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Legal Transplants in Patent Law: Why Utility is the New Industrial Applicability

Sivaramjani Thambisetty*

Abstract: This paper focuses on the transplantation of the ‘utility standard’ from the US legal system into the industrial applicability criterion of patentability as seen in EPO and UKIPO case law. The Specific, Substantial and Credible standard (SSCS) of utility is growing in prominence as a new gatekeeping criterion in European patent law. This legal transplant lacks explicit statutory basis, is largely driven by a process of mimesis following collaboration between patent offices, and carries the potential to generate collateral damage to a number of neighbouring legal standards in European patent law. The SSCS potentially undermines the ‘technical’ requirement in Europe and highlights a growing conflation between industrial applicability and disclosure requirements. Additionally the SSCS may increase research tool patentability in Europe, a development that exposes potential inadequacies in the institutional arrangements of the receiving legal system. The legal transplant is aided by institutional dynamics that incrementally entrench a policy choice or legal standard, accompanied by little or no discussion on its viability and legitimacy. The significant normative impact of the process of transplantation of the SSCS places the patent office at the centre of legal and policy change – an entity that is arguably not fit for this purpose.

INTRODUCTION

Policy-making in the patent system is a complex mix of economic, political and legal standards involving a number of institutions such as patent offices, research funding bodies, generalist and specialist courts, and government departments. Dominant institutions often have agenda-setting power to orchestrate policies including legal doctrine. In recent times legal standards in patent law have shown remarkable migratory aspects, moving between countries with an Anglo-American

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legal tradition with ease, aided in part by the pressures of international harmonisation and in part by competitive pressures of global business. Analysis of such migration showcase a number of institutional mechanisms and processes of change that aid in the transplant, evolution and modification of legal standards. The object of this paper is to emphasise that the substantive outcome of legal standards cannot improve unless we pay adequate attention to the normative content of the decision-making process in the patent system.

The migration of one such legal transplant with significant explicatory power is the Specific, Substantial and Credible standard (SSCS) of the USPTO's 2001 Utility Examination Guidelines.¹ This standard redefines the 'utility' criterion of patentability, and although it was framed as a direct response to the problem of gene sequence patentability, it is a standard that is currently applied across the board to all inventions in US law. In 2002 it was adopted by a board of the Opposition Division of the EPO in the *ICOS Corp/Novel V28 seven transmembrane receptor (ICOS)* decision² and in October 2005, the SSCS was applied by the UK intellectual property office (UKIPO) to reject a patent application on the basis of lack of industrial applicability in *Aeomica Inc.*³ Remarkably, the transplant is accompanied by little or no debate on viability and the legitimacy of the process by which it has come to be used in the host legal systems.

This paper has two main aims. Firstly, it charts the growth of the SSCS as the gate-keeping criterion for biotechnological inventions. This growth in Europe and in the UK has come about incrementally through patent office practice, and is not supported explicitly by the wording of domestic UK or European patent legislation. Part I starts with an analysis of industrial applicability as it was understood in UK law and in the European Biotechnology Directive before the advent of the SSCS, Part II analyses the utility criterion in US law and how it adds content to the SSCS. Part III explains the EPO and UKIPO's decision to incorporate the SSCS in their practice and analyses the implications of this move. The emphasis throughout this study is to present the various ways in which the SSCS threatens doctrinal coherence in UK law. These include the possible watering down of the 'technical' requirement; encroachment on the inventive step standard, confusion in the line between industrial applicability and sufficiency of disclosure and the potential increase in research tool patentability.

Second, this paper illustrates the prevalence of inadequate theorisation, incrementalism, and institutional learning arguments in the development of patent law doctrine particularly when it comes to the migration of legal standards from one jurisdiction to another. These processes stem from institutional design and dynamics of the patent system and facilitate the transplantation of rules even in the absence of due consideration of the legitimacy and viability of the transplanted

¹ USPTO Utility Examination Guidelines, 66 Fed Reg 1092 (2001).

² *ICOS Corp/Novel V28 seven transmembrane receptor* [2002] 6 OJ EPO 293.

³ *Aeomica Inc* BL O/286/05.

rule. Some of the mechanisms such as ‘satisficing’ and ‘incrementalism’ are familiar elements of the literature on neo-institutional economics, particularly on increasing returns and path dependence.⁴ This paper demonstrates that institutional dynamics within the patent system increase the likelihood of legal transplants and concludes with an analysis of the normative impact of the transplantation process for patent law in general.

THE ‘OLD’ INDUSTRIAL APPLICABILITY: EVOLUTION AND MECHANICS OF CHANGE

In both EPC 1973⁵ and EPC 2000, art 57 stipulates what it means for patentable subject-matter to be susceptible of industrial application – that the invention must be capable of being ‘made or used in some kind of industry’, including agriculture. This is reiterated in the (UK) Patents Act 1977 s 4(1). Rule 27(1)(f) of the Implementing Regulations to the EPC also provides that the description must indicate explicitly, where it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry.⁶ The *UK Manual of Patent Practice* emphasises that ‘industry’ is intended to cover anything of a useful and practical nature. It is not restricted to tangible material, or to artefacts made by mechanical methods of manufacture. ‘Industry’ is also not restricted to purely commercial or profitable activities.

In the UK the case that comes closest to providing guidance on the meaning of this expression continues to be the Australian judgment in *National Research Development Corp v Comr of Patents (NRDC)*.⁷ Many inventions currently excluded as

⁴ Increasing returns is essentially the idea that the value of adopting a particular policy choice rises with the number of entities adopting the same policy. Path dependence is a separate phenomenon, and is often used in the literature to indicate rigid sequential development where initial events can lock in specific outcomes. Recent developments in neo-institutional theory, in contrast to the old institutionalism borne by path dependence and rigid institutional inertias, support the possibility of conditions under which institutions can respond to change in their external environments, while also identifying preconditions that may translate into constraints preventing change and consisting mostly of ‘increasing returns processes’ and ‘imperfect markets’. The new context is evident for example in Paul Pierson’s work. P. Pierson, ‘Increasing Returns, Path Dependence and the Study of Politics’ (2000) 94 *Am Polit Sci Rev* 251, P. Pierson, ‘Not Just What, but When: Timing and Sequence in Political Processes’ (2000) 14 *Stud Am Pol Dev* 72; P. Pierson, ‘When Effect Becomes Cause: Policy Feedback and Political Change’ (July 1993) 45 *World Politics* 595. In general see W.B. Arthur, *Increasing Returns and Path Dependence in the Economy* (Ann Arbor, Mich: University of Michigan Press, 1994), O.A. Hathaway, ‘Path Dependence in the Law: The Course and Pattern of Legal Change in a Common Law System’ (2001) 68 *Io L Rev* 601 and K.J. Arrow, *Social Choice and Individual Values* (New York: John Wiley and Sons, 1963). I address the specific question of increasing returns in the patent system in another paper. S. Thambisetty ‘Increasing Returns in the Patent System: Mechanisms and Consequences’ Paper to be presented the Workshop on The Politics of IP, ECPR Joint Session, Rennes, April 2008.

⁵ Unless specified otherwise, all references to EPC are to EPC 1973. EPC 2000 came into force on 13 December 2007.

⁶ Implementing Regulations to the Convention on the Grant of European Patents [1973] (as amended by the Decision of the Administrative Council of the European Patent Organisation [2004]).

⁷ *National Research Development Corp v Comr of Patents* 102 CLR 252 (1959), [1961] RPC 134 (Full Ct of the HCt Austl) [hereafter cited to CLR 252 (1959)] (*NRDC*).

lacking industrial applicability would have been rejected under the previous law as not being a ‘manner of manufacture’, hence this case is still regarded as a guide to the current meaning of ‘industrial application’ in UK law.⁸ The applicability of this decision was reaffirmed as recently as 2001 by the UKIPO in an explanatory note on ‘industrial applicability’ to the Standing Committee on Patents at the WIPO.⁹

NRDC held that there must be a new and useful effect, be it a creation or an alteration, in the patentable product. It must be useful in practical affairs as distinct from a ‘fine art’. ‘Manner of manufacture’ (and consequently ‘industrial applicability’), indicated the burgeoning fields of endeavour that could be patented. Rather than asking the question whether a particular product or process is a new manufacture or not, the judgment famously states that the proper question to ask is: ‘Is this a proper subject of letters patent according to the principles which have been developed for the application of s 6 of the Statute of Monopolies?’¹⁰ This case thus establishes the broad sweep of the concept of ‘eligible subject-matter’, which includes public policy concerns.¹¹

Until the advent of biotechnology, industrial applicability in European patent law was considered a relatively easy standard to fulfil.¹² Indeed, many patent offices in a variety of jurisdictions rely on extraordinary examples to illustrate inventions that may not possess this feature.¹³ But by the time the Biotechnology Directive¹⁴ was being debated, case law in the UK had already stumbled on the problematic question of industrial applicability for inadequately characterised gene sequences.¹⁵ Art 5(3) of the Directive states that ‘the industrial application of a

⁸ Manual of Patent Practice Guidance for Interpreting the Patents Act 1977, [4.01]–[4.07].

⁹ Statement from UKIPO (Email communication 19 February 2001) <<http://listbox.wipo.int/wilma/scpeforum/2001/msg00013.html>> accessed 10 January 2008. Also see Communication dated 22 January 2003 where the UK has updated its views on industrial applicability to suggest that ‘specific, substantial, and credible utility’ is the correct ‘methodology’ to determine industrial applicability under Substantive Patent Law Treaty (SPLT). Available here <listbox.wipo.int/wilma/scp-eforum/2003/msg00013/SPLT_industrial_applicability_comments_Feb2003.doc> accessed 10 January 2008.

¹⁰ *NRDC*, n 7 above, 269

¹¹ The force of the observations in *NRDC* was affirmed when the Australian Patent Office declined two business method patents. In both *Re Peter Szabo and Associates Pty Ltd* [2005] APO 24 and in *Re Grant* [2004] APO 11 the Hearing Officer found that the invention was not patentable, because the phrase ‘artificially created state of affairs’ from *NRDC* required the application of science or technology in some material manner, which was lacking. The invention in *Re Grant* was a patent for a method that in effect allowed individuals to avoid the full force of Australia’s bankruptcy laws. On appeal, the Federal Court of Australia confirmed the decision, observing that the invention does not add to the economic wealth of Australia or otherwise benefit Australian society as a whole. See *Grant v Comr of Patents* [2005] AIPC 92.

¹² M. Llewelyn, ‘Industrial Applicability/Utility and Genetic Engineering: Current Practices in Europe and the United States’ [1994] 11 *Eur Intell Prop Rev* 473, n 2.

¹³ Such as those that are contrary to well-established physical laws - a perpetual motion machine, a ghost catcher, and a method for preventing the increase in ultraviolet rays associated with the destruction of the ozone layer by covering the whole surface of the earth with an ultraviolet ray absorbing film. WIPO Standing Committee on the Law of Patents, “Industrial Applicability” and “Utility” Requirements: Commonalities and Differences’ (2003).

¹⁴ Directive (EC) 98/44 for the legal protection of biotechnological inventions (hereafter Biotechnology Directive).

¹⁵ *Chiron Corp v Murex Diagnostics Ltd* [1996] FSR 153 (CA) 176–178. See R Gold and A Gallochat, ‘European Directive on the Legal Protection of Biotechnological Inventions: History, Implementation and Lessons for Canada’ (2001) prepared for the Canadian Biotechnology Advisory Committee <<http://www.cbac-cccb.ca/epic/site/cbac-cccb.nsf/en/ah00383e.html>> accessed 10 January 2008.

sequence or partial sequence of a gene must be disclosed in the patent application'. This was a new requirement created specifically for partial sequences of genes and does not apply to genetic material in general or even the partial sequences of proteins. Further amplification of this requirement is provided in Recitals 23 and 24.¹⁶

The combination of the article and Recitals makes it clear that explicit disclosure of industrial applicability is necessary in order to make a sequence or partial gene sequence patentable. Although there is no reference to the *degree of experimental evidence* that should be available to support the function of the gene or the gene product, the wording of Recital 24 indicates that mere use as a 'probe' for further research will not fulfil the specific requirements. These provisions came in for severe criticism from groups, such as the British Technology Group that contended that to seek a specific function goes beyond the mandate of the Biotechnology Directive.¹⁷ Nevertheless, it is generally accepted that the articles and the Recitals of the Directive do not support the patentability of research probes and other such 'uncertain' research uses.

'INDUSTRIAL' AND 'TECHNICAL': SAME DIFFERENCE?

Although the requirement that an invention be technical is not present in the EPC 1973, rules 27(1) and 29(1) of the Implementing Regulations to the EPC require it.¹⁸ The EPO Boards of Appeal have consistently required that for an invention to be patentable it must be 'technical', based on the reasoning that the activities listed in EPC 1973 art 52(2) as excluded subject matter all imply something non-technical, therefore an invention must be 'technical' in order to be patentable. This reasoning has come under some discredit, not least because of the cognitive limitation of perceptions of 'technical'.

Generally many decisions imply a connection between eligible subject-matter *and* industrial applicability. Thus in the UKIPO decision in *Melia's Application*,¹⁹ an application relating to a scheme for exchanging all or part of a prison sentence for corporal punishment was held to lack industrial applicability *and* also to be a method for doing business. In *Kirin Amgen Inc v Roche Diagnostics GmbH*²⁰ the court held that although the essential feature of the invention was the discovery of a

¹⁶ The Biotechnology Directive has two components, whereas the articles are directly binding on member states, the Recitals provide non-binding context in which both member states and the ECJ can interpret the article. But see R. Brownsword, 'Why Recital 26 of the EC Directive on the Legal Protection of Biotechnological Inventions Should be Implemented in National Law' [2000] 4 IPQ 1

¹⁷ The British Group of the Association Internationale pour la Protection de la Propriété Intellectuelle (AIPPI), for example, called for 'industrial applicability to apply for such inventions in Europe, in other words 'the low threshold standard that was being used for all other technologies'. C. Baldock and others, 'Report Q 150: Patentability Requirements and Scope of Protection of Expressed Sequence Tags (ESTs), Single Nucleotide Polymorphisms (SNPs) and Entire Genomes' (2000) 22 Eur Intell Prop Rev 39, 40–41.

¹⁸ Rule 27(1) requires that the description shall specify the technical field to which the invention related. It also requires that 'the claim shall define the matter for which protection is sought in terms of the technical features of the invention': Implementing Regulations (n 6 above).

¹⁹ BL O/153/92.

²⁰ [2002] RPC 1.

DNA sequence, it nonetheless made a *technical contribution* suitable to the claimed purpose. The invention was thus neither excluded nor lacked industrial applicability. This overlap of the ‘invention’ requirement with industrial applicability has resulted in confusion in recent times, heightened by the seeming indifference of the EPO to the notion of ‘invention’ as an independent requirement.²¹

Normally, inventions that are excluded are not rendered patentable even if they are capable of industrial application.²² However, under the watered down ‘technical features’ test used by the EPO, use of an invention in an industrial context may well provide the ‘technical’ requirement needed to escape the exclusionary language. This may be true even in the UK as a consequence of the decision in *Halliburton*²³ where it was confirmed that bolting on a manufacturing claim at the end of an essentially non-technical invention may make it patentable.

