The Possibilities of a Regulatory Approach to Answer the Question: Should Genetic Inventions be Patentable?

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I Introduction

This article picks up on Di Nicol’s suggestion that the “role of law in regulating and facilitating … innovation must be adequate and appropriate”¹ and argues that what is lacking now is, in fact, an adequate and appropriate understanding of how patent legislation operates as a regulatory instrument. The Australian Patents Act 1990 (Cth) (the ‘Patents Act’) has been selected for analysis of this issue. In one sense, this makes the contribution parochial; however, the concerns at the heart of the patent system in this country are substantially similar to the concerns evident in the regimes in other countries — in part because the Agreement on Trade-Related Aspects of Intellectual Property Rights² (the ‘TRIPS Agreement’) binds most national systems and in part because the economic understanding that underpins the TRIPS Agreement is accepted, almost as gospel, in the majority of developed countries. This examination of the Patents Act, therefore, can be seen as a case study that has implications for regimes in other countries.

It may not be going too far to suggest that the plethora of reviews into the Australian patent system over the past couple of decades is indicative of an incomplete understanding of the

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purposes, and limitations, of the *Patents Act*. Here, I am not positing what the purposes of the Act are (or should be), but I am suggesting that a new perspective on the role of the Act will be useful. To be clear, this paper is a shift away from the position taken by others that the intellectual property system should be better regulated. The approach adopted here, instead, is to view the *Patents Act* itself as performing a regulatory function. That is, it sees the Act as a piece of legislation that has, as a focus, the “intentional activity of attempting to control, order or influence the behaviour of others”. Intellectual property generally is not often seen through a regulatory lens, though this is changing. If a wide understanding of regulation is used, such as regulation being the “promulgation of an authoritative set of rules, accompanied by some mechanism … for monitoring and promoting compliance with these rules”, then the *Patents Act* falls within that definition.

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4 See, for example, the various contributions to the special issue of (2004) 16(1) *Information Economics and Policy*.


It is acknowledged that many understandings of regulation focus on firms or industry sectors with defined roles and responsibilities. That is, regulatory efforts have involved regulatory organisations active in the monitoring of compliance with standards set either by the state alone or by the state in consultation with the targeted industry sector. Obvious examples are the WorkCover Authority that has regulatory responsibilities in the area of occupational health and safety and the Australian Competition and Consumer Commission. These regulators are active, and pro-active, in terms of the regulation of those under their purview. Such a regulator does not exist in the regulation of patented inventions. Despite the lack of central institution however, there are aspects of the Patents Act that render it amenable to analysis through the use of regulatory theory; those aspects include the setting of standards of patentability and the facilitation of enforcement of the standards (through civil and criminal penalties). This article does not prescribe reforms based on this regulatory approach (there is not the space); it does, nonetheless, discuss a number of benefits that arise from the adoption of the approach.

2 The Historical Context and the Lack of Clear Normative Standards

First, though, there needs to be a discussion of the problems with the current view of the system. Key here are the assumptions made about the patent system that do not take

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*Patents Act*, therefore, with its authorisation of limited monopolies and the inclusion of mechanisms for monitoring both patent grants and the behaviour of those with a responsibility for seeking the monopolies is a key aspect of the regulation of the innovation economy.

8 They monitor compliance with the law; they have a role in the enforcing of the law and, importantly, they set policies — with the policies being grounded in a clear set of regulatory objectives.

9 While IP Australia does have a role in granting inventions, it does not have a role in enforcing patents (patentees have to bring actions themselves), preventing infringement or monitoring the behaviour of patent attorneys. IP Australia does consider reforms to the operation of the *Patents Act*; however, it does not have a role in setting overall policy with respect to the patent system.

10 *Patents Act* s 18.

11 The Act, for example, establishes the opposition procedure (Chapter 5) which enables parties to assert that a patent application, despite having been examined, does not meet the requirements of patentability. The Act also contains prescribes a number of offences, including those relating to the making of false representations: ss 177-178.
account of the historical context of the rules that we have in place now. Commentators seem to perceive the system as stable despite the changes that have taken place over time and despite the contingent nature of what are seen as the underlying principles of the law. The contextualised nature of two aspects of the system will be highlighted here — the conception of “knowledge” and the discipline of economics.

