

Question 1:

Economic objectives of limiting patentable subject matter (Part 3)

Can placing limits on inherently patentable subject matter be justified on economic grounds?

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?

Answer 1:

Summary:

The potential economic benefit of new technologies encouraged through the patent system probably justifies the limited term restriction on trade of a patent in all areas of technology. Compulsory licence provisions can prevent patent owners from unreasonable royalty rates, or withholding consent to work the invention, essentially providing for a “fair price” for new, useful inventions. We consider it would be impractical to conduct an economic assessment for each invention prior to awarding a patent. The administrative burden placed on defining excluded technology areas in practice would probably be unwarranted.

Discussion:

The development of new technologies has played an important role in transforming human society over millennia and especially in the last few hundred years¹. Whether this has happened because of, or in spite of the patent system has been the subject of much debate.

There are a number of examples of dramatic changes in technologies over many years in areas that are patentable, such as cost reductions in and improvements in efficiency of artificial lighting² and increases in the speed of computers³. We are not suggesting that this is evidence that patents have somehow caused those changes, but it is evidence that the patentability of these technologies⁴ does not preclude such changes.

There have also been dramatic improvements in human health over the last few hundred years, an area that in many countries may be excluded in part from the patent system. The exclusion of methods of medical treatment from patentability in Europe has not caused the halt of medical research in Europe, nor has their patentability in Australia caused a halt in health improvements.

The special nature of information has played a key part in this phenomenon.

Unlike physical goods such as a product that one person has or another has, information about how to make a product can be possessed by many without diminishing another's capacity to have the information. Furthermore, unlike physical goods, information can be reproduced and distributed at relatively low cost.

1 Maddison (2006) *The World Economy: A millennial perspective and historical statistics*, OECD.

2 Nordhaus (1998) *Do real-output and real-wage measured capture reality? The History of Lighting Suggests Not*, Cowles Foundation Paper No. 957, Yale University.

3 Nordhaus (2007) *Two Centuries of Productivity Growth in Computing*; *The Journal of Economic History*, Vol. 67, No. 1

4 The Nordhaus study on the history of lighting includes evidence from time periods well prior to the development of the patent system. The most dramatic changes that have occurred in cost and efficiency have occurred since the Industrial Revolution when the patent system was in existence.

The economic benefit of an improved technology - a more efficient or more effective product or process- is a function of how often it is used. A given fluorescent light produces more light for a given amount of energy compared to an incandescent light, saving perhaps tens of watts of energy, however if millions of people use fluorescent lights, billions of watts of energy may be saved.

While there may be a cost associated with the development of a new technology, for example, supporting the inventors and purchasing equipment they may require, the fewer times the development cost needs to be born by society as a whole, the more resources can be directed towards new technologies.

In short, there is a tremendous economic benefit that derives from more efficient, more effective technologies being created *once* and then having the information teaching that technology being widely distributed and adopted.

On first looking into the role that patents may play in the economic benefits of technology, one may consider two alternatives:

- (a) That an invention is patented; or
- (b) That an invention is not patented.

We present an analysis of the costs of these alternatives in a field familiar to us at ResMed, that of medical devices.

The costs of the patent system fall into the following categories:

- Costs born by the patentee in securing a patent (~\$AU10k in Australia⁵)
- Temporary premium or royalties paid on patented products or processes during the ~20 year term of the patent (e.g. 1% to 25% of sale price⁶).

For contentious patents there may be the following additional costs:

- Legal advice to patentees
- Legal advice to potential defendants
- Court costs in the event of litigation⁷.

In Australia it seems few patent cases go to trial. In the decade 1990 to 2000, there were 59 patent disputes before the Australian courts⁸, 22 of which were appeals. Yet in this period there were potentially 192,409 Australian patents that could have been litigated⁹. This suggests court costs at least play a relatively small actual role, although fear of court costs may play a much larger role.

ResMed's primary business is in the field of the treatment of Sleep Disordered Breathing (SDB). A subset of SDB is Obstructive Sleep Apnea (OSA). Until Prof. Sullivan's invention of the use of

5 http://www.ipaustralia.gov.au/patents/fees_index.shtml. Anecdotal evidence suggests the costs are similar in other countries. A study from 2005 indicates the costs in Europe are larger at around E 32,000 (http://www.european-patent-office.org/epo/new/costs_ep_2005_en.pdf). This study was conducted prior to the London Agreement which may have reduced translation costs, however the EPO has also increase its fees.