In spite of intense pressure on the UKIPO to converge standards of patentability of computer implemented invention and business methods to the much more liberal attitude of the European patent office, the UK Court of Appeal has consistently applied a different and principled approach to the question of the exclusions in S 1(2).²⁴ The recent decision in *Aerote*²⁵ underlines this approach where the court of appeal decided that the EPC in fact excludes ‘computer programs in a practical and operable form’. Justice Jacob decided that the excluded subject matter in S 1(2) were in fact ‘positive categories of non inventions’ that called for a robust interpretation rather than negative ‘exceptions’ that would justify a more narrow interpretation. The decision seems to underplay the role of ‘technical’ as a requirement of patentability although the four step legal test laid out here ultimately maintains this requirement. It is unsurprising that the decision has been attacked by the Technical Board of Appeal of the EPO as being ‘against the EPC’.²⁶

‘Industrial’ and ‘technical’ are clearly related requirements and patentable subject-matter is constrained by both ‘industrial applicability’ and the ‘technical’ requirement. Hence any changes to the meaning or scope of ‘industrial’ holds the potential to shift the goal posts of patentability considerably. In Europe the conceptual link between the two requirements will have to be revisited in the

²¹ “The term “industry” should be understood in its broadest sense as including any physical activity of “technical character” *i.e.*, an activity which belongs to the useful or practical arts as distinct from the aesthetic arts”: EPO, ‘Guidelines for Examination in the European Patent Office’, Part C, Chapter IV (4.1) <http://www.european-patent-office.org/legal/gui_lines/e/index.htm> accessed 10 January 2008. Generally, when the subject-matter of the application as a whole lacks technical character, an objection cannot be raised under art 57; instead, it has to be based on art 52.

²² Manual of Patent Practice Guidance: UKIPO (n 11) [4.03]; see also *WELLCOME/Pigs I* [1989] OJ EPO 13; [1988] EPOR 1.

²³ *Halliburton Energy Services Inc v Smith International (North Sea) Ltd* [2005] EWHC 1623 (Pat), [2006] RPC 2 (Ch (Pat Ct)).

²⁴ This is clear from a comparison of the different decisions in almost identical facts. See *Merrill Lynch’s Application* [1989] RPC 561 (CA) and *Sobei General Purpose Management System* OJ EPO 8 (1995).

²⁵ *Aerotel Ltd vs Telco Holdings Ltd and others* [2007] RPC 7

²⁶ *Estimating Sales Activity/ DUNS LICENSING ASSOCIATES T 154//04* (2006).

context of EPC 2000, art 52 which requires patents to be granted for any invention in all fields of ‘technology’. However the more imminent problem is that of the erosion of ‘industrial’ as a threshold subject matter criterion. As elaborated below the new SSCS standard plays no small part in this.

Discussions at WIPO on the proposed Substantive Patent Law Treaty (SPLT), often equate the ‘technical’ requirement with ‘industrial’. The US, particularly, has adopted a negotiating position that opposes the introduction of either of these requirements because of the association of ‘industrial applicability’ in certain legal systems, including European, with ‘technical character’ or ‘technical effect’ of a claimed invention. Pursuing the possibility of patents being granted in ‘all fields of activity’ (rather than technology), the US position can be summed up as follows:

The delegation of the United States of America stated that it could support neither a ‘technical’ requirement in the SPLT nor the importation of the very *minimal* standards of protection that were to be found in the TRIPS Agreement, nor an ‘industry’ or ‘*industrial-based*’ standard on the issue of industrial applicability or utility. The Delegation expressed the view that the inclusion of ‘technical’ or ‘industrial’ requirement would result in the standards for protection for inventions throughout the world to slip backwards, eroding the level of protections for inventions throughout the world.²⁷

‘USEFUL ARTS’ AND TECHNOLOGICAL ARTS

Utility in the US is a constitutional requirement and not merely a statutory one.²⁸ Patentable subject-matter is constrained by the constitutional phrase ‘useful arts’. According to Walterscheid, given the lack of indication as to what the term meant, it was judged to embrace industrial, mechanical and manual arts of the eighteenth century.²⁹ In 1952, an amendment of the Patents Act in § 101 replaced the words ‘new and useful art’ with ‘new and useful process’ – an aspect of US patent law that has come under great scrutiny due to business method inventions.

The Supreme Court has never tried to define the term ‘useful art’ as it appears in the constitution. The Court of Customs and Patents Appeals on a number of occasions stated that the equivalent of ‘useful arts’ in modern-day terminology was

²⁷ WIPO Standing Committee on the Law of Patents, ‘Seventh Session, Geneva, May 6 to 10, 2002’ (Report) SCP/7/8, [171] <http://www.wipo.int/edocs/mdocs/scp/en/scp_7/scp_7_8.pdf> accessed 10 January 2008.

²⁸ ‘The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility’. *Brenner v Manson* (1966) 383 US 519, 534. Whether an application discloses a utility for a claimed invention is a question of fact.

²⁹ R.I. Coulter, ‘The Field of the Statutory Useful Arts’ (1952) 34 J Pat Off Socy 487, 496 as cited in E.C. Walterscheid, ‘The Nature of the Intellectual Property Clause: A Study in Historical Perspective’ (Buffalo, NY: William S Hein and Co, 2002) 349.

‘technological arts’.³⁰ In the past this ‘test’ has been applied by the USPTO as a ground for rejecting many business method claims that are not tied to a computer or other electronic device. More generally, this rejection is based on subject-matter that is not associated with a known science or technology. This seems analogous to the conflation of ‘industrial’ in ‘industrial applicability’ with ‘technical’ in UK law.

The ‘technological arts’ requirement was recently removed by the USPTO in a decision by the BPAI that is bound to have far-reaching, if as yet untested, implications for European patent law. In a case that was prosecuted for a number years by the USPTO, patent applicant Carl Lundgren claimed a method for compensating managers, which reduces the incentive for collusion in an oligopolistic industry. The invention, essentially a method of calculation, does not use a computer. On appeal by the applicant and remand by the BPAI, an Examiner found it to be unpatentable for the second time, on the ground that the invention was ‘outside the technological arts, namely an economic theory expressed as a mathematical algorithm without the disclosure, or suggestion of a computer, automated means or apparatus of any kind’.³¹

On appeal, the rejection was reversed on a divided opinion at the BPAI. Three out of five judges on the Board found no judicial basis for the ‘technological arts’ test, specifically rejecting judicial precedent.³² This decision is a development of the USPTO’s position on business method and software patents post *State Street Bank and Trust v Signature Financial Group*.³³ The majority opinion at the BPAI held that there can be no ‘technological arts’ test separate from the enumerated classes in § 101. However, judge Jerry Smith dissented to say that the test necessitates at least a threshold nexus to some field of technology, noting that the Examiner’s finding was based on a fundamental position that the claimed invention did not fall within the constitutional mandate regarding inventions which may be patented.³⁴

Whatever the legal merits of the position, this is the clearest signal yet that the USPTO intends to steer the law away from ‘technology’ and towards all ‘fields of

³⁰ *In re Bergy* 596 F 2d 952, 959 (1979); *In re Waldbaum* 457 F 2d 997, 1003 (1972) and *In re Musgrave* 431 F 2d 882, 893 (1970). See also Walterscheid, *ibid*, 348–370. This interpretation is also supported by the view of the constitutional clause as both a grant of power and a limitation: *Graham v John Deere Co* 383 US 1, 5 (1966).

³¹ *Ex p Lundgren* 76 USPQ 2d 1385, 1386 (Bd Pat App & Inter 2005).

³² *In re Musgrave* 167 USPQ 280 (CCPA 1970) and *Toma* 197 USPQ 857 (1978).

³³ *State Street Bank and Trust Co v Signature Financial Group Inc* 149 F 3d 1368 (Fed Cir 1998). The court held that there was no patentability exception for ‘methods of doing business’.

³⁴ n 31 above. The CAFC recently ordered an en banc rehearing in *In re Bilsky* (Fed Cir 2008, 07-1130 order) involving claims to a method of managing the risk of bad weather through commodities trading. The BPAI in its decision observed that *Lundgren* should not be read as eliminating the ‘technology’ requirement for patents. The five questions raised by the CAFC in this sua sponte action promise to raise the constitutional implications of the traditional categories of exclusions, including the ‘useful, tangible and concrete’ test for patentable subject matter set in *State Street Bank* n 33 above. A decision is due later this year. See *Ex p Bilski* (Bd Pat App & Inter 2006).

activity'.³⁵ Within a few weeks of the decision, interim examination guidelines enforcing the outcome of the Board's decision were put in place.

Title 35 of the United States Code does not recite, explicitly or implicitly, that inventions must be within the 'technological arts' to be patentable' ... Moreover although there has been some judicial discussion of the expression 'technological arts' and its relationship to patentability, this dialogue has been rather limited and its viability is questioned.³⁶

More generally, the interim guidelines specify that an invention falls within the scope of 35 USC §101 if (a) the claimed invention physically transforms an article or physical object to a different state or thing, or (b) if the claimed invention otherwise produces a useful, concrete and tangible result. The application itself should enable one of ordinary skill in the art to understand the utility of the invention. It seems likely that this doctrinal position will come up for judicial review in some form,³⁷ but institutionally the *Lundgren* decision and the subsequent interim guidelines are interesting for at least three reasons:

First, the decision represents policy-making by the USPTO, which is in a position to build expectations around a legal position. As is amply clear from the European context, reliance on 'technology' or 'technical aspect' is not without problems, since mere association with banal computer equipment should not make otherwise unpatentable subject-matter patentable. However, removing the 'technological arts' test from the USPTO's examining process implies a doctrinal shift of radical proportions. The shift is the result of an abbreviated decision-making process that recasts substantive changes in 'operational' terms – in this case as a matter of removal of one of the steps in the examining procedure.

Secondly, the USPTO clearly sees itself as a global agenda-setter in undermining the 'technical' aspect of patent eligibility. Specifically, the interim guidelines themselves state that:

... the United States is a leader in the protection of intellectual property and strongly supports patent protection for all subject-matter regardless of whether there is a 'technical aspect' or the invention is in the 'technological

³⁵ What is amazing about *Lundgren* is not the unremarkable holding but, rather, that the entire set of opinions comprises more than 35,000 words and is a work that was many years in the making, all conducted in camera since a first decision of the Board in 1999 with subsequent shenanigans including intervention from PTO officials that led to the stacked deck enlarged panel': H.C. Wegner, 'Recent Software Patent Protection Trends' (2005) Software Information Center (SOFTIC) Symposium 9 Nov 2005 <http://www.foley.com/files/tbl_s31Publications/FileUpload137/2991/DOC.PDF> accessed 10 January 2008.

³⁶ USPTO, Interim Guidelines for the Examination of Patent Applications for Patent Subject Matter Eligibility (22 November 2005) 42–43.

³⁷ It was expected that a certiorari granted in *Laboratory Corp of America Holdings v. Metabolite Laboratories Inc* 370 F 3d 1354 (Fed Cir 2004) would allow for a reconsideration of patent eligibility under 35 USC § 101 and therefore an appraisal of the 'technological arts' test. However by a vote of 5-3, the SC dismissed the certiorari as having been improvidently granted *Laboratory Corp of America Holdings v. Metabolite Laboratories, Inc* 126 S Ct 2921 (2006).

arts'. The application of a 'technological art' requirement could be used to preclude the patenting of certain inventions, not only in the United States but also in other jurisdictions.³⁸

Clearly, this move is designed to strengthen the negotiating position of the US in international fora such as the WIPO and will aid the case for greater protection than the TRIPS Agreement's use of the term 'technology'.

Thirdly, the removal of 'technological arts' emphasises 'useful' as a term with significant and substantial meaning(s). The USPTO will be looking, as a starting point, for inventions that are 'useful and accomplish a practical application'³⁹ and 'that must produce a 'useful, tangible and concrete result'.⁴⁰ The defeat of the 'technical' aspect requirement should thus be seen as a spectacular resurgence of the idea of 'utility'. Specific, credible and substantial utility facilitates the patentability of 'activities' as opposed to the limiting requirement of 'technical'. The patent examination shifts away from a question of inherent unpatentability to one of acceptable degree of substantiation (via written description requirements for example) required to support a claim of utility of 'activities'.⁴¹

INDUSTRIAL APPLICABILITY: SHRINKING TIES TO PUBLIC POLICY

The exclusionary impact of the term 'industry' in 'industrial applicability' is nowhere more obvious than in the law relating to the protection of medical inventions. As per s 4(2) of the Patents Act 1977, and before the 2004 amendments, 'an invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application'. As commentators have pointed out the wording of this provision is curious as medical treatment methods are, and have been for a long time, the subject of commercial and economic activity. Many decisions have struggled to justify the wording on the basis of

³⁸ n 36 above, 45.

³⁹ 'The purpose of this enquiry is to limit patent protection to inventions that possess a certain level of "real world" value as opposed to subject-matter that represents nothing more than an idea or concept, or is simply a starting point for future investigation or research': *ibid.*

⁴⁰ n 33 above, 1373.

⁴¹ Illustratively In *Raytheon Co v Roper Corp*, for example, it was held that proof of utility (not just nonobviousness) may be supported when a claimed invention meets with commercial success. 724 F 2d 951, 959 (Fed Cir 1983).

poorly constructed public policy grounds.⁴² Often, the confusion has worked in favour of ever-expanding patent rights.⁴³

Following this general direction, the 2004 amendments introduce into the 1977 Act a new s 4A(1), according to which methods of medical treatment are no longer deemed to be lacking in industrial applicability; instead, they simply cannot be patented. The amendment replaces the existing s 4(2) and mirrors EPC 2000, which presents methods of medical treatment in art 53(c) as being merely an ‘exception to patentability’. ‘Currently, such inventions are treated as incapable of industrial application, a fiction which EPC 2000 regards as undesirable to uphold since methods of treatment and diagnosis are excluded from patentability in the interests of public health.’⁴⁴ Since substances and compositions for use in such methods remain patentable, according to the UKIPO, the new exclusion is of the same scope.⁴⁵

Removing the lack of industrial applicability language from s 4 removes the ethical or public policy dimension of this criterion in the only statutory instance where it was used to represent such interests, however poorly interpreted. This further undermines the status of industrial applicability as a ‘gate-keeping’ eligibility criterion. This legislative move, although characterised as an ‘operational’ one which has ‘no effect in practice’, in fact brings industrial applicability as it is implemented in the UK, closer to the ‘utility’ criterion in US patent law which, as elaborated below has shed nearly all connection to public policy principles.

A recent Enlarged Board of Appeal decision from the EPO cements this particular weakening of the meaning of industrial applicability.⁴⁶ The Board was trying to arrive at the proper construction of the term ‘diagnostic method practised on the human or animal body’ under EPC 1973 art 52(4). The decision limits the exception to methods that are applied on the human or animal body,

⁴² ‘The thinking behind the exception is not particularly rational: if one accepts that a patent monopoly is a fair price to pay for the extra research incentive, then there is no reason to suppose that that would not apply also to methods of medical treatment’: *Bristol Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1999] RPC 253, 274 (Jacob J). ‘The policy behind the exclusion of such methods is clearly to ensure that those who carry out such methods as part of the medical treatment of humans or the veterinary treatment of animals should not be inhibited by patents’ *Device and Method for Sampling of Substances using Alternating Polarity/CYGNUS Inc* T 964/99 [2002] OJ EPO 4, 10. In *Eli Lilly and Co’s Application* Graham and Whitford JJ had already referred to it as an exception ‘based on ethics rather than logic’. [1975] RPC 438.

⁴³ Justine Pila notes that the cases in UK and Australia on methods of medical treatment are characterised by a failure on the part of decision makers to resolve convincingly or consistently: (a) the basis for the exclusions of methods of medical treatments and (b) ‘the extent (if any) to which legal constructions of inherent unpatentability can legitimately accommodate ethical and other (non commercial) public policy considerations. J. Pila, ‘Methods of Medical Treatment in Australian and United Kingdom Patents Law’ (2001) 24 UNSWLJ 421, 422.

⁴⁴ Explanatory Notes to the Patents Bill (2003–04 HL) <<http://www.publications.parliament.uk/pa/ld200304/ldbills/018/en/04018x--htm>> accessed 10 January 2008.

⁴⁵ Additionally, the amendment allows for a simpler and clearer form of claim for second medical uses of the form ‘Substance X for use in the treatment of disease Y’, rather than ‘The use of X for the manufacture of a medicament to treat Y’. It is on this basis that the UKIPO states that it is not expected to lead to any change in what is or is not patentable. UKIPO, ‘Examination Guidelines for Patent Applications Relating to Medical Inventions in the UK Patent Office’ (2004) <<http://www.patent.gov.uk/patent/reference/mediguidlines/index.htm>> accessed 10 January 2008.

