals, otherwise eligible for *sui generis* protection; and
- A medical and veterinarian methods exclusion, supplementing the Commissioner’s existing discretionary power to refuse to accept an application for a standard patent or grant a standard patent ‘on the ground that the specification claims as an invention: (i) a substance that is capable of being used as ... medicine (whether for human beings or animals and whether for internal or external use) and is a mere mixture of known ingredients; or (ii) a process producing such a substance by mere admixture’.²³

4.1 An *ordre public*/morality exclusion

Australian law could adopt a threshold public interest exclusion from patentability modelled on the *ordre public*/morality exclusion of Article 53(a) EPC and Rule 28 of the EPC Implementing Regulations (reproducing Article 6 of the European Biotech Directive²⁴) as follows.

- ‘1. Australian patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to “ordre public” or morality. Such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
2. On the basis of paragraph 1., and without limitation to the subject matter excluded under that

¹⁸ See Opinion of the Economic and Social Committee on the Proposal for a Directive of the European Parliament and of the Council on the patentability of computer-implemented inventions, COM(2002) 92 final — 2002/0047(COD) (19 September 2002) [3.1]. For an analysis see Justine Pila, ‘Dispute Over the Meaning of “Invention” in Article 52(2) EPC: The Patentability of Computer-Implemented Inventions in Europe’ (2005) 36 IIC 173-191.

¹⁹ See *Aerotel Ltd v Telco Holdings Ltd* [2006] EWCA Civ 1371, ¶27.

²⁰ See generally Pila, above n 18. For a recent discussion of the centrality of technical character in European inherent patentability jurisprudence see T_154/04 (Estimating sales activity/Duns Licensing Associates) [2008] OJ EPO 46 (15 November 2006).

²¹ Patents Act 1990, s18(2).

²² Patents Act 1990, s50(1)(a).

²³ Patents Act 1990, s50(1)(b).

²⁴ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (‘European Biotech Directive’).

paragraph, the following in particular shall be considered unpatentable:

- a. Processes for cloning human beings;
- b. Processes for modifying the germ line genetic identity of human beings;
- c. Uses of human embryos for industrial or commercial purposes;
- d. Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.'

Any provision of this nature could also incorporate the existing exclusion in section 18(2) covering 'human beings, and the biological processes for their generation', either in that form or adapted to correspond to Article 5 of the European Biotech Directive (reproduced in Article 29 of the EPC Implementing Regulations).²⁵

In my view, there are sound policy reasons in support of such a provision. One is the appropriateness of recognising public interest limits to the scope of any law which exists for the purpose of benefitting society. Another is the desirability of requiring the courts to engage directly with the public interest issues raised by granting patents, in recognition of the fact that such issues exist, and that not providing expressly for their consideration will result in them being resolved by default, or inappropriately expressed as a function of some other patentability requirement. (A case in point is methods of medical and veterinarian treatment, the patentability of which in Australia and Europe has historically been treated as turning on the requirement for a vendible product and industrial applicability respectively, and only recently recognised as turning on questions of ethics.²⁶)

For these reasons, the question is not whether issues of *ordre public* and morality ought to be relevant in determining patentability, but whether the Legislature is prepared to recognise their relevance by making express provision for the refusal of patents on their basis. As the European Biotech Directive recognises, making such provision does not undermine the limited (exclusionary) nature of the patent grant, nor turn the patent system into a regime for regulating research and its results. Thus, it remains true in Europe (where such provision exists) that:

'a patent for invention does not authorise the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes; [and] consequently, substantive patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation of its results, notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards'.²⁷

The combination in the exclusion proposed of a general principle (paragraph 1.) followed by a non-exhaustive list of excluded subject matter (paragraph 2.) achieves an appropriate balance between the requirements of certainty and flexibility, noting the additional importance of the former in the case of public interest-based provisions due to their nature, and the courts' reluctance to engage with them directly without a legislative mandate.²⁸ The text also combines morality and *ordre public* exclusions in a single provision, representing in this sense something like the public interest defence to the common law breach of confidence action. Finally, it harmonises Australian law with European law, and is consistent with Australia's international obligations. (This latter is clear from Article 27.2 of TRIPS and Article 17.9(1)(a) of AUSFTA, which expressly permit the exclusion from patentability of inventions the commercial exploitation of which is contrary to *ordre public* or morality.)

With respect to the content of paragraph 2. specifically: many if not all of these subject matter are already excluded from Australian patentability in practice; though if this practice comes to be regarded

²⁵ Article 5 provides as follows: '1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. 2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. 3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.'

²⁶ See generally Justine Pila, 'Methods of Medical Treatment Within Australian and United Kingdom Patents Law' (2001) 24 UNSWLJ 421-462, and the discussion below.

²⁷ European Biotech Directive, Recital 14.

