Submission to the Productivity Commission's Review of National Competition Policy Arrangements

A Critique of Industrial Property – Patents

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SUMMARY

- While there is no doubt that Australia must implement the *Agreement on Trade Related Aspects of Intellectual Property Rights* (TRIPs) minimum standards patent scheme, the issues raised in this submission is not about whether or not to have a patent scheme, but rather, the content of that scheme. Once this is accepted the issue then becomes one of the desirability of measures that implement *more* than the minimum standards required by TRIPs (so-called 'TRIPs-plus measures') in the *Patents Act 1990* (Cth) and the *Trade Practices Act 1974* (Cth).
- The submission asserts that in considering TRIPs-plus measures the guiding principle of the *Competition Principles Agreement* (CPA) should be applied to the existing and proposed TRIPs-plus measures in both the *Patents Act 1990* (Cth) and the *Trade Practices Act 1974* (Cth).
- This submission challenges the existing basis for adopting TRIPs-plus measures and some of the governmental approaches to justifying a conclusion that TRIPs-plus measures are necessarily appropriate to Australia's economic and social circumstances according to the CPA.
- TRIPs' 'flexibility' is also examined to illustrate that there is considerable potential to develop patent laws suited to Australia's particular economic and social circumstances.

1. INTRODUCTION

1.1 The submission asserts that in considering *any* measures that restrict competition in Australia, including patent privileges under the *Patents Act 1990* (Cth) ('*Patents Act*') and *Trade Practices Act 1974* (Cth) ('*Trade Practices Act*'), the guiding principle of the *Competition Principles Agreement* ('CPA') should be applied. This submission challenges the existing basis for adopting TRIPs-plus measures and some of the governmental approaches to justifying a conclusion that TRIPs-plus measures are necessarily appropriate to Australia's economic and social circumstances according to the CPA.

1.2 As a starting point, any patent policy in Australia must accommodate the minimum standards now required of World Trade Organisation ('WTO') members, such as Australia, in compliance with the *Agreement on Trade Related Aspects of Intellectual Property Rights* ('TRIPs').[1] The minimum standards required by TRIPs are that 'patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial.[2] Significantly 'patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced'.[3] The only allowable exclusions are 'inventions … necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment',[4] 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals'[5] and

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[1] *Marrakech Agreement Establishing the World Trade Organisation* [1995] ATS 8, Annex 1C ('TRIPs').

[2] TRIPs Art 27(1); noting that the terms 'inventive step' and 'capable of industrial application' are equivalent to the terms 'non-obvious' and 'useful' respectively.

[3] TRIPs Art 27(1).

[4] TRIPs Art 27(2).

[5] TRIPs Art 27(3)(a).

'plants[6] and animals other than micro-organisms, and essential biological processes for the production of plants or animals other than non-biological and microbiological processes'.[7] These minimum standards are enforceable through a dispute settlement scheme proscribed in TRIPs.[8]

1.3 While these TRIPs minimum standards are open to some interpretation,[9] there is no doubt that Australia must implement at least some form of patent scheme similar to the *Patents Act*. The issues raised in this submission is not about whether or not to have a patent scheme, but rather, the content of that scheme, and the desirability of measures that implement *more* than the minimum standards required by TRIPs (so-called 'TRIPs-plus measures'). This is an issue worthy of further consideration as Australia has been at the vanguard of the TRIPs agreement. Australia has championing its implementation though a rapid adoption of its minimum standards[10] and adopting additional TRIPs-plus measures (such as more restrictive compulsory licensing, patent term extensions and failing to take advantage of the allowable exceptions under TRIPs). Further Australia has sought to ensure its effects are passed through to other international and regional agreements.[11] This same approach is now reflected in the proposed *Australia-United States Free Trade Agreement.*[12] This submission challenges the basis for adopting TRIPs-plus measures and the various governmental approaches under the guise of the CPA to justifying a conclusion that TRIPs-plus measures may necessarily be justified.

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[6] Noting that plant varieties must be protected either by 'patents or by an effective *sui generis* system or by any combination thereof': TRIPs Art 27(3)(b).

[7] TRIPs Art 27(3)(b).

[8] TRIPs Art 64.

[9] See for example Dianne Nicol and Jane Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 363-364.

[10] See *Patents (World Trade Organisation) Amendment Act 1994* (Cth).

[11] See for example the *Singapore-Australia Free Trade Agreement* [2003] ATS 16, ch 13 Art 2(1).

[12] See *Australia-United States Free Trade Agreement* ('AUSFTA') Art 17(9).

1.4 The Australia Government's stance reflects the underlying economic objective that '[i]nnovation – developing skills, generating new ideas through research and turning them into commercial success – is a key driver of productivity and economic growth',[13] of which intellectual property is believed to assists as an incentive to innovate, in capturing the commercial success and in accessing new technology and know how.[14] An apparently similar consensus exists among other developed nations.[15] However, the exact place and role of TRIPs-plus patent measures in Australia's innovation policy, expressed in *Backing Australia's Ability*,[16] the central innovation policy articulated by the Australian Government, is not very clear.

1.5 This submission challenge the reasoning for adopting TRIPs-plus measures under the *Patents Act* and suggests that the modern Australian policy grasp for 'strengthened' intellectual property rights has failed to consider the lack of evidence actually demonstrating the benefits from adopting more than TRIPs' minimum patent requirements for the Australian economy. The submission concludes the TRIPs-plus measures in the *Patents Act* should be reviewed and removed unless justified because the restriction to the community as a whole outweigh the costs and that the objectives can only be achieved with these measures. This is the principle and standard against which laws restricting competition must be assessed according to the requirements of the CPA.[17]

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[13] Commonwealth, *Backing Australia's Ability: Real Results Real Jobs – Innovation Report 2002-2003* (2003) 1 (BAA 2002-03); see also Commonwealth, *Backing Australia's Ability: Real Results Real Jobs – Innovation Report 2003-2004* (2003) 1; Commonwealth, *Backing Australia's Ability: An Innovation Action Plan for the Future* (2001) 7 (BAA 2001).

[14] BAA 2001, above n 13, 18

[15] See BAA 2002-03, above n 13, 1; Organisation for Economic Co-operation and Development, *OECD Science, Technology and Industry Scoreboard 2003* (2003) 16-17.

[16] BAA 2001, above n 13.

[17] The *National Competition Policy* comprises a series of agreements between the Commonwealth, States and Territories (see National Competition Council, *Compendium of National Competition Policy*

1.6 In challenging the contention that Australia's approach to patent policy reasons that the most developed nations have benefited from innovation with a strong intellectual property regime, and so with a similarly strong patent regime in Australia, those same benefits will accrue to Australia, the submission is structured as follows:

- Part 2 examines the theoretical justifications for patents restricting competition. This is a significant question as the detailed justification and objectives of patents as a policy tool to promote invention are not settled.
- Part 3 examines the place of patents in the Australian Government's implementation of competition policy under the CPA. The analysis raises concerns about the approach adopted by the Intellectual Property and Competition Review Committee ('IPCR Committee') and the National Competition Council ('NCC') in reviewing patent laws under the CPA and whether this is in effect an adequate assessment of patent laws according to the requirements of the CPA.
- Part 4 examines some of the 'flexibility' in TRIPs that Australia might take advantage of to develop patent laws suited to its particular economic and social circumstances. Notably, this 'flexibility' was not considered by reviews of the patent laws by the IPCR Committee or NCC.
- Part 5 then sets out the conclusions that without the assessment required by the CPA, the existing and proposed TRIPs-plus measures are presumed to be an unnecessary restriction on competition, unless the Australian Government (and other proponents of maintaining TRIPs-plus measures in Australian laws) can demonstrate the benefits of restricting competition and that the objectives can only be achieved through restricting competition.

Agreements (1997)), legislative measures to limit anti-competitive conduct and ensure access to essential facilities (such as the *Trade Practices Act 1974* (Cth)) and government bodies to oversee the application of the NCP (such the Australian Competition and Consumer Commission and the National Competition Council).

1.7 This submission assumes that patent law set out in the *Patents Act* and competition law set out in the *Trade Practices Act* both seek to promote invention with the objective of enhancing consumer welfare. Patents achieve this through addressing the market failure for invention and competition law through protecting the process of competition (rather than competitors). In practice, the *Patents Act* establishes the threshold criteria for the grant of the statutory privilege (the 'exclusive rights') with some exemptions from competition (such as compulsory licensing and so on). The *Trade Practices Act* seeks to establish the boundaries of lawful conduct necessary to sustain and promote vibrant competition. While the place of competition law is central to establishing an appropriate balance, competition laws are not considered here although their effectiveness in Australia in limiting a patent privilege holder's conduct is unlikely.[18]

2. THEORETICAL JUSTIFICATION FOR RESTRICTING COMPETITION

2.1 Patents are a utilitarian measure to promote invention[19] and address the market failure for invention.[20] According to this model, effective competition together with good market information may create a disincentive to markets inventing (the

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[18] For an assessment of this contention see Charles Lawson, 'Patenting Genes and Gene Sequences and Competition: Patenting the Expense of Competition' (2002) 30 *Federal Law Review* 97.

[19] Although the current imperative of economic policy in Australia is to foster economic growth: see for example BAA 2001, above n 13, 1; Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000) 5; Commonwealth, *Investing for Growth* (1997) 3-7; an alternative justification for promoting competition is to more efficiently and effectively allocate existing scarce resources for the benefit of consumers.

[20] This submission distinguishes between 'invention' and 'innovation', the term 'invention' being a step in the process of 'innovation'. In this distinction, 'innovation' would include all the other commercial requirements to place an 'invention' on the market, including product development, marketing, and so on. This distinction is important as patents are an incentive to 'invention', but it is *not* clear whether they should also be an incentive to 'innovation'. In effect, this distinction reflects the differences between the 'reward' and 'prospect' theories justifying patent privileges: see Kevin Rhodes, 'The Federal Circuit's Patent Non-obviousness Standard: Theoretical Perspectives on Recent Doctrinal Changes' (1991) 85 *New York University Law Review* 1051, 1076-1100.

market failure) because new developments may be rapidly copied without the recovery of the inventor's development costs (a free ride).[21] A patent under the *Patents Act* compensates for this disincentive to invent.[22] The limited period of 'exclusive rights'[23] is justified so that the inventor may exclude others in order to recover the development costs (confounding the free riders) and contribute to beneficial invention (and enhanced competition for the welfare of consumers) by investing in new developments (with the added benefit of disclosure of the invention).[24]

2.2 While the economic theory justifies a patent privilege in the form of statutory 'exclusive rights', it is certainly not clear whether the social costs in Australia's particular economic circumstances always outweigh the social benefits from

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[21] Trade Practices Commission, *Application of the Trade Practices Act to Intellectual Property* (1991) 8.

[22] Such as, 'the uncertainty of pay off from R&D and innovation activity' and 'the limited ability of the inventor/innovator to appropriate profits arising from the use of the new knowledge generated': see Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984) 12; Bureau of Industry Economics, *The Economics of Patents*, Occasional Paper No 18 (1994) 13.

[23] *Patents Act* s 13; thus, for a period of up to 20 years from the date of lodging the claim (s 67 provides a minimum term of 20 years from the lodgment of a claim and s 77 provides the term may be extended for certain pharmaceuticals up to 25 years from lodgment), including the 'exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention' (s 13(1)) which is 'personal property … capable of assignment and devolution by law' (s 13(2)). The term 'exploit', in relation to a product invention, includes 'make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of these things' (sch 1). In relation to a process invention, it includes 'use the method or process or do any act mentioned [for the product invention] in respect of a product resulting from such use' (sch 1).

[24] Trade Practices Commission, *Application of the Trade Practices Act to Intellectual Property* (1991) 8; for a review of the policy objectives of patenting see Thomas McCarthy, 'Intellectual Property and Trade Practices Policy: Coexistence or Conflict? The American Experience' (1985) 13 *Australian Business Law Review* 198, 200-203; note that there are different views about whether disclosure is a primary purpose of patenting, or merely an additional benefit: see for example Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003) ch 1 (6).

current patenting practices[25] and what are the appropriate patent scope and allocation.[26] Recent developments in the application of the internationally agreed minimum standards set by the TRIPs confirm the uncertain standard of the patent threshold requirements, and suggest considerable 'flexibility' in how WTO member states may satisfy these minimum patent standards (considered further in Part 4). The challenge for Australia's patent policy makers is to develop an 'effective and adequate' patent scheme[27] that fulfils its obligations under TRIPs, noting that the over-riding objective of TRIPs was that:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[28]

2.3 In developing an appropriate domestic patent policy, patent privileges should only be granted to the extent necessary to encourage invention (the incentive).[29] Further, the onus is on those advocating patent privileges in addition to the minimum standards required by Australia's commitment to international agreements (such as TRIPs), to demonstrate that:

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[25] Some commentators have expressed concerns that the highly protective patent standards applied by the United States and the European Union may be unduly favoring the private rights of inventors at the expense of competitors and users, particularly in economies that are net technology importers: see for example Keith Maskus, *Intellectual Property Rights in a Global Economy* (2000) 237-238.