⁴⁶ *Diagnostic Methods* G 0001/04 OJ EPO (2006) 334.

implying an interaction with such bodies rather than any *in vitro* method. The EPO observed that the scope of such methods in art 52(4) is the same as in art 53(c) of EPC 2000. This according to the EPO, is because present inventions under art 52(4) are actually industrially applicable within the meaning of art 57, so the scope of the exception continues to have the same extent under art 53(c) of EPC 2000. The Board explains the dropping of ‘industrial applicability’ from art 53(c) of EPC 2000 as ‘a purely editorial change’ that ‘does not change the actual legal position’. The disingenuous reasoning is justified by the Board on the basis that ‘the motive for the change (in the EPC 2000) was the realisation that these methods were excluded from patentability for reasons of public health and that, consequently, one should not base the argument on lack of industrial applicability any more’.⁴⁷

Far from a *mere editorial change*, the dropping of ‘industrial applicability’ from the new art 53(c) of the EPC is a doctrinal shift of some importance. The EPO is implying in its latest decision that ‘public health’ was not something that can, or ever intended to be encompassed within ‘industrial applicability’. However one can trace ‘fields of endeavour’ as a constraint on ‘industrial applicability’ from *NRDC*. Some fields of endeavour were economic or commercial and therefore gave rise to patentable subject-matter, and other fields were just not suitable for patents.⁴⁸ The EPO’s present argument masks a doctrinal shift in incremental or ‘operational’ terms. Underlying this judgement is the misguided view that as per art 4(3) of the EPC, the task of the EPO is to grant patents, therefore any exceptions to this mandate, such as those in art 52(4) are to be construed narrowly.⁴⁹

From an institutional point of view, it is interesting to note that the EPO drafted Implementing Guidelines upon completion of the revision of the EPC without waiting for ratification or accession by 15 states. The Guidelines add additional pressure on national patent offices such as the UKIPO to harmonise their own practices to be in conformity with the EPO practice, which cannot in turn be done without early legislative changes in domestic patent law.⁵⁰ This again throws patent office practise into prominence as a mechanism of accelerating legal changes.

⁴⁷ *ibid* 359.

⁴⁸ Such connotations are explicit in Japanese law where methods of medical treatment and ‘commercially inapplicable’ inventions – such as one applied only for personal use – are not industrially applicable: Japanese Patent Law art 29(1).

⁴⁹ n 46 above, 342. This view while in keeping with the nature of the EPO as a special interest body can be attacked on many grounds, the most straightforward of which is the imperative to interpret the statute including exceptions to patentability, appropriately based on the mischief redressed.

⁵⁰ Hansard HL (2003–04) vol 659 col 662.

UTILITY, PUBLIC POLICY AND MORALITY

In the patent law, “utility” is synonymous with usefulness.⁵¹ This statement by author Edward Walterscheid about US law is misleading in its simplicity. Not only is the word ‘usefulness’ ‘pregnant with ambiguity when applied to the facts of life’,⁵² but it also covers more than one type of usefulness.⁵³ Some of the multiple ways of addressing the utility requirement represent doctrinal shifts in response to specific kinds of subject-matter. An understanding of these shifts in addition to the conflation between the constitutional ‘useful’ and the scope of the statutory requirement of ‘useful’ is essential to make sense of utility, and therefore by extension the new industrial applicability in European patent law.

One of the most frequent ways of thinking about ‘usefulness’ of an invention in US law has been as a constitutional imperative.⁵⁴ Thus, according to the Supreme Court, ‘the basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility’.⁵⁵ The constitutional reference and the introductory language ‘to promote the progress of science and useful Arts’ is often cited in spite of what Walterscheid refers to as a ‘lack of specific direction’.⁵⁶ The concept of ‘utility’ itself has maintained a central place in all US patent legislation,⁵⁷ culminating in the present law’s provision. The Patents Act, 35 USC § 101, in addition to setting forth the categories of patent-eligible subject-matter,⁵⁸ requires that an invention be ‘useful’ in order to receive patent protection.

In his early landmark treatise, Professor William Robinson observed that in order to be patentable, an invention must be more than ‘a mere curiosity, a scientific process exciting wonder yet not producing physical results, or a frivolous or trifling article or operation not aiding in the progress nor increasing the possession of the human race’.⁵⁹ Merges and others refer to utility in this sense as ‘*general utility*’- signifying a low threshold.⁶⁰ Perpetual motion machines that simply oscillate back and forth, for instance, were kept out by this definition.

⁵¹ Walterscheid, n 29 above.

⁵² *Brenner v Manson* (n 28 above) 529.

⁵³ One leading textbook identifies three separate types of utility arguments that have been used by the courts in rejecting patent applications: R.P. Merges, P.S. Mennell and M.A. Lemley, *Intellectual Property in the New Technological Age* (New York: Aspen Publishers, 2003) 141.

⁵⁴ US Constitution art 1, s 8(8).

⁵⁵ *Brenner* (n 28 above) 534

⁵⁶ Walterscheid, n 29 above, 344. Arguably, the introductory clause provides enough direction of the purpose and appropriate contours of the law.

⁵⁷ Since the first Act of April 10, 1790, Ch 7, 1 Stat 109.

⁵⁸ The categories were discussed at length in the case of *Diamond v Chakerabarty* on the basis that if an invention does not fall into one of these categories, it cannot be patented. 206 USPQ 193 (1980). However, the CAFC has modified this approach. ‘The question of whether a claim encompasses statutory subject-matter should not focus on which of the four categories of subject-matter a claim is directed to ... but rather on the essential characteristics of the subject-matter, in particular, its practical utility.’: *State Street Bank and Trust Co v Signature Financial Group Inc* 47 USPQ 2d (BNA) 1596 (1998), 1602.

⁵⁹ W Robinson, *Treatise on the Law of Patents for Useful Inventions* (Boston, Mass: Little Brown and Company, 1890) 463.

⁶⁰ n 53 above, 141.

A related notion of utility is that of ‘*moral or beneficial utility*’, the contours of which are derived from Justice Story’s claim that ‘utility’ means utility that has ‘no obnoxious or mischievous tendency’.⁶¹ This doctrine was used to hold patents invalid well into the twentieth century, particularly nineteenth century gambling devices⁶² and inventions that intended to defraud. In cases such as a fake seam in stockings⁶³ or a process for treating tobacco plants to make their leaves look spotted,⁶⁴ patents were rejected as they did not change or improve the structure or utility of the article. In the relatively recent case of *Juicy Whip Inc v Orange Bang Inc*⁶⁵ (*Juicy Whip*) the line of cases dealing with inventions that could be used to defraud was reviewed and rejected by the CAFC. In *Juicy Whip* the CAFC stated that ‘the fact that one product can be altered to make it look like another is in itself a specific benefit sufficient to satisfy the statutory requirement of utility’.⁶⁶

In arriving at its decision, the court used a number of examples, such as cubic zirconium, synthetic fabrics, imitation leather etc, where much of the value of the products lies in the fact that they appear to be something they are not. Although these specific circumstances of social inutility or immorality no longer seem objectionable, it is possible that other circumstances surrounding technology in the future may create disquiet in the minds of judges.⁶⁷ In such an eventuality it may be possible to revive the social benefit aspect of utility, but for now the *Juicy Whip* case marks a doctrinal shift in the downgrading of the utility requirement’s public policy dimensions.⁶⁸ This development is, however, in keeping with the CAFC’s broad patent-friendly approach.

⁶¹ Justice Story defined ‘useful’ as the antonym of ‘mischievous’ or ‘immoral’. *Lowell v Lewis* 15 F Cas 1018 (CCD Mass 1817), 1019: ‘The law does not look to the degree of utility; it simply requires that it shall be capable of use, and that the use is such as sound morals and policy do not discountenance or prohibit’. *Bedford v Hunt* 3 F Cas 37 (D Mass 1817).

⁶² *National Automatic Device Corp v Lloyd* 40 F 89, 90 (N D Ill 1889). Here a patent on a toy horse racecourse was denied on evidence that a toy course was used in bars for betting purposes.

⁶³ *Scott & Williams v Aristo Hosiery Co* 7 F 2d 1003 (2d Cir 1925). The imitation seam was a false indication of higher quality.

⁶⁴ *Richard v Du Bon* 103 F 868 (2d Cir 1900). At the time of the invention, cigar smokers considered cigars with spotted wrappers to be of superior quality.

⁶⁵ 185 F 3d 1364 (Fed Cir 1999).

⁶⁶ *ibid* 1367. The case involved a juice-dispensing system that included a glass bowl on top that appeared to circulate fresh juice whereas in reality it circulated an undrinkable liquid. The actual juice was dispensed from tanks hidden underneath the glass bowl display. The fact that customers might believe they are receiving fluid directly from the display tank did not deprive the invention of utility.

⁶⁷ In spite of its seeming relevance, moral utility has not been applied in biotechnology cases in the US by courts. *Diamond v Chakrabarty* only suggests that the moral questions about biotechnology inventions should be left to Congress: 447 US 303, 304 (1980). In the past the USPTO has relied on unconstitutionality rather than moral utility for potential human clone patenting. This position, generally regarded as flawed, is based on the Thirteenth Amendment of the US constitution that prohibits slavery. See Statement by Donald Quigg, Assistant Secretary and Commissioner of the USPTO, 7 April 1987, as cited in K.D. DeBre, ‘Patents on People and the US Constitution: Creating Slaves or Enslaving Science’ (1989) 16 *Hastings Const L Q* 221, n 12.

⁶⁸ But cf S.M. Coughlin, ‘The Newman Application and the USPTO’s Unnecessary Response to Patentability of Human and Human Embryos’ (2006) 5 *Chi-Kent J Intell Prop* 90. On one noteworthy occasion, inventor Stuart Newman in 1997 filed a patent application for human-animal chimeras, embryos and methods of making and using them, as a test of USPTO response despite never having made any part of the invention. In a press statement the USPTO noted that ‘It is the position of the USPTO that inventions directed to a human/non-human chimera could, under certain circumstances,

An aspect related to utility that Merges and others term ‘*specific utility*’, is the requirement that the invention should actually perform the function it claims to perform, otherwise it is not ‘useful’ for that function.⁶⁹ Inventions that do not fulfil this requirement include ‘non-operable’ inventions that contradict scientific principles. This particular aspect of utility has given rise to some interesting and high-profile cases including *Newman v Quigg*.⁷⁰ The relationship between utility and the need to describe a working invention that actually achieves the declared use has become very significant in the age of biotechnology. Conceptually there is considerable confusion and conflation of disclosure and utility or industrial applicability, with interesting consequences, discussed below.

UTILITY AS A PRECURSOR OF THE NEW INDUSTRIAL APPLICABILITY

In 2001 Utility Examination Guidelines were published at the USPTO after the public were consulted on the interim guidelines set out in 1999.⁷¹ Based on these guidelines, the Examiner, upon ensuring that the claims describe statutory subject-matter, has to find a *well-established* utility. Then he assesses whether the claims disclose any *particular practical purpose* that can be described as a *specific and substantial* purpose. This particular and practical purpose should also be one that is *credible* to one of ordinary skill in the art. Thus general utilities (such as those associated with partial gene sequences or expressed sequence tags (ESTs)) would not meet the statutory requirement because they are non-specific and/or insubstantial. The Guidelines, however, will allow patents on ESTs that have a specific, substantial or credible utility; or that have a well-established utility that is in turn also specific, substantial and credible. While credible utility is one that is believable to a person having ordinary skill in the art, based on the totality of evidence and reasoning

not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement’. ‘Moral utility’ in this case can be further traced to one ‘Office Action’ in 2003 where the Examiner stated that before ‘useful’ was defined by 35 USC § 101, it had been construed to exclude frivolous or injurious inventions that were counter to the good morals of society. Additionally, whether humans should be the subject of patent protection ‘raises grave issues going to the core of what a useful invention is’. However ‘moral utility’ was not asserted in the rejection of the application. See S.M. Coughlin, ‘The Newman Application’ fns 10, 11 and 12, quoting the case history file of US Application 08/993.

⁶⁹ n 53 above, 141.

⁷⁰ 877 F 2d 1575 (Fed Cir 1989). Newman claimed that his invention produced more energy than was put into it. Some conspiracy theorists believe there was a blatant attempt by the bureaucracy, legislature and courts to prevent commercial exploitation at the behest of oil companies: D. Pavlos, ‘A Layman’s View of the Law: The Story of Joseph Newman’ <<http://www.lawrecord.com/oldsite-pre20050412/articles/23rlr2/newman.html>> accessed 10 January 2008.

⁷¹ Judging from most of the comments that were received (summarised in the Preamble to the Guidelines), the Guidelines were perceived as a direct response to the rising number of gene and gene-related patent applications that were opposed by many scientists, bio-ethicists and the popular media: USPTO Utility Examination Guidelines, 66 Fed Reg 1092 (2001).

provided,⁷² substantial utility is defined on the basis of case law, where it is synonymous with practical utility to mean ‘real world value to claimed subject-matter’.

Well-established utility is significant in the context of genetic technologies as it allows the degree of predictability to change inversely with the degree of sophistication of the state of the art. Well-studied and relatively predictable areas of art are likely to be treated to a less stringent standard of utility, because a well-established utility is one that is ‘well known, immediately apparent or implied by the specification’ disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.⁷³

Additionally, the 2001 Utility Examination Guidelines import the ‘specific, substantial and credible’ utility test into the ‘well-established utility’ test. In order for a well-established or asserted utility to be specific, substantial and credible, it has to have only the barest utility, as illustrated in the preamble to the Guidelines and the accompanying training material for examiners. A negative test is used: a specific and substantial utility is one that excludes so-called ‘throw-away’ utilities, such as the use of a complex invention as a landfill, or the use of a transgenic mouse as snake food.⁷⁴ Recently the CAFC held that the SSCS is not a higher threshold standard than what existed before, in spite of the sentiment that previously utility as a threshold bar was easy to overcome.⁷⁵

THE SSCS - AN INVITATION TO EVALUATE DEGREE OF ‘USE’

The SSCS can be traced to a then controversial line of cases beginning with *Brenner v Manson*,⁷⁶ the last Supreme Court case to rule on the issue of utility, and developed in the companion cases of *In re Kirk*⁷⁷ and *In re Joly*.⁷⁸ These cases and the vigorous dissenting judgments in the latter two are set against burgeoning innovation in the pharmaceutical industry.⁷⁹ They provide substance and background to the application of the SSCS and point towards broad trends we may expect in the development of this legal standard.

A novel chemical process for producing a previously identified class of steroids was the invention at issue in *Brenner*. The first of three arguments advanced by the patent applicant before the Supreme Court asserted that the

⁷² *ibid* 1098.

⁷³ USPTO Manual of Patent Examining Procedure, ‘Revised Interim Utility Guidelines Training Materials’ (1999) 7 <<http://www.uspto.gov/web/offices/pac/utility/utilityguide.pdf>> accessed 10 January 2008.

⁷⁴ n 71 above, 1098.

⁷⁵ *In Re Fisher; Ragbunath v Lalgudi* 421 F 3d 1365 (Fed Cir 2005) 1377–1378.

⁷⁶ *Brenner*, n 28 above. JC Benson ‘Resuscitating the Patent Utility Requirement Again: A Return to *Brenner v Manson*’ (2003) 36 U C Davis L Rev 267.

⁷⁷ *In re Kirk* 54 CCPA 1119 (1967).

⁷⁸ *In re Joly* 54 CCPA 1159 (1967).

⁷⁹ The Court of Customs and Patents Appeals (CCPA) applied a *de minimis* utility standard, holding that the applicant did not have to demonstrate utility for the product as long as the product was not ‘detrimental to public interest’.

known utility of the adjacent homologues of the products of the claimed process provided the required utility. In dismissing this, the court deferred to the finding of the Examiner that there was not a *sufficient likelihood* that the steroids produced by the process would have tumour-inhibiting properties. The second and third arguments advanced by the applicant were that a chemical process is patentable if it yields the intended product and the product is not ‘detrimental to public interest’; and that the compounds and the processes that produce them are the subject of serious scientific investigation.