6 <http://patentbaristas.com/archives/2005/11/17/whats-a-reasonable-royalty-rate/>. Note the author's misgivings about the merits of quoting such royalty rates.

7 Anecdotal evidence for the cost of US patent litigation suggests actual or perceived costs in the order of several million US dollars.

8 Drummond D (2000) Intellectual Property Forum 42

9 Based on search results from IP Australia's AusPat 1.1 search engine, there were 192,409 patents with an acceptance published date from 1 Jan 1980 to 31 December 1999.

nasal Continuous Positive Airway Pressure (nasal CPAP) as a treatment for OSA¹⁰, the recommended treatment for severe OSA was a tracheotomy. Nasal CPAP treatment involves wearing a mask connected to a supply of air or breathable gas at positive pressure generated by a nasal CPAP device. Nasal CPAP devices per se were not invented by Sullivan, hence the method of treating OSA with nasal CPAP was an important aspect of Sullivan's invention.

Whether methods of treatment should be patentable is the subject of much debate, and particularly familiar to us when as ResCare, we brought an action against a commercial rival and bore the cost of answering the question of whether methods of medical treatment should be patentable in Australia. It was decided in the affirmative, both at trial and on appeal¹¹, although the patent claims were held by the Appellant court to have been not fairly based on the provisional application.

A recent study¹² by David Hillman and others estimated the overall economic cost of sleep disorders to Australia in 2004 at approximately \$US7,500 million. In the Hillman study it was reported that sleep disorders affect approximately 6% of the population, the most common of these is Obstructive Sleep Apnea which affects about 4% of the population. Attributing about 2/3 of the Hillman estimate of the total cost, and based on a 2004 Australian population of about 20 million people, this would correspond to an average cost of approximately \$US6,200 per person with untreated OSA.

The current cost of buying a nasal CPAP device in Australia¹³ is in the range of \$AU1,000 to \$AU2,000. The cost of a mask is in the range of \$AU100 to \$AU300. Hence the total cost for the initial purchase of the apparatus is in the range of \$AU1,100 to \$AU2,300. An hypothetical 1% to 25% patent royalty would be relatively small compared to the approximate \$US6,200 "cost" per person with OSA of the Hillman study.

A study¹⁴ by Prof. Guest and others estimates the cost benefit of treating OSA on the UK National Health Scheme. The Guest study concludes that nasal CPAP was clinically more effective than no treatment and the cost-effective strategy, from the perspective of the UK's NHS, after a minimum of 2 years' treatment. Untreated patients were expected to cost the NHS £10,645 per patient over 14 years compared to £9,672 per nasal CPAP-treated patient.

Whilst the conclusion is the generally same in both these studies, the methods of carrying out these studies and final numbers in the results were quite different. We suggest this is evidence of the complexity of making an analysis of the economics.

A number of questions are raised:

Since the monopoly right of a patent relates to the claims, presumably an economic analysis should be based on the claimed invention rather than the disclosure of the specification. If an economic study were required prior to patenting, what form should the study take? What thresholds should mean a patent was acceptable? What would happen if the results of more than one study showed different conflicting results? What would happen if the economic circumstances changed with time?

10 See US Patent 4,944,310

11 *Anaesthetic Supplies Pty Limited v Rescare Limited* [1994] FCA 1065; (1994) 122 ALR 141 (1994) Aipc 91-076 (5 May 1994)

12 Hillman DR, Murphy AS and Pezzullo (2006), *Sleep*, **29**, pp. 299-305

13 Based on advertised prices by internet-based retailer www.cpaustralia.com.au

14 Guest et al (2008) Cost-Effectiveness of using CPAP in the treatment of OSA/Hypopnea Syndrome in the UK, *Thorax Online First*, 11 April 2008.

The question of economic cost and benefits of patenting the original invention of nasal CPAP is only part of the picture. Today, more than 20 years later, there are many technology features of both nasal CPAP devices and masks that are the subject of patents. For example, a given mask may be the subject of patents relating to its cushion, vent, headgear, clips to fasten the headgear to the mask.