2.1 Patents and History of Knowledge

One of the key shifts in the operation of the patent system that has taken place from Elizabethan to the present is noted by all but remarked on by few. The patents granted by the early modern monarchs, and as encapsulated in Coke’s use of the term “new manufactures”, were for practical devices — to the extent they weren’t granted for regulating industries or allowing individuals to not abide by the statutes of Parliament. These days, the “public interest in allowing patents is said to flow from the fact that the numerous patents that have been granted over time constitute a substantive and valuable database of technical and scientific knowledge”. That is, there has been a shift in focus from the creation of artefacts to an emphasis, in this century, on how an invention adds to the body of technical knowledge — if it doesn’t, then the invention fails the test for novelty.

This shift does not surprise those with a familiarity with the history of science. What came between the Statute of Monopolies 1624 (the “Statute”) and the current Patents Act was the (English) Enlightenment. Though there is no precise date for that event, or more properly the period, the general indicators of it centre on the second half of the seventeenth century.

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12 Coke is understood to be the drafter of the Statute of Monopolies 1624. The term “new manufactures” is contained in s 6 of the statute; see, generally, C Dent, “Generally Inconvenient”: The 1624 Statute of Monopolies as Political Compromise’ (2009) 33 Melbourne University Law Review 415.


15 Patents Act s 18(1)(b)(i).
A Regulatory Approach to the Question: Should Genetic Inventions be Patentable?

From an intellectual perspective, Isaac Newton published his *Principia Mathematica* in 1687 and the Royal Society was granted its first Royal Charter in 1662.\(^\text{16}\) Porter, more generally, states that the “half-century after 1660 brought decisive transformations” to the structures and ideologies of England.\(^\text{17}\) In other words, the manner in which people thought about ideas, and even the process of thinking itself,\(^\text{18}\) changed radically in the decades after the passing of the Statute.

The effect of this on the understanding of the conception of the patent system is that there can be no certainty as to how Coke would have perceived the possibility of patenting “ideas”.\(^\text{19}\) Patents in the late sixteenth and early seventeenth centuries covered whatever was already in existence. They were granted for things such as cutlery, mills for grinding corn and devices for raising water from mines.\(^\text{20}\) If the patents that covered the regulation of industries are included, it is easy to see the grants of these monopolies in terms of the Crown wanting to maintain control — either of sectors such as ale-houses or of industries such as mining.\(^\text{21}\) The patented inventions themselves tended to be devices that were known

\(^{16}\) From a political perspective, the “Glorious Revolution” of 1688 is seen as a marker for the beginning of the period.


\(^{18}\) Even Descartes’ *Discourse on Method*, with its first iteration of “je pense, donc je suis”, was not published until 1637 (the Latin version, *cogito ergo sum*, was contained in 1644’s *Principles of Philosophy*).

\(^{19}\) There is, of course, the matter of the changes in the use of particular words over the past four centuries. A seventeenth century writer considered that the “best inventions have not been found out by the richest, but by the most prudent, and industrious, observers”: T Sprat, *The History of the Royal Society* (Kessinger, first published 1667, 2003 ed) 79. This quote either equates inventions to discoveries or observers to what we now consider to be inventors. Either way, to assume that the words used by Coke and his contemporaries have the same meaning as they do today is fraught with risk.


\(^{21}\) For Supple, the “Tudor and Stuart governments directed their regulatory efforts to the maintenance of social order, public peace, national security and the achievement of economic prosperity”: B Supple, *Commercial Crisis and Change in England 1600-42: A Study in the Instability of a Mercantile Economy* (Cambridge University Press, 1959) 226 (emphasis added). The Crown and governments of the time,
in Europe but had yet to be used in England. A “new manufacture” was one that was new to
England — not new to the world. If the monopoly was granted for an invention that was
already used in that country then that would have been an exercise in favouritism on the
part of the Crown — an abusive monopoly.22

In short, in the early modern period the conceptualisation of knowledge, in particular new
knowledge, was still tied to dogma — to established and settled modes of thought. For Gay,
it was in the century of Enlightenment (1660-1760) that “innovation, traditionally an
effective term of abuse, became a word of praise”.23 An “idea”, a “new idea”, as a separate,
knowable, construct for analysis is a product of the Enlightenment — to see principles as
objectively patentable (or not) requires such a conception of the intangible.24 It is arguable
that it was as late as 1799 that there were doubts in the minds of judges as to the
patentability of discoveries.25 More generally, it is clear that the issue of whether or not

22 The form of governance in England at the time seemed to lend itself to abuse. A significant amount of
anger aimed at the Crown arose from matters such as the sale of ward-ships: J Hurstfield, ‘Lord Burghley
as Master of the Court of Wards, 1561-1598’ (1949) 31 Transactions of the Royal Historical Society 95;
the abuse of customs duties: D Hirst, The Representative of the People? Voters and Voting in England
under the Early Stuarts (Cambridge University Press, 1975); and the abuses by informers: M Beresford,
‘The Common Informer, the Penal Statutes and Economic Regulation’ (1957) 10 Economic History
Review 221.