²⁸ Methods of medical treatment are again an example in point. See Pila, above n 26, 437-438.

as inappropriate in the light (for example) of the Lockhart Review,²⁹ the paragraph could be omitted leaving the more open-textured paragraph 1. on its own. In this case, however, the exclusion of human beings and the biological processes for their generation should be preserved in a stand-alone provision as exists currently with section 18(2).

4.2 An exclusion covering plants and animals, varieties of plants and animals, and/or biological processes for the production of plants and animals

The definition of ‘invention’ proposed above is capable of embracing plant and animal inventions, and at least some biological processes for the creation of plants and animals. It follows that for such subject matter to be excluded from Australian standard patentability, the Legislature would need to include a separate exclusion as exists for the Australian innovation patent. The appropriate form of that exclusion would depend on its underlying justification. If it were *ordre public*/morality, the relevant subject matter could be added to the non-exhaustive list of public interest exclusions proposed above. If it were failure to constitute an invention, no provision should be made, as the definition of ‘invention’ should be sufficient to ensure their exclusion. The only other legitimate justification in my view would be eligibility for *sui generis* protection under another (breeders’ rights or equivalent) regime. In that case however the exclusion would only be justified in respect of the animals, plants and/or processes for which such protection exists.

In no case should the exclusion contained in Article 53(b) of the EPC 1977/2000 be adopted in Australia. The reason is that it covers subject matter for which *sui generis* protection is not available (eg, animal varieties), and has been construed by the EPO Boards of Appeal in a tortuous fashion described by one Board of Appeal as ‘not comply[ing] with the normal rules of logic’.³⁰ As a result of that interpretation, the European exclusion – which unlike the Australian innovation patent exclusion is expressed to cover plant and animal *varieties*, and *essentially* biological processes for the production of plants or animals – is limited to specific varieties of plant or animal, and does not cover individual plants or animals, inventions applicable to different varieties of plant or animal, or technical processes for producing plants or animals.³¹ The justification offered for this interpretation relies on the legislative purpose of Article 53(b) in complementing the UPOV Convention.³² The problems with this justification however are apparent from the fact that sections 18(2) and 18(3) of the Australian Act have the same legislative purpose,³³ and yet cover precisely those subject matter which the EPO Boards have held not to be covered by Article 53(b), namely, plants and animals.

For this reason alone, Australian law should not include a provision modeled on Article 53(b) EPC. Nor should it adopt Articles 4 and 2 of the European Biotech Directive, which were introduced to clarify the uncertainty surrounding Article 53(b), but which give statutory form to the EPO Boards’ interpretation of that Article above.³⁴ If Australia were to decide to extend the effect of sections 18(3) and 18(4) to standard patents in a manner consistent with European law, it ought to proceed by statutory codification of European practice itself. Doing so would result in an exclusion having the

²⁹ Australian Government, *Legislative Committee Review Reports: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002* (December 2005).

³⁰ See G_1/98 (Novartis/Transgenic plant systems) [2000] EPOR 303 (20 December 1999), supporting a view of the varieties exclusion of Article 53(b) EPC described by the referring Board (in T_1054/96 – 3.3.4 (Novartis/Transgenic plant systems) [1998] OJ EPO 511 (13 October 1997) [36]) as ‘not appear[ing] to comply with the normal rules of logic’. For a detailed discussion see Justine Pila, ‘Article 53(b) EPC: A Challenge to the Novartis Theory of European Patent History’ (2008) 21 University of Oxford Legal Research Paper Series (available at <http://ssrn.com/abstract=1160191>).

³¹ See G_1/98 (Novartis/Transgenic plant systems) [2000] EPOR 303 (20 December 1999) [3.7], [3.10], cf [6]; T_19/90 (Harvard/transgenic animals) [1990] EPOR 501 (3 October 1990) [4.4], [4.9.1]; T_315/03 (Harvard/transgenic animals) [2005] EPOR 31 (6 July 2004) [11.8]. For a detailed discussion see Pila, *ibid*.

³² See especially G_1/98 (Novartis/Transgenic plant systems) [2000] EPOR 303 (20 December 1999).

³³ See Issues Paper, 15 (n 26).

³⁴ See Articles 4 and 2, introduced for the explicit purpose of clarifying the uncertainty surrounding Article 53(b) EPC, and having the effect of entrenching a restrictive view of the same as not covering the following categories of subject matter: biological processes involving non-natural phenomena; technical processes; individual plants and animals; inventions having technical feasibility for two or more varieties of plant or animal; and processes not involving, performed upon, or resulting in microbiological material. The result is that each of these categories is patentable, subject to the general requirements of law. See further Pila, above n 30.

limited coverage described above, namely, specific varieties of plant or animal.³⁵

As noted in the Issues Paper, however, even an exclusion of such limited breadth as this may put Australia in breach of its obligations under Article 17.9 of the AUSFTA Agreement. While it would also discriminate against inventions on the basis of their field of technology, it would not contravene the non-discrimination provision of Article 27.1 of TRIPS on account of Article 27.3, which makes express allowance for exclusions of this type.

