encouraging the uptake of services that promote competition, and protecting business and consumers from anti-competitive conduct and unfair trade practices. Important elements of this include:

- enforcing the Act;
- maintaining workable access regimes;
- developing effective compliance and educational materials; and
- liaising with agencies in other jurisdictions.

Patents, substitution, imitation and competition — Amgen, TKT and the erythropoietin patents

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Theoretically there is a disincentive to innovate in a competitive market because effective competition, together with market information, will favour competitors copying an innovation without having to pay out any of the development costs.[1] The statutory grant of a patent under the *Patents Act 1990* compensates this impediment to innovation (the market failure) and justifies the limited period of 'exclusive rights'[2] during which the innovator may exclude others while recovering the development costs (confounding the free riders). Thus, in theory, the patent helps innovation by encouraging investment in new developments that produce economic benefit[3] while at the same time having minimal social costs.[4]

For patenting biological materials,[5] the Patent Office and courts set an extremely low threshold in applying the legislated requirements of invention[6] and non-obviousness.[7] This means the patentee's 'exclusive rights' are being granted to a wide range of products and processes for very limited contributions to economically useful innovation. Generally, these concerns may be of minimal consequence because, '[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

1 Trade Practices Commission, *Application of the Trade Practices Act to Intellectual Property* (Commonwealth of Australia, Canberra, 1991), p. 8; Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (Patent Office, Canberra, 1984), p. 12; Bureau of Industry Economics, *The Economics of Patents — Occasional Paper 18* (AGPS, Canberra, 1994), p. 13.

2 '[D]uring the term of the patent, to exploit the invention and to authorise another person to exploit the invention': *Patents Act 1990* s. 13(1).

3 With the added benefit of disclosure of the innovation: see generally Trade Practices Commission, op. cit. n. 1, p. 8; for a review of the policy objectives of patenting see T McCarthy, 'Intellectual property and trade practices policy: coexistence or conflict? The American experience' (1985) 13 *Australian Business Law Review* 198, pp. 200–203.

4 See for example, Second Reading, *Intellectual Property Laws Amendment Act 1998* (Cth), House of Representatives, *Hansard*, 26 November 1997, p. 11274; but for some criticism of this view, see Industrial Property Advisory Committee, op. cit. n. 1, pp. 12 and 79; the social costs include higher prices, restricted outputs, subsidised foreign inventors and the administrative costs of the patenting scheme.

5 Such as inventions involving non-human organisms, plants, bacteria, fungi, algae, viruses, nucleic acids, amino acids, cell organelles, enzymes, etc.: see IP Australia Pamphlet, *Australian patents for: microorganisms, cell lines, hybridomas, related biological materials and their use, genetically manipulated organisms* (IP Australia, Canberra, 1998), pp. 1–2; for recent analyses of the relevant patenting issues see D Nicol and J Nielsen, 'The Australian medical biotechnology industry and access to intellectual property: issues for patent law development' (2001) 23 *Sydney Law Review* 347; C Lawson and C Pickering, 'The conflict for patented genetic materials under the *Convention on Biological Diversity* and the *Agreement on Trade Related Aspects of Intellectual Property Rights* (2001) 12 *Australian Intellectual Property Journal*, p. 104.

6 *Patents Act 1990* s. 18(1); reviewed in C Lawson, 'Patenting genetic diversity — old rules may be restricting the exploitation of a new technology', (1999), 6 *Journal of Law and Medicine* 373, pp. 377–84.

7 *Patents Act 1990* s. 18(1)(b)(ii); reviewed in C Lawson and C Pickering, 'Patenting genetic materials — failing to reflect the value of variation in DNA, RNA and amino acids', (2000), 11 *Australian Intellectual Property Journal* 69, pp. 72–6.

scope for imitation almost always exists'.[8] However, for biological material patenting, this is unlikely to be true as very broad claims to the composition of the biological materials,[9] and their applications,[10] effectively tie up most possible commercial uses of the materials for the term of the patent.[11]

The recently published opinion of Judge Young in the US District Court for the District of Massachusetts in *Amgen Inc. v Hoechst Marion Roussel Inc. and Transkaryotic Therapies Inc.*[12] (*Amgen v TKT*) confirms the limited scope for biological material patents to be substituted or imitated. This dispute was about the protein erythropoietin, a hormone that promotes the production of red blood cells in bone marrow tissue and is used to treat anaemia. For Amgen, the patented erythropoietin products were reported to have sales of US$1.96 billion in 2000 and account for approximately 60 per cent of Amgen's revenue. This case showed that the court accepted that alternative ways of producing the erythropoietin through genetic manipulation could not substitute or imitate Amgen's patented cloned gene product and effectively delivered control over erythropoietin to Amgen (and its licensees and assignees) for the term of the patents.