In rejecting both these arguments, the court based its decision on policy.⁸⁰ The court observed that the reason the constitution and the Congress grant a patent monopoly is the benefit that the public derive from an invention of substantial utility.⁸¹ Without going deeper into the parameters of this so-called ‘quid pro quo’, the court concluded that a claimed invention must have a ‘specific’ and ‘substantial’ practical utility. While the utility must be specific to the claimed invention, the decision does not specify the requisite *degree of use* to establish ‘substantial’ utility.

The use of additional terms in *Brenner* has been criticised in later cases as unhelpful in explicating the language of the statute.⁸² The most significant question in this context seems to be: ‘To whom should an invention be useful?’⁸³ It is submitted that the way to understand the multitude of qualifications to ‘useful’ employed in *Brenner* is to see it as an invitation to judicially evaluate evidence, experimental or otherwise, for an unspecified quantity of utility for an unspecified class of beneficiaries. In this specific case the court affirmed that, as a rule, utility of a compound may not reside in its ‘potential as an object of use testing’,⁸⁴ there must be ‘specific benefit in currently available form’.⁸⁵

As a consequence of the emphasis on ‘research use’ in the majority’s judgement as a negative test of utility in *Brenner*, the criterion came to function as a timing device in gauging when an invention on the assembly line of scientific enquiry is ready to be patented. The way this requirement is set means that researchers may have to invest resources in experimentation before their innovations are patentable, a result which can have far-reaching impact in a

⁸⁰ The court ‘remitted to an analysis of the problem in light of the general intent of Congress, the purpose of the patent system, and the implications of a decision one way or the other’: 383 US 519 (1966) at 532; For a critical discussion see K Sibley, ‘Practical Utility: Evolution Suspended?’ 32 IDEA 203.

⁸¹ *Brenner*, n 28 above, 534.

⁸² ‘Note on the Patent Laws’ 3 Wheat App 13, 24.

⁸³ *Nelson v Bowler* 206 USPQ 881 (1980) elaborately discussed why any degree of utility to anybody was legal utility.

⁸⁴ However in his dissent Justice Harlan points out that the notion of utility articulated by the majority goes against what was regarded as ‘useful’ during ‘a long and prolific period of chemical research and development in this country’. *Brenner*, n 28 above, 540. The existence of this productive phase, helped by a patent system that granted monopoly over chemical products of ‘inherent usefulness’ is itself a strong reason against any change of standards. Such a change can only be mandated by the Congress on the basis of empirical information that the court in the instant case did not possess. Judge Smith in his dissenting opinion in *In re Joby*, also suggested that at least a minimal enquiry should be pursued into how a particular industry determines whether or not a given chemical composition (in this case) is ‘useful’ and how it promotes the progress of the science and the useful arts. n 78 above, 1159, 117.

⁸⁵ *Brenner*, n 28 above, 540.

particular industry. In a nod to the future, the court notes that it is not ‘blind to the prospect that what now seems without “use” may tomorrow command the grateful attention of the public’.⁸⁶

Subsequent cases look to *Brenner* for broad direction, but then concentrate on a rule-based approach to utility that sidelines the per se rule excluding ‘research uses’. Thus, later decisions (particularly *In re Brana*⁸⁷) appear to contradict *Brenner* by allowing research uses of various specificities. The correct way to understand these, it is submitted, is to see subsequent cases as setting forth the standard of substantiation required for a claim of utility. Thus, in *In re Brana* an appropriate use of homologous art was held to provide credible support or well-established utility.⁸⁸ In *Cross v Iizuka*⁸⁹ the CAFC rejected the argument that in vivo tests were necessary to establish practical utility, holding instead that demonstration of the in vitro activity of a novel pharmaceutical agent was enough to establish statutory utility. Citing *Brenner* as a source for ‘broad guidelines’, the CAFC declared:

There is a reasonable correlation between the disclosed in vitro utility and in vivo activity, and therefore a rigorous correlation is not necessary where the disclosure of pharmacological activity is reasonable based upon the probative evidence.⁹⁰

‘SOUND PREDICTION’ STANDARD IN CANADA

It is fruitful here to consider the law in Canada that also uses the ‘new and useful’ terminology.⁹¹ Patent law has to keep up to date with the increasing skills of a person skilled in the art in the context of maturation of technology, while being sure that the monopoly is true to what has been disclosed. The doctrine of ‘sound prediction’ reaffirmed by the Canadian Supreme Court in *Apotex v Wellcome Foundation Ltd*⁹² tries to achieve this balance. The origin of the doctrine of sound prediction is linked to the requirement that claims be ‘fairly based’ on patent disclosure and was framed in *Olin Mathieson Chemical Corp v Biorex Laboratories Ltd*⁹³ in the following way: ‘If it is really possible according to the evidence, to make a sound prediction about a certain area, then prima facie it would be reasonable that

⁸⁶ *ibid* 536.

⁸⁷ 34 USPQ 2d 1436 (Fed Cir 1995).

⁸⁸ *ibid*. The judgment in *In re Brana* does not mention *Brenner*. In *In re Brana* the applicants relied on more than just evidence from structurally similar compounds. They used in vivo and in vitro mouse model systems to test the antitumour activities of their compounds and further submitted an affidavit containing evidence of the utility *in vivo*, even though they had only tested in vitro. In contrast, in *Brenner* the compounds were highly unpredictable and no additional evidence to show common properties with other homologous compounds known to have tumour-inhibiting properties was provided.

⁸⁹ 224 USPQ 739 (Fed Cir 1985).

⁹⁰ *ibid* 747.

⁹¹ The Patents Act 1977 s 2 defines an invention as ‘any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any process, machine, manufacture or composition of matter.’

⁹² [2002] SCC 77.

⁹³ [1970] RPC 157.

the patentee should have a claim accordingly.⁹⁴ This doctrine was explicitly applied in *Monsanto Co v Commr of Patents*⁹⁵ to allow standards of patentability to be changed by maturation of particular technologies. A rejection of broad product claims not supported by an adequate number of tested examples was reversed by the Supreme Court, on the basis that ‘architecture of chemical compounds was no longer a mystery, but within limits, soundly predictable’.⁹⁶

In *Apotex v Wellcome*⁹⁷ the Canadian Supreme Court noted that the key was to avoid ‘speculation’. The utility requirement is met at the priority date only if either it is demonstrated or there is sound prediction based on the information and expertise then available. The following three steps involved in the doctrine of ‘sound prediction’ are comparable to the ‘well established’ doctrine in US law: First, there must be a factual basis for the prediction. Secondly, the inventor must have, on the date of the patent application, an articulable and sound line of reasoning from which the desired result can be inferred on the factual basis; Thirdly, there must be adequate disclosure of the logic or reasoning used to achieve the prediction.⁹⁸ These steps seem to provide a method to cut through the fog of utility for biotechnological inventions and to make a crucial distinction from ‘speculation’.

‘Sound prediction’ does not mean ‘certainty’. The court’s decision was based on the need to balance

the public interest in the disclosure of new and useful inventions even before their utility has been verified by tests, and the public interest in avoiding cluttering of the public domain with useless patents, and granting monopoly rights in exchange for misinformation.⁹⁹

The doctrine of sound prediction is an attempt to bridge the conceptual gaps between the need for ‘utility’, the cognitive ability to foresee technological innovations and improvements, and the information function of the patent system, which requires, in various terms, sufficient disclosure, enablement, enabling disclosure, or written description.

⁹⁴ *ibid* 182.

⁹⁵ [1979] 2 SCR 1108, 1118–1119.

⁹⁶ *ibid*. The Court also noted that predictability of a particular result was essentially a question of fact, though in some situations it may be a matter of common knowledge.

⁹⁷ *Apotex v Wellcome Foundation Ltd* (n 92 above).

⁹⁸ *ibid* [70]. The only factual information that Wellcome possessed at the priority date was that AZT was active against certain retroviruses, a finding that required subsequent testing to show activity against HIV. However, the Supreme Court found that Wellcome had a sufficiently clear understanding of how this might be relevant to the treatment of HIV infections, the mechanism by which this might occur, and that therefore a sound prediction was possible.

⁹⁹ *ibid* [66].

UTILITY AND ENABLEMENT: THE WEAKEST LINK?

The court in *Brenner* attempted to provide a basic taxonomy of research utilities by drawing a distinction between the monopoly effects created by a patent on a process of unspecified utility and those on a product with similarly unspecified utility. In doing this, the court touched upon a related doctrinal issue that makes the transplant of the SSCS into European patent law that much more complex.

A process patent that is not reduced to a product in the chemical field that has not been developed and which does not have a specific utility creates a monopoly of knowledge that is greater than if it were a product. The majority found this reason to deny the monopoly to be more compelling than a reason to grant the monopoly in order to encourage disclosure. The inability to patent a process clearly gives the inventor an adverse incentive to keep the invention secret while uses for resulting products are investigated; however the court referred to at least three reasons that work against the argument that granting a patent here would be an incentive to disclose information

First, the court approached warily the argument based on the virtue of disclosure, given the ‘highly developed art of patent claims drafting’ aimed at disclosing as little information as possible while broadening the scope of the claim as widely as possible. This comment is resonant of similar problems in English common law between ‘utility’ and ‘workability’ although here it is directed to the difficulties in enforcing the enablement or the written description requirements in 35 USC § 112.¹⁰⁰ Secondly, the pressure for secrecy is highly exaggerated because if the inventor of a ‘process cannot himself ascertain a “use” for that which his process yields, he has every incentive to make his invention known to those able to do so’.¹⁰¹ Finally, the court observed that it was not likely that the disclosure of a patented process would spur research by others into the uses to which the product may be put. ‘To the extent that the patentee has the power to enforce his patent, there is little incentive for others to undertake a search for uses.’¹⁰²

The above precautionary arguments are significant, for they are early indications of a lack of clarity surrounding the enablement and written description requirements that have surfaced in biotechnology. In a dissenting opinion in a subsequent case, Judge Smith observed that the effect of *Brenner’s* rule was that the Patent Office Examiners often found that an application lacked utility, unless it included disclosure of ‘use’ of the invention in detail unnecessary for those skilled in the art; and this was seriously impeding the development of the useful arts, contrary to the pre-eminent purpose of the patent system.¹⁰³ This concern is

¹⁰⁰ To satisfy the enablement requirement of 35 USC § 112, an application must disclose the claimed invention in sufficient detail to enable a person of ordinary skill in the art to make and use the claimed invention. To satisfy the written description requirement under the same provision, the description must show that the applicant was in possession of the claimed invention at the time of filing.

¹⁰¹ This seems to beg the question, as it is precisely the patent that gives the inventor of the process the incentive to disclose the process widely, so that other researchers can find additional uses for the product.

¹⁰² *Brenner*, n 28 above, 534.

¹⁰³ n 78 above, 1165.

partially addressed in the Revised Utility Examination Guidelines, with the notion of ‘well-established utility’ being defined as a ‘specific, substantial and credible utility which is well known, immediately apparent, or implied by the specification’s disclosure of the properties of a material, alone, or taken with the knowledge of one skilled in the art’.¹⁰⁴

Post-*Brenner* the law relating to research and other uncertain utilities is characterised by the link between utility and sufficient disclosure of the invention, a point on which many subsequent ‘research uses’ failed. *In re Joly*,¹⁰⁵ decided by the CCPA, involved a claim for ‘esters of 2-enols of steroids and preparation thereof’ that the applicants claimed would be useful starting materials to make ‘2,3-keto compounds’, which would be intermediates for preparing other compounds. However neither the starting materials nor the subsequently produced ‘intermediates’ had any value, other than to make compounds of unknown use. The court rejected the argument that ‘the disclosure of a steroid as useful as an intermediate to make other steroids by specified reactions (was) an adequate disclosure of utility’.¹⁰⁶ The CCPA pointed out that it would also find insufficient utility for a product obtained from intermediates belonging to some class of compounds that now is, or might in the future be, the subject of research. Similarly, in *In re Kirk*, the CCPA affirmed the Patent Examiner’s rejection of the application on the ground that the claim amounted to nebulous expressions of the usefulness of the compounds.¹⁰⁷ Even if the specification had claimed that the compounds were similar to other useful compounds, such a statement would be incredible since steroids were known to be *unpredictable*.

Subsequent to *Brenner* it is well established that the enablement requirement in § 112 of the US law incorporates the utility requirement of § 101. Thus:

The ‘how to use’ prong of § 112 incorporates as a matter of law the requirement of 35 USC § 101 that the specification disclose as a matter of fact a practical utility for the invention. If the application fails as a matter of fact to satisfy the 35 USC § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 USC § 101.¹⁰⁸

In *Amgen Inc v Chugai Pharmaceutical Co*¹⁰⁹ the CAFC briefly addressed utility in the context of enablement. The court invalidated broad claims that were unsupported

¹⁰⁴ n 73 above, 7.

¹⁰⁵ n 78 above.

¹⁰⁶ *ibid* 1161.

¹⁰⁷ n 77 above. The applicants claimed the steroid compounds they invented had valuable ‘biological properties’, including value in preparing other ‘biologically active compounds’ that could be ‘applied to veterinary or medical practice in the form of tablets, elixirs, injections, implants or other pharmaceutical preparations’. They claimed unsuccessfully that the compounds would aid in the ‘furtherance of steroidal research’. This case also confirmed that *Brenner* (n 28 above) overruled *In re Nelson* 280 F 2d 172 (CCPA, 1960).

¹⁰⁸ *In re Zeigler* 26 USPQ 1600, 992 F 2d 1197 (Fed Cir 1993) 1200–1201.

¹⁰⁹ 927 F 2d 1200 (Fed Cir 1991).

by a sufficient number of examples of use, which were needed to validate Amgen's claims. In recognising the lack of predictability in the art of isolating and using purified DNA sequences encoding for human Erythropoietin, the court declared that 'for DNA sequences, [an applicant must disclose] how to make and use enough sequences to justify the grant of the claims sought'. This therefore suggests that if the applicant was able fully to enable his invention or discovery, the court would have been less stringent in applying the requirement of utility. Correspondingly, if the enablement is weak, the court will demand complete and specific indication of utility.¹¹⁰ The overlap between utility and enablement in this way is noteworthy when combined with the specific rules created by the CAFC for written description of genetic sequences that does not seem to apply in other areas.¹¹¹

The written description requirement under 35 USC § 112 was applied for the first time in 1997 as a general disclosure requirement in place of enablement in *Regents of the University of California v Eli Lilly and Co*¹¹² (*Eli Lilly*). This is because in *Eli Lilly*, the CAFC for the first time required the written description of the specification to provide 'adequate support' to the claims. The legal basis for this unprecedented role for written description as well as the standard for 'adequate disclosure' is unclear. In *Enzo Biochem Inc v General Probes Inc*¹¹³ (*Enzo Biochem*) this 'new validity' requirement resulted in the CAFC's decision that the mere deposit of three nucleotide probes, specifically disclosed in the American Type Culture Collection, did not amount to sufficient disclosure of the invention even when the claims were limited to the deposited material. Following *Eli Lilly*,¹¹⁴ the court required a nucleotide by nucleotide recitation of the invention.

Judge Rader in his dissenting opinion in *University of Rochester v GD Searl and Co Inc, Monsanto, Pharmacia Corporation and Pfizer Inc*¹¹⁵ observes that the decision created a 'firestorm' and in an appendix lists the academic commentary: 31 articles criticising the *Eli Lilly* doctrine, 7 articles defending the doctrine and 16 neutrally commenting on the state of this evolving case law.¹¹⁶ The amicus curiae brief filed by the United States in *Enzo Biochem* suggests that a reading of the plain text of § 112 and the case law of the CAFC reveals at least three different possible tests for an adequate written description requirement.¹¹⁷ Thus, it seems fair to say that

¹¹⁰ *ibid* 1212–1215; also see C.D. Lopez-Beverage, 'Should Congress Do Something About Upstream Clogging Caused by the Deficient Utility of Expressed Sequence Tag Patents?' (2005) 10 J Tech L & Policy 35, 62.