Whilst nasal CPAP treatment is highly successful, some patients find it uncomfortable and discontinue treatment. Much of the comfort of the treatment depends on the mask. Efforts continue to develop new, more comfortable masks. Particular efforts are directed by mask engineers to creating new more comfortable cushions. The cushions are the subject of many patents, and a number of patent disputes.

Whilst an economic assessment of, say treatment of OSA with nasal CPAP vs. not treating with nasal CPAP may be possible, we hypothesise that rigorous economic cost benefit analyses of, for example the impact of different curvatures of cushions used in nasal masks, or of the stiffness of side stabilising portions of a headgear arrangement would be difficult. Yet each of these is the subject of patent claims.

The above discussion is not intended to imply that, but for a patent, Professor Sullivan would not have invented nasal CPAP treatment for OSA. Furthermore, while the original Australian patent was overturned, the corresponding patent in the United States was not. ResMed is now a thriving global business and the Australian market is a relatively small portion of the overall business of the company.

ADDITIONAL ALTERNATIVES:

In the discussion above, it was assumed that there were only two alternatives (a patent, or not a patent) however, a different consideration of the alternatives includes:

- (a) technology invented, published and subject to royalty during patent term (~ 20 years)
- (b) technology invented, published and no patent restrictions
- (c) technology invented and kept confidential
- (d) technology not invented

If it were to be argued that certain areas of technology should not be patentable, then the following must be true:

That society would be better off if the technology does not exist, or

That if the technology were to exist then it should either be kept secret, or

That if the technology were not to be kept secret, it should be compulsorily acquired from the inventor within about 20 years of creation with only unreasonable compensation permitted.

If reasonable compensation for compulsory acquisition were acceptable, then that could be achieved via a compulsory patent licence. If it were acceptable for the invention to be freely available after 20 years, then a patent would be acceptable. If it were not acceptable that the invention could be kept secret, then patents provide a suitable solution through compulsory publication. A law preventing patenting of a technology would not of itself prevent the invention and dissemination of a socially undesirable technology. Similarly such a law would not ensure that a socially desirable technology would be come available.

We suggest it would be better to decide what to do with inventions once they have been created.

It seems contradictory that an invention could be both:

- (i) so economically beneficial that all should have access to it without reasonable compensation to the inventor, and
- (ii) that keeping it secret would be just as acceptable when society may need to bear the cost of creating the same invention multiple times.

We suggest that the alternative, a system that encourages and rewards disclosure of inventions is a preferred option.

If it were to be argued that a given invention must be free for all prior to the date when a patent term would have expired, proper consideration should be given to the word “free”.

When the terms “free education” and “free healthcare” are used, it is generally not the case that proponents argue doctors, nurses, teachers and suppliers of goods or services to schools or hospitals go unpaid. Instead, these services are paid for by levying taxes on individuals and businesses.

If it is argued that an invention should be free for all, would not some form of compensation to the inventor be similarly justified? The answer may hang on the price that had to be paid to compensate the inventor.

What would be reasonable compensation?

When considering what might constitute an estimate of a "reasonable royalty" use may be made of the test under US Patent Law know as the Georgia Pacific factors (See Appendix).

Another consideration is the burden that would be placed upon a Patent Examiner by an obligation to apply an economic test for patentability. Such an obligation would place a large responsibility on Examiners and it is unclear how the Examiners would make such an assessment. Would individual Examiner's views on inventions be justified considering the majority of Examiners are not trained in business development or marketing disciplines? In one scenario, the Applicant may be required to provide evidence of business plans and other information to support the patenting of an invention. This additional information places additional burden on both the Examiner and the Applicant. We do not believe Examiners should be burdened with such a responsibility that may impact the success or failure of a business venture.

Question 2 – Economic effect of inherent patentability test.

What would be the consequences on innovation of imposing or removing limits on patentable subject matter? Are you aware of any empirical data on such consequences?

Summary:

Imposing or removing limits on patentable subject matter may affect the value of existing businesses with products or services relating to that subject matter. It may also affect the ability of new businesses to start up and offer products or services in that market.

Making a technology attractive to businesses may lead to a competitive market, with an associated constant drive for cost reductions and improved product features, even when patents are allowed. The presence of patents does not necessarily exclude competitors from selling products into that market. The existence of a patent may drive businesses to innovate and develop non-infringing alternative technologies. This is reflective of ResMed's experience in the field of medical devices.