The Amgen patents claimed products and processes for a non-naturally occurring erythropoietin. It was obtained from vertebrate cells or mammalian cells and comprised a non-human erythropoietin promoter DNA operatively linked to DNA encoding the mature erythropoietin amino acid sequence disclosed in the claim. In other words, a cloned erythropoietin gene linked to regulatory sequences was inserted into the genome of a mammalian cell to produce erythropoietin that could be purified from a culture and then used as an active pharmaceutical.

The market value of erythropoietin was sufficient incentive for Hoechst Marion Roussel Inc. (now Aventis Pharmaceuticals Inc.) and Transkaryotic Therapies Inc. (collectively called TKT) to attempt to develop a competing product. TKT used its own gene targeting technology to produce erythropoietin. TKT's technology was unique because there was no need to introduce a cloned erythropoietin gene. The natural genes in the cells were activated to produce higher levels of erythropoietin. This resulting erythropoietin could then be purified from a culture and used as an active pharmaceutical.

Judge Young accepted TKT's technology was substantially different and did not infringe Amgen's claims. However, Amgen's stranglehold on the erythropoietin protein as an application of its other claims to the inserted cloned erythropoietin gene construct was decisive. So, even though TKT produced erythropoietin by an entirely different technique, Amgen's earlier claims to the erythropoietin gene product were broad enough to lock out the competitors.

Complex and detailed evidence about the various claims was presented by the parties, together with contorted explanations about the usage of some ordinary and technical words. Amgen's skilfully drafted broad claims to the erythropoietin were successful and this in part reflected the vocabulary of biology which has developed terms of art to categorise broad classes of distantly related biological materials (such as vertebrates meaning all back-boned organisms including humans), thereby allowing very broad claims to be made and substantiated. Further, Amgen was first to patent the cloned erythropoietin gene which gave it the opportunity to broadly claim the potential applications, many of which were obvious but for the 'invented' gene sequence.

Judge Young's opinion is significant because it shows that Amgen's broadly claimed erythropoietin patent has confounded substitution or imitation. This affects competition theory and practice because the inability to substitute or imitate a product (or process) protected by a patent imposes an immediate high social cost through a prolonged period of higher price and restricted access to the product (or process). For biological material patents, this high social cost is exacerbated by a minimal contribution to innovation because of the low thresholds of invention and non-obviousness.

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[8] Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (IP Australia, Canberra, 2000), p. 138; see also National Competition Council, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974* (National Competition Council, Canberra, 1999), p. 158.

[9] See Lawson, op. cit. n. 6, pp. 381–384.

[10] See Lawson and Pickering, op. cit. n. 7, pp. 78–79.

[11] For an illustration of this for gene and gene sequences see Lawson and Pickering, op. cit. n. 5.

[12] 126 F Supp 2d 69 (2001); for a similar decision with a similar effect for a number of European erythropoietin patents, including Transkaryotic Therapies Inc.'s, see *Amgen Parties v Roche Parties* [2001] EWHC Patents 433 (11 April 2001).

The notion of competition regulated by the *Patents Act 1990* and the Trade Practices Act is 'economic law', or workable or effective competition in a market.[13] The intention of this legislation is to promote economic benefit by promoting economically useful innovation (the patent) and restricting anti-competitive conduct. But it is assumed that the immediate social cost of the patent through relief from competition is outweighed by the promise of future economic benefit from innovation, albeit unquantifiable. It is further assumed that substitution and imitation reduce the social costs of a patent. While the unquestioning acceptance of these assumptions has coloured recent reviews of the patenting scheme,[14] the opinion in *Amgen v TKT* should now be a wake-up call that the practice of biological material patenting undermines both assumptions. Thus, *Amgen v TKT* starkly illustrates that encouraging investment in new and economically useful technology for the benefit of consumers may be hampered by broad patents. The immediate consequence of this decision is reduced competition through prolonged high prices and restricted access to erythropoietin, while the long-term consequence is less incentive to invest in new technology while the old broad patents remain in place.

Erratum: Journal 36, forum section (page 1). In the introduction to the presentation by Mr Allan Asher it was incorrectly stated that he had taken a position with the Australian Consumers Association. Mr Asher has been appointed as Director of Campaigns and Corporate Communications of the Consumers Association in the UK.

[13] See for example, Industrial Property Advisory Committee, op. cit. n. 1, p.11; Deane J in *Queensland Wire Industries Pty Ltd v BHP Co Ltd* (1989) 167 CLR 177, 191.

[14] See for example, Intellectual Property and Competition Review Committee, op. cit. n. 8.