[26] See for example Dan Burk and Mark Lemley, 'Policy Levers in Patent Law' (2003) 89 *Virginia Law Review* 1575, 1595-1630.

[27] Recognising that TRIPs was intended to '… to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade': TRIPs Preamble.

[28] TRIPs Art 7.

[29] It is generally accepted that patent privileges are necessary in some form, although they should not be absolute: see James Langenfeld, 'Intellectual Property and Antitrust: Steps Towards Striking a Balance' (2001) 52 *Case Western Reserve Law Revue* 91, 96-98.

(a) The benefits of the restriction to the community as a whole outweigh the costs; and

(b) The objectives of patent privileges can only be achieved by restricting competition.[30]

2.4 A key measures in assessing the adequacy of the incentive is that the incentive is directed to the true inventor (and their investors) and only for inventions that would not otherwise have been made.[31] In particular, patents should not protect inventors (and their licensees and assignees) from competition from other inventors (and their licensees and assignees) for an investment in invention they would be making anyway as part of their innovation strategy to remain competitive.[32]

2.5 In essence, patents impose social costs even when they are within the bounds of lawful use under competition laws. The threshold and other criteria for access to the statutory privileges under the *Patents Act* are important to ensure efficiencies – too low a threshold and competition is unnecessarily fettered to the detriment of consumers (and the community as a whole) and too high and the incentive is extinguished. The challenge is to tailor patent privileges to the appropriate level of incentive. This question remains contentious with a number of other regulatory

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[30] This is the 'guiding principle' of the *Competition Principles Agreement*: see *Competition Principles Agreement* cl 5(1).

[31] See for example Justice Posner in *Roberts v Sears Roebuck & Co* 723 F.2d 1324, 1346 (1983): 'if a court thinks an invention for which a patent is being sought would have been made as soon or almost as soon as it was made even if there were no patent laws, it must pronounce the invention obvious and the patent invalid'.

[32] Recognising that this 'but for' requirement has proved very difficult to articulate as a general, non-discriminatory threshold standard: see Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003) ch 1 (10).

factors affect the appropriate settings (including the appropriate competition and taxation policy).[33]

3. COMPETITION POLICY IN AUSTRALIA

3.1 As a measure of the collective concern about the high social costs from restrictions on competition (together with the inefficiencies in the market from less than optimal allocation of resources), Australia has undertaken an extensive review of its regulations and government actions to remove anti-competitive arrangements that cannot be justified to achieve an identifiable 'public interest'.[34] The following sections consider the key aspects of the developed *National Competition Policy* (NCP) from its foundations in the *Independent Committee of Inquiry into Competition Policy in Australia* (Hilmer Committee) report and the CPA to the following legislative reviews required by the CPA and conducted by the NCC and the IPCR Committee. The IPCR Committee approach to patent privileges is then contrasted with its approach to parallel import restrictions under the *Copyrights Act 1968* (Cth).

3.1 Hilmer Committee and the CPA

3.1.1 The Hilmer Committee undertook a broad ranging policy review of the restrictions on competition in Australia and proposed a number of reforms directed to removing barriers to competition with the aim of benefiting

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[33] See for example Keith Maskus, 'Intellectual Property Challenges for Developing Countries: An Economic Perspective' (1998) *University of Illinois Law Review* 457.

[34] This process may be traced back to the establishment of a NCP following the Hilmer Committee report (Independent Committee of Inquiry into Competition Policy in Australia, *National Competition Policy* (1993) ('Hilmer Committee')), the enactment of provisions following the Government response to the Hilmer Committee (*Competition Policy Reform Act 1995* (Cth)) and formal agreement of a NCP between the Commonwealth, States and Territories (see National Competition Council, *Compendium of National Competition Policy Agreements* (1997)); see Ministerial Statement, House of Representatives *Hansard*, 12 March 1991, 1761 (Prime Minister); details about the stewarding of the NCP agreement are reviewed in E Harman, 'The National Competition Policy: A Study of the Policy Process and Network' (1996) 31 *Australian Journal of Political Science* 205, 208-217.

consumers, promoting business competition, fostering innovation and making the Australian economy more flexible, thereby 'improving its capacity to respond to external shocks and changing market opportunities'.[35] The Hilmer Committee report identified two aspects of intellectual property that required further review:

(a) The exemption of certain conditions in licenses and assignments of intellectual property in the *Trade Practices Act* – here the Hilmer Committee report expressed some concern about the existing scheme of exemptions saying '[t]he Committee was not presented with any persuasive arguments as to why intellectual property rights should receive protection beyond that available under the authorization process [in the *Trade Practices Act*]'.[36] The Hilmer Committee 'saw force' in arguments suggesting the exemptions be reformed but concluded it was not placed to make 'expert recommendations' and suggested that the matter should be examined further to 'assess whether the policy reflected by the exemption is appropriate'.[37] The NCC and IPCR Committee subsequently undertook the review of the exemption, and this is considered in the following sections; and

(b) The regulatory restrictions on competition contained in statutes or subordinate legislation – here the Hilmer Committee report identified the 'temporary monopolies' given to protect intellectual property as a regulatory barrier to market entry.[38] The Hilmer Committee recommended that '[a] mechanism to promote reform of regulation that unjustifiably restricts competition form a central plank of a national competition

[35] Hilmer Committee, above n 34, xvi.

[36] Hilmer Committee, above n 34, 150.

[37] Hilmer Committee, above n 34, 151.

[38] Hilmer Committee, above n 34, 195.

policy'[39] and then recommended all Australian governments abide by a series of principles, including that:

- '[t]here should be no regulatory restrictions on competition unless clearly demonstrated to be in the public interest';[40]
- '[p]roposals for new regulation that have the potential to restrict competition should include evidence that the competitive effects of the regulation have been considered; that the benefits of the proposed restriction outweigh the likely costs; and that the restriction is no more restrictive than necessary in the public interest';[41] and
- '[a]ll existing regulation that imposes a significant restriction on competition should be subject to regular review to determine' that the restriction on competition is 'clearly demonstrated' to be in the 'public interest'.[42]

3.1.2 Following the Hilmer Committee report, a number of measures were initiated to put the report's broader recommendations into effect.[43] These included amendments to the *Trade Practices Act* and *Prices Surveillance Act 1983* (Cth),[44] three inter-governmental agreements (including the CPA), and related reforms to the electricity, gas, water and road transport industries.[45] A significant part of the CPA was that governments around Australia review the anti-competitive effects

[39] Hilmer Committee, above n 34, 211.

[40] Hilmer Committee, above n 34, 212.

[41] Hilmer Committee, above n 34, 212.

[42] Hilmer Committee, above n 34, 212.

[43] For a review of the key measures and operation of the National Competition Policy see R Deighton-Smith, 'National Competition Policy: Key Lessons for Policy-making from its Implementation' (2001) 60 *Australian Journal of Public Administration* 29.

[44] See *Competition Policy Reform Act 1995* (Cth); see also the Second Reading, Competition Policy Reform Bill 1995, House of Representatives *Hansard*, 30 June 1995, 2793-2801 (Assistant Treasurer); corresponding legislative amendments were also to be introduced in the various States and territories.

[45] See National Competition Council, *Compendium of National Competition Policy Agreements* (1997).

of their existing legislation[46] and ensure those proposals for new legislation that restricts competition be consistent with the 'guiding principle':[47]

> … that legislation (including Acts, enactments, Ordinances or regulations) should not restrict competition unless it can be demonstrated[48] that:
>
> (a) the benefits of the restriction to the community as a whole outweigh the costs; and
>
> (b) the objectives of the legislation can only be achieved by restricting competition.[49]

3.1.3 A timetable for reviewing legislation was agreed in 1996.[50] In compliance with the CPA, and the agreed timetable for reviewing legislation, the NCC[51] reviewed the exemption of certain intellectual property dealings from the pro-competition provisions of the *Trade Practices Act*,[52] and the IPCR Committee[53] reviewed most

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[46] *Competition Principles Agreement* cl 5(3).

[47] *Competition Principles Agreement* cl 5(5).

[48] The construction of the *Competition Principles Agreement* cl 5(1) relies on the term 'demonstrated' in setting out the standard to be achieved in applying the 'guiding principle' in reviewing existing legislation and proposed legislation that restricts competition, while the *Competition Principles Agreement*, cl 5(5) expressly requires 'evidence' that proposed legislation restricting competition is consistent with the 'guiding principle'. While this might be construed as a lower standard for reviewing existing legislation, the preferable construction is evidence demonstrating that the guiding principle has been satisfied. That is, 'legislation that restricts competition must be accompanied by evidence that the benefits of the restriction to the community as a whole outweigh the costs, and that the objectives can only be achieved by restricting competition': Productivity Commission, *Regulation and Its Review 2002-03*, Annual Report Series (2003) 7; see also National Competition Council, *National Competition Council Legislation Review Compendium* (2002) 1.

[49] *Competition Principles Agreement* cl 5(1).

[50] Council of Australian Governments, *Communiqué – 11 April 1995* (1995) 7; this timetable was extended to 30 June 2002 (Council of Australian Governments, *Communiqué – 3 November 2000* (2000) 5), and presumably has now been extended again: see Productivity Commission, *Regulation and Its Review 2002-03*, Annual Report Series (2003) 73-74 (outstanding reviews).

[51] National Competition Council, Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974 (1999) (NCC).

[52] NCC, above n 51, 148-246.

[53] IPCR Committee, above n 19.

Commonwealth intellectual property legislation, including the *Patents Act*.[54] The approach to conducting and the content of these legislation reviews under the CPA is primarily addressed in the Terms of Reference, although there may be additional consideration,[55] mandatory procedures[56] and guidance from other sources.[57] Essentially, the objectives in conducting the legislation reviews is to assess whether the arrangements restrict competition, whether the benefits to the community as a whole outweigh the costs (including the broader assessment of the 'public interest'), that it can clearly be demonstrated that the benefits exceed the costs and whether the same objectives can be achieved by other better means.[58] Further, the regulation in force should be both 'efficient', in terms of 'minimizing compliance and other costs imposed on the community'[59] and 'effective' in 'addressing an identified problem'.[60] The following sections review the approach and findings of the NCC (section 3.2) and IPCR Committee (section 3.3) in applying the CPA criteria. These approaches are then contrasted with the approach of the majority of the IPCR Committee to dealing with parallel import restrictions under the *Copyright Act 1968* (Cth) (section 3.4).

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[54] IPCR Committee, above n 19, 134-178.

[55] For example, *Competition Principles Agreement* cl 5(9) provides: 'Without limiting the terms of reference of a review, a review should: (a) clarify the objectives of the legislation; (b) identify the nature of the restriction on competition; (c) analyse the likely effect of the restriction on competition and on the economy generally; (d) assess and balance the costs and benefits of the restriction; and (e) consider alternative means for achieving the same result including non-legislative approaches'.

[56] See for example Office of Regulation Review, *A Guide to Regulation* (1998) that apply to 'Commonwealth departments, agencies, statutory authorities and boards making, reviewing and reforming regulation' (A1).

[57] See for example Centre for International Economics, *Guidelines for NCP Legislation Reviews* (1999).

[58] See Centre for International Economics, *Guidelines for NCP Legislation Reviews* (1999) 7.

[59] Productivity Commission, *Regulation and Its Review 2002-03*, Annual Report Series (2003) 1.

[60] Productivity Commission, *Regulation and Its Review 2002-03*, Annual Report Series (2003) 1.

3.2 National Competition Council

3.2.1 The NCC's Terms of Reference provided, in part, that the NCC 'have regard to the analytical requirements for regulation assessment by all Australian governments set out in the CPA'.[61] However, the NCC's task to review the exemption of certain intellectual property dealings from the pro-competition provisions of the *Trade Practices Act* was complicated by the nature of the legislative scheme. The *Trade Practices Act* imposes pro-competition regulation onto the conduct of firms,[62] which are then relaxed by specific exemptions.[63] The *Trade Practices Act* is expressly stated to apply to any rights exercised under the *Patents Act* (and some other intellectual property legislation),[64] with an exception for certain license and assignment conditions 'relating to' the patent.[65] The exemptions sanctioned relate to anti-competitive agreements,[66] exclusive dealings[67] and mergers,[68] but not to resale price maintenance[69] or misuse of market power.[70] The NCC addressed the issues by considering the exemptions from the *Trade Practices Act* to constitute restrictions on competition because they restricted the operation of the imposed pro-competition regulation.[71] Further, the NCC confined the scope of its review to be 'whether, and if so, how [the imposed pro-competition regulation] of the *Trade Practices Act* should regulate licensing and assignment of intellectual property rights'.[72] However, a significant limitation

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[61] NCC, above n 51, vi.

[62] *Trade Practices Act* pt IV.

[63] *Trade Practices Act* s 51.

[64] *Trade Practices Act* s 51(1); although the *Plant Breeder's Rights Act 1994* (Cth) is not currently included in this exemption arrangement.