24 The different conceptualisation of ideas was one of Descartes’ key contributions: B Russell, History of
Western Philosophy (George Allen & Unwin, London, 2nd ed, 1961) 549ff. Further, writing of another
Cartesian philosopher Nicholas Malebranche, it has been said that debate on the “nature of ideas ... was
one of the major intellectual events of the early modern period”: T Schmaltz, ‘Malebranche on Ideas and
the Vision in God’ in S Nadler (ed), The Cambridge Companion to Malebranche, (Cambridge

25 To be accurate, the patentability of principles was not completely ruled out — “If it were necessary to
consider whether or not mere abstract principles are the subject of a patent, I should feel great difficulty in
deciding that they are”: Hornblower v Boulton (1799) 8 TR 95, 106; 101 ER 1285, 1291 (Lawrence J). Of
tangential relevance to the patentability of genes issues, in another decision in that series, medicinal
principles were patentable was raised as a concern in the decisions of the courts only after the Enlightenment.\textsuperscript{26} It may, now, be law that mere principles are not patentable,\textsuperscript{27} but this is just a construct of the modern mindset — this does not make it wrong, just historically contingent.

\subsection*{2.2 Patents and History of Economics}

There has also been a significant shift in the understanding of matters economic since the time of the Statute to today. During the time of James I, the patent system operated in accordance with the mercantilist understanding of the market. I say the “market” advisedly as the concept of the “economy” came later in the history of ideas.\textsuperscript{28} The system supported the mercantilist worldview in that it reduced unemployment and improved England’s balance of trade.\textsuperscript{29} It also allowed the Crown, through its agents (the patentees) to regulate important, or problematic,\textsuperscript{30} industries.

During the nineteenth century, patents were understood in terms of the classical economists. John Stuart Mill argued that those who are granted a patent for an invention compounds were expressly stated as being within the term “new manufactures”: \textit{Boulton v Bull} (1795) 2 H. Bl. 463, 482; 126 ER 651, 660 (Heath J).

\begin{footnotesize}
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\item \textsuperscript{26} The first such case in Hayward’s compilation of patent decisions is \textit{Dollond v Champneys} (1758) 1 CPC 28 – Dollond’s “patent is for glasses completely formed, not for mere principles”: at 30 (Buller J).
\item \textsuperscript{27} \textit{National Research Development Corp v Commissioner of Patents} (1959) 102 CLR 252 (the “NRDC case”).
\item \textsuperscript{28} See, for example, R Walter, ‘Governmentality Accounts of the Economy: A Liberal Bias?’ (2008) 37 \textit{Economy & Society} 94.
\item \textsuperscript{29} See Dent, above n 13, 77-89.
\item \textsuperscript{30} One of the specified exceptions in the \textit{Statute of Monopolies} was the patent for the regulation of taverns: s 12. The regulation of ale-houses, for example, was seen as a necessity because of “constant complaints of drunkenness and the resort of undesirable characters to the ale-houses”: H Fox, \textit{Monopolies and Patents: A Study of the History and Future of the Patent Monopoly} (University of Toronto Press, 1947) 175. There was also a problem with “unlicensed brewing” at the time: S Hindle, \textit{The State and Social Change in Early Modern England}, 1550-1640 (Palgrave Macmillan, 2002) 152.
\end{itemize}
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“ought to be both compensated and rewarded for it”.\textsuperscript{31} This is also evident in the decisions of the courts. For example, the Privy Council stated that “when a party has shown great ingenuity in an invention, and, from want of capital and means, has not been able to obtain an adequate return, we have over and over again extended the patent”.\textsuperscript{32} In a later case, the Council also noted that it was appropriate that the “inventor who … made the invention public for the benefit of the community, has his fair reward for his ingenuity, and his industry, and the capital which he has employed”.\textsuperscript{33}

These days, most economists argue for patents on the basis that they are an incentive for firms, or individuals, to invest in research and development (R&D).\textsuperscript{34} According to one commentator, “economic theory tells us that more investment in R&D should lead to more innovation and more innovation should fuel GDP growth”.\textsuperscript{35} The courts have acknowledged that this is now a key justification for the patent system.\textsuperscript{36} There is, however, a significant difference between seeing patents as rewards and patents as incentives.\textsuperscript{37} In the former, an individual who exhibits the requisite inventiveness should receive a reward for her or his endeavours. On the other hand, if a patent is only an incentive, there is no guarantee that an inventor will financially benefit from her or his ingenuity — the inventor,