Discussion:

There is a parallel between imposing or removing limits on patentable subject matter and patent litigation where a patent is upheld or overturned. The following table summarises some recent news reports where the share prices of companies fall when patents are overturned, or rise when they are upheld.

Date	Company	Share Price Change	Notes	Source
July 2004	Pfizer		Chinese Patent Re-examination board rules Viagra patent invalid.	www.iprights.com
5 June 2006	Pfizer	+ ~1%	Intermediate Chinese court rules Viagra patent valid	moneynews.com
5 Nov 2007	Pfizer		Beijing High People's Court rules Viagra patent valid.	Seeking Alpha
8 August 2006	Bristol-Myer Squibb	- 7%	Generic company launches product competing with blood thinner Plavix drug, stating patent is invalid.	CBS Online news
27 October 2006	Bristol-Myer Squibb		<i>“Still reeling from a generic assault on its top-selling product, Plavix, Bristol-Myers Squibb said yesterday that it lost up to \$600 million in sales of the drug to a Canadian rival</i>	New York Times online

			<i>during the third quarter, accounting for part of a 65 percent decline in earnings.”</i>	
2 July 2008	AstraZeneca	+ 7%	US District court upholds patent on Seroquel antipsychotic drug.	Healthcare Digital
2 July 2008	AstraZeneca	+ 5%	Court awards Summary Judgement in favour of AstraZeneca	International Herald Tribune
16 June 2008	Broadcom	+ 3.5%	US International Trade Commission rules that patents of a competitor, SiRF Technology did not cover a subsidiary of Broadcom	Boston.com, International Business Times

These changes in share prices represent perceived change in the value of these companies. Whilst these are all large companies, we suggest there is a similar process for small companies. There is evidence¹⁵ of small companies being formed whose chief assets are a patent portfolio. Absent such a patent portfolio, such companies may face significant challenges in attracting investors.

A range of factors may influence the result of imposing or removing limits on what is patentable:

- The importance of the Australian market: In cases where the Australian market is relatively small, it may be of relatively small importance to an inventor whether the invention is patentable in Australia.
- The timing of a change: If a change to patentability of certain technologies was made after filing of a patent application, an applicant may have little choice but to cancel or amend claims. If a change was made prior to lodgement, an inventor may choose not to file a patent application and rely on keeping their invention secret, depending on the nature of the invention.
- The existence of a proprietary right to certain technologies can represent value to an individual or business and can influence the amount of money they may be able to obtain from venture capitalists or raise via issuing shares, or simply the day-to-day value on a stock exchange.

15 Study on evaluating the knowledge economy What are patents actually worth? The value of patents for today's economy and society Tender n° MARKT/2004/09/E, Lot 2 Final Report.

Question 3 – Ethical reasons for limiting patentable subject matter (Part 4)
Can placing limits on inherently patentable subject matter be justified on ethical grounds? Is it appropriate for legislation to predetermine ethical limitations on patentable subject matter, or is it more appropriate for courts to determine such limitations on a case-by-case basis?

Is patent law an appropriate avenue for dealing with ethical issues? If not, what is an appropriate avenue?

Summary:

No. The patent system is an inappropriate and impractical avenue for dealing with ethical issues. It is suggested that parliament, the courts, or a specialist body appointed by parliament would be a more appropriate avenue to address ethical issues.

Discussion:

There may be considered two alternative situations with respect to the ethics of a given invention:

- (i) The invention may be considered "unethical"; or
- (ii) It would be "unethical" for the invention to be the subject of a patent right (the "virtuous" technology).

"Unethical" inventions might be in technology areas relating to weapons, instruments of torture, or certain forms of medical intervention. Such areas may indeed be unethical if they were to be practiced.

However, it is a misconception that the grant of a patent gives a patentee the right to practice their invention. In fact, patents only provide the right to exclude others from practicing the invention since another patent holder might have a right that precludes the patentee. Furthermore preventing patents in a certain technology area actually removes an impediment from someone using an "unethical" technology.

In any case, the mere existence of a patent does not prevent government from passing a law banning the use of any technologies considered unethical.