¹¹¹ For a general discussion on industry specific practice related to written description see M.A. Lemley and D.A. Burk, 'Policy Levers in Patent Law' (2003) 89 Virginia L Rev 1575.

¹¹² 119 F.3d 1559 (Fed Cir 1997).

¹¹³ 323 F.3d 956 (Fed Cir 2002).

¹¹⁴ n 112 above.

¹¹⁵ *University of Rochester v GD Searl* 71 USPQ 2d 1545 (Fed Cir 2004).

¹¹⁶ The CAFC declined to resolve en banc the conflicting pronouncements on the enablement and written description requirements. Judges Rader, Bryson, Newman, Linn and Gajarsa dissented. According to Judge Newman: 'This question has been promoted from simple semantics into a fundamental conflict concerning patent scope and the support needed to claim biological products. The appropriate forum is now in the en banc tribunal not in continuing debate in panel opinions applying divergent law': *ibid* 1546.

¹¹⁷ Brief of Amicus Curiae United States at 5, *Enzo Biochem* (n 136), cited in n 115 above, n 5.

currently there is no authoritative interpretation of the written description requirement as applied to genetic sequences in US law.¹¹⁸ The present SCCS has more in common with the now discarded standard of ‘utility’ in the old English patent law than the modern criterion of industrial applicability, and as a transplant into European and UK patent law brings with it the threat of significant doctrinal confusion.

INDUSTRIAL APPLICABILITY AND INSUFFICIENCY – THE THREAT OF CONFUSION

Enablement has no direct analogy in UK law, although aspects of sufficiency of disclosure can clearly be used to ground similar attacks. Sufficiency of disclosure in the UK is subject to a standard of ‘enabling disclosure’ a composite of two different requirements – disclosure and enablement.¹¹⁹ Classic insufficiency is when one can show that the patent simply does not deliver at all in relation to the subject-matter claimed. In such a case the patent is invalid on usual principles. Insufficiency can also result when the patent claims something that has not yet been developed. In *Biogen v Medeva*¹²⁰ it was held that a principle of general application can include any element of a claim, and a patentee does not have to have worked out every means of achieving a principle of general application if all of the claims of the invention can be expected to work reasonably.¹²¹

The litigation over the Hepatitis C vaccine, particularly *Chiron v Organon Teknika (No 3)*,¹²² provides a good example of the second type of insufficiency. Chiron successfully sequenced the genome of the virus that causes Hepatitis C and applied for very broad protection for many applications, including test kits, cell cultures and the vaccine for Hepatitis C. However, at the time of the litigation there was no vaccine in sight, only animal trials that appeared promising. It could not be known if the trials would be successful enough to yield a marketable

¹¹⁸ Based on an analysis of the diverging CAFC case law, Bostyn argues that the CAFC regards written description and enablement as ‘severable’ requirements in § 112, a position he finds untenable. S.J.R. Bostyn, ‘Written Description After *Enzo Biochem*: Can the Real Requirement Step Forward Please?’ (2003) 85 J Pat and Trademark Off Socy 131; see also dissenting opinion of Judge Rader on the severability of the written description and enablement requirement in *Enzo Biochem II* 296 F 3d at 1324 (Fed Cir 2002).

¹¹⁹ *Synthon v Smithkline Beecham* [2005] UKHL 59.

¹²⁰ *Biogen v Medeva* [1997] RPC 1 (HL). The Court of Appeal stated in *Kirin Amgen v Hoechst and Transkaryotic Therapies*, that there is only one form of insufficiency, whether it is biogen insufficiency or classic insufficiency [2003] RPC 3 (CA (Civ Div) [71]–[72]. The Court of Appeal was responding to Neuberger J’s use of the two terms at the Patents Court. *Kirin-Amgen v Roche Diagnostics and Transkaryotic Therapies (No 1)* [2002] RPC 1. Nonetheless, the two ways of thinking about insufficiency are valuable especially in the context of ‘predicted uses’. See D Alexander, ‘Patentability and Scope of Rights’ (2004) Presentation at workshop on Bioethical Issues of Intellectual Property in Biotechnology, Tokyo, Sept. 6, 2004 <<http://www.ipgenethics.org/conference/transcript/session4.doc>> accessed 10 January 2008.

¹²¹ “If the invention discloses a principle capable of general application, the claims may be in correspondingly general terms ... [I]f the patentee ... has disclosed a beneficial property which is common to [a class of products] he will be entitled to a patent for all products of that class (assuming them to be new) even though he has not himself made more than one or two of them” *Kirin Amgen v Hoechst Marion Roussel Ltd and Transkaryotic Therapies (No 2)* [2004] UKHL 46 [111] citing *Biogen* (n 120) at 48–49.

¹²² [1994] FSR 2002 (Ch (Pat Ct)).

product. The scope of the claims was not commensurate with the invention in question and the vaccine claims were revoked for insufficiency.¹²³

The question whether the claim has been sufficiently disclosed will obviously be related to the state of the technology, which provides greater insight as it matures.¹²⁴ Contrary to the position in US law, sufficiency of disclosure in UK law is a well-developed doctrine that evolved from ambiguous roots in the 1932 and 1949 legislation, and should not therefore be seen as a doctrine in transition. It does not directly rely on per se rules that are technology specific. Clearly, the SCCS promises to bring with it some of the confusion existing in US law between utility and disclosure requirements.

WORKABILITY AND INSUFFICIENCY

Any misplaced juxtaposition of industrial applicability and insufficiency in UK law would in many respects be a throwback to elements of UK patent law in the period between 1932 and 1977. The UK Patents Act 1932 introduced, for the first time, the requirement of ‘utility’ as a separate ground on which a patent could be revoked, in addition to the requirement that the complete specification should sufficiently and fairly describe the nature of the invention and manner in which the invention is to be performed.¹²⁵ The entrenchment of these two as separate grounds was an attempt to remove considerable uncertainty that existed previously in common law.

Before 1932, these two requirements were often difficult to distinguish in the case law, particularly as ‘utility’ was defined as ‘workability’. The overlap and relationship is explained in the 1973 case of *Valensi v British Radio Corporation Ltd*:

The objections of inutility and insufficiency overlap. To prove inutility it is, in our view, necessary to show that the invention, so far as claimed, will not work as described or with any modification which the addressee can properly be expected to make. If any proposed modification is one which he cannot be expected to make then the specification is insufficient.¹²⁶

¹²³ Since Chiron was able to uphold product claims to the gene sequences themselves, it was clear that any vaccine developed in the future would have to license the use of the relevant polypeptides from Chiron: *ibid*.

¹²⁴ A positive example of this rule working in favour of the patentee appears in *Genentech I/Polypeptide expression*. Here, the patentee claimed in general terms a plasmid suitable for transforming a bacterial host, which included an expression control sequence to enable the expression of exogenous DNA as a recoverable polypeptide. Although the invention had not been tried on every plasmid, every bacterial host or every sequence of exogenous DNA; nonetheless the invention was held to be fully enabled because it could reasonably be expected to work with any of them.

¹²⁵ s 25(2)(e) and s 25(2)(f).

¹²⁶ [1973] RPC 337, 378.

Blanco White explains this complicated position very elegantly when he says ‘insufficiency is when you cannot make the thing, inutility is when you can but it doesn’t work when you have’.¹²⁷

From 1932 to 1977, the link between ‘utility’ and sufficiency of description was used increasingly to solve the problem of broad claims in the specification. The requirement was interpreted to mean that every claim in the invention must be useful,¹²⁸ and if a claim covers a mechanism or a process that does not produce the result or one of the results claimed, expressly or impliedly, in the specification, the entire patent was deemed invalid.¹²⁹ This was regarded as a harsh position by the Banks Committee, which recommended in 1970 that the lack of utility should be a ground for revocation only if the ‘invention claimed covers no useful embodiments’;¹³⁰ if part of the subject-matter of the application was useful, the patent should be granted.

The Committee was concerned about relaxing the ‘utility’ requirement and the consequent danger of wide and speculative claims being filed, but dealt with this by identifying the different functional possibilities of sufficiency of disclosure and inutility; it recommended that only the former be used to tackle broad claims. A statutory requirement was proposed to deal with claims that were unduly wide, having regard to the disclosure in the complete specification.¹³¹ ‘Utility’ as ‘workability’ was therefore deemed redundant under the 1977 Act.

The explanation why the ground of ‘utility’ was dropped in the UK Patents Act 1977 in favour of the requirement of sufficiency is clear from this observation of Ford J in *Roussel Uclaf v Imperial Chemical Industries plc (No 3)*:

It is perhaps surprising that the law should look with so much disfavour on monopolies of things which do not work and which, by definition, accordingly cannot be used, instead of overlooking that point and concentrating on the real question, which is whether the patentee has claimed things which do work but which he has not actually described, without reasonable justification.¹³²

¹²⁷ T.A. Blanco White, *Patents for Inventions and the Protection of Industrial Designs* (London: Stevens and Sons, 5th ed, 1983) [4]–[404].

¹²⁸ Ng-Loy Wee Loon, ‘Patenting of Genes – A Closer Look at the Concepts of Utility and Industrial Applicability’ (2002) 33 IIC 393, 403.

¹²⁹ See, for example, *Norton and Gregory Ltd v Jacobs* (1937) 54 RPC 271. This position, Ng-Loy Wee Loon, mirrors the literal construction of claims, an approach that was subsequently softened by the ‘purposive’ approach to claim construction. Ng-Loy Wee Loon, *ibid* 403–404. See also *Roussel Uclaf v Imperial Chemical Industries plc* [1991] RPC 51.

¹³⁰ Committee on the Patent System and Patent Law, ‘British Patent System: Report of the Committee to Examine the Patent System and Patent Law’ (1970–71) Committee chaired by Maurice Banks, Cmnd 4407 [376].

¹³¹ Banks Committee Report [533]. This view coincided with a more ‘modern’ and favourable view of patents’. See UK Patents Act 1977 s 14(3).

¹³² [1991] RPC 51, 67.

In *Chiron Corporation v Murex Diagnostics Ltd*¹³³ Morritt LJ described sufficiency as a matter of producing a workable prototype of the invention. The move away from workability is also expressed in this case as a move away from ‘susceptible’ or ‘capable’ as part of the requirement of industrial applicability.¹³⁴

It is important to remember that the old law which provided for revocation if the claims were not fairly based on the description or lacked utility was swept away by the 1977 Act. The law is now that set out in the 1977 Act. Section 4(1) states that inventions shall be taken to be capable of industrial application ‘if it can be made ... in any kind of industry’.¹³⁵

This observation crystallises the different functional roles played by ‘industrial applicability’ and ‘sufficiency of disclosure’ in modern UK law.

The Biotechnology Directive juxtaposes industrial applicability of a gene with disclosure in the application.¹³⁶ Taken together with the uncertainty of how the written description requirement will be evaluated together with the SSCS, it suggests a conflation between industrial applicability and ‘sufficiency of disclosure’, where the latter is presented as fulfilling the functional role of the former. In fact sufficiency of disclosure is a different sort of criterion of patentability and will only be evaluated once requirements of patentability including industrial applicability are met.¹³⁷

The distinct function of industrial applicability and disclosure requirements should not be confused particularly when tackling the problem of broad unfounded claims. To use an analogy, finding industrial applicability of an invention is akin to having an idea, expressing this idea through disclosure is a different kind of task. Under some circumstances, it may be possible to mask the lack of ‘ideas’ through a detailed and useless expression that is not based on anything tangible. This is particularly true if we do not have a clear notion of the kind of idea we are looking for in the first place. Assessing the expression of the idea should not then become a proxy for the idea itself. This is the threat of confusion that is presented by the emphasis on disclosure to the detriment of industrial applicability.

To conclude, a comparative evaluation of the EPC industrial applicability standard and the US utility standard is revealing in three different ways. First, the language of the utility requirement is poised to become a key subject-matter eligibility requirement and an alternative to the ‘technical’ or ‘technological arts’ requirement in US law. Comparably, industrial applicability is considerably

¹³³ n 15 above.

¹³⁴ Relying on the words ‘capable’ and ‘can’, according to the appellants’ submission in *Chiron*, would allow a claim in respect of useful items at the edge of a claim of something for which there was no present or foreseeable use, in other words subject-matter that has potential or speculative uses.

¹³⁵ n 15 above, 177.

¹³⁶ Biotechnology Directive art 5(3) and Recital 23.

¹³⁷ It is referred to as an ‘internal requirement’ of patentability by the leading textbook. Bently and Sherman, *Intellectual Property Law* (Oxford: Oxford University Press, 2004) 488.

undermined by the increasingly awkward interpretation of ‘technical’ requirement and by the dilution of public policy implications of this criterion.

Second, utility in the US is linked to disclosure requirements in a way that industrial applicability, as conventionally understood, is not. The key problem with respect to disclosure and biotechnology is that of ‘foreseeable’ technological innovations. US patent language seems to rely on ‘utility’ as the criterion to bridge the gap between speculation and specificity, based on actual experimental evidence or ‘well-established’ conventions in a technological field. This context provides scope for confusion between the functional roles of utility and the written description and enablement requirements. Industrial applicability, on the other hand, conventionally has been associated with insufficiency of disclosure only in rare cases of some extraordinary inventions such as perpetual motion machines.¹³⁸

Thirdly, under US law, utility of ‘research uses’ and ‘research tools’ are largely a question of substantiation of the research context with an adequate level of experimental evidence. As per the *Manual of Examination Procedures* of the USPTO, it is inappropriate to label certain types of inventions as incapable of having a specific and substantial utility based solely on the setting in which the invention is used, for example inventions used in a research or laboratory setting.¹³⁹ Any per se unpatentability of research uses is undermined by the evolution of ‘utility’ and the focus on degree of substantiation; instead, the SCS introduces the notion of research ‘activities’ supported by varying degrees of experimental evidence and prediction of uses based on technological maturity. The transplant of this standard therefore has implications for research use patentability in the UK.

THE LEGAL TRANSPLANT OF SCS IN EUROPEAN PATENT PRACTICE

In September 2002 the UKIPO issued Examination Guidelines for patent applications relating to biotechnological inventions.¹⁴⁰ It stated that the requirement under US law of utility is *somewhat* similar to industrial applicability required under the UK Patents Act 1977. The UK Guidelines go on to say that the US standard of ‘specific, substantial and credible’ is ‘*arguably* the sort of *disclosure*

¹³⁸ While such machines do not have industrial applicability, an alternate objection may be that the specification is not completely enough to allow the invention to be performed. See *Eastman Kodak Co v American Photo Booths Inc* BL/O/457/02 and Manual of UK Patent Practice [4.05].

¹³⁹ USPTO Manual of Patent Examining Procedure (2005) § 2107.01 <<http://www.uspto.gov/web/offices/pac/mpep/documents/front.htm>> accessed 10 January 2008. Applicants use of labels like ‘research tool’, ‘intermediate’ or ‘for research purposes’ should not in itself be determinative of whether the claimed invention has a specific, substantial and credible utility. Kunin and others, ‘Reach Through Claims in the Age of Biotechnology’ (2002) 51 Am U L Rev 609, 624.