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\item \textsuperscript{32} \textit{Downton’s Patent} (1839) 1 WPC 565, 567.
\item \textsuperscript{33} \textit{In re Card’s Patent} (1848) 6 Moo PC 207, 215; 13 ER 663, 666.
\item \textsuperscript{34} See, for example, F Scherer and D Ross, \textit{Industrial Market Structure and Economic Performance} (Houghton Mifflin, 3\textsuperscript{rd} ed, 1990).
\item \textsuperscript{36} See, for example, \textit{Advanced Building v Ramset} (1998) 194 CLR 171; and \textit{Aktiebolaget Hassle v Alphapharm} (2002) 212 CLR 411.
\item \textsuperscript{37} Of course, economic thought these days is not limited to the neo-classical school. There is, however, not the space here to consider the perspectives of the heterodox economics.
\end{itemize}
and not the state, accepts the risk that the inventive effort will be both technically beneficial and commercially successful.

3 Benefits of Seeing Current Patent System through a Regulatory Lens

Taken together, the discussion of the antecedent bodies of knowledge demonstrates that there are no “eternal truths” to the patent system — the bases of the system have changed since its inception. If there are no such truths, then there is no concrete foundation upon which to found normative claims about the system. And yet it makes sense that there are limits to what is patentable — otherwise, if everything was entitled to a patent then the system becomes meaningless. The alternative offered here is an approach that does not require eternal truths. To see the patent system through a regulatory lens allows for the adoption of reforms that support an internally consistent view of the overall system that will facilitate the better regulation of innovation in this country. There is not the space here to articulate completely a regulatory view of the Patents Act; however, there is the space to highlight key benefits of such an approach.

3.1 Clarity of Scope of the Patent System

If the goal of the system is to be seen as regulatory, then there is pressure to be clear about the limits and purposes of the regime. It is when the reach and the expected standards of behaviour are effectively communicated that compliance is enhanced. The first question to be asked in this context, then, is what is actually meant by the “patent system”?

3.1.1 Clarity about the extent of the patent system

For many commentators, the patent system is — and is only — the set of rules regarding patentability, with those rules arising from the national patent laws and the international agreements on patents. This paper argues from the position that the system is much

38 There may, nonetheless, be statements that can be seen to be “temporary” truths or, more properly, norms. One example of that, relating to patents for genetic inventions, would be the ratio of the NRDC case relating to the requirement that an invention, to be patentable, has to reflect an “artificial state of affairs”.

39 One leading textbook has a chapter entitled “The Patent System” with all but one paragraph devoted to a history of patent law and a description of the processes of gaining patent protection (that odd paragraph out is headed “Role of patent attorneys”): J McKeough, A Stewart and P Griffith, Intellectual Property in
broadly than that. The additional breadth is two-fold. First, there is an acknowledgment that there is more to the Patents Act than just the tests of patentability. Second, the patent system can be seen to include all the decisions, and the constraints on those decisions, that are made by parties when they are dealing with aspects of the Act.

With respect to the Act itself, it is a complex piece of legislation. Not only does it regulate patent applicants and patentees, it controls the behaviour of the Commissioner of Patents (and the Commissioner’s delegates) including the maintenance of the Register of Patents. Importantly too, the Act regulates the patent attorney profession, the Crown and the courts — to the extent they have jurisdiction to hear patent cases. In other words, the Act is not just about the validity of patents.

Further, the system can be best seen as the totality of decisions and actions made by those parties who operate within it — with those actions and decisions being constrained by a number of factors that includes the limits of the Act as well as other, non-legal, concerns. Attorneys, for example, advise clients as to the patentability of technological developments made by the client; the decision of the client as to whether to apply for a patent will also depend on the overall business strategy of the company (it may be noted that a decision to not seek patent protection should also be seen as part of the patent system). Other research has shown that firms also have multiple reasons for pursuing patent protection. These

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40 It is acknowledged that some commentators do consider matters beyond the legislation when they consider the patent system. Those that do tend not to define the boundaries of the system. See, for example, E Kitch, ‘The Nature and Function of the Patent System’ (1977) 20 Journal of Law and Economics 265.

41 Patents Act Ch. 19.

42 Patents Act Ch. 20.

43 Patents Act Ch. 17.

44 Patents Act Ch. 16.
include a desire to protect technology; create “retaliatory power against competitors”; create “better possibilities of selling licences”; provide “motivation for employees to invent”; provide a “measure of R & D productivity”; and improve the “corporate image”. These reasons are the result of the monopoly protection offered by the patent, the economic value of that protection as seen by other companies and individuals as well as the non-economic value that attaches to a patent as an indicator of innovation. These reasons, therefore, stem directly from the operation of the Act and, as a result, the decisions that are based on these reasons should be seen as part of the overall patent system.