[65] *Trade Practices Act* s 51(3).

[66] *Trade Practices Act* ss 45 and 45A.

[67] *Trade Practices Act* s 47.

[68] *Trade Practices Act* ss 50 and 50A.

[69] *Trade Practices Act* s 48.

[70] *Trade Practices Act* s 46.

[71] NCC, above n 51, 3.

[72] NCC, above n 51, 3.

of the NCC's approach was based on its interpretation of the Terms of Reference to take account of existing intellectual property laws and 'assume that the [existing intellectual property laws] will continue to exist and provide a strong indication of the Government's preferred policy approach for the regulation [of intellectual property]'.[73] Having adopted this view, the NCC could only ever examine the existing legislative provisions without challenging the broader debates about the appropriateness of existing patent thresholds and the likely anti-competitive effects of different threshold standards under the *Trade Practices Act* scheme.

3.2.2 The NCC then accepted that general property rights and intellectual property rights share similar attributes[74] so that they are 'neither particularly free from scrutiny under the antitrust laws, nor particularly suspect under them'[75] and similarly, the exercise of intellectual property rights did not inherently conflict with pro-competition laws necessarily requiring an exemption from competition law.[76] The NCC acknowledged that other jurisdictions do not provide any form of exemptions for restrictive conditions in licenses and assignments.[77] However, the NCC then 'accepted'[78] that the existing exemption 'has some continuing relevance in terms of providing businesses with greater certainty when engaging in licensing and assignment activity'[79] with the benefit that '[t]his greater certainty can help reduce the costs associated with compliance with trade practices law and encourage more licensing activity'.[80] This 'acceptance' carried through to the

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[73] NCC, above n 51, 17.

[74] NCC, above n 51, 149.

[75] NCC, above n 51, 160; citing the United States Department of Justice and Federal Trade Commission, *Anti-trusts Guidelines for the Licensing of Intellectual Property* (1995) s 2.1.

[76] NCC, above n 51, 163.

[77] Most notably the United States: NCC, above n 51, 150 and 186-192.

[78] NCC, above n 51, 150.

[79] NCC, above n 51, 150 and 167; presumably this was confined to 'clarifying whether licensing conditions which have the effect of subdividing intellectual property rights may be anti-competitive' (167).

[80] NCC, above n 51, 150 and 167.

analyses of the benefits[81] and costs[82] of the exemption, and then to the conclusion.[83]

3.2.3 Finally, the NCC considered the various options to retaining the benefits from the exemption while minimising the costs of anti-competitive conduct. The NCC concluded, against the criteria of reducing the potential for anti-competitive conduct, minimising uncertainty, minimising costs and practical implementation,[84] that 'the best option is to amend [the exemption] to remove price restrictions, quantity restrictions, and horizontal arrangements from the scope of the exemption'.[85] In making this assessment the NCC considered the consequences of repealing the exemption, and accepted that there was no international treaty obligation, such as TRIPs, on constraining how competition law might be applied to intellectual property:[86]

> Repealing [the exemption] would remove the potential that anti-competitive conduct could be exempted from the operation of the *Trade Practices Act*. However, the [NCC] accepts that repeal would impose some uncertainty and costs on parties in checking that their agreements do not breach [the pro-competition regulations in the *Trade Practices Act*], particularly in cases where it is difficult to assess the market potential of intellectual property rights or the boundaries of the markets in which the intellectual property rights might be commercialised at some future date. Guidelines may not be sufficient to fully alleviate this uncertainty, particularly in circumstances where investors need absolute certainty about the validity of licensing conditions before they may proceed to invest in research and development.[87]

3.2.4 The NCC then recommended that the exemption be retained, 'but amended to remove protection from price and quantity restrictions and horizontal

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[81] NCC, above n 51, 193-200.

[82] NCC, above n 51, 201-213.

[83] NCC, above n 51, 213.

[84] NCC, above n 51, 241.

[85] NCC, above n 51, 241.

[86] NCC, above n 51, 227-230.

[87] NCC, above n 51, 242.

agreements'.[88] The NCC also recommended that guidelines be formulated to assist in determining when intellectual property licenses and assignments might be exempt from, or breach, the *Trade Practices Act*, and what breaching conduct might be authorised under the *Trade Practices Act*.[89]

3.2.5 Although the NCC did undertake a process of identifying the benefits and costs of the exemption from competition,[90] the final conclusions were based on the NCC's 'acceptance'[91] and 'consideration'[92] that, subject to price and quantity restrictions and horizontal agreements, restricting competition by patent privileges was desirable. At best the benefits were merely 'greater business certainty',[93] while the costs in terms of anti-competitive conduct ranged across all conduct, but with most being confined to horizontal arrangements and vertical arrangements that facilitate horizontal agreements.[94]

3.2.6 Interestingly, the NCC posed significant counter arguments to those put to it that were not then addressed, including the residual uncertainty about the operation of the existing exemption,[95] the absence of a similar exemption in other jurisdictions that does not appear to have harmed investment in research,[96] the minor factor

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[88] NCC, above n 51, 243.

[89] NCC, above n 51, 245.

[90] NCC, above n 51, 193-213.

[91] See for example NCC, above n 51, 242.

[92] See for example NCC, above n 51, 200 and 213.

[93] NCC, above n 51, 200.

[94] NCC, above n 51, 213.

[95] NCC, above n 51, 196.

[96] NCC, above n 51, 196 and 200; although it was noted that in these circumstances the courts may take into account the 'special features' of intellectual property when assessing whether particular conduct is anti-competitive (186-187); for an analysis of the difference between the intended policy and its application by the courts in the United States, and likely application in Australia see Charles Lawson, 'Patenting Genes and Gene Sequences and Competition: Patenting the Expense of Competition' (2002) 30 *Federal Law Review* 97, 117-128.

favorable competition law treatment would be in any decisions about investing in innovation,[97] and the global nature of licensing intellectual property meaning that favorable treatment in one jurisdiction may not apply in another jurisdiction thus questioning the need for favorable treatment.[98] Each of these matters should have challenged the 'acceptance' and 'consideration' of benefit from excluding some intellectual property related conduct from the *Trade Practices Act*. Further, the NCC failed to consider that the *Trade Practices Act* is directed to limiting only some *per se* anti-competitive conduct (such as some horizontal anti-competitive arrangements),[99] and other conduct only when that conduct passes a threshold of anti-competitiveness (such as misuse of market power).[100] In these circumstances much of the anti-competitive conduct (both unilateral and multilateral)[101] exempted or up to the threshold set by the *Trade Practices Act* will be sanctioned, even where the costs to consumers may be significant. An example of such conduct is the ability of some patent holders (and their licensees and assignees) to license the patent protected products rather than sell them to avoid exhaustion (whether regional, national or international) of the patentee's 'exclusive rights', thus avoiding a competitive control on prices. In these circumstances the higher prices to individual purchasers may be low, but across an economy such increased prices might be a considerable inefficiency.[102]

3.2.7 Further, the NCC acknowledged that in some circumstances products protected by patents might not be substitutable (such as 'a newly discovered vaccine for a

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[97] NCC, above n 51, 200.

[98] NCC, above n 51, 200.

[99] *Trade Practices Act* s 45.

[100] *Trade Practices Act* s 46.

[101] Noting that the NCC accepted that anti-competitive conduct ranged across all conduct: see NCC, above n 51, 213.

[102] Inefficient regulation imposing substantial costs on consumers through cross-subsidies and reduced incentives for firms to innovate was a general concern to the Hilmer Committee: see Hilmer Committee, above n 34, 189.

formerly incurable disease')[103] thereby creating a product market with significant potential to exercise market power.[104] The only evidence that the NCC appeared to consider in this context were arguments that repealing the exemption would then require these patent holders to seek authorisation and at some considerable cost and disincentive to further innovation.[105] Unfortunately, the NCC did not express any specific views about this evidence, although this appears to have been 'accepted' as a benefit to retaining the exemption in some form.[106] There was, however, no assessment of the problems of substitutability in high technology markets and the effects of the incidents of there being no substitutes in some industries (particularly in the pharmaceutical and biotechnology industries).[107]

3.2.8 The Government is still considering its response to the NCC report,[108] although this has been overtaken by the IPCR Committee's review of the NCC's conclusions and recommendations.[109] This is considered, in part, in the next section.

3.3 Intellectual Property and Competition Review Committee

3.3.1 Following on from the NCC's inquiry into the exemptions of intellectual property privileges from the *Trade Practices Act*, the IPCR Committee undertook a review of intellectual property legislation (excluding the *Plant Breeder's Rights Act 1994*

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[103] NCC, above n 51, 172.

[104] Although, the NCC considered this was only likely in 'some rare cases ... [where] … certain technologies … will have no or few close substitutes': NCC, above n 51, 172; however, it is these cases where the anti-competitive effects of patents are most likely to be most pronounced.

[105] NCC, above n 51, 225-227.

[106] NCC, above n 51, 230.

[107] This is an issue also addressed by the IPCR Committee, but again without resolution: see IPCR Committee, above n 19, 143.

[108] See National Competition Council, *National Competition Council Legislation Review Compendium* (2002) 31.

[109] IPCR Committee, above n 19, 202-215.

(Cth)),[110] as part of the requirements under the CPA to review legislation restricting competition. The Terms of Reference provided, in part, that the IPCR Committee 'shall have regard to: (a) the determination, in the CPA, that legislation which restricts competition should be retained only if the benefits to the community as a whole outweigh the costs, and if the objectives of the legislation can only be achieved by restricting competition'.[111] However, the Terms of Reference also included specific matters that the IPCR Committee 'shall inquire into and report … on', including 'the objectives of, including the nature and magnitude of the problems sought to be addressed by … the *Patents Act 1990*', 'the nature of the restrictions in the legislation on competition', 'the likely effect of those restrictions on competition', alternative means of achieving the same objectives, and the 'costs and benefits' and 'appropriateness, effectiveness and efficiency' of the legislation, restrictions on competition and alternatives.[112] These requirements are consistent with the CPA.[113]

3.3.2 The IPCR Committee set out its vision of the impact of intellectual property rights on competition, including patents:

> … it is important to recognise that competition occurs in a number of dimensions. More specifically, firms do not only compete in the prices they set but also in their ability to develop new processes and to design and market new products. This dynamic competition is of special importance. In effect, rather than simply reallocating existing resources, it expands the resources on which society can draw and allows for sustainable increases in living standards. It is also important because in practice it is the main way established market positions are over-turned, and the threat of competition made into an ever-present constraint on the conduct of firms. An effective system to define and enforce intellectual property rights is critical for this type of dynamic competition to occur on a material scale.[114]

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[110] The reasons for excluding this legislative scheme from the review are uncertain.

[111] IPCR Committee, above n 19, 217.

[112] IPCR Committee, above n 19, 217.

[113] *Competition Principles Agreement* cl 5(9).

[114] IPCR Committee, above n 19, 5.

3.3.3 Importantly, the IPCR Committee expressed its view that the interaction between intellectual property and competition was 'largely complementary' with intellectual property promoting innovation and competition policy 'keeping markets open and effective, preserves the primary source of the pressure to innovate and to diffuse innovations'.[115] However, recognising that intellectual property rights do have social costs, the IPCR Committee conceded:

> Intellectual property laws must … involve some balance between the incentives to invest in creative effort and the incentives for disseminating material that is the subject of intellectual property protection. This balance turns on determining the appropriate scope of protection, in terms of the conditions under which protection is granted, the scope and effectiveness of the exclusive privileges provided by protection, and the duration of the protection given. Balancing between providing incentives to invest in innovation on one hand, and for efficient diffusion of innovation on the other, is a central, and perhaps the crucial, element in the design of intellectual property laws. In the Committee's view, it is essential that the terms of this balance be clearly set out in the intellectual property laws themselves, so that rights owners and users can be certain about the scope and content of the grants being made.[116]

3.3.4 In addressing patents specifically, the IPCR Committee rejected the notion that Australia might apply a higher threshold standard to non-resident patent applicants,[117] and presented a particular perspective on the benefits of patents in Australia:[118]

> … effective patent protection facilitates trade in technology, both domestically and internationally. An effective patent system, accessible to foreign technology suppliers, allows Australian firms to

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[115] IPCR Committee, above n 19, 6.

[116] IPCR Committee, above n 19, 6.

[117] IPCR Committee, above n 19, 139.

[118] See for example the dissenting opinion in Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984); for a recent overview of the competing theories about optimal division and scope of patents see Dan Burk and Mark Lemley, 'Policy Levers in Patent Law' (2003) 89 *Virginia Law Review* 1575, 1595-1631 and the references therein.