Furthermore, it would seem impractical to place the burden for making decisions about whether the practice of a certain technology is unethical with a patent examiner. Such decisions should be made by parliament or a specialist body appointed by parliament. During debate about the "Onco-mouse" patent application before the European Patent Office, there was reportedly much controversy. *New Scientist* magazine reported the following¹⁶:

Staff at the EPO are already tired of having to grapple with issues of public morality. 'We wish someone would invent a transgenic cat to eat this transgenic mouse,' said one exasperated patent officer in Munich last week. 'Then we could go back to ordinary work.'

An example of a "virtuous" technology that might be considered unethical to be the subject of a patent right is one in the area of medical treatment, such as a drug or method of treatment. For example, it might be considered unethical or immoral that a business might charge a patent royalty

16 Issue 1791 of *New Scientist* magazine, 19 October 1991, page 11

for a potentially lifesaving drug or method of treatment. Another area might be some form of safety procedure - a method of landing an aeroplane - which it might be unethical to withhold.

However, we believe that, like arguments about the economic benefits of technology, it is a mischaracterisation to consider that the alternatives are:

- (i) that the virtuous technology exists and is free for all; or
- (ii) that the virtuous technology exists and is owned by someone who charges a fee for it.

Instead, one must also consider that absent a patent right, the technology might not exist, or might be confidential. Hence if indeed a technology is so vitally important that it would be immoral for it be withheld without payments of fees, it would seem immoral to go down a course of action that might lead to the virtuous technology not existing or being secret.

Surely it is better for the virtuous technology to exist, be known and, for example, be the subject of a compulsory licence giving the inventors some form of reasonable royalty.

The New Zealand government, in discussing¹⁷ a case against the patentability of methods of medical treatment has stated:

“In any case, financial rewards may not be the only incentives to innovation in the field of medical treatment, particularly where the innovator is a doctor or other medical practitioner. Rewards such as prestige, peer recognition, and respect by society may be other drivers of innovation. Some doctors may be motivated to develop new medical treatments by the need to improve the health or quality of life of their patients rather than by any desire for personal advancement.”

Just because an invention is patentable, doesn't mean that a person has to apply for a patent, nor to enforce it. Some may choose to do so as part of a medical business.

Further, it was stated:

“235. The granting of patents to methods of medical treatment may raise ethical problems. Doctors who have a financial interest in a patented method of treatment may use that method, or refer patients to doctors who use that method in preference to others, even though that method may not be the most appropriate for that particular patient.”

It seems difficult to make a distinction between this rational to deny patentability for methods of treatment, and yet allow patents for a pharmaceutical treatment. By the same argument, a doctor may have an incentive to prescribe a certain patented drug because they may have shares in the company selling the drug, or will receive some other financial incentive from the company.

A similar line of argument could suggest that doctors might be recommending unnecessary treatments, whether patented or not, just to create extra business for themselves. This would raise ethical questions regarding the doctors' conduct rather than an ethical issue with the patent system.

An alternative conclusion might be to rely on the integrity of doctors to act in the best interests of their patients.

We do not believe that patent law is the most appropriate forum to determine ethical issues. Ethical issues do not arise because a patent is granted, they arise in the manner in which the invention is applied or used by an individual.

17 http://www.med.govt.nz/templates/MultipageDocumentPage___1462.aspx

For certain technology areas it seems difficult to rationalise patentability being allowed for apparatus carrying out a method, while dictating the non-patentability of the method itself. In our experience, some inventions are most appropriately characterised as methods, rather than apparatus, and the lack of patentability of the method drives patentees to seek creative claim solutions.

Advanced methods of medical treatment are not necessarily carried out by hand, but may be performed through the use of sophisticated devices, even by robots. The invention in such cases is not a collection of nuts, bolts, actuators and particle beams, but a method that may be impossible to carry out by the hand of a surgeon.

One example is the “Gamma Knife”, a device used to treat certain forms of brain tumour. Radiation therapy has been recognised for many years as a way of killing cancer cells. One challenge with such therapy is damage to healthy tissue. This may be a particular challenge when a tumour lies in a region surrounded by healthy tissue.