3.1.2 Clarity about who it is that will be regulated

This understanding of the scope of the system means that a broad range of people are seen to be regulated by the system. A simplistic view of the Act would have the regulated be limited to inventors — as it is the inventors who are seen as benefiting from the monopoly on offer. A more nuanced view would see the regulated as including the companies who employ the inventors as, for many industries, it takes the capital of a firm (or capital available to a firm) to invest in R&D. The approach taken here, however, sees all who make decisions, and take actions, around the patenting of innovations as those to be regulated by the system — though the scale of the regulatory action would vary depending on the extent to which the individuals use aspects of the system.

A key aspect of this regulatory approach to the patent system is that it enables the acknowledgement, and use, of a specific understanding of those who are to be regulated. Two features of this understanding may be highlighted here. The first is that all who are part of the system are seen as individuals who have interests and have the capacity to make decisions that can further those interests. That is, individuals are seen to understand the

45 O Granstrand, *The Economics and Management of Intellectual Property: Towards Intellectual Capitalism* (Edward Elgar, 1999) 78. Other reasons that have been cited include “to obtain financing and boost market valuation”; to use “as signalling mechanisms”; and “to deter others from suing”: M Lemley and C Shapiro, ‘Probabilistic Patents’ (2005) 19 *Journal of Economic Perspectives* 75, 81.

46 Most commentary does not separate out the incentive offered to inventor from the incentive offered to the patentee. For an attempt at this, see C Dent, ‘Negotiating Control of Artefacts of Creation: Intellectual Property, Know-How, Confidential Information and Contracts’ (2012) 43 *International Review of Intellectual Property and Competition Law* 248.
options available to them and to weigh them up and decide which option to take based upon their own interests. Further, tied to the assertion of the “calculating individual” is the assumption that any decision made by an individual will be constrained by a number of factors. Many of these factors will be consciously, or unconsciously, acknowledged norms of behaviour that have been internalised of the course of the individual’s life. It is these norms that guide an individual’s calculation in a given set of circumstances. Norms, here, are understood as a fundamentally important part of the “regulatory conversations” that take place in the processes of regulation, a part that relates to the establishment of standards of conduct that are “the common measure” of behaviour and the “modern form of the social bond”. The acknowledgement of these constraints reinforce the common sense view that an individual’s actions are not entirely controlled by the laws and regulations but it does allow for the perspective that an individual will base her or his behaviour, in part at least, on her or his knowledge of what the law allows.

This understanding of the nature of those who are seen to be regulated ties in with the understanding of the regulated that is central to Julia Black’s notion of “decentred

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47 The assertion of the individual being “calculating” is distinct from an assumption that all individuals are rational. As the consequences may be physical, emotional, psychological or financial, the motivations and justifications that form an individual’s choice may arise from the rational or emotional aspects of her or his self. The suggestion that individuals are fully “rational” beings is further problematised with the creation of the economics sub-discipline of behavioural economics. See, for example, M Altman (ed), *Handbook of Contemporary Behavioural Economics* (Sharpe, 2006).

48 See, for example, J Black, “Regulatory Conversations” (2002) 29 *Journal of Law and Society* 163.


50 The centrality of norms to the regulation of those involved in the patent system then prompts the question as to the role of “old” norms after a system has been changed radically. The precise link between norms and laws varies depending upon the theoretical framework adopted; for this article, however, it is sufficient to suggest that the consideration of the patent system from a regulatory perspective is not likely to result in radical amendments to the *Patents Act* and, therefore, most of the existing norms will continue to guide the actions and decisions of those subject to its regulation.
regulation”.

For Black, there are five aspects of this form of regulation; these are: “complexity, fragmentation, interdependencies, ungovernability and the rejection of a clear distinction between public and private”. The nature of the regulated comes under the feature of “ungovernability”. The five components of this feature relate to the behaviour, attitudes, and autonomy of those who are sought to be guided by the regulation. Taken together, the components do not suggest that those who are subject to a specific set of regulations are ungovernable. Instead, the components indicate the capacity of actors in a system to regulate their own behaviour — not by relying on a central institution to control their actions but compliance with the norms learned by the individuals in the course of their life.