> import technology that would otherwise be unavailable, or would only be available at higher cost. This increases productivity and enhances competition in the Australian economy. The importance of technological imports is illustrated by the more than 90 per cent of patents registered in Australia, which are owned by foreigners. In addition, there are more indirect cross-border spillovers through importing of goods which embody innovations and which may be used as intermediate inputs or sold directly to end-users.[119]

3.3.5 The IPCR Committee did, however, present some assertions in support of its perspective about the benefits of patent privileges. It argued that the private value of research and development was much less than the social value,[120] and that patent privileges was the best system yet devised to balance the trade-off between maintaining incentives to invest and fostering the diffusion of new technology.[121] Unfortunately these assertions, while not contentious as a generalisation, gloss over a hotly contested and disparate debate about the appropriate scope and allocation of patent privileges that the IPCR Committee itself had identified in discussing balancing incentives and exploiting intellectual property generally[122] and cited as 'imperfections' in the patent privilege scheme.[123] Further, the IPCR Committee's analysis and conclusions were not based on Australia's experience with patent privileges, but rather relied on international comparisons that were then assumed to be applicable to Australia.[124] The IPCR Committee then concluded that patent privileges can lead to 'losses in allocative and productive efficiency' but '[i]n practice … a patent holder can rarely act as a pure monopoly, because of the availability of alternative and substitute products and processes, and also because some scope for imitation almost always exists'.[125] The loss of

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[119] IPCR Committee, above n 19, 139.

[120] IPCR Committee, above n 19, 137.

[121] IPCR Committee, above n 19, 143.

[122] See IPCR Committee, above n 19, 6.

[123] See IPCR Committee, above n 19, 143.

[124] Such assumptions are certainly open to question, especially where a state is a net technology importer like Australia: see for example Keith Maskus, *Intellectual Property Rights in a Global Economy* (2000) 237-238.

[125] IPCR Committee, above n 19, 138.

some ‘dynamic efficiency’ in the development of derivative innovations was also acknowledged, but again, ‘[t]o some extent dynamic losses are counteracted by the disclosure of ideas as part of the *quid pro quo* of granting a patent and that the patent system itself … facilitates the use of licensing’.[126] The IPCR Committee then reached an ‘overall’ conclusion:

> Overall, the Committee agrees with Scherer that ‘the patenting system is recognised to be an imperfect instrument. Nevertheless, it may be the best solution policy man can devise to the difficult trade-off between, on the one hand, maintaining incentives for investment and, on the other hand, fostering the diffusion of new technology’s benefits to consumers and to those who might make leapfrogging inventions’.[127]

3.3.6 Having adopted the view that compliance with international patent standards was beneficial to Australia[128] and a part of Government policy,[129] and its gloss on the debates about appropriate patent scope and allocation, then it was open to the IPCR Committee to accept the existing legislated scheme for patent privileges. The flaw in this approach, albeit an approach that was open to the IPCR Committee according to its Terms of Reference, was to avoid any analysis of the controversy about the most appropriate threshold requirements in the *Patents Act*. For example, different theories about the objectives of patent privileges propose very different threshold standards depending on what the patent scheme is intended to achieve, with the IPCR Committee failing both to clearly identify what patent privileges in Australia are intended to achieve[130] and consider the

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[126] IPCR Committee, above n 19, 139.

[127] IPCR Committee, above n 19, 143.

[128] IPCR Committee, above n 19, 27 and 139-141.

[129] The Terms of Reference required the IPCR Committee’s deliberation to ‘have regard to … the intentions and policies of the Government’: IPCR Committee, above n 19, 216-217.

[130] See IPCR Committee, above n 19, 136-138; the IPCR Committee variously considering patent privileges seek to stimulate invention and innovation, increase the public availability of information about new technology, encourage entrepreneurs, promote investment or address free-riding on investment in intellectual effort.

most appropriate test of non-obviousness in achieving this objective.[131] Comparing the 'reward theory' and the 'prospect theory' illustrate this contention. The 'reward theory' views a patent as an incentive to undertake uncertain invention with an opportunity to appropriate greater commercial returns thus fostering socially beneficial inventions, but with significant social costs on short term inefficiencies in the market from the anti-competitive effects of the patent (primarily restricted output and higher prices) appropriating public goods (ideas) that would otherwise be used.[132] In contrast, the 'prospect theory' views patents as promoting the commercial development of inventions with patents granted to early stage inventions facilitating the bringing of a usable invention to the market and acting as an incentive to maximise the commercial value from exploiting the invention with relief from free-riders.[133] These different theories pose significantly different consequences for short term competition, the 'reward theory' imposing high thresholds for patentability seeking to limit patents to only those inventions that would not have been made with significant concerns about the effects on competition, while the 'prospect theory' imposes lower thresholds giving the patent holder control over the development process and possibly increasing the efficiency of development (that otherwise may not occur) with less concern about the effects on competition.

3.3.7 With these limitations already imposed the IPCR Committee then examined elements of the *Patents Act* and identified a number of improvements that might

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[131] See IPCR Committee, above n 19, 154-156; the IPCR Committee considered the prior art limb of the inventive step threshold but failed to consider the non-obviousness limb and how the standard might be applied to exclude inventions that result merely from the application of labour and resources.

[132] There is an extensive literature about this theory; see for example the Subcommittee on Patents, Trademarks and Copyrights of the Senate Committee on the Judiciary, *An Economic Review of the Patent System*, 85th Congress, 2nd Session (1958) (also known as the Machlup Report).

[133] There is an extensive literature about this theory; see for example its recent articulation in E Kitch, 'The Nature and Function of the Patent System' (1977) 20 *Journal of Law and Economics* 265 and its later articulation in R Merges, 'Uncertainty and the Standard of Patentability' (1992) 7 *High Technology Law Journal* 1.

promote more competition in the application of the threshold tests and the duration of the patent term.[134] However, these issues were examined from the IPCR Committee's particular concern about the economic effects of the certainty of the patent grant,[135] both granting patents that should not be granted and not granting patents that should be granted.[136] From this perspective the IPCR Committee considered threshold test improvements including requiring a specific, substantial and credible use be defined[137] and that the scope of prior art be expanded for assessing inventive step.[138] It was suggested that other requirements be restricted including prior use[139] and compulsory licensing.[140] On patent term, the IPCR Committee 'believed' there was not enough evidence to extend the patent term,[141] although it did suggest that raising renewal fees might be applied to 'extract a lower economic rent'.[142] While these assessments and recommendations certainly affect competition, the IPCR Committee approach avoided assessing the details about the appropriate balance of how the threshold requirements might be applied and countered when the social costs were judged to be too high (such as the appropriate threshold of public interest before a compulsory license was to be granted).

3.3.8 A further flaw in the IPCR Committee's approach was accepting that 'Australia was complying with most of the current requirements of TRIPs before they were

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[134] IPCR Committee, above n 19, 144.

[135] IPCR Committee, above n 19, 143-144.

[136] See IPCR Committee, above n 19, 153.

[137] IPCR Committee, above n 19, 151-154.

[138] IPCR Committee, above n 19, 154-156 and 168-170.

[139] IPCR Committee, above n 19, 157-159.

[140] IPCR Committee, above n 19, 162-163.

[141] Interestingly, the IPCR Committee did not consider the patent term extension provisions and their likely effect on competition: see *Patents Act* ss 70-79A.

[142] IPCR Committee, above n 19, 144 and 156; although it is not clear whether the IPCR Committee considered this only shortened the term for less innovative patents or also lowered the social costs by recouping the costs of administering the scheme.

adopted and so only relatively minor adjustments to the *Patents Act* were required to make it TRIPs-compliant'[143] as establishing that the existing *Patents Act* set the threshold for compliance with TRIPs, when in fact, many of the *Patents Act* provisions apply standards higher that TRIPs requires,[144] TRIPs leaves open the applicable standard of the patent threshold requirements,[145] and TRIPs 'flexibility' allows considerable scope to develop more appropriate laws to Australia's particular economic and technological needs. This flaw was particularly apparent in the IPCR Committee's failure to consider the expressly allowed exemptions under TRIPs and their likely effects on competition.

3.3.9 The IPCR Committee then examined the NCC's report about the exemption of certain patent license and assignment conditions under the *Trade Practices Act*.[146] The Terms of Reference *only* required the IPCR Committee to 'have regard to … the conclusions and recommendations' of the NCC's report.[147] In addressing the Terms of Reference the IPCR Committee carefully confined its comments to the existing legislative scheme 'considering the effects that (given the [*Trade Practices Act*] as it stands) would flow from different approaches to the coverage by the Act of conduct relating to the exercise of IP rights'.[148] With these riders in place the IPCR Committee recommended that the *Trade Practices Act* should be amended applying a test of whether the exempt conditions in licenses and assignments substantially lessened competition as applied in other parts of that *Trade Practices Act*.[149] The IPCR Committee also recommended that the Australian Competition and Consumer Commission issue guidelines to clarify the

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[143] IPCR Committee, above n 19, 141.

[144] For example, Australia applies a higher standard to the granting of compulsory licenses than TRIPs requires: compare *Patents Act* ss 133-135 and TRIPs Art 31.

[145] Dianne Nicol and Jane Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 363-364.

[146] IPCR Committee, above n 19, 202-215.

[147] IPCR Committee, above n 19, 217.

[148] IPCR Committee, above n 19, 210.

[149] IPCR Committee, above n 19, 11 and 215; this would include a refusal to deal (213).

types of conduct that are likely to breach the modified provision.[150] This was significant as the IPCR Committee considered that the *Trade Practices Act* 'should come into play when intellectual property rights are used in ways that go beyond the scope of the right being granted'.[151] Without addressing the appropriateness of patent scope and allocation the likely pro-competitive and anti-competitive consequences of exemptions from the *Trade Practices Act* remain uncertain.

3.3.10 The IPCR Committee also accepted that exercising the patent privileges that is less than 'going beyond market power' is an acceptable restriction on competition:[152]

> … the system of IP rights acts to provide to those who invest in creative effort a claim on the differential efficiency associated with the results of their investment – that is, of the social gain consequent on that investment's outcomes. Those rights should not be used to secure a gain that goes beyond that differential efficiency through the exercise of market power. Thus, it is an inherent element in the IP right that the owner of a patent on an invention can secure an income dependent on the unique efficiency that invention allows; but it ought not to be acceptable for the owner of that patent to, say through the formation of a patent pool with owners of competing patents, effect a horizontal cartel, raise prices and secure monopoly rents. The grant of IP rights seeks to provide for creators a return on their investment in creation – the rights should not be used to secure returns that do not come from the social contribution that creation makes.[153]

3.3.11 Unfortunately, this again fails to assess that the restriction on competition from a patent privileges before there is actually a substantially lessening of competition is justifiable. With respect, the IPCR Committee's view that a restriction on competition only becomes a subject of concern when some anti-competitive threshold is reached is not the policy justification of the CPA, or the Hilmer

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[150] IPCR Committee, above n 19, 11 and 215.

[151] IPCR Committee, above n 19, 24.

[152] IPCR Committee, above n 19, 211.

[153] IPCR Committee, above n 19, 211.

Committee report.[154] The CPA is concerned with *any* restriction on competition, appreciating that even minor restrictions on competition, such as unnecessary regulation, imposes inefficiencies that should be removed unless they can be justified according to the CPA's criteria. The IPCR Committee should have, at the very least, identified the theoretical justifications for its conclusions and based them in the context of the Australian community.

3.3.12 However, the criticism of the IPCR Committee's dealing with patent privileges under the *Trade Practices Act* must be tempered by the uncertain Terms of Reference and the significant burden that the existing *Trade Practices Act* pt IV, as the IPCR Committee itself noted,[155] was fashioned in a different economic era and probably should be subjected to its own independent review whereupon the place of patent privileges might be more certainly addressed. Despite this reservation, the approach of the IPCR Committee in having failed to address the broader debates about the appropriateness of the existing thresholds was that it was then in no position to assess the likely anti-competitive effects of different threshold standards under the *Trade Practices Act* scheme.

3.3.13 The following section highlights the flawed approach of the IPCR Committee in assessing patent privileges by examining the IPCR Committee's approach to assessing the anti-competitive effects of the parallel import restrictions under the *Copyright Act 1968* (Cth). The significance of this assessment is to show that it was open to the IPCR Committee to challenge and analyze the details of patent privileges, such as the debates about appropriate patent scope and allocation.

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[154] The Hilmer Committee was quite explicit: 'there should be no regulatory restriction on competition unless clearly demonstrated to be in the public interest': Hilmer Committee, above n 34, 190; thus here the issue for the IPCR Committee to address should arguably have been how much incentive in sufficient to promote invention in Australia, and once that had been justified (or at least setting out the IPCR Committee's favoured theoretical perspective), then whether any kind of exemption from the *Trade Practices Act* would upset this incentive.

[155] See IPCR Committee, above n 19, 209-210.