¹⁴⁰ *Aeomica Inc* n 3 above

(emphasis added) relating to industrial applicability which we would expect to appear in a UK application'.¹⁴¹

The facts in *ICOS Corp/Novel V28 seven transmembrane receptor*¹⁴² are largely unremarkable. An opposition was filed by Smithkline Beecham and Duphar International Research to a patent granted to ICOS Corporation, which claimed a patent on a 'second generation sequence' which coded for a protein, listing a number of speculative functions of the protein. The opposition asserted lack of inventive step, insufficiency, industrial applicability and lack of invention. The patentee claimed that the mere disclosure of the sequence of the protein sufficiently enabled all the claims and that isolation of ligands and antibodies to the protein was possible through further methods disclosed in the specification. Based on the facts, the patentee argued that his limited disclosure of speculative functions and a method of verification of such speculative functions fell within the abilities of one skilled in the art. Subsequent research had also confirmed the predicted function of V28 as a receptor to be in fact accurate. However given the contemporary state of technology at the time of filing of the application and the minimal disclosure, millions of candidate compounds would have to be screened. The disclosure of the methods of verification of function was therefore, according to the Opposition Division, not technically undemanding.¹⁴³

The Opposition Division required clarification of biological function for appropriate industrial applicability. The patent was revoked on the ground that the disclosure of a *predicted* function of a protein, even in combination with disclosure of a method of verification of this function, is not necessarily adequate to sufficiently disclose the *function* of the protein. A list in the description based on speculative function is not a reliable basis for acknowledging the industrial application of the protein and a DNA sequence encoding a protein without credible function is not a patentable invention. According to the Opposition

¹⁴¹ UKIPO, 'Examination Guidelines for Patent Applications relating to Biotechnological Inventions' (2005) [45] <<http://www.patent.gov.uk/patent/reference/biotechguide/index.htm>> accessed 10 January 2008.

¹⁴² *ICOS* n 2 above. Bert Claes from the EPO expressed reluctance to call the *ICOS* decision 'case law', as this was only a decision of the opposition board. (B. Claes, 'Novelty and Inventive Step Within the EPO: The European Patent Office Perspective' (2003) Roundtable on the Bioethical Issues of Intellectual Property Rights 28–29 March 2003, Intellectual Property Unit, University of Cambridge: <<http://www.shef.ac.uk/ipgenethics/workshopabstract.htm#BClaes>> accessed 10 January 2008). The EC's report on the Biotechnology Directive, however, refers to the *ICOS* decision as a favourable development, noting that an appeal is imminent. (The appeal did not materialise). European Commission, 'Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering' COM (2002) 545 Final 18, n 52 above.

¹⁴³ Research that was conducted subsequent to the grant of the patent led to such an assessment. One of the post-grant publications relied on by the Opposition Division, by way of example, showed V28 to be a co-receptor that binds to the HIV-2 virus. The entity that first correctly identified V28 as a receptor was in fact a virus and not a compound. This cast doubt on the appropriateness of the 'methods of verification' disclosed by the patent as they were directed to the isolation of compounds that bind to the V28 as a receptor. *ICOS* n 2 above 301.

Division, speculative uses do not amount to industrial applicability. A speculative use is use that is not ‘specific, credible or substantial’.¹⁴⁴

The Opposition Division stopped short of saying that ‘research use’ alone is insufficient to show industrial applicability, although the first opponent, Smithkline Beecham, specifically argued that the use in research of a newly discovered protein did not amount to industrial applicability. This decision therefore reserves judgment on whether a research use alone, or other circumstances that include experimental data and specificity of research path, can amount to industrial applicability.

The decision is noteworthy for a number of reasons. Under Recital 23, a mere DNA sequence that does not have an *indication of function* does not have technical information and therefore is not a patentable invention.¹⁴⁵ The Opposition Division stated that ‘DNA sequences with indication of function that are not substantial, specific and credible shall not be patentable inventions according to Article 52(1) because they lack technical character’.¹⁴⁶ Another way to read this statement is as a set of two conditions for patent-eligible subject-matter – either the clear indication of ‘technical character’ or the ‘indication of a specific, substantial and credible function’. This therefore appears to equate ‘technical character’ with ‘specific, substantial and credible’ function and reaches into the threshold question of patent-eligible subject-matter. From this point potentially the SSCS can also reach into the ‘inventive step’ standard because of the problem solution approach that the EPO uses to assess this criterion takes into account technical effect or function of the claimed compound. The examination of inventive step according to a senior examiner at the EPO already focuses on the specificity and credibility of the technical functions claimed.¹⁴⁷

SSCS AND NON OBVIOUSNESS

Clearly, the SSCS is emerging as a method to assess the patent applicant’s and patentee’s contribution within the context of the state of technology. The skilled person has to fill in the dots of what has been disclosed, drawing on what already exists. However the ‘industrial applicability’ criterion in the UK, and to a lesser extent the ‘utility’ criterion in the US, do not explicitly involve a prior art enquiry

¹⁴⁴ A proposed use in a speculative activity of the protein V28 along with a substance it has not been shown how to prepare, is a use that lacks credibility: *ICOS* n 2 above 304, 307.

¹⁴⁵ ‘In view of the requirements of industrial application as set in Art 57 EPC in conjunction with Rule 23(b) – 23(e) EPC, the invention cannot be acknowledged to be industrially applicable because industrial applications are not disclosed in the patent application.’ Further, ‘potential uses of the invention are disclosed in the specification which however are based on a proposed function of the V28 protein as a receptor which is not sufficiently disclosed in the specification’: *ICOS* n 2 above 304.

¹⁴⁶ *ICOS* n 2 above 307.

¹⁴⁷ Siobhan Yeats, a senior biotechnology patent Examiner at the EPO, linked SSCS in the *ICOS* decision to the ‘inventive step’ requirement. S. Yeats, ‘Latest Developments in Biotech Examination’ (2003) Eurolegal Conference: The New Generation of Biotech Patenting: Legal Strategies for Protecting the Latest Innovations in a Changing Landscape, as cited by R.J. Aerts, ‘The Industrial Applicability and Utility Requirements for the Patenting of Genomic Inventions: A Comparison Between European and US Law’ (2004) 26 *Eur Intell Prop Rev* 349.

and are therefore ill-suited to assess what exactly the patentee has disclosed with respect to what is already known in the field. In *In re Fisher; Raghunath v Lalgudi*,¹⁴⁸ the conceptual closeness between SSCS and the ‘inventive step’ standard was noted by Rader J in his dissent. He concluded that policy concerns with inventions such as ESTs are better addressed through the nonobviousness doctrine – a doctrine that has been handicapped in this technological area in US law by the *In re Deuel* decision.¹⁴⁹

Rader J’s argument in the context of US law indicates potential lines of development in UK and European patent practice – that the SSCS will reach into the ‘inventive step’ standard as a way of evaluating an appropriate ‘advance in the art’. Although in *ICOS* the Opposition Division itself did not refer to the standard directly in the context of inventive step, it may be considered a legitimate direction of doctrinal development for the SSCS by the EPO. The link between inventive step and the invention requirement in general makes this likely.¹⁵⁰

Does the prior art component of SSCS work in a way that the ‘inventive step’ standard in the UK or European patent practice cannot, hence justifying the possible use of the SSCS under the ‘inventive step’ requirement? No, because it is possible to use the ‘inventive step’ standard as it is applied in the EPO to place the invention in the context of maturity of a technology. Thus, in cases of new technological areas where well-established knowledge is lacking and there is considerable uncertainty, the successful application of a simple technique could itself involve an inventive step. To illustrate, in *Biogen NV/Alpha Interferon II*,¹⁵¹ an EPO Board of Appeal found a relatively simple technique to possess inventive step due to the general immaturity of the technology.¹⁵²

A related question is whether adopting the SSCS as part of the ‘inventive step’ requirement can protect against over-broad claims in a uniquely effective way. In *Triazololes/AgrEvo*,¹⁵³ the EPO Board of Appeal found that simply identifying a

¹⁴⁸ 421 F 3d 1365 (Fed Cir 2005).

¹⁴⁹ *In re Fisher* (n 75 above) 1381–1382, citing *In re Deuel* 51 F 3d 1552 (Fed Cir 1995).

¹⁵⁰ An interesting illustration of the link between inventiveness and invention is provided by the Australian case of *NV Phillips Gloeilampenfabrieken v Mirabella International Pty Ltd* (1995) 183 CLR 655, decided under the Patents Act 1952. The High Court declared analogous use claims as unpatentable as a matter of subject-matter eligibility, without undertaking an express ‘inventive step’ enquiry. The court reasoned that the concept of an ‘invention’ includes as a matter of minimum threshold the idea of ‘inventiveness’. Unresolved issues in this case, particularly what level of inventiveness is required by this threshold test, were addressed by the Federal Court of Australia in *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* [2000] FCA 316. Admittedly the connection is less obvious in EPO practice as examiners rarely invoke the connection between art 52 and art 57 in isolation from other issues. Where the connection is cited, this is usually by way of complementary objection when raising other objections such as insufficient disclosure of the invention or lack of an inventive step

¹⁵¹ T 0500/01 [1995] EPOR 69

¹⁵² “...having regard to the fact that the area of genetic engineering here under consideration was relatively new at the relevant date, having further regard to the uncertainty at that date about the facts influencing the success of the attempted recombinant-DNA techniques, and to the absence of a well-established general level of knowledge in this particular technical area, the present successful technical application of recombinant-DNA techniques, according to Claims 1 and 2 under consideration, involves an inventive step.” *ibid* [2.4].

¹⁵³ T939/92 [1996] OJ EPO 309. *Pharmacia v Merck* [2002] RPC 41 applied the basic principle in the UK.

class of compounds does not fulfil the requirement of ‘inventive step’. Further, the decision in *AgrEvo* had also made it clear that all aspects of a claim must meet the requirement of ‘inventive step’ in order to be valid. This was received as a significant tool in combating over-broad claims that incorporated subject-matter with no useful purpose, particularly in biotechnology.

Thus, existing elements within the UK ‘inventive step’ standard already fulfil significant SSCS-like aspects, particularly with respect to patentability of compounds of unknown use, and broad claims over such subject-matter. Introduction of the SSCS as an additional aspect of the ‘inventive step’ requirement is unnecessary and it is submitted will threaten doctrinal clarity. Any value in incorporating the SSCS standard into the requirement of ‘inventive step’ should be clearly articulated and monitored closely.

THE SSCS IN THE UK PATENT OFFICE

The UKIPO has adopted the SSCS somewhat cautiously (though the standard is yet to be tested by UK courts) in a move that strongly suggests that the acceptability of the SSCS has grown in the period between the *ICOS* decision in 2002 and the *Aeomica* decision.¹⁵⁴ Although the UKIPO has in the past, on occasion diverged from EPO practice to follow the court of appeal notably in the case of patentability of computer implemented inventions, here the Hearing Officer adopted the SSCS in order to maintain consistency with EPO practice.¹⁵⁵

The patent application in *Aeomica* is remarkable because it lacks ‘wet-lab experimentation’ and is based on bioinformatics.¹⁵⁶ The nucleic acid sequences claimed were identified using bioinformatic algorithms from which the sequence for the protein ZZAP1 was deduced. Taken together, the list of putative protein functions indicate that the resultant ZZAP1 protein is likely to be associated with the development of certain types of cancer and other diseases. Claims 1–29 include broad and general claims such as the use of the gene sequence in transgenic non-human animal models, a method of diagnosing or monitoring disease caused by the altered expression of the human protein ZZAP1, a diagnostic composition comprising the nucleic acid suitable for in vivo administration, any pharmaceutical composition containing the nucleic acids disclosed, and a list of diseases in which ZZAP1 may be involved. None of these

¹⁵⁴ *Aeomica* (n 3 above). It was only in September 2007 that the Examination Guidelines were updated to reflect this significant decision and the SSCS, albeit cautiously with the words ‘.. in the absence of a judgment from the UK courts or of a decision from the EPO, there can be no certainty that such an approach would be upheld in the UK if challenged by the applicant.’ Examination Guidelines for Patent Applications Relating to Biotechnological Inventions in the UK Intellectual Property Office’ [50] (September 2007) <<http://www.ipo.gov.uk/biotech.pdf>> accessed 10 January 2008.

¹⁵⁵ *Aeomica* n 3 above [30]. The application entitled ‘Human ZZAP1 protein’ (GB 0218205.3) was filed on 6 August 2002.

¹⁵⁶ Bioinformatics can at the broadest level be defined as the use of computers to handle biological information. Cf C. Ouzounis, ‘Two or Three Myths About Bioinformatics’ (2000) 16 *Bioinformatics* 187. According to this Editorial, bioinformatics is a genuine scientific discipline requiring imagination and theoretical argument, and should not be considered subordinate to experimental biology.

claims were supported by evidence of experimentation, but are accompanied by examples that are ‘laboratory procedures that would be obvious to undertake with such a sequence’ that did not in themselves ‘exemplify the underlying utility or function of the gene’.¹⁵⁷

Since the application disclosed only *possible* functions for the nucleic acids and without a specific utility of the gene, the Examiner concluded that the requirement of industrial application was not met. As industrial application must be disclosed in the patent application as filed, paragraph 6 of Schedule A2 to the Patents Act 1977 was not satisfied. The ZZAP1 protein had been ascribed a function similar to the V-ATPase class of proteins, for which prior art showed a list of predicted functions, but further experimentation would be required to verify the specific V-ATPase motif of the protein in the present application.¹⁵⁸ The Hearing Officer affirmed the rejection of the application.

A number of significant strands emerge from the decision of the Hearing Officer. First, the SSCS was clearly applied as a cumulative standard. Given that further experimentation would be required in order to verify the proposed uses of the gene, the disclosed use was not a *substantial* one. Even if it were accepted that the use of genes as diagnostics, and probes for further research, are common uses of gene sequences and therefore *credible* from the perspective of a person skilled in the art, the definitive role for such probes and diagnostics is not *specific*. Therefore, in order to be patentable a substantial, specific *and* credible use must be disclosed.¹⁵⁹

Secondly, the Hearing Officer partially accepted the applicant’s arguments that according to *ICOS*, predicted functions may be acceptable as sufficient in certain cases.¹⁶⁰ Such cases are, however, restricted to situations where a claimed protein is highly homologous to a previously characterised protein ‘with highly specific activities, similar targets and downstream effects’.¹⁶¹ The limited possibility of predicted uses for industrial applicability makes the following precept explicit – the specificity of predicted uses is a function of an unstipulated degree of experimental evidence including from homology.¹⁶² In other words, in light of

¹⁵⁷ *Aeomica* n 3 above [10].

¹⁵⁸ *ibid* [31].

¹⁵⁹ *ibid*.

¹⁶⁰ This argument was based on the following passage in the headnote of *ICOS*: ‘The disclosure of a predicted function of a protein in combination with a method of verification of this function is not necessarily adequate to sufficiently disclose the function of the protein.’ In the body of the decision it is worded slightly differently, referring to the need for a ‘technically undemanding’ method of verification: *ICOS* 300.

¹⁶¹ *Aeomica* n 3 above [36]. Here, ZZAP1 bore very little homology to the V-ATPases which are implicated in a wide range of cellular activities that have varying downstream effects.

¹⁶² Homology can be arrived at through computational means and does not require wet-lab experimentation. The applicant unsuccessfully drew an analogy with conventional chemical compounds with a predicted utility where not every compound falling within the scope of the claim would be tested in a human pharmaceutical context. Usually it is rare to have human or even animal data in such applications. Nonetheless, even in such cases, the specification must identify at least one compound that had been shown to work: *Aeomica* n 3 above [40].

ICOS, predicted uses supported by methods of verification (not necessarily verification itself) may be sufficient. Here no such method was disclosed.

Thirdly, the *Aeomica* decision formalises the combined application of disclosure and industrial applicability in the context of gene sequences as seen in paragraph 6 of Schedule A2 of the UK Patents Act. In the patent application, each of the many uses described are techniques that are based on the detection of expression or amplification of the *ZZAP1* gene. However, without a disclosed utility for the gene or the protein expressed by the gene, the techniques are not useful and the application cannot be said to disclose an industrial application.¹⁶³

Fourthly, the decision brings the link between the SSCS and the ‘inventive step’ standard in UK law into focus. In *Aeomica* the sequences were also held to be obvious in light of the prior disclosure of the related macaque sequence and common general knowledge at the priority date. Thus

the skilled person would be able to routinely determine the function of any human sequence identified using the macaque sequence as a starting point and once this function is determined he would appreciate exactly what the possible variations could be.¹⁶⁴

However, in US law the structural similarity between previously known non-human gene sequences and their human variants is unlikely to be obvious because of the emaciated content of this doctrine in the context of gene structure. Consequently, as previously argued, the ‘predictive’ or ‘speculative’ aspects of utility applied in the US may be an attempt to incorporate prior art assessments under the SSCS in order to make up for deficiencies within the ‘inventive step’ standard. A similar emphasis in the UK application of the SSCS may be prevented by the continued robust application of nonobviousness in the context of structural similarity of genetic variants.