3.2 Clarity of Purpose/s of Patent System

The detail of the nature of those who are regulated in the system is necessary because the understanding of the decision-making processes of the individuals drives the understanding of the role of any incentives (either positive or negative) that are built into the system. Negative incentives include the threat of legal action for potentially infringing behaviour or the costs involved in patenting where the invention is not commercialisable; positive incentives include those referred to above (the protection of technology, licensing opportunities and image) — all of which stem from the idea of the monopoly itself being an


52 Ibid above n 51, 4.

53 Ibid 6-7.

54 This aspect is, therefore, close to Foucaultian understandings of the manner in which the governed operate in today’s society. See, generally, M Foucault, ‘Governmentality’ in G Burchell, C Gordon and P Miller (eds), The Foucault Effect – Studies in Governmentality (Harvester Wheatsheaf, 1991). Black discussed the links between her work and that of Foucault: Black, above n 51, 3 n 4.
incentive. However, it is also important to note that the purpose, or purposes, of the whole system may not be the same as the purpose of an individual patent.\textsuperscript{55}

As a case in point, the Advisory Council on Intellectual Property (ACIP) considered the objectives of the Act in their \textit{Patentable Subject Matter} Report. The ACIP’s Recommendation was that the statement of objectives ... should describe the purposes of the legislation as being to provide an environment that promotes Australia’s national interest and enhances the well-being of Australians by balancing the competing interests of patent rights holders, the users of technological knowledge, and Australian society as a whole.\textsuperscript{56}

At best, this recommendation focuses on the \textit{quid pro quo} of patents — the exchange of a temporary monopoly for technical information. In short, the ACIP’s broad description does not provide a sufficient normative guidance to assist in the effective regulation of the patent regime. This is not surprising as the ACIP took a narrow view of the role of a statement of objectives — the ACIP saw the purposes of the statement to be for the interpretation of the statute\textsuperscript{57} and, therefore, to be used by the courts. To see the Act as having a wider regulatory role acknowledges its function in guiding the behaviour of others — including patent applicants, patentees, patent attorneys and those who may infringe patents. A bland statement suggesting the balancing of interests will not be effective when players are likely to privilege their own interests over those of others.

Another way of seeing the purposes is to view them in terms of what behaviours are sought to be regulated of those who are seen to be the subjects of the regulatory efforts — to

\textsuperscript{55} Further, not all participants in the system may have the same view as to the purpose of a patent. One recent commentator suggested that the “patent system” was “originally conceived to ... protect inventors’ creative efforts from being copied without reward”: G Maile, ‘Don’t Forget the Inventor!’ \textit{Managing IP}, 4 April 2012, <http://www.managingip.com/Article/3006778/Archive/Comment-Dont-forget-the-inventor.html?LS=EMS635224>. This characterisation of the purpose is not the same as seeing patents as incentives.


\textsuperscript{57} Ibid 22.
acknowledge the necessary link between the norms of a regulatory system and its purpose/s. Given the range of behaviours that are sought to be regulated by the system, it is not too much of a stretch to consider that there may be more than one purpose to the patent system. One of the key insights from the theory of decentred regulation is that a regulatory regime may be “fragmented”. This means that there does not have to be a single regulatory goal. In turn, this means that any objectives inserted into the Act may reflect the multiple purposes that the Act has in the innovation system. Further, the goals and those who are to be regulated are “interdependent”. That is, the purposes align with the interests of those who participate in the system in that the motivation for an individual’s participation is that the purposes do align with her or his interests. The range of individuals and interests they possess almost requires that there is more than one purpose to the system.

A key decision with respect to the interests of individuals considered here is the one that an innovator, or her or his employer, will make is whether or not to seek a patent for an innovation. The Act will be most applicable where the innovation both meets the requirements for patentability and it makes commercial sense to apply for a patent. Trade secrecy, for example, is used much more in some industries than patents are. The purposes of the system, as opposed to just the Act, have to incorporate those aspects of the

58 To take an example from outside the patent system, the purposes associated with the road rules include efficient transit and safety. The norms that have been set, via the rules, around road use include speed limits and traffic signals. There is a clear link between the two — the success of the approach is evident in the very low number of accidents. One study has shown that there was a rate of 5 crashes per million trip kilometres for 26-29 year old males (one of the most at risk groups) in Victoria where a crash was defined as a crash where at least one person was injured: B Kam, ‘A Disaggregate Approach to Crash Rate Analysis’ (2003) 35 Accident Analysis and Prevention 693, 703. The study used data collected from 1991 to 1998 and statistics such as the road death toll have only improved since then.

59 Black, above n51, 4.

60 Dent, above n 51, 357.

61 Black, above n 51, 4.

62 A purpose of the patent system may be to facilitate the commercial exploitation of innovation. This would have links to the regulatory/control of markets purpose of the 17th century system.