3.4 Parallel import restrictions in the *Copyright Act 1968* (Cth)

3.4.1 The IPCR Committee's majority's assessment of parallel importing under the *Copyright Act 1968* (Cth)[156] objected to many of the very same issues that were glossed over in its analyses of the *Patents Act*,[157] and yet, it was able to structure its analysis of the issues very differently and reach a very different conclusion suggesting that the benefits of parallel import restrictions did not outweigh the detrimental anti-competitive effects and that the restrictions should be repealed entirely.[158]

3.4.2 The IPCR Committee's majority accepted that copyright had a 'utilitarian justification of protecting and promoting investment in creative effort to secure, for the Australian community, gains associated with investment'[159] so that the privileges granted needed to be 'assessed in terms of whether the benefits they may bring, in improved investment in, and access to the results of, creative efforts, outweigh the costs they impose'.[160] Further, '[t]his assessment of the impact of the restrictions needs to include analysis of the wider costs and benefits associated with those impacts'.[161] The majority's key concern about parallel import restrictions appeared to be market segmentation with the ability to then charge higher prices (and possibly restrict availability) for copyrighted materials.[162] In effect, this was an assessment about international exhaustion of copyright.

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[156] Noting the parallel import restrictions in the *Copyright Act 1968* (Cth) on sound recordings, books and non-copyright products were already relaxed: see *Copyright Amendment Act (No 1) 1998* (Cth); *Copyright Amendment Act (No 2) 1998* (Cth).

[157] IPCR Committee, above n 19, 134-178.

[158] IPCR Committee, above n 19, 5.

[159] IPCR Committee, above n 19, 61.

[160] IPCR Committee, above n 19, 62.

[161] IPCR Committee, above n 19, 62.

[162] IPCR Committee, above n 19, 62.

3.4.3 From this basis the majority was able to reject arguments about economic incentives to create,[163] prices and availability,[164] remainder books,[165] marketing and services,[166] censorship,[167] piracy,[168] and economic analysis that favored maintaining the existing restrictions,[169] as failing to satisfy the CPA criteria.[170] The most significant difference between the majority's dealing with parallel imports and patent privileges was the detailed approach to addressing the analysis of whether a restriction on competition was justified:

> The Committee started from the premise that restrictions on competition need to be justified. In other words, the Committee, consistent with the NCP and the CPA, accepts that the onus of making a case lies with those who would prevent, limit, or in other ways restrict, competitive forces from operating.
>
> More specifically, we accept that those who would restrict competition should establish the restrictions are in the public interest, rather than merely serving the interests of particular producers. The Committee believes that this well-established principle – requiring those who would restrict competition to demonstrate the need to do so – appears to be fully justifiable.
>
> However, experience and analysis amply demonstrate the importance of competition in promoting efficiency and underpinning prosperous, open economies. It also demonstrates the frequency with which restrictions on competition, though claimed to serve wider interests, have been used to confer above normal profits on narrow groups at the expense of the community. A presumption, albeit a rebuttable one, in favour of competition, is consequently clearly reasonable.
>
> Such a presumption also places the evidentiary burden on those best placed to demonstrate the position. The reality is that the benefits from restrictions on competition generally accrue to concentrated groups, while the costs of these restrictions are spread widely throughout the

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[163] IPCR Committee, above n 19, 49-51 and 66-69.

[164] IPCR Committee, above n 19, 51-53 and 64-69.

[165] IPCR Committee, above n 19, 54-55 and 64.

[166] IPCR Committee, above n 19, 55-56 and 66-69.

[167] IPCR Committee, above n 19, 56-57.

[168] IPCR Committee, above n 19, 57-60.

[169] IPCR Committee, above n 19, 65.

[170] IPCR Committee, above n 19, 73.

community. Given this spreading of costs, it is far more difficult for those adversely affected by restrictions to organise themselves and present their case, than it is for the direct beneficiaries to support the restrictions.

As a result, the Committee believes that it is reasonable to expect those who would introduce or perpetuate restrictions to provide convincing evidence of why the restrictions are in the public interest.

It follows that the relevant test is whether the material made available to the Committee establishes that the restrictions these provisions impose on competition confer benefits on the community that outweigh their costs.

In cases where arguments put to us appear weak, the Committee actively sought further information and tried to analyse the arguments in the best light. As a result, we are convinced that we have provided the differing points of view with a fair and thorough hearing.[171]

3.4.4 The different approach of the IPCR Committee's majority in directly addressing the arguments about theoretical benefits of particular policy settings for the parallel importing and the absence of this analysis for patent privileges is perplexing and unexplained, most significantly, as the majority questioned the assumptions and assertions of benefit that copyright privileges under the *Copyright Act 1968* (Cth) were protecting and promoting investment. Had the IPCR Committee applied a similar critical analysis of patent privileges then the debates about appropriate patent scope and allocation and the potential of TRIPs would probably have been more closely examined and the requirements of the CPA more properly addressed. Further, broader issues such as the high costs of patented pharmaceuticals, non-tariff trade barriers, ethical considerations about patenting life, and so on, would probably have required consideration in more broadly assessing the public interest. With respect, this approach appears to more closely fit with the CPA and the principle articulated in the Hilmer Committee report. Further, such an analyses of patent privileges is more likely to deliver

[171] IPCR Committee, above n 19, 61.

some insight into the various consequences of patent privileges and their likely benefits for the Australian community.

3.4.5 With parallels to the IPCR Committee's approach to patent privileges, the IPCR Committee's minority view accepted the assumptions and assertions of benefit and therefore justified parallel import restrictions in the *Copyright Act 1968* (Cth):

> It is true that the ability to restrict parallel imports gives rise to an economic rent in favor of the copyright owner. However this rent encourages innovation and investment, and is precisely the foundation on which copyright is based. Allowing parallel imports reduces the incentives to innovate or invest. It is submitted that the costs incurred in removing the restriction will exceed the costs (in economic terms) of retaining that power.[172]

3.4.6 The consequence of the minority accepting this approach, and this was certainly open to the IPCR Committee, was to avoid the broader assessment of the anti-competitive effects of copyright and a proper assessment of the criteria set out in the CPA. These are the very same flaws in the IPCR Committee's assessment of the *Patents Act* and the relevant parts of the *Trade Practices Act.*

3.4.7 The conclusion from this assessment is that the underlying perspectives accepted by the NCC and the IPCR Committee should have been challenged and the evidence (and reasoning) supporting their conclusions that restrictions on competition were justified transparently identified. The following part explores some of this 'flexibility' in TRIPs.

4. PATENTS AND TRIPS

4.1 This submission contends that TRIPs is an evolving agreement and that there is likely to be considerable 'flexibility' within the current agreement to craft domestic laws to suit the particular needs of member states. For Australia this is an opportunity to develop and apply patent laws (and competition laws) in a way

[172] IPCR Committee, above n 19, 74.

that promotes Australia's particular and different economic and technological interests. The following analysis of various TRIPs provisions illustrates this contention and suggests that Australia should be careful to exploit this considerable 'flexibility' to tailor its patent laws (and competition laws) to suit its particular economic and social circumstances. This is particularly important to take into consideration now as most of these developments have taken on new impetus following the TRIPs Ministerial Council statement at the Doha meeting.[173] Notably, this 'flexibility', or even potential 'flexibility' was not considered by reviews of the patent laws by the IPCR Committee or the NCC.

4.1 Objectives and principles – Art 7 and 8(1)

4.1.1 TRIPs sought to establish new rules and disciplines moving intellectual property into the realm of international trade laws:

> … to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.[174]

4.1.2 The 'effective and adequate' patent standards recognise the underlying public policy objectives and principles of TRIPs:

(a) Objective – 'The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner

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[173] See Ministerial Conference, *Declaration on the Trips Agreement and Public Health* (2001) T/MIN(01)/DEC/2; Council of Trade-Related Aspects of Intellectual Property Rights, *Special Discussion on Intellectual Property and Access to Medicines* (2001) IP/C/M/31.

[174] TRIPs Preamble

conducive to social and economic welfare, and to a balance of rights and obligations';[175] and

(b) Principle – 'Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement'.[176]

4.1.3 The WTO member states have not yet reached a consensus on the effect of these provisions or the interpretation and implementation of TRIPs' obligations. As a generalisation, developed states consider patents are a necessary incentive to promote investment in new inventions and, as a consequence, this promotes the objectives and principles of Arts 7 and 8.[177] In contrast, developing and least developed states[178] consider each provision of TRIPs should be read in light of these objectives and principles and that TRIPs co-exists with other public policy objectives so that its provisions may be overridden to meet these other policy objectives.[179] Despite these different perspectives, most member states consider TRIPs is sufficiently 'flexible' to enable member states to implement their TRIPs

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[175] TRIPs Art 7.

[176] TRIPs Art 8(1).

[177] See for example Council of Trade-Related Aspects of Intellectual Property Rights, *Special Discussion on Intellectual Property and Access to Medicines* (2001) IP/C/M/31, 36; Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from the European Communities and their Member States* (2001) IP/C/W/280, 2.

[178] The distinction between developed, developing and least developed are set out in TRIPs, Arts 65 and 66 and deal with the time delay in implementing TRIPs obligations and assistance in technology transfer.

[179] See for example Council of Trade-Related Aspects of Intellectual Property Rights, *Special Discussion on Intellectual Property and Access to Medicines* (2001) IP/C/M/31, 4; Council for Trade-Related Aspects of Intellectual Property Rights, *Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela* (2001) IP/C/W/296, 5-6.

obligations as well as their public policy objectives. Thus, the majority consensus now appears to be:

> … we remain committed to [the] implementation of the TRIPs Agreement based on its proper and flexible interpretation and in accordance with the objectives and principles contained in Arts 7 and 8 … Some provisions of the TRIPs Agreement may elicit different interpretations. This 'room to manoeuvre' served the purpose of accommodating different positions held by members at the time of negotiation of the Agreement. We strongly believe that nothing in the TRIPs Agreement reduces the range of options available to governments to promote and protect public health, as well as other overarching public policy objectives.[180]

4.1.4 This view is consistent with the dispute settlement scheme Panel decision in *Canada – Patent Protection of Pharmaceutical Products*.[181] There the European Union, in opposition, argued the phrase in Art 8(1), 'provided that such measures are consistent with the provisions of this [TRIPs] Agreement' meant that any other considerations beyond the patent holders rights were subordinate to the protection of the minimum intellectual property rights guaranteed by TRIPs.[182] The Panel rejected the European Union argument and accepted adjustments to a patent holder's rights were contemplated according to the objectives and principles of Arts 7 and 8(1) (and other relevant provisions of TRIPs).[183] However, the Panel expressed the view that these provisions were to be 'borne in mind' and a re-negotiation of the balance of TRIPs was not appropriate.[184] This approach has now been confirmed in the *Declaration on the TRIPs Agreement*

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[180] Council for Trade-Related Aspects of Intellectual Property Rights, *Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela* (2001) IP/C/W/296, 3.

[181] (2000) WT/DS114/R.

[182] (2000) WT/DS114/R, 50.

[183] (2000) WT/DS114/R, 154.

[184] (2000) WT/DS114/R, 154.

and Public Health (the Declaration)[185] in response to member states 'taking measures to protect public health':

> … while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPs Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.[186]

4.1.5 It remains to be seen how broadly these provisions apply and the limitations that may be imposed. Although, it is certainly clear after the Declaration that some member states consider these provisions 'flexible' enough to allow 'exclusive rights' to be curtailed to make pharmaceutical products protected by patents accessible in cases of epidemics.[187] For example, some developing and least develop states have asserted:

> The objective of the promotion of technological innovation and the transfer and dissemination of technology places the protection and enforcement of [intellectual property rights] in the context of the interests of society. Such an objective is essential for the promotion of health policies, as it encourages the development of domestic production of pharmaceutical products … Where the patent holder fails to meet the objectives of the TRIPs Agreement and of public health policies, however, Members may take measures to ensure transfer and dissemination of technology to provide better access to pharmaceuticals.[188]

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[185] Ministerial Conference, *Declaration on the Trips Agreement and Public Health* (2001) T/MIN(01)/DEC/2.

[186] Ministerial Conference, *Declaration on the Trips Agreement and Public Health* (2001) T/MIN(01)/DEC/2, 1.

[187] Council for Trade-Related Aspects of Intellectual Property Rights, *Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela* (2001) IP/C/W/296, 5-6.

[188] Council for Trade-Related Aspects of Intellectual Property Rights, *Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela* (2001) IP/C/W/296, 6.

4.1.6 Arguably, according to this approach, Art 8(1) principles will be interpreted according to the Art 7 objectives, so that measures may be consistent with TRIPs if they are implemented to meet the broadly stated Art 7 objectives. If this is correct then there is considerable 'flexibility' in TRIPs for Australia and other member states to interpreted TRIPs and develop and apply laws that promote Australia's particular interests, including interests that might be unrelated to patenting.