The Gamma Knife uses a frame to hold the head still and starts with a series of scans such as CT or MRI, to determine the precise location of the tumour. Treatment uses 201 beams of radiation in a hemispherical arrangement around the head, aimed at the tumour. Because the energy of each individual beam is relatively low, surrounding tissue suffers less damage, however the point at which the beams converge receives a relatively higher dose. Patients can receive treatment in a single outpatient treatment session without general anaesthesia.

A core concept in this treatment is the method of treatment with multiple low doses focussed around the tumour. When inventive, ought not such methods of treatment be recognised, lauded, and encouraged? Publishing the details of the method through a patent could lead to non-invasive treatment of other organs, and businesses focussed on providing lower cost alternatives. Not allowing patents could run the risk that aspects of the method remain confidential.

Question 4 – Ethical effect of inherent patentability test.

What would be the ethical consequences of imposing or removing limits on patentable subject matter? Are you aware of any examples of such consequences?

SUMMARY:

We believe the consequences of imposing limits on patentable subject matter would be to reduce the likelihood of private research in the relevant technological area. From an ethical perspective this may result in inventors keeping their inventions secret and society being withheld from important developments, such as a new medical procedure. If an inventor was to develop a new medical procedure and was not able to gain compensation for the invention through the patent system they may choose to only disclose the invention to a limited number of people being those whom they choose to treat or even keep aspects of the invention secret. Furthermore, the lack of a patent would not prevent the inventor from charging for the procedure but may be a reason for the teaching of the invention not being made generally available to the public. Thus, society as a whole would not gain the full benefit of this inventive development.

What would be the consequences for existing patents if new limits on patentable subject matter were imposed that rendered the subject matter unpatentable? If a business had been established based on such patents this change may significantly harm the future of the business as it may allow a number of competitors to come into the market providing a 'free' benefit from the original, earlier investment in innovation.

The two crucial tests for patentability involve measuring the subject application against standards that are circumscribed by the past, namely novelty and obviousness. In contrast, as must be the case for an examination of economic considerations, an inquiry into the ethical dimension of an invention might not reach an appropriate conclusion when performed at only one point in time. The relevance of such inquiries must be in relation to the future, looking forward from the time that the patent application is filed. For this reason alone it is unclear as to how a useful inquiry into the ethical aspects of a technology can be made at the time of examination of a patent application. For example, one can foresee a situation where a new field of technology initially passes the "ethical inherent patentability test" (i.e. proceeds to patent) simply because the benefits the technology will render to society are presently unknown or are only recognised by the excited inventor. As the benefits of the new technology become universally celebrated because of its success subsequent to disclosure should it be come unpatentable?

*Question 5 – Other reasons for limiting patentable subject matter.
Other than economics, ethics and national security, can placing limits on inherently patentable subject matter be justified on any other grounds?*

No.

Question 6 – Content and structure of current Australian law (Part 7)

Does the content of current Australian law meet the objectives of the system? Are decision makers focusing on the appropriate principles?

Is the legislative structure of current law appropriate for the content?

Is the current law clear to decision makers and users of the system? Does the content or structure of the current test cause you any significant problems?

The general objectives of the patent system are met by the current Australian law.

Key principles of the patent system must be whether the invention is novel, inventive and useful. Currently utility is considered under Manner of Manufacture but the utility requirement should be more specific. With these key principles stated in the law there is no need to limit the technology areas for inventions.

Past decisions and interpretations of the law facilitate the understanding of the system and any changes in the system or the law must be considered in view of these interpretations.

Question 7– Issues with current Australian law

Do you have any comments on issues A to H identified in Part 11.3.1?

- combination of flexible and proscriptive tests*
- value of existing body of case law*
- general inconvenience, mischievous to the state and hurt of trade*
- archaic language*
- threshold of inventiveness*
- threshold of utility*
- scope of rights awarded*
- requirement for grant*

We believe the “general inconvenience” and “mischievous to the state” language is unclear. While a lack of clarity is not necessarily bad, it is probably inappropriate that a Patent Examiner, or even the Patent Office should be making judgements about these questions. The grant of a patent does not prevent Parliament from enacting legislation that would prevent the sale of products or services thought to be “generally inconvenient” or “mischievous to the state”. Of course, what may be “generally inconvenient” or “mischievous” to one government may not be to another.