63 Australian Bureau of Statistics, 8158.0 Innovation in Australian Business, 2008-09, Table 1.
system that give rise to the decisions made that avoid the Patent Office. That is, the purposes of the system should be clear with respect to the policy desire to increase, or decrease, the level of patenting (as opposed to the level of innovation). It is possible that the level of patenting now, despite the variation across industries, is currently optimal; it is perhaps more likely that it is sub-optimal. To better know the purposes of the system will facilitate the implementation of better innovation policy; further, to the extent that patents are monopolies, to better know the purposes of the patent system may also facilitate the implementation of better competition policy.

3.3 Clarity of Exceptions to Patentability

The work has not yet been done with respect to detailing all the purposes of the broad patent system. An encompassing understanding of the scope and purposes of the patent system, however, will allow for an assessment of those inventions that should not be patentable on the grounds that they are not consistent with the system and its purposes. Alternatively, just knowing what a patent is (if the purpose of the system is simply about the patent bargain) does not give any insight into what should not be patented (save for those innovations that do not meet the tests for patentability).

An example of how an exception from patentability may be inherent in a purpose of the system may be found in the early history of the system. One of the key exceptions to patentability in the early modern period was for inventions that have put people out of work — this is a dominant understanding of the “generally inconvenient” provision in the Statute.\textsuperscript{64} This is not surprising because the encouragement of employment was a central justification of the patent system in the early modern period.\textsuperscript{65} To allow labour-saving inventions to be patented, therefore, would have been counter to the regulatory goal of the system.

The justification for this exception was, in part, moral. Both of the key reporters of the 1602 case \textit{Darcy v Allen} (the infamous playing cards decision) cited scripture in their reports —

\textsuperscript{64} Dent, above n 12, 445-6.

\textsuperscript{65} Dent, above n 13, 77-85.
Coke referred to Deuteronomy 24 verse 6 and Noy quoted 2 Thessalonians 3 verses 8-10. The latter quote being “every man should live by labour, and that he that will not labour, let him not eat” — if a person could not work, the person would starve. It would be possible, too, for there to be a moral basis for any exceptions inherent in today’s patent system. The normative standard for such an exception may, however, be difficult to achieve consensus over. The lack of dominant religious doctrine now (unlike in early modern England) may, for example, mean that some would find an invention for euthanasia morally repugnant, while others may applaud it as a tool for enhancing “death with dignity”.

Instead, the basis for any exceptions to patentability inherent in the system may be secular. A good example of this may be the “research use exemption” that has recently become part of the current Act. If the purposes of the system include one related to accountability, then the incorporation of an exception for infringement that allows people other than a patentee to check the limits of an innovation against the claims of the patent enhances the level of accountability. This also accords with the conceptualisation of those regulated by the system as being self-interested — it is in the interests of a patentee’s competitors to see

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66 11 Co Rep 84b, 86b; 77 ER 1260, 1263.
67 Noy 173, 174; 74 ER 1131, 33.
68 While there was a significant division between the Catholics and Protestants at the time, the moral codes (as embodied by the Bible) followed by both groups were substantially the same. As an aside, the role of Puritanism in the development of the patent system is an unexplored aspect of its history. It is possible that the shift away from regulation of industry through patents (and the focus of patents for “manners of new manufacture”) resulted from the fact that Puritan leaders were, due to their faith, “universally among the most passionate opponents of this type of politically privileged commercial … capitalism”: M Weber, The Protestant Ethic and the Spirit of Capitalism (Routledge, 1992) 179.
69 Patents Act s 119C.
70 Given that a court action testing the validity under the current Act is aimed at holding the patentee to account (as is the opposition procedure under s 59), then it is not too much of a stretch to see processes of accountability as central to the system. Accountability has been described elsewhere as a principle underlying the current system: C Dent, ‘An Exploration of the Principles, Precepts and Purposes that Provide Structure to the Patent System’ (2008) Intellectual Property Quarterly 456, 465-7.
71 Patents Act s 119C(2)(d).
if the claims in a patent (that deny the competitors access to a market) delimit, accurately, the innovation. Of course, the aspect of the exemption relating to the improvement of patented inventions also accords with any purpose of the system that privileges innovation.

A reconceptualising of the purposes of the system could also lead to a revisiting of the current exceptions. As highlighted above, discoveries are currently excluded from patentability. Given that the High Court has acknowledged that the “distinction between discovery and invention is not precise,” it may be open to see discoveries as patentable. From this perspective, such “inventions” would be understood as extreme upstream research — the research use exemption would allow other researchers to improve it. Any follow-on researchers would still be able patent any practical developments they make, though a licensing fee may be payable to the original “inventor” if the subsequent invention uses the discovery in its operation. This may, in effect, operate as an incentive for “pure science” research — a public policy goal that many would agree with.