4.2 Prior intellectual property conventions – Art 2(1)

4.2.1 TRIPs expressly provides, in Art 2(1), that member states shall, in respect of Parts II (standards concerning the availability, scope and use of intellectual property rights), III (enforcement of intellectual property rights) and IV (acquisition and maintenance of intellectual property rights and related *inter-partes* procedures) of TRIPs, 'comply' with Arts 1 to 12 and 19 of the Stockholm Act of the *Paris Convention for the Protection of Industrial Property* (Paris Convention 1967).[189] This may extend the scope of TRIPs to incorporate parts of the Paris Convention 1967. The relevant parts of the Paris Convention 1967 provide:

(a) Compulsory licensing and forfeiture – 'Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work',[190] and '[f]orfeiture of the patent shall not be provided for

[189] TRIPs Art 2.1; *Paris Convention for the Protection of Industrial Property* ('Paris Convention 1967') of 20 March 1883, as revised at Brussels on 14 December 1900, at Washington on 2 June 1911, at The Hague on 6 November 1925, at London on 2 June 1934, at Lisbon on 31 October 1958, and at Stockholm on 14 July 1967 (Stockholm, 14 July 1967); entry into force generally of substantive provisions (Articles 1-12) on 26 April 1970 and entry into force generally of administrative provisions (Articles 13-30): 26 April 1970; entry into force for Australia of substantive provisions on 27 September 1975 and entry into force for Australia of administrative provisions on 25 August 1972.

[190] Paris Convention 1967 Art 5.A(2).

except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses'.[191] The only limits set out in the Convention is that compulsory licenses for 'failure to work' or 'insufficient working' can not be made *before* either 'four years from the date of filing of the patent application' or 'three years from the date of the grant of the patent', or if the 'patentee justifies his inaction by legitimate reasons'. [192] Further, if a compulsory license is granted, then it must be non-exclusive and 'shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license'.[193]

(b) Unfair competition – 'Any act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition'.[194] States are required to implement 'effective protection'.[195]

4.2.2 By expressly capturing parts of the Paris Convention 1967, TRIPs is a later treaty dealing with the same subject matter, and according to the *Vienna Convention on the Law of Treaties*, '[w]hen all the parties to the earlier treaty are parties also to the later treaty … the earlier treaty applies only to the extent that its provisions are compatible with those of the later treaty'.[196] The effect of this provision in Australia is arguably that TRIPs saves the operation of the identified parts of the Paris Convention 1967 that are 'compatible' with the exceptions scheme set out in

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[191] Paris Convention 1967 Art 5.A(3).

[192] Paris Convention 1967 Art 5.A(4).

[193] Paris Convention 1967 Art 5.A(4).

[194] Paris Convention 1967 Art 10*bis*(2).

[195] Paris Convention 1967 Art 10*bis*(1).

[196] *Vienna Convention on the Law of Treaties*, Art 30(3); noting that where 'a State [is] party to only one of the treaties, the treaty to which both States are parties governs their mutual rights and obligations' (Art 30(4)); this approach has been endorsed by the WTO's dispute settlement scheme, see for example *United States – Standards for Reformulated and Conventional Gasoline* (1996) WT/DS2/AB/R, 16-17; *India – Patent Protection for Agricultural and Chemical Products* (1998) WT/DS50/R, 46.

TRIPs. The issue is to determine whether compulsory licensing and unfair competition measures in the Paris Convention 1967 are 'compatible' with the provisions of TRIPs? These additional provisions in the Paris Convention 1967 and how they apply through TRIPs remains uncertain, although some of the developing and least developed states have asserted the saving of these provisions and their application to limit 'exclusive rights'.[197] If this These are potential grounds for Australia to develop and apply patent and competition laws that promote Australia's particular interests.

4.3 Exhaustion of rights – Art 6

4.3.1 Art 6 provides that '[f]or the purposes of dispute settlement under this [TRIPs] Agreement subject to the provisions of Arts 3 [National treatment] and 4 [Most-favoured-nation treatment][198] nothing in this [TRIPs] Agreement shall be used to address the issue of the exhaustion of intellectual property rights'. This provision reflects the long history and ongoing dispute about the merits of limiting the patent holder's control to permit the free exchange of products protected by a patent.[199] Among member states exhaustion is regulated at the state, international

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[197] See for example Council for Trade-Related Aspects of Intellectual Property Rights, *Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela* (2001) IP/C/W/296, 7-8.

[198] As a generalisation these provisions require WTO members states to treat nationals of other members states no less favorable than their own nationals and any advantage, favour, privilege or immunity granted to nationals of another country must also be accorded to all other nationals of WTO member states.

[199] This was particularly contentious during the TRIPs negotiations: see for examples Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, *Trade in Counterfeit Goods: Compilation of Written Submissions and Oral Statements* (1988) MTN.GNG/NG11/W/23, 14; Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, *Meeting of Negotiating Group of 3-4 July 1989* (1989) MTN.GNG/NG11/13, 13; Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, *Meeting of Negotiating Group of 12-14 July 1989* (1989) MTN.GNG/NG11/14, 9-10 and 14-15; Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, *Meeting of Negotiating Group of 2, 4 And 5 April*

and regional levels.[200] In most cases patent holders (and their licensees and assignees) carefully commercialise their patent privileges through arrangements that seek to avoid exhaustion, until the final consumer purchases the product protected by the patent. However, territorial distribution monopolies (also known as 'parallel importing' or 'grey marketing') are susceptible to exhaustion and reflect the lack of international consensus, even among developed states.[201] As a generalisation, 'parallel importing' or 'grey marketing' is the importing of legitimately purchased goods protected by intellectual property rights in one state jurisdiction into another state jurisdiction with the same, or similar intellectual property right, for resale without authorisation.[202]

4.3.2 The contentious issue is that restrictions on importing allow distinct territorial distribution markets with price discrimination levying higher prices onto some consumers. Removing these territorial barriers limits price discrimination through international arbitrage. As a generalisation, those advocating strong 'parallel import restrictions' argue that price discrimination is an essential part of the incentive to innovate, there are efficiencies in distribution by the right holder and the restrictions maintain important product standards and quality (such as pre-sales advice and customer service programs). Again, as a generalisation, those

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1990 (1990) MTN.GNG/NG11/20, 10-11; Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, Meeting of the Negotiating Group of 1 November 1990 (1990) MTN.GNG/NG11/27, 1-2.

[200] For examples see Margreth Barrett, 'The United States' Doctrine of Exhaustion: Parallel Imports of Patented Goods' (2000) 27 *Northern Kentucky Law Review* 911, 915-917.

[201] See for example Ann Capling, 'The Conundrum of Intellectual Property Rights: Domestic Interests, International Commitments and the Australian Music Industry' (1996) 31 *Australian Journal of Political Science* 301; this disagreement is also compounded in trading zones that require the free movement of goods within the zones and across national borders (such as the European Union): see for example Isabel Britton and Ian Karet, 'Parallel Imports Continue: The Exhaustion Principle Upheld' (1997) 4 *European Intellectual Property Review* 207.

[202] See generally Louise Logdin, 'Making the Most of Article 6: Parallel Importing in Australia and New Zealand' (2001) 45 *Intellectual Property Forum* 22, 36-37; Warwick Rothnie, *Parallel Imports* (1995).

advocating removing 'parallel import' restrictions argue goods protected by intellectual property rights are in the same position as all other goods, only legitimately purchased goods can be imported and consumers are not paying excessive prices. These positions are reflected among the member states. For example, some of the developing and least developed states maintain that there should be no limitations on exhaustion allowing the right of exhaustion to be exercised 'without hindrance' in accordance with the goal of reducing distortions and impediments to international trade.[203] In contrast, the United States asserts:

> There is no question that Art 6 denies Members the ability to avail themselves of dispute settlement in relation to questions involving parallel imports, except where those questions involve national or most-favoured nation treatment. However, Art 6 of the TRIPs Agreement does not, in our view, authorise parallel imports. Members must remember that Art 6 does not alter the substantive obligations of the TRIPs Agreement, particularly those …[establishing the minimum patenting standards]. In our view, advocates of parallel importing overlook the fact that permitting such imports discourages patent owners from pricing their products differently in different markets based upon the level of economic development because of the likelihood that, for example, products sold for a low price in a poor country will be bought up by middle men and sent to wealthiest country markets and sold at higher prices, for the benefit primarily of the middle men.[204]

4.3.3 The Declaration in effect maintained the *status quo*, providing:

> … while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: … (d) The effect of the provisions in the TRIPs Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the most favored nation and national treatment provisions …[205]

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[203] Council of Trade-Related Aspects of Intellectual Property Rights, *Special Discussion on Intellectual Property and Access to Medicines* (2001) IP/C/M/31, 5.

[204] Council of Trade-Related Aspects of Intellectual Property Rights, *Special Discussion on Intellectual Property and Access to Medicines* (2001) IP/C/M/31, 40.

[205] Ministerial Conference, *Declaration on the Trips Agreement and Public Health* (2001) WT/MIN(01)/DEC/2, 1.

4.3.4 The significance of the Declaration is to confirm that the provisions in Art 28 that sets out the 'exclusive rights' to include the right to prevent third parties from importing patent protected products without consent does not limit member states from implementing separate exhaustion schemes. Thus, parallel import restrictions on legitimately obtained patent protected products are allowable under TRIPs, and cannot be subject to the dispute settlement scheme. In Australia this is a significant issue as the approach to 'parallel import' restrictions for some copyright and other products protected by intellectual property rights has not been extended to products protected by patents.[206] Applying exhaustion schemes to products protected by patents may reduce distortions in the domestic market and make products more accessible and affordable.

4.3.5 However, before adopting a liberal exhaustion scheme, there are other issues that remain unresolved and may need further consideration depending on what form of exhaustion is proposed:

(a) It is not clear whether TRIPs establishes a self-contained scheme for intellectual property outside the GATT rules[207] that excludes prohibitions and restrictions that are not duties, taxes or other charges.[208] If GATT rules apply, national exhaustion schemes that block the import of patent protected products may be challenged;

(b) The threshold for determining when a patent privilege is exhausted is uncertain, as the term 'exhausted' is not defined. Any resolution to this

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[206] For a recent analysis of some 'parallel importing' issues in Australia see IPCR Committee, above n 19, app 5.

[207] See Marco Bronckers, 'The Exhaustion of Patent Rights under World Trade Organisation Law' (1998) 32 *Journal of World Trade* 137.

[208] *General Agreement on Tariffs and Trade* Art XI(1), made at Geneva, 30 October 1947; entry into force generally and for Australia on 1 January 1948 (provisionally).

will be by negotiation as an interpretation through the dispute settlement scheme would seem to be excluded by Art 6 itself; and

(c) It is not clear whether regional exhaustion schemes are inconsistent with Arts 3 and 4, and the general requirement in Art 27(1) that there be no 'discrimination' with respect to place of invention, field of technology and whether products are imported or locally produced.

4.4 Anti-competitive measures – Arts 8(2) and 40

4.4.1 To address the particular concerns of developing and least developed states about the exercise of intellectual property rights in the TRIPs negotiations, Arts 8(2) and 40 were included.[209] Art 8(2) specifically addressed abuses and restrictions against trade and technology transfer, while Art 40 is concerned specifically with anti-competitive licensing practices.

4.4.2 Art 40 provides that member states may adopt 'appropriate measures' to 'protect or control' some 'licensing practices and conditions' in contractual licenses. Significantly TRIPs accepts that 'some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology'.[210] The uncertain language of Art 40 means that the scope of this provision is unclear and reflects the lack of international consensus about regulating competition.[211]

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[209] See for example Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, *Standards and Principles Concerning the Availability, Scope and Use of Trade-Related Intellectual Property Rights: Communication From India* (1989) MTN.GNG/NG11/W/37, 8.

[210] TRIPs Art 40(1).

[211] For example the United Nations suspended negotiation of the *Code of Conduct on the Transfer of Technology* in 1985: see Secretary General, Negotiation on an *International Code of Conduct on the Transfer of Technology* (1995) DOC.TD/CODETDT/60; for a recent analyses of this issue see Joel

4.4.3 While there have been no disputes specifically about 'appropriate measures' between member states, the decision in *Canada – Patent Protection of Pharmaceutical Products*[212] accepted, in the context of public health, that measures to limit the *de facto* extension of a patentee's 'exclusive rights' beyond the term of the patent as a result of regulatory approval delays was an 'appropriate measure'.[213]

4.4.4 The key issues in applying these provisions are to determine what conduct falls within the scope of the provisions and then whether the proposed measures to address that conduct are 'consistent with the provisions of this [TRIPs] Agreement' and 'appropriate'. This remains uncertain and in large part will depend on the interpretation of the objectives and principles in Arts 7 and 8(1). Further, it is unclear:

(a) What status Art 8(2) has as a substantive rule within TRIPs, or whether it is merely a statement of principle;

(b) The interaction between Arts 8(2) and 40, and especially the consultation provision of Art 40, as it is unlikely that much of the conduct within the scope of Art 8(2) could not also be characterized within the scope of Art 40;

(c) What types and classes of conduct that Art 8(2) contemplates, given the uncertain origin of the language and the pre-existence of comprehensive pro-competition schemes in most developed states to address intellectual property abuses and restraints on trade;

Davidow and Hal Shapiro, 'The Feasibility and Worth of a World Trade Organisation Competition Agreement' (2003) 37 *Journal of World Trade* 49.

[212] *Canada – Patent Protection of Pharmaceutical Products* (2000) WT/DS114/R.

[213] (2000) WT/DS114/R, 154.