Whether the patenting of a particular technology would be “hurtful of trade” is a difficult question to answer and should probably not be a ground that is considered during examination. Should there be a concern about the high price for a patent licence, then clear guidelines about the kind of reasonable royalties that would be provided in the event of compulsory licences being ordered may address such concerns.

The current interpretation of use of the manner of manufacture incorporates the broadest range of technologies.

The importance of past interpretations and decisions regarding the understanding of the Act must be valued and considered with respect to any changes.

Question 8 – International integration

Is it more important to achieve best practice or to harmonise with a major jurisdiction? Are any jurisdictions preferable over others?

The most important result is that Australians have access to the most effective and most efficient technologies. It is likely that the majority of new technologies will be invented outside Australia. To the extent that harmony of Intellectual Property law with major inventing jurisdictions such as the United States, Japan, Europe and South Korea facilitates access to these technologies, harmony is important.

Similarly the open nature of Australia's markets means that home-grown inventions must compete locally with offerings from the world. For this reason a suitable return on investment will not necessarily be made in Australia alone, but rather must be yielded from world markets. This means that a local inventor should seriously consider seeking patent protection beyond Australia. That task may be simpler where Australian patent law is harmonized with major jurisdictions and the patent laws of those major jurisdictions are harmonised amongst themselves.

*Question 9 – International compliance of current Australian law
Is current Australian law compliant with our international obligations?*

It is believed Australian law is currently compliant with the obligations under the TRIPS agreement.

Question 10 – Preferred patentable subject matter

According to what you believe are the appropriate objectives and constraints of the patent system, what sorts of subject matters do you think should be inherently patentable and what should not?

Option 1: All “man-made” technologies should be potentially patentable.

Would your preferred content be compliant with Australia’s international obligations?

Yes.

Question 11 – Legislative structure

What sort of legislative structure would be appropriate to achieve your preferred content identified in Question 10? Are any foreign structures preferred?

In principle, when should statutory provisions excluding specific subject matters be used? Should such provisions be expanded, such as by including the exceptions from patentability allowed under TRIPS?

A flexible and broad legislation that provides for all forms of technology would be considered most appropriate. Thus, there would be no statutory provisions to exclude any specific subject matter within the patent legislation. The use of technology areas considered unethical would be dealt with under different legislation if deemed required. For patents related to technologies deemed to be required without the impediment of patent infringement issues, a compulsory license provision may be considered. Examples of technologies where compulsory licences may be appropriate include where the patent is not being worked, or where the claims cover a necessary new treatment. This would require clear compulsory license rules and guidelines to support the system.

Question 12

Do you have any other comments?

APPENDIX

*Georgia-Pacific v. United States Plywood Corp.*¹⁸

In the 1970 case of Georgia-Pacific v. United States Plywood Corp. (318 F. Supp. 1116), the U.S. District Court for the Southern District of New York used the following 15 factors to determine what type of monetary award would compensate for infringement:

- 1. The royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty.*
- 2. The rates paid by the licensee for the use of other patents comparable to the patent in suit.*
- 3. The nature and scope of the license, as exclusive or nonexclusive, or as restricted or nonrestricted in terms of territory or with respect to whom the manufactured product may be sold.*
- 4. The licensor's established policy and marketing program to maintain a patent monopoly by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly.*
- 5. The commercial relationship between the licensor and licensee, such as whether they are competitors in the same territory in the same line of business, or whether they are inventor and promoter.*
- 6. The effect of selling the patented specialty in promoting sales of other products of the licensee, the existing value of the invention to the licensor as a generator of sales of non-patented items, and the extent of such derivative or convoyed sales.*
- 7. The duration of the patent and the term of the license.*
- 8. The established profitability of the product made under the patent, its commercial success, and its current popularity.*
- 9. The utility and advantages of the patent property over the old modes or devices, if any, that had been used for working out similar results.*
- 10. The nature of the patented invention, the character of the commercial embodiment of it as owned and produced by the licensor, and the benefits to those who have used the invention.*
- 11. The extent to which the infringer has made use of the invention and any evidence probative of the value of that use.*
- 12. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.*
- 13. The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.*
- 14. The opinion testimony of qualified experts.*

¹⁸ http://www.aicpa.org/pubs/jofa/sep2008/reasonable_royalty.htm

15. The amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement, that is, the amount obtain a license to manufacture and sell a particular article embodying the patented invention—would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.