Of course, just because a category of inventions isn’t excluded on the basis of a proper understanding of the scope and purposes of the system does not mean that the Parliament could not legislate to exclude it from patentability. A number of exceptions are currently allowed under the TRIPS Agreement, including “diagnostic, therapeutic and surgical methods for the treatment of humans or animals” and inventions that are against “ordre

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72 Ibid s 119C(2)(c).

73 National Research Development Corp v Commissioner of Patents (1959) 102 CLR 252, 264.

74 To maintain the historical thread, it may be noted that the TRIPS Agreement is one that binds nations and not individuals. It, therefore, is founded on a conception of the world and politics that is historically contingent; and, of course, the patent system is not necessarily bound to such a worldview. The system predates the 1648 Peace of Westphalia — the agreement that has been seen as foundational to the present international order: A Osiander, ‘Sovereignty, International Relations and the Westphalian Myth’ (2001) 55 International Organization 251, 251. It is arguable that the rise of the internet will lead to a (limited) breakdown of this order in the innovation sector. The consequences of this are beyond the scope of this article.

75 TRIPS Agreement art 27(3)(a).
A Regulatory Approach to the Question: Should Genetic Inventions be Patentable?

public or morality”\textsuperscript{76}. The TRIPS Agreement also sets out the rights to be conferred by national legislation\textsuperscript{77} and the allowable exceptions to those rights.\textsuperscript{78} The Agreement may, therefore, permit exceptions that are not consistent with all the purposes of the Act. It is arguable that such exceptions would weaken the overall regulatory effect of the system as the limits of the Act no longer match the justification for the bulk of its rules. The extent to which inconsistent exceptions would damage the efficacy of the system would only be established through further research.

4 Concluding Remarks

This article has, in effect, introduced a suite of work that will both enhance our understanding of the patent system as a system and will highlight those inventions that should not be patented because they are not in keeping with the purposes of the system. It has, through the use of the system’s historical context, enabled the adoption of a fresh perspective that allows new possibilities to be seen for what we have now — and how it could be amended to become.\textsuperscript{79} A shift, for example, in the conceptualisation of the patent system that takes into account its contextualisation within the history of ideas may throw up the possibility of corporations as inventors (instead of just applicants) on the basis that it is, in reality, employed teams of researchers that develop many inventions. If the nexus

\begin{footnotes}
\item[76] The provision reads more fully as “members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality”: TRIPS Agreement art 27(2).
\item[77] Art 28.
\item[78] Arts 30, 31. The research use exemption is justified as an exception by failing within the scope of art 30. For a discussion, see C Dent, ‘The TRIPS Agreement and an Experimental Use Exception for “Research Tools”’ (2011) 44 Australian Economic Review 73.
\item[79] Any amendment would, of course, have to be compliant with the TRIPS Agreement; the Parliament may also wish to take note of other factors — such as a desire for the harmonisation of patent laws and procedures across the globe. It should, however, be emphasised that a regulatory perspective on the Act would not necessarily lead to substantial changes to the Act. It may be that the current regime is more cohesive than would be suggested by its ad hoc development. If it is, then few, if any, amendments may be recommended on the basis of this new perspective.
\end{footnotes}
between the “Enlightenment individual” and the creative spark is severed,\textsuperscript{80} then a collection of individuals could “invent”. If the goal of the system is to better regulate decisions made in the innovation sector, then if decisions are, in effect, made by a corporate entity then to have the entity be more fully engaged in the regulation may be useful.

Of course, the focus of this special issue is the patentability of genetic inventions. This article can only suggest that more work needs to be done with respect to understanding the system as a system before a coherent position on the patentability of such inventions is possible. The limits of patentability should be linked to the purposes of the system. The better regulation of inventors and commercialisers of inventions can only be achieved when the norms established by the Act are tied to the reasons for the norms. Without this clarity, the self-interested nature of firms means that the boundaries will be pushed and the courts may not have the structural basis upon which to rule against any abuses of the system. And without an effective forum for accountability, those in the community who may benefit from an innovation may be subject to unreasonable charges or be denied access all together. Acknowledging the purposes, and limits, of the system will not prevent monopoly pricing; it may, however, provide sufficient justification to mollify the concerns of Parliamentarians and other interested parties.

\textsuperscript{80} The severing would occur on the basis that to see inventiveness residing only in the individual is a product of the intellectual, Enlightenment, tradition rather than a pre-ordained fact.