Fifthly, the decision appears to entrench the notion of ‘industrial’ context. The applicant contended that the sale of polynucleotides similar to the ones in the present patent application on the website of a biotechnology company was evidence of ‘industrial applicability’ of such polynucleotides.¹⁶⁵ However, the Hearing Officer decided that such sale of research materials, for the launch of a research programme, does not mean that such materials have industrial

¹⁶³ In this context it is worth noting an innovative argument made by the applicant. *Aeomica* Inc argued that the industrial application of nucleic acids should be regarded separately from industrial applicability of proteins. It is only when the two are wrongly regarded together that the lack of a demonstrable credible utility for the protein results in lack of industrial applicability of the nucleic acid. A nucleic acid is more than just an intermediate in the manufacture of the protein. The Hearing Officer rejected this based on the ‘central dogma’ of biochemistry that links DNA and the protein in function and use: *Aeomica* n 3 above [32].

¹⁶⁴ *ibid* [71].

¹⁶⁵ This discussion echoes the debate in *In re Fisher* (n 75 above) about the possibility of ‘commercial utility’ to bolster speculative uses.

applicability. In an observation that resonates with *Chiron v Murex*,¹⁶⁶ the decision states that:

just because something is for sale does not necessarily mean that anybody will purchase that item and find a use for it. Selling an item does not necessarily make it ‘useful’ for the purposes of industry or otherwise. ... The industrial application comes later, following the research when the polynucleotides and their expressed products have been properly characterised and their function determined.¹⁶⁷

Maintaining the importance of the ‘industrial’ context of industrial applicability and finding the ‘research’ context and ‘research materials’ as falling outside of it, appears to adapt the SSCS in a form that is specific to the UK. For example the morphing of the SSCS in this way is contrary to the careful avoidance of the ‘research’ context in *ICOS*; In *Aeomica*, reference to the research context is underpinned by the lack of specificity of uses and the sale of the polynucleotides as research materials. Beyond this the scope or meaning of ‘research’ is left indeterminate. It remains to be seen whether the UKIPO will be able to sustain this doctrinal distinction given the need to maintain consistency with EPO practice, the direction of development of the SSCS in the US, and institutional pressures to converge interpretation of industrial applicability and utility.

SSCS AND RESEARCH TOOL PATENTS

‘Research tool’ is a fairly new term of art within patent law.¹⁶⁸ Different kinds of research tools present different challenges for a patent system that seeks to balance adequate protection for the inventor with the need to maintain future innovation. No jurisdiction has dealt with research tools in biotechnology by systematically characterising them or by creating special rules that only apply to them. It can be argued, however, that the 2001 Utility Guidelines of the USPTO were primarily a response to the ‘research use’ problem of some biotechnology inventions.¹⁶⁹ Therefore it is important to explore the specific implications of the SSCS for research tool patentability in the UK.

The problematic nature of research tool patents came to public attention in the early 1990s when the NIH filed applications in the USPTO to partial gene

¹⁶⁶ *Chiron Corporation v Murex Diagnostics Ltd*, n 15 above.

¹⁶⁷ *Aeomica* n 3 above [34].

¹⁶⁸ A number of CAFC decisions in the US have attempted to characterise the term, and recently the US Supreme Court addressed some aspects of the problem of research tools in *In re Fisher*, n 75. Also see *Integra Lifesciences I v Merck KgaA* 331 F 3d 860 (Fed Cir 2003); C. Raubichk and others, ‘*Integra v Merck: A Mixed Bag for Research Tool Patents*’ (September 2003) 21 *Nature Biotechnology* 1099. Cf J.C. Low, ‘Finding the Right Tool for the Job: Adequate Protection for Research Tool Patents in a Global Market?’ (2005) 27 *Hous J Int L* 345, 354 (arguing that the term ‘research tools’ should not in itself have legal significance).

¹⁶⁹ C.D. Lopez-Beverage, n 110 above.

sequences or expressed sequence tags (ESTs) of unknown function. The preliminary report rejecting the applications stated lack of patentable utility as one of the reasons for rejection.¹⁷⁰ The NIH filed thousands of applications; the scale gripped the public imagination, caused outrage among leading researchers in genetics¹⁷¹ and led directly to the initiative of the USPTO in drafting its Utility Examination Guidelines.

By comparison, the EPO and JPO were slow to establish a definitive policy on EST patentability, largely because relatively few EST applications were being filed in these jurisdictions. Also, it should be noted that, unlike the USPTO, the EPO and the JPO publish patent applications 18 months after filing, whether or not they are yet granted, a feature that may put off some would-be patentees. Furthermore, the Biotechnology Directive had already stated that, although ESTs are not a priori unpatentable, they are unlikely to meet the requirements of 'inventive step' or 'industrial applicability'. Given the uncertainty in patentability in addition to the other factors, the controversy over ESTs was sharply contested in the US while Europe waited and watched.¹⁷²

In institutional terms this gave the USPTO a crucial lead mover advantage in setting the agenda. Because of the uncertainty about whether these patents should be granted or not and the expectations of would-be patentees, the USPTO's efforts in drafting detailed guidelines, based on an informed debate, quickly became a focal point for patent offices in other jurisdictions. Some form of mimesis was bound to follow, given the 'risky' nature of coming up with policy from scratch. The popularity of the SSCS has to be seen in the context of the apprehension, whether justified or not, that the 'wrong' policy could drive away important business and R & D to more conducive jurisdictions.

In the UK in general, the SSCS has been received as a positive development that curtails rather than enhances the patentability of research tool patents. Thus, the Nuffield Bioethics Foundation welcomed the introduction of the SSCS and its

¹⁷⁰ 'It would be necessary for one to do further work in order to establish a utility for any of the nucleotides embraced by the claims': USPTO, 'Report of the USPTO' (1992) 258 *Science* 210.

¹⁷¹ 'International collaborative venture as bold as the Human Genome Project should not be jeopardised by the possibility of irrevocable damage inflicted by EST patents ... Let us strive to ensure that patents are obtainable ... that [they] will still allow commercial exploitation of genetic information, but not so early in the process that it will stifle individual scientific endeavour and lead to international chaos.': 'Letter from Human Genome Committee and Board of Directors, American Society of Human Genetics, to the Editor' (1991) 254 *Science* 1711–1712. Similarly, the Human Genome Organization ('HUGO') issued a statement expressing 'serious concerns' about the negative impact on research and exploitation should broad claims of the so-called 'having' and 'comprising' type be issued for ESTs. HUGO, 'HUGO Statement on Patenting DNA Sequences' <<http://www.gene.ucl.ac.uk/hugo/patent2000.html>> accessed 10 January 2008. For an early legal history of human genome patents, see S. Thambisetty, 'Human Genome Patents and Developing Countries' (Study Report 10) Prepared for the UK Government Commission on Intellectual Property Rights (CIPR, London 2002) <www.iprcommission.org/papers/pdfs/study-papers/10_human_genome_patents.pdf> accessed 10 January 2008.

¹⁷² 'Patenting ESTs: Is it Worth It?' (Editorial) (1999) *Nature Genetics* 21, 145–146. Research tool patents are not unique to developed countries, in spite of general opinion that such patents may not be pursued outside of the United States. See J. Barton, 'Research-tool Patents: Issues for Health in the Developing World' (2002) 80 *Bulletin of the WHO* 121–125 <[http://www.who.int/bulletin/archives/80\(2\)121.pdf](http://www.who.int/bulletin/archives/80(2)121.pdf)> accessed 10 January 2008.

endorsement by the EPO. Although the Foundation's report expresses some concern about the possibility that mere theoretical utility could be patented under 'credible' utility, it generally receives the SSCS as leading to a welcome reduction in patents on DNA that are also research tools.¹⁷³ In a report to the Department of Health, an independent study by leading patent scholars also welcomes the incorporation of the SSCS in the UKIPO Examination Guidelines as part of a clear and balanced statement of policy.¹⁷⁴

If the SSCS were a standard that adequately tackled the problem of research tool patents, it may justify its awkward transplantation into UK law. However, the SSCS solves the problem of only the most speculative of uses, ie use in future research where prognosis is uncertain. The SSCS is currently projected as the most serviceable means of dealing with research tool patents, although the problem is, again, not one of patentability alone. Any process that addresses it as such is likely to fail to achieve the adequate level of responsiveness.

The difficulty in characterising the subject-matter of research tool patents highlights the acuity of the problem. While researchers view the resources they rely on in the laboratory as tools, firms whose primary business is to manufacture and sell these resources may consider the same tools as end products. Both the Nuffield Bioethics Council¹⁷⁵ and the NIH recognise this aspect and fall short of providing a definition. Similarly, the NIH guidelines use the term 'unique research resource' interchangeably with 'research tools' and include

the full range of tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinational chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines.¹⁷⁶

Both the above descriptions are broad and generic; there is no principle or parameter to determine when the subject-matter of a patent might be considered a

¹⁷³ Nuffield Bioethics Foundation, 'The Ethics of Patenting DNA: A Discussion Paper' (London, July 2002) [3.35], [5.41], [6.11].

¹⁷⁴ W.R. Cornish and others, 'Intellectual Property Rights and Genetics: A study into the Impact and Management of Intellectual Property Rights within the Healthcare Sector' (2003) 32: <http://www.phgu.org.uk/about_phgu/resources/word/s-ipr1.doc> accessed 10 January 2008. Interestingly, the Association of the British Pharmaceutical Industry, in response to the Nuffield Bioethics Foundation paper on the 'Ethics of Patenting DNA', stated that they 'support the adoption by the EPO and JPO of the USPTO's utility guidelines into their own guidelines'. Since the ABPI is unlikely to support a legal standard that curtails patentability of biomedical subject-matter; their enthusiasm may reflect either a perceived uniformity in standards that makes it easier for patent applications seeking global protection or the view that the SSCS generally enhances the patentability of research tools (or a combination of both). Association of the British Pharmaceutical Industry, 'The Ethics of Patenting DNA: Response to Nuffield Bioethics Council Discussion Paper' (2003) <http://www.abpi.org.uk/information/industry_positions/nuffield_revised_03.doc> accessed 10 January 2008.

¹⁷⁵ n 173 above. See also J.M. Mueller, 'No "Dilettante Affair": Rethinking The Experimental Use Exception To Patent Infringement for Biomedical Research Tools' (2001) 76 Wash L Rev 1.

¹⁷⁶ NIH, 'Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources' (1999) 64 NIH Federal Register Notices) 72092 <http://ott.od.nih.gov/policy/rt_guide_final.html> accessed 10 January 2008.

research tool.¹⁷⁷ Conceptually, given the range of ‘research tools’, it is important to distinguish between their use in research and their use in order to conduct research on something else, and those that straddle both of these characteristics such as ESTs.¹⁷⁸ The following provide additional clarity on the definitional discussion:¹⁷⁹

- i. ‘Research tools’ should include only those patented tools used in the development of new biotechnological or pharmaceutical products that do not themselves physically incorporate the tool.¹⁸⁰ Thus defined, the sale of such products would not trigger the ‘sell’ or ‘offers to sell’ liability provisions of patent legislation. Rather, infringement of patents on these research tools (absent a licence or exemption) would occur only under the ‘uses’ (and in some case the ‘makes’) provision of patent statutes.
- ii. The definition of ‘research tools’ should also be limited to those products or processes that have no independent use apart from their use in research in creating further products/ services.

THE SSCS POTENTIALLY INCREASES PATENTABILITY OF RESEARCH TOOLS

It can be argued that a standard such as the SSCS allows for the introduction of expansive ‘precepts’ that generally increase patentability.¹⁸¹ At least two such precepts can be discerned from the CAFC decision on ESTs that first applied the SSCS to reject patentability. *In re Fisher; Raghunath v Lalgudi*,¹⁸² the applicant contended, unsuccessfully, that the correct standard of utility was a general one that simply required that the invention not be frivolous or harmful,¹⁸³ and that the SSCS was a heightened standard referring to some undefined spectrum of knowledge relating to the corresponding gene function. Significantly, the applicant relied on cases subsequent to *Brenner*, such as *In re Jolles*,¹⁸⁴ *In re Nelson*¹⁸⁵ and *Cross*

¹⁷⁷ Richard Nelson, in his seminal paper on the economics of basic scientific research, attempts to draw a line between basic scientific research and applied technology based on proximity to solution to a practical problem or the creation of a practical object. R.R. Nelson, ‘The Simple Economics of Basic Scientific Research’ (1959) 67 J Pol Econ 297, 300. Nelson’s observations are used as the basis for an ontology of research tools in S. Thambisetty and S. Basheer, ‘Patenting Research Tools in Human Genome Studies: View From a Technologically Proficient Developing Country’ Roundtable on the Bioethical Issues of Intellectual Property Rights (28–29 March 2003, Cambridge University) <<http://ipgenethics.group.shef.ac.uk/roundtable/papers/SThambisetty.pdf>> accessed 10 January 2008.

¹⁷⁸ However deciding on the appropriate scope of protection for each of these categories is controversial. See *Integra Lifesciences I v Merck KgaA*, n 168 above.

¹⁷⁹ I am grateful to Shamnad Basheer for this point.

¹⁸⁰ Mueller, n 175 above, 4–5, 14, 58.

¹⁸¹ J. Barton, ‘Non-obviousness’ (2003) 43 IDEA 471. Barton argues that an expansive ‘precept’-based approach to inventive step in US law has replaced a ‘common sense’ approach.

¹⁸² *In re Fisher*, n 75 above.

¹⁸³ Adopting Justice Story’s view of a useful invention in *Lovell v Lewis* 15 F Cas 1018–1019 (No 8568) (CC Mass 1817).

¹⁸⁴ 628 F 2d 1322 (CCPA 1980).

¹⁸⁵ 626 F 2d 853 (CCPA 1980).

v Iizuka,¹⁸⁶ each of which found utility in certain pharmaceutical compounds.¹⁸⁷ The CAFC drew a distinction between the current facts and the facts in those cases based on the nature of evidence of utility, as significant *in vivo* experimental data were what helped ground utility in those three cases.

Additionally, the applicant attempted to use ‘commercial significance’ to demonstrate ‘utility’, but failed on facts as he was unable to present evidence of any agricultural company’s interest in his maize ESTs. These two findings add credence to the view that the SSCS standard actually opens the possibility of patents on research uses and research tools, based on a case-by-case approach to the degree of experimental evidence, as opposed to an outright denial of patentability of ‘research uses’. The enquiry shifts from questionable patentability due to research context to evaluation of the degree of experimental data.¹⁸⁸ Further, ‘commercial utility’ may be added to the enquiry similar to ‘commercial success’ in nonobviousness, further improving the chances of patenting ‘research uses’.¹⁸⁹

Crucially, the incremental adoption of the SSCS in UK law takes it out of the institutional setting of its origin and is therefore not supported by the comparable institutional features of the US patent system- some of which are better equipped to deal with the question of ‘research uses’ and ‘research tools’ comprehensively. In the legal system of origin for the SSCS, the presence of the NIH is a significant factor that can temper the post-grant exploitation of research tool patents developed with public funding within a large pool of scientist that rely on grants administered by this federal agency.¹⁹⁰ The NIH is a powerful norm-setting

¹⁸⁶ 753 F 2d 1040 (Fed Cir 1985).

¹⁸⁷ *In re Fisher*, n 75 above.

¹⁸⁸ The direction of change is in keeping with the general trend of transformation of threshold subject-matter enquiries to non threshold subject-matter enquiries, implying increased patentability. J. Pila, ‘Bound Futures: Patent Law and Modern Biotechnology’ 9 (2003) B U J Sci & Tech L 326.