4.3 A medical and veterinarian methods exclusion

The definition of ‘invention’ proposed above is also capable of embracing methods of medical and veterinarian treatment. The same analysis therefore applies with respect to such methods as for plant and animal inventions and biological processes above, namely, that if Australian law were to exclude them, it would need to be by separate provision, either in an *ordre public*/morality exclusion or in a stand-alone exclusion as exists in Article 53(c) EPC 2000.³⁶ Again, the critical thing is the normative basis of any exclusion. In Anglo-Australian and European law, lawmakers have historically sought to exclude medical and veterinarian methods with reference to the requirement for a vendible product and industrial applicability so as to avoid direct engagement with the issues of policy their patenting raises.³⁷ More recently however they have recognised that any such exclusion can only be justified on public interest grounds. In Europe this has led to the relocation of the relevant exclusion from Article 54 to Article 53(c) of the EPC as part of the EPC 2000 revisions. Similar reconceptions of the exclusion have occurred in Australia and New Zealand.³⁸

The question therefore arises whether sufficient policy justification exists for denying patent protection to methods of medical and veterinarian treatments otherwise constituting inventions. My view is that they do, and that such subject matter ought to be included in the non-exhaustive list of *ordre public*/morality exclusions proposed above.³⁹ An alternative would be to follow European law by creating a stand-alone (public interest) exclusion for methods of medical treatment in the form of Article 53(c) EPC 2000, as follows:

‘Australian patents shall not be granted in respect of methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body.’

This wording omits the second clause of Article 53(c) (‘this provision shall not apply to products, in particular substances or compositions, for use in any of these methods’) included in the EPC to support so-called ‘Swiss-style claims’; though if Australia maintains its support for such claims that clause could equally be included.⁴⁰

5. BEST PRACTICE VERSUS HARMONISATION

By ‘best practice’⁴¹ I understand ACIP to mean a law created without regard to such political and social realities as the desirability of complying with international legal obligations (including the Paris Convention and TRIPS), the desirability of regional harmonization, and other regional trade and economic considerations (including the need to comply with AUSFTA).

³⁵ As is clear from the discussion above, this would not be achieved by extending the applicability of sections 18(3) and 18(4) of the Patents Act 1990 (in so far as they relate to plants) to standard patents; for Article 53(b) EPC applies in respect of *varieties* of plants and animals, and has been construed by the EPO as not covering plants and animals per se.

³⁶ *Contra* Issues Paper, 51, describing methods for treatment of the human or animal body as ‘listed as inventions which are not susceptible of industrial application’. As explained below, the location of the methods of treatment exclusion was changed by the EPC Revision Act 2000.

³⁷ See generally Pila, above n 26 (analysing the history of the treatment of medical methods in Anglo-Australian patent law and its impact on the development of the law of inherent patentability, including the tendency of the courts before the 1970s to dress the essentially ethical question of whether patents ought to be available for medical methods in black letter principle).

³⁸ In Australia see *Joos v Commissioner of Patents* (1972) 126 CLR 611 (discussed in Pila, above n 26, 437). In New Zealand see *Pfizer Inc v Commissioner of Patents* [2004] NZCA 104 (28 June 2004) ¶114.

³⁹ For a summary of the policy arguments in favour of excluding medical methods from patent eligibility see Pila, above n 26, 421-422 (and references therein).

⁴⁰ See generally Pila, above n 26, 440-441.

⁴¹ Issues Paper, 67-68.

In my view, Australian law should be neither written in a political vacuum nor copied from another jurisdiction solely in the interests of harmonisation. If the experience of European harmonisation teaches anything, it is that laws need a solid policy basis if they are to be interpreted and developed in a coherent fashion, and that adopting a common legislative code without a common court to interpret its provisions is more likely to create disharmony than harmony on account of the inevitable differences that result when courts with different decision-making practices and traditions and social and legal values interpret a common text.

For these reasons, Australia should fashion its own patent policies in a manner appropriate to its own social and economic context, and then consider the extent to which those policies need to be compromised in the interests of compliance with international obligations, and the extent to which they might be expressed in the statutory language of another jurisdiction in the interests of harmonisation. Of course, even if approximation to the laws of other jurisdictions is not supported, those laws remain a rich source of instruction and possible solution to the specific challenges which Australia faces in formulating its law of patentable subject matter.

With respect to the choice specifically between European and US law as a focus for future harmonisation: as the comments above reflect, my own view is that Australian values are closer to European than US values in the field of intellectual property. This is apparent from a comparison of the Australian, US and European copyright regimes, which reveals a much closer alignment between Australia and Europe than Australia and the US in statutory provision, judicial methodology, and direct reliance on judicial authority.⁴²

⁴² Examples of each type of alignment include respectively the statutory inclusion of moral rights, the courts' strict distinction between issues of subsistence and infringement, and the Australian courts' frequent reference to English authorities, including (recently) in *Burge v Swarbrick* [2007] HCA 17.