(d) Whether Art 8(2) extends to changing the structures of a market (rather than just to conduct in a market), such as regulation of mergers and acquisitions; and

(e) The ongoing and uncertain nature of obligations on developed states to transfer technology to developing and least developed states under TRIPs and other international agreements (such as the *Convention on Biological Diversity*).[214]

4.4.5 The major developments in dealing with the interaction between patents and competition law are likely to be in bilateral agreements between member states[215] and the development of guidelines by developing states to direct conduct in their jurisdictions.[216]

4.5 Exception to rights conferred – Art 30

4.5.1 TRIPs expressly recognises in Art 30 that 'limited exceptions' to the patentee's 'exclusive rights', 'provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties'.[217] The extent of this exception is unclear, although the WTO Panel decision in *Canada – Patent Protection of Pharmaceutical Products*[218]

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[214] Arts 15 and 16; [1993] ATS 32.

[215] This is particularly the case as the WTO is more concerned with market access issues that are likely to be complicated by attempts to address competition policy issues in the same forum: see for a review of international actions on trade and competition Joel Davidow and Hal Shapiro, 'The Feasibility and Worth of a World Trade Organisation Competition Agreement' (2003) 37 *Journal of World Trade* 49.

[216] In Australia: Trade Practices Commission, *Application of the Trade Practices Act to Intellectual Property* (1991); in the United States: United States Department of Justice and Federal Trade Commission, *Anti-trusts Guidelines for the Licensing of Intellectual Property* (1995).

[217] TRIPs Art 30.

[218] *Canada – Patent Protection of Pharmaceutical Products* (2000) WT/DS114/R.

established that a patentee's 'exclusive rights' could be limited in certain circumstances.

4.5.2 In that case, Canada introduced the domestic law exceptions to a patent holder's 'exclusive rights' to promote competition in the domestic pharmaceutical market in an attempt to overcome the price distortions caused by the patents. This was also a mechanism to reduce the cost of pharmaceuticals for the publicly funded health system. This case found that exceptions to a patent holder's 'exclusive rights' should be interpreted flexibly to allow adjustments to meet broader policy objectives other than just the rights of inventors within the scope of the patent grant.

4.5.3 The Panel stated:

> In the Panel's view, Art 30's very existence amounts to a recognition that the definition of patent rights contained in Art 28 would need certain adjustments. On the other hand, the three limiting conditions attached to Art 30 testify strongly that the negotiators of the [TRIPs] Agreement did not intend Art 30 to bring about what would be equivalent to a renegotiation of the basic balance of the [TRIPs] Agreement. Obviously, the exact scope of Art 30's authority will depend on the specific meaning given to its limiting conditions. The words of those conditions must be examined with particular care on this point. Both the goals and the limitations stated in Arts 7 and 8(1) must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes'.[219]

4.5.4 The Panel accepted that the 'limited exceptions' contemplated by Art 30 should be narrowly defined to 'connote a narrow exception – one which makes only a small diminution of the rights in question'.[220] Significantly, the Panel concluded that in the absence of other indicators, 'it would be justified in reading the text [of Art 30] literally, focusing on the extent to which legal rights have been curtailed,

[219] (2000) WT/DS114/R, 154.

[220] (2000) WT/DS114/R, 155.

rather than the size or extent of the economic impact'.[221] So in the present dispute, the Panel found the Canadian law allowing pharmaceutical stockpiling before the patent term expired was without limits on the quantity that could be stockpiled and was therefore a 'substantial curtailment' rather than a 'limited exception', and so contrary to Art 30.[222] Given this finding it was not necessary for the Panel to consider the other elements of Art 30 for stockpiling. However, the Panel expressly left open the question of how much curtailment of the patent holder's 'exclusive rights' was sufficient to constitute a 'substantial curtailment' and so 'whether a particular exception constitutes a limited exception, the extent to which the patent owner's rights have been curtailed must be measured'.[223] In reaching this conclusion the Panel noted that each possible limitation needed to be considered independently and the commercial detriment to the patent holder's 'exclusive rights' was also relevant in assessing curtailment.[224]

4.5.5 In contrast, the Panel accepted that the Canadian law allowing an exception for regulatory review was a 'limited exception' because 'the exception is confined to conduct needed to comply with the requirements of the regulatory approval process, the extent of the acts unauthorized by the right holder that are permitted by it will be small and narrowly bounded'.[225] Perhaps reading into the Panel's decision, the presence of regulatory review provisions in a number of member states' laws (including Australia) seemed to be significant in persuading the Panel that such exceptions were in fact limited. The Panel considered that the 'normal practice' of exploitation by patent owners was 'to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity'.[226] In the present matter the Panel

[221] (2000) WT/DS114/R, 155.

[222] (2000) WT/DS114/R, 156.

[223] (2000) WT/DS114/R, 155.

[224] (2000) WT/DS114/R, 155.

[225] (2000) WT/DS114/R, 158.

[226] (2000) WT/DS114/R, 161.

considered that market exclusivity beyond the patent term as a result of delayed regulatory approval (*de facto* 'exclusive rights') was not a 'normal practice',[227] and therefore the further element of 'unreasonableness' was not considered.[228] Significantly, the Panel accepted that the term 'normal' can 'be understood to refer either to an empirical conclusion about what is common within a relevant community, or to a normative standard of entitlement'.[229] The Panel therefore accepted the regulatory review provisions were within the scope of this limb of Art 30.

4.5.6 In assessing the final limb of Art 30, the Panel considered the term 'legitimate interests' in the context of Art 30, 'must be defined in the way that it is often used in legal discourse – as a normative claim calling for protection of interests that are 'justifiable' in the sense that they are supported by relevant public policies or other social norms'.[230] This view was supported by the negotiating records of the TRIPS that showed an early draft of Art 30 contemplated exceptions for private use, scientific use, prior use, a traditional exception for pharmacists, and the like,[231] although this approach was abandoned in favour of a general authorization.[232] The Panel expressed some sympathy for including the policy justifying national patent laws as determining the scope of a 'legitimate interest' and this was broader than just legal interests.[233] Further, the Panel concluded 'on balance' that 'the interest claimed on behalf of patent owners whose effective period of market exclusivity had been reduced by delays in marketing approval was neither so compelling nor so widely recognized that it could be regarded as a

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[227] (2000) WT/DS114/R, 161-162.

[228] (2000) WT/DS114/R, 162.

[229] (2000) WT/DS114/R, 161.

[230] (2000) WT/DS114/R, 164.

[231] See Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, *Status of Work in the Negotiating Group* (1990) MTN.GNG/NG11/W/76, 18.

[232] *Canada – Patent Protection of Pharmaceutical Products* (2000) WT/DS114/R, 165.

[233] (2000) WT/DS114/R, 163-165.

'legitimate interest' within the meaning of Art 30'.[234] In this case market exclusivity beyond the patent term was not a 'legitimate interest' for the purposes of Art 30 and so could not be 'unreasonably prejudiced'.[235]

4.5.7 The Panel concluded because Canada's regulatory review provision complied with each limb of Art 30 the domestic law was therefore not in conflict with TRIPs. Further, no discrimination as to the field of technology was found (a requirement of Art 27) as Canada asserted the regulatory review provision was available wherever regulatory approval was required.[236] The European Union was unable to rebut this contention even though the Canadian laws had been enacted with pharmaceuticals in mind suggesting that skillful drafting of legislation can avoid claims of discrimination.

4.5.8 The significance of this case is to suggest that the objectives and principles in Arts 7 and 8(1) do not in themselves provide a mechanism to limit 'exclusive rights', but rather, affect the interpretation of the other parts of TRIPs. In the context of Art 30, this allows considerable scope to interpret the key terms 'unreasonably conflict', 'normal exploitation', 'unreasonable prejudice' and 'legitimate interests'. A broad interpretation of any of these terms might justify a 'limited exception' to the patentee's 'exclusive rights', particularly if the 'legitimate interests of third parties' are taken to have considerable weight in assessing what are the 'legitimate interests of the patent owner'. However, this should not be a 're-negotiation of the basic balance of the [TRIPs] Agreement'.[237]

4.5.9 This is likely to be an area of considerable development as member states seek to take advantage of TRIPs to promote domestic innovation and technology transfer for the benefit and advantage of their domestic markets and economies. The Panel

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[234] (2000) WT/DS114/R, 168.

[235] (2000) WT/DS114/R, 169.

[236] (2000) WT/DS114/R, 171-174.

[237] (2000) WT/DS114/R, 154.

decision established that early working provisions (Bolar exceptions) are an 'appropriate measure',[238] and that other collateral advantages from patent privileges may be restricted. However, while the scope of collateral advantages that may be restricted may be uncertain, it is unclear whether Art 30 is confined to these collateral advantages or might extend further to restrict the 'core' 'exclusive rights', and if so, how far.

4.6 Other use without the authorization of the right's holder – Art 31

4.6.1 TRIPs allows, in Art 31, for Member states to have laws that allow 'other use of the subject matter of a patent without the authorization of the right holder' subject to respecting conditions aimed at protecting the 'legitimate interests' of the rights holder. The 'other use' refers to 'use other than that allowed under Art 30'.[239] This includes government use and uses by a third party that has been authorised by government. Most importantly, this provision has been cited as the authority for member states to implement compulsory licensing schemes[240] and originated from a proposal to restrict compulsory licensing in the initial TRIPs proposal.[241] While this provision *does not* specify the grounds for issuing a compulsory license, it *does* impose procedural requirements on the circumstances in which a compulsory license may be issued. The requirements are that each authorisation is to be considered on its merits and subject to review, that efforts to obtain authorization on reasonable commercial terms and conditions have been unsuccessful within a reasonable time, the authorization has a limited scope and duration, the authorized use is not exclusive, the authorized use is not assignable, the authorized use is

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[238] See also National Economic Research Associates, *Policy Relating to Generic Medicines in the OECD: Final Report for the European Commission* (1998).

[239] TRIPs Art 31 (footnote).

[240] See for example Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from the European Communities and their Member States* (2001) IP/C/W/280, 2.

[241] Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, *Suggestion by the United States for Achieving the Negotiating Objective, United States Proposal for Negotiations on Trade-Related Aspects of Intellectual Property Rights* (1987) MTN.GNG/NG11/W/14, 7.

'predominantly for the supply of the domestic market', the authorized use may be terminated when the circumstances requiring authorization cease and there is adequate remuneration and this decision is reviewable.[242] The issuing of compulsory licenses for anti-competitive conduct is treated separately,[243] and additional requirements are imposed for the proper working of another patent (dependent patents).[244] Significantly, the requirement to first seek authorization on commercial terms and conditions can be waived in cases of 'national emergency', 'other circumstances of extreme urgency'[245] and in cases of public non-commercial use.[246]

4.6.2 Compulsory licensing was included in TRIPs negotiations, accepting that compulsory licensing is an appropriate limitation on a patentee's 'exclusive rights'.[247] However, the scope of compulsory licensing remains controversial (particularly the ground of 'non-working'),[248] with resolution being found in a

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[242] TRIPs Art 31(a)-(j).

[243] TRIPs Art 31(k).

[244] TRIPs Art 31(l).

[245] There appears to be consensus among WTO member states that the level of HIV/AIDS infection reported in some developing countries is within the meaning of a 'national emergency' or as a 'circumstance of extreme urgency': see for example Council for Trade-Related Aspects of Intellectual Property Rights, *Communication from the European Communities and their Member States* (2001) IP/C/W/280, 3.

[246] TRIPs Art 31(b).

[247] See Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, *Suggestion by the United States for Achieving the Negotiating Objective, United States Proposal for Negotiations on Trade-Related Aspects of Intellectual Property Rights* (1987) MTN.GNG/NG11/W/14, 4.

[248] For examples of this controversy compare the European Communities stance (Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, *Guidelines and Objectives Proposed by the European Community for the Negotiation on Trade-Related Aspects of Substantive Standards of Intellectual Property Rights* (1988) MTN.GNG/NG11/W/26) with India's stance (Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, *Standards and Principles Concerning the Availability, Scope and Use of Trade-Related*

final TRIPs text focussing instead on procedural requirements.[249] This however leaves the controversial issue of the grounds justifying a compulsory license open to further negotiation and dispute.

4.6.3 This provision has not been directly considered under the dispute settlement scheme. However, in *Argentina – Certain Measures on The Protection of Patents and Test Data*[250] the United States asserted that 'Argentina fails to provide certain safeguards for the granting of compulsory licenses, including timing and justification safeguards for compulsory licenses granted on the basis of inadequate working'.[251] The concern appears to have been that Argentinean laws established a scheme for the granting of a compulsory license in circumstances the laws defined to be 'anti-competitive' practices without reference to an adjudication that the practice was also in breach of competition laws. Following consultations, the parties notified a mutually agreed solution that Argentina would not issue a compulsory license in circumstances the laws defined to be 'anti-competitive' practices unless an adjudication had first been made that the circumstances was also an abuse of a dominant position in a market according to domestic competition laws.[252] The parties agreed that this compromise was consistent with Argentina's obligations under TRIPs Art 31(k).[253]

Intellectual Property Rights: Communication from India (1989) MTN.GNG/NG11/W/37); this reflects in part the domestic tensions in the United States upholding the absolute right of the patentee to exclude others from using the invention: for an analysis of United States cases see Joseph Yosick, 'Compulsory Patent Licenses for Efficient Use of Inventions' (2001) *University of Illinois Law Revue* 1275, 1279-1282.