¹⁸⁹ If ‘commercial utility’ is established as one such ‘precept’, what sort of direction might it take? Newman J, in her dissenting judgment in *Integra v Merck*, makes a distinction of scale as to when the research exemption should apply. This may be useful here by analogy to give direction to any future development of ‘commercial utility’. Thus: “there is a generally recognized distinction between ‘research’ and ‘development’, as a matter of scale, creativity, resource allocation, and often the level of scientific/engineering skill needed for the project; this distinction may serve as a useful divider, applicable in most situations.” *Integra v Merck* (n 168) 876. Newman J’s observations arise from concern that post *Madey v Duke*, research in an academic setting is no longer covered *prima facie* under a ‘research exemption’. *Madey v Duke* 64 USPQ 2d 1737 (Fed Cir 2002); see T.V. Garde, ‘Supporting Innovation in Targeted Treatments: Licenses of Right to NIH Funded Research Tools’ (2005) 11 Mich Telecomm & Tech L Rev 240.

¹⁹⁰ See S. Thambisetty ‘The Institutional Structure of the Patent System and its Implications for Bioethical Decision-Making’ in Lenk et al (Ed.) *Ethics and Law of Intellectual Property: Current Problems in Politics, Science and Technology* (Aldershot: Ashgate, 2007) 247-253. This difference can be easily gathered from a comparison of the case of WARF stem cell lines. In the US the Wisconsin Alumni Research Foundation was forced by the NIH as the funding body of the research to grant non-exclusive licenses for academic research. Maria Freire, ‘Access to Intellectual Property Rights: The Research Tool Issue, Commission on Intellectual Property Rights, Workshop 10 Research Tools, Public Private Partnerships and Gene Patenting (22nd January 2002) <<http://www.iprcommission.org/papers/text/workshops/workshop10.txt>> accessed 10 January 2008. In the EPO, the ongoing stem cell patent litigation centres on ethical concerns over use of embryos; research access is likely to remain a serious issue without comparable solutions. Primate Embryonic Stem Cells T 1374/04 (2006).

organisation that can enforce extramural and intramural guidelines backed by a threat of withholding future funding. Additionally under the Bayh Dole Act the NIH can exercise 'march in' rights in furtherance of the public interest if the contractor or assignee has not taken or is not expected to take, within reasonable time effective steps to achieve practical application of an invention developed through federal money. In the UK or in Europe there is no organisation of similar norm-setting power.¹⁹¹

In US law, written description and the enablement requirement, and in the UK sufficiency of disclosure, will continue to be important in dealing with claims to research uses of all kinds. However, the SSCS is fast becoming the tool of choice to assess such claims.¹⁹² This is evident from the trilateral 'comparative' project of the US, European and Japanese Patent Offices on 'reach-through' claims, which approaches such claims mainly from a utility/industrial applicability perspective.¹⁹³ In all four case studies, all three Patent Offices agree as to the standard of utility/industrial applicability.¹⁹⁴ The trilateral project reports are also influential in WIPO discussions on the SPLT, and the Trilateral Offices (as they are called) frequently put forward proposals as a single entity.¹⁹⁵

The problem of research tool patents includes the problem of 'reach-through' claims, the applicability of the research use exemption to such patents,¹⁹⁶ as well as broad questions of the proportionality of patent protection in protecting future innovation. A response to the problem of research tool patents should span both doctrinal and institutional challenges.

¹⁹¹ The newly established European Research Council may grow to become one such organisation. For a detailed discussion see S. Thambisetty, *ibid.*

¹⁹² Kunin and others, n 139 above, 638.

¹⁹³ Trilateral Project B3b, 'Report on Comparative Study on Biotechnology Patent Practices' (2001) <http://www.trilateral.net/projects/biotechnology/reach_through_claims/B3b_reachthrough_text.pdf> accessed 10 January 2008.

¹⁹⁴ In the context of proteomics, the trilateral offices are willing to accept the crystalline form of a protein as novel as long as it has a 'specific, substantial and credible industrial application'. The position arose out of a trilateral report on protein 3D structure and related claims. Trilateral Project WM4 'Report on Comparative Study on Protein 3-dimensional (3-D) Structure Related Claims' (2002) <http://www.trilateral.net/projects/biotechnology/protein_3d/> accessed 10 January 2008.

¹⁹⁵ WIPO, 'Proposal by the United States of America, Japan and the European Patent Office for Establishing a New Work Plan for the Standing Committee on the Law of Patents (SCP)' (2004) WO/GA/31/10, www.wipo.org/documents/en/document/govbody/wo_gb_ga/doc/wo_ga_31_9.doc, accessed 10 January 2008. The WIPO and the Trilateral Offices in 2003 agreed to 'reinforce ties' and 'ensure delivery of more efficient services to users and promote the benefits of the patent system'. Press release 'WIPO and Trilateral Offices agree to Reinforce Ties' (2003) PR/2003/361. <http://www.OMPI.int/edocs/prdocs/en/2003/wipo_pr_2003_361.html> accessed 10 January 2008.

¹⁹⁶ The scope of established exemptions from infringement for patented subject-matter that can be described as research tools is complicated and, as in the case of the CAFC's decision in *Integra v Merck*, can be applied differently to other patented subject-matter. The majority in this case was unwilling to apply a 'research exemption' to inventions that are also research tools; a position that, in the opinion of Newman J, went against even the normal level of protection competitors have under the 'research use exemption'. *Integra v Merck*, n 168, 875. Although the Supreme Court reversed the majority decision, they explicitly declined to evaluate the common law research exemption as applied to research tools. See *Integra KGA v Merck Lifesciences I Ltd* 125 S Ct 2372 (2005) fn 7.

CONCLUSION

It is highly likely that the SSCS standard will grow further in its position as the ‘gate-keeping’ criterion of choice in biotechnology. Institutionally, the legal transplantation of the SSCS can be cast in terms of the power of the ‘first mover’ and ‘learning arguments’ about decision-making processes in complex situations. ‘Learning arguments’ build on work in decision-making and institutional development¹⁹⁷ that emphasise techniques such as ‘satisficing’ or ‘muddling through’ that are used to cope with limited cognitive capabilities.¹⁹⁸ Satisficing is the strategy of choosing the first reasonable option – this may not always be the best option, but it may be the best strategy given that unlimited resources may be required to search for the elusive ‘best option’. ‘Muddling through’ refers to the related notion of incrementalism.¹⁹⁹ Overwhelmed by the complexity of the problems they confront, decision-makers lean heavily on pre-existing policy frameworks, adjusting only at the margins to accommodate distinctive features of a new situation.

The USPTO was the first patent office to produce detailed and comprehensive Guidelines to examine gene sequences. The existence of such comprehensive measures in a complex technical area ensures that some form of mimesis in patent offices in other jurisdictions is likely, for two reasons. First, Examiners, like other individuals, can be expected to not want to learn anything new that is resource intensive. Secondly, Examiners are also likely to be risk-averse. By adopting measures implemented in the US, the EPO, and therefore the UKIPO, is ‘satisficing’ rather than engaging in comprehensive analysis of doctrine suitable to ‘home-grown’ conditions. Thus, it avoids controversy and the possibility of costly policy reversal by relying on a ‘proven’ standard in another system, a self-proclaimed ‘leader in intellectual property’.²⁰⁰

Further, there are strong indications that the US is keen to pursue the SSCS as an alternative to the ‘technological’ requirement in international and bilateral agreements as well as domestically, thereby extending patent protection to ‘non-technical’ subject matter. The SSCS is part of the bilateral trade agreement with Australia,²⁰¹ a development that entrenches the standard in US law too. The SSCS

¹⁹⁷ D.C. North, ‘Economic Performance Through Time’ (1994) 84 Am Econ Rev 359.

¹⁹⁸ The basic ideas of ‘muddling through’ were described in an extremely well-known series of publications, one of which (Lindblom, 1959) was reprinted in about 40 anthologies. C. Lindblom, ‘The Science of Muddling Through’ (Spring 1959) 19 Pub Adm Rev 79–88; D. Braybrooke and C. Lindblom, *A Strategy of Decision* (New York: Free Press of Glencoe, 1963); C. Lindblom, ‘Still Muddling, Not Yet Through’ (1979) 39 Pub Adm Rev 517–26. One of the best known of Lindblom’s claims is that making small policy changes is often superior to making radical ones. The theory received its fair share of pointed criticism and its effectiveness was neither refuted nor established. See also J. Bendor, ‘A Model of Muddling Through’ (December 1995) 89(4) Am Polit Sci Rev 819.

¹⁹⁹ This approach is directly dictated by institutional limitations and fits Lindblom’s argument that uncertainty increases as search for policy alternatives become less incremental, and the distribution and evaluation of new policies become riskier and ‘noisier’. Bendor, *ibid*, 825.

²⁰⁰ n 36 above, 45.

²⁰¹ Australia–United States Free Trade Agreement (AUSFTA) arts 17.1 and 17.9

is also a key point of negotiations under the SPLT at the WIPO. Since the BPAI decision in *Lundgren*,²⁰² it is clear that the SSCS undermines the ‘technical’ requirement by being presented as an ‘equivalent’ alternative to it.

The Opposition Division may have intended to provoke a reference to an enlarged Board of Appeal through its decision in *ICOS*. Unfortunately, the appeal did not take place. The European Commission, in its report on the state of patent law protection for biotechnological inventions since the Biotechnology Directive, refers to the *ICOS* decision as a development that aligns European law with US law.²⁰³ It is to be expected that the EC as an institution will follow the advice and expert opinion of the EPO in such a technical context as this. However, it once again exposes the limitations of the institutional structures that comprise the (European) patent system. When institutional pressures lead to one standard gaining pre-eminence, the effort to maintain dialogue about other intellectual alternatives is clearly undermined.

Does the transplantation of a ‘good’ law trump all the arguments presented here? The enterprise of evaluating a ‘good’ or ‘efficient’ standard in patent law is in some senses misguided because of the lack of consensus about global theoretical and empirical touchstones. At best such an evaluation may be based on one or more of numerous trade-offs. Empirically this paper has demonstrated the threat of doctrinal confusion and the risk of an unprincipled increase in patentability. Other hard to predict effects may also result from the interaction of institutional structure with change.

There is nothing remarkable about the incidence of legal transplants – they are ‘extremely common’²⁰⁴ and are often catalysts for formal and informal legal change and development. Legal transplants can move in a number of different pathways and take different forms in different areas of the law. Recent scholarship suggests that it is outmoded to assume that legal transplants retain their original form and identity in the host legal system without significant changes.²⁰⁵ Indeed it is hard to imagine that a borrowed rule or standard would operate in exactly the same way as it did in its original jurisdiction; they are often adapted into the receiving legal system in specific ways driven by local contexts. To this extent the trajectory of the SSCS is in keeping with the normative understanding of legal transplants; the SSCS in Europe and in the UK is in the process of transforming,

²⁰² *Ex p Lundgren*, n 31 above.

²⁰³ Clearly, this development is cited as some sort of touchstone of success, but why it should be so is less clear. COM (2002) 545 Final 18 (n 142 above). Article 16(c) of the Biotechnology Directive requires the Commission to undertake an evaluation of the application of patent law over biotechnological inventions every five years.

²⁰⁴ Watson actually claimed that transplants are inevitable. However his and subsequent scholarship supports a more modest observation. See Alan Watson, *Sources of Law, Legal Change and Ambiguity*, Philadelphia, 1984, A Watson, *Legal Transplants* (Edinburgh: Scottish Academic Press, 1974); O. Kahn-Freund, ‘On Use and Misuse of Comparative Law’ (1974) 37 MLR 1 and D. Berkowitz and K. Pistor, ‘Economic Development, Legality and the Transplant Effect’ (2003) 47 (1) *European Economic Review*, Elsevier Vol, 165-195.

²⁰⁵ See William Twining ‘Generalising About Law: The Case of Legal Transplants’ The Tilburg Warwick Lectures 2000, Lecture IV. Available here <http://www.ucl.ac.uk/laws/jurisprudence/docs/twi_til_4.pdf> accessed 10 January 2008.

albeit in a number of unpredictable ways, to suit local conditions. In the final analysis, mapping out the exact degree of difference or similarity between the legal rule in the exporting and importing legal order may not amount to anything more than ‘privileging differences over similarities in making comparisons’.²⁰⁶

The aim in this paper is to draw attention to the process of transplantation of law and policy in the European patent system. Crucially, legal standards transplanted from other jurisdictions via operational measures of domestic patent offices are often not subject to the same level of scrutiny on viability and legitimacy as comparative legal processes in other judicial bodies.²⁰⁷ There are at least two aspects of the process of receiving and adaptation of the SSCS into European and UK legal systems that ought to develop into determinants of the transplant’s acceptance and efficacy. The following observations, grounded empirically in the context of the SSCS, suggest normative implications for legal transplants in patent law in general.²⁰⁸

First, incorporating a legal standard through operational or examining procedures of patent offices belies the extent to which effectiveness of a rule depends on knowledge and understanding of the underlying value of the rule. The patent office is not institutionally designed to investigate policy or values during the examination of individual patent applications. The SSCS as detailed here spearheads a significant lowering of the barriers to patentability. By opening up the possibility of patents on non-technical subject matter, a fundamental and legally valid threshold rule in European systems has been put under threat. Additionally, it is well known that expectations of value can quickly coalesce around legal standards when they are first introduced through patent office operations, as they often function as signals to R & D sectors with knock-on effects on investments. Therefore substantive standards of patentability ought to be introduced only when there is a chance to explore and articulate the underlying values it is likely to give effect to.

Secondly, a legal system will be more receptive to a legal transplant if it is adapted to suit local constraints, such as institutional set up or design. While such an adaptation does not always necessitate that the rule be changed significantly, at the very least an informed choice about alternative rules ought to be made. Again, the patent office is not in a position to canvass comparative alternatives. It may be argued that the familiarity of the American legal system justifies an abbreviated decision-making process. However, common legal roots or history between the

²⁰⁶ *ibid* 41

²⁰⁷ The efficiency and quality of patent office function is a key determinant of substantive legal outcomes, a fact that is gaining increasing recognition and belies their status as ‘administrative bodies’. See Peter Drahos “‘Trust me’: Patent Offices in Developing Countries’ Centre for Governance of Knowledge and Development Working Paper (Nov 2007) <http://ssrn.com/abstract=1028676>.

²⁰⁸ The following conclusions are derived among others, from the observations on legality of successful legal transplants in the major study by Berkowitz and Pistor, noting that the ability to successfully adapt transplanted law to local conditions has a major impact on economic development. Berkowitz and Pistor, n 204 above. Also see N Garoupa and A. Ogus ‘A Strategic Interpretation of Legal Transplants’ Available here <http://mle.economia.unibo.it/Papers%20MTM/Garoupa%20-%20Legal%20Transplants.pdf> accessed 10 January 2008.

US and UK or European patent systems alone are insufficient, particularly given contemporary divergences. To cite two of these differences, European (and therefore UK) patentability is built around statutory exclusions linked by the general purpose or policy behind patent legislations, even though in recent times it has been difficult to clearly articulate what this purpose or policy may be. The premise of the US system on the other hand, is much more liberal and built around ever-shrinking judge-made exclusions, accurately if not precisely summed up by this statement on patentability by the SC: ‘Anything under the sun made by man is patentable’.²⁰⁹ To give a second example, the UK HL has steadfastly refused to go the ‘American way’ and adopt the pro-patentee doctrine of equivalents, citing this as a particularly problematic aspect of the US patent system.²¹⁰ These two examples signal fundamental differences in the values and informal constraints under which US and UK (and to a lesser extent European) patent systems function.

The transplantation of the SSCS has unleashed an evolutionary dynamic that may well result in it being reconstructed in a uniquely European way. Doctrinal incoherence along the way may then be explained as growing pains of the move towards greater efficiency. However, this paper sheds light on an alternate view of the quotidian nature of the institutional processes driving law making in the patent system. This perspective demonstrates that the current role of the patent office goes well beyond its original administrative and quasi-judicial mandate. Either the patent office must be encouraged to keep to the purpose for which it was designed, or we need to urgently re-appraise its functional role.

²⁰⁹ *Diamond v Chakerabarty* 447 U.S 303 (1980) (quoting S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952).

²¹⁰ [2004] UKHL 46