[249] See GATT Secretariat, *Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations* (1990) MTN.TNC/W/35/Rev.1, Art 34.

[250] (2000) WT/DS196/1.

[251] *Argentina – Certain Measures on The Protection of Patents and Test Data* (2000) WT/DS196/1, 1.

[252] (2000) WT/DS196/4, 2.

[253] (2000) WT/DS196/4, 2.

4.6.4 Then in *Brazil – Measures Affecting Patent Protection*[254] the United States requested consultations with Brazil under the dispute settlement scheme because Brazil had included a 'local working' requirement subject to a obligatory compulsory license for 'failure to manufacture or incomplete manufacture of the product' or 'failure to make full use of the patented process' in Brazil. The complain was later withdrawn and a joint communication from the parties set out their agreement that the Brazilian Government would consult with the United States Government before issuing a compulsory license over a patent held by a United States resident.[255] This dispute illustrated the ongoing differences of opinion about the grounds for issuing compulsory licenses and that issuing a compulsory license on the ground of 'local non-working' of a patent remains open to question.[256] Further, the different perspectives on the operation of this provision generally divide among developed and developing and least developed member states. For example, the developed states assert that Art 31 must be read in conjunction with the other provisions of TRIPs, such as Art 27, so that only domestic production can justify a compulsory license.[257] In contrast the developing and least developed states assert that Arts 27 and 28 address different matters and circumstances and that these provisions therefore do not limit the issuing of compulsory licenses.[258] The Declaration affirmed these different positions and failed to provide any further guidance:

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[254] (2000) WT/DS199/1.

[255] See Office of the United States Trade Representative, *United States and Brazil Agree to Use Newly Created Consultative Mechanism to Promote Cooperation on HIV/AIDS and Address WTO Patent Dispute*, Press Release, 25 June 2001, 01-46; World Trade Organisation, *Brazil – Measures Affecting Patent Protection: Notification of Mutually Agreed Solution* (2001) WT/DS199/4G/L/454IP/D/23/Add.1.

[256] Note the discussion above about the ongoing dispute about the maintenance of this ground through adoption of the Paris Convention 1967 provisions by TRIPs Art 2(1).

[257] See for example Council of Trade-Related Aspects of Intellectual Property Rights, *Special Discussion on Intellectual Property and Access to Medicines* (2001) IP/C/M/31, 37-38.

[258] See for example Council for Trade-Related Aspects of Intellectual Property Rights, *Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India,*

> … while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: … (b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.[259]

4.6.5 Subsequent negotiations have brought these different positions into view. The Declaration identified problems in TRIPs that required further work and ongoing negotiation with an instruction 'to find an expeditious solution to this problem' for member states with 'insufficient or no manufacturing capacities in the pharmaceutical sector' to enable effective compulsory licensing.[260] As a measure of the strong disagreement among member states about the grounds for issuing compulsory licenses and the consequences of conceding any 'new' grounds, this problem has required a separately negotiated decision.[261] The solution is to modify the operation of Art 31(f) and (h),[262] with the prospect of amending TRIPs according to this decision at some time in the future.[263] The decision imposes conditions about the amounts manufactured and labeling,[264] extensive reporting requirements[265] and measures to limit the diversion of the patent protected products entering other territories.[266] Significantly, the decision attempts to isolate

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Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela (2001) IP/C/W/296, 8.

[259] Ministerial Conference, *Declaration on the Trips Agreement and Public Health* (2001) WT/MIN(01)/DEC/2, 1.

[260] Ministerial Conference, *Declaration on the Trips Agreement and Public Health* (2001) WT/MIN(01)/DEC/2, 2.

[261] See Council for Trade-Related Aspects of Intellectual Property Rights, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health* (2003) WT/L/540.

[262] WT/L/540, above n 261, [2] and [3].

[263] WT/L/540, above n 261, [11].

[264] WT/L/540, above n 261, [2(b)(i)] and [2(b)(ii)].

[265] WT/L/540, above n 261, [2(a)], [2(b)(iii)] and [2(c)].

[266] WT/L/540, above n 261, [4] and [5].

the impact of these modifications of TRIPs from the other parts of TRIPs[267] and other TRIPs issues under negotiation.[268]

4.6.6 The prospective amendment of TRIPs to reflect the expanded scope of Art 31(f) and (h) is unlikely to be easy. As a generalisation, in negotiating the solution the developing and least developed states favoured authoritative interpretations or amendment of Art 31,[269] while developed states favoured adding a new clearly circumscribed exception to Art 31[270] or a waiver of obligations or moratorium on dispute settlement dealing with the particular circumstances of each case separately and in isolation from TRIPs' obligations.[271] The significance of these developments is that any acceptance that TRIPs should be authoritatively interpreted or amended will flow through to the negotiations about other aspects of TRIPs. This is a particularly important issue for any future interpretation of TRIPs about the grounds for issuing compulsory licenses that allows it to meet its objectives and principles according to Arts 7 and 8(1) outside the scope of patents and the saving of the Paris Convention 1967 non-working grounds for issuing compulsory licenses. This potential to expand the review of TRIPs is already apparent in comments by developing and least developed states on other apparently unrelated aspects of reviewing TRIPs.[272]

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[267] WT/L/540, above n 261, [9].

[268] WT/L/540, above n 261, [9].

[269] See for examples Council for Trade-Related Aspects of Intellectual Property Rights, *Proposals on Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health* (2002) IP/C/W/351, 3-7; Council for Trade-Related Aspects of Intellectual Property Rights, *Proposals on Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health* (2002) IP/C/W/355, 3-6.

[270] See Council for Trade-Related Aspects of Intellectual Property Rights, *Paragraph 6 of the Doha Declaration of the TRIPs Agreement and Public Health* (2002) IP/C/W/352, 2.

[271] See Council for Trade-Related Aspects of Intellectual Property Rights, *Proposals on Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health* (2002) IP/C/W/358, 6-7.

[272] For examples, the 'Review of the Provisions of Article 27.3(b)' (see for example Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting* (2003) IP/C/M/39, 19), the 'Relationship between the TRIPS Agreement and the *Convention on Biological Diversity*' (see for example

4.6.7 This analysis shows that TRIPs is an evolving agreement and that there is considerable 'flexibility' within the current agreement to develop and apply patent laws (and competition laws) in a way that promotes Australia's particular and different economic and technological interests. The following Part 7 analyses the patent privilege related provisions of the AUSFTA to show that much of TRIPs' 'flexibility' is being given up, and further that the policy challenges raised in Part 5 about the lack of evidence demonstrating the benefits of TRIPs-plus patent laws probably have not been addressed.

5. CONCLUSIONS

5.1 This submission deals with patents as a utilitarian measure to promote invention and their role in addressing the market failure for invention. According to this model, effective competition together with good market information may create a disincentive to markets inventing (the market failure) because new developments may be rapidly copied without the recovery of the inventor's development costs (a free ride). A patent compensates for the disincentive to invent. This justifies a limited period of 'exclusive rights' during which the inventor may exclude others in order to recover the development costs that theoretically enhances competition for the welfare of consumers by investing in new developments (with the added benefit of disclosure of the invention). However, patents do restrict competition and the challenge for patent laws (and competition laws) is to achieve a balance that adequately encourages invention without unduly restricting competition.

5.2 Both patent law and competition law are putting into regulation the theory about competition and market failures resulting from that competition through a property right. This, by its very nature of being a theory, does not have a certain

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Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting* (2003) IP/C/M/39, 26), and the overlapping issues in the Declaration and the 'Review of the Implementation of the Agreement under Art 71.1'(see for example Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting* (2003) IP/C/M/38, 56).

answer, and various views are evolving through experience of the patent and competition schemes. Taking this into account, this submission asserts that the fundamental framework that should be applied to assessing and developing patent laws is the CPA requirements. There are other measures that might be considered in framing and applying the patent laws (and competition laws) that do seek to balance the competing policy objectives of these schemes – the policy levers to fine-tune the schemes – such as taxation incentives and effective and workable competition laws. These measures, however, require 'flexibility' in applying patent laws to suit the particular economic circumstances addressing the circumstances of the market at its particular stage of development.

5.3 The policy objective set out in the CPA was to promote competition by removing unjustified restrictions on competition in Australia.[273] For statute based intellectual property rights, like patent privileges set out in the *Patents Act* and the *Trade Practices Act*, the Hilmer Committee report expressed clear concern that these regulations potentially created barriers to entry that might restrict competition,[274] and that the need for exemptions for certain license and assignment conditions from the *Trade Practices Act* were uncertain.[275] This submission has examined the various reports addressing patent privileges set out in the *Patents Act* and *Trade Practices Act* and legislative amendments to the *Patents Act* to assess the foundation evidence that might satisfy the requirements of the CPA. These analyses show important controversial issues have been glossed over, even though such an approach was open to both the NCC and IPCR Committee, and that a detailed competition analysis of the appropriate threshold requirements set out in the *Patents Act* and the exemptions in the *Trade Practices Act* has been avoided.

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[273] *Competition Principles Agreement* cl 5(1)

[274] See Hilmer Committee, above n 34, 195.

[275] Hilmer Committee, above n 34, 150.

According to this assessment these legislation reviews and amending legislation therefore fail to meet the CPAs requirements.[276]

5.4 Perhaps the most revealing part of the Hilmer Committee report was the recognition that '[r]egualtion that confers benefits on particular groups soon builds a constituency with an interest in resisting change and avoiding rigorous and independent re-evaluation of whether the restriction remains justified in the public interest'.[277] To address this particular constituency problem, the Hilmer Committee recommended that the onus of proving that the restriction on competition was justifiable should change from those advocating change to those advocating that the restriction on competition remain in place, or be imposed.[278] This was carried through to the CPA,[279] although it does not appear to have featured in the NCC's and IPCR Committee's review of patent privileges. Although, the IPCR Committee's majority's approach to parallel importing under the *Copyright Act 1968* (Cth) suggests that a different approach and focus has significant potential to improve the assessment of patent privileges, and might expand the scope of analysis applied to the *Patents Act* and *Trade Practices Act* in future reviews.

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[276] The recent United States' Federal Trade Commission (FTC) and Anti-trust Division of the Department of Justice have conducted an inquiry into the interaction between patents and competition law, although only the FTC report has been released examining the patent system maintaining a proper balance with competition law and policy: see Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003); interestingly, the report states '[t]he US economy also reflects the belief that limited exclusive rights in intellectual property – as distinguished from tangible property – can encourage innovation, which also benefits consumers' (ch 1(4)), but in its analysis of the scope and allocation of patent rights, the FTC reviews the changing ascendancy of patent and competition law over the last century, but does not address the issue of the quantum of incentive and the different views about how much incentive is sufficient. This may reflect the particular circumstances of the United States as a net technology exporter with a strong interest in maintaining intellectual property rights.

[277] Hilmer Committee, above n 34, 191.

[278] Hilmer Committee, above n 34, 190.

[279] *Competition Principles Agreement* cl 5(1).

5.5 The submission suggests that assessing the controversy over appropriate patent scope and allocation are central to adequately addressing the CPA, although uncertainties about the threshold necessary for the benefit to outweigh the costs under the CPA and how they are to be applied and assessed leaves open further superficial analyses. However, in future reviews further guidance might be set out in the Terms of Reference, noting that there was not an express requirement in the NCC's or IPCR Committee's references to address the appropriateness and consequences of the different views about patent scope and allocation, even though such an assessment was certainly open under the broad language set out in their Terms of Reference.[280] The recent transparency requirements agreed by the Council of Australian Governments (CoAG) to the application of the 'public interest' test in the CPA should also assist in understanding how the test has been applied and promote further meaningful refinements in its application to some of the broader debates about patent privileges.

5.6 Perhaps the next review of patent privileges according to the CPA,[281] and future amendments taking the CPA into account will more comprehensively address the controversy about patent scope and allocation, and more likely deliver a more rational patent policy that is more likely suited to the Australian community. Importantly, while the outcome may be similar, it is the process that is more likely to deliver better regulation and the comprehensive assessment contemplated by the Hilmer Committee and the CPA:

> … experience makes clear that the most important contribution to quality decisions is not the precision of calculations, but the action of analysis – questioning, understanding real world impacts, exploring assumptions.[282]

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[280] See NCC, above n 51, v-vi; IPCR Committee, above n 19, 216-217.

[281] The CPA provides that legislation restricting competition should be 'systematically' reviewed 'at least once every ten years': *Competition Principles Agreement* cl 5(6).

[282] Industry Commission, *Regulation and Its Review 1995-96*, Annual Report Series (1996) 11.