Textualisation as Mode of Persuasion in Patent Law and What it Means for Legitimacy

Sivaramjani Thambisetty

LSE Law, Society and Economy Working Papers 7/2015
London School of Economics and Political Science
Law Department

Textualisation as Mode of Persuasion in Patent Law and What it Means for Legitimacy

Sivaramjani Thambisetty*

Abstract: Patent law is rife with apparently inexplicable outcomes that only make sense within hyper-contextualised domains. The scale and degree of such outcomes warrants a closer look at the text of patent law – in this paper, the text of patent Examination Guidelines. These guidelines – an intermediary product of legal, judicial and quasi-judicial decision-making – convert contested legal standards into acceptable claim language that is arguably the very nub of patent law. Using the examples of diagnostic methods, Swiss-type patent claims and industrial application of gene patents, I demonstrate how language is compacted and abstracted in a process that 'textualises' substantive meaning. Textualisation in patent law is a system of persuasion that does not use semantic meaning to communicate and influence, relying instead on rhetorical modalities to frame contested legal positions and support prevailing outcomes. The ensuing difficulty in comprehending the law is a potential threat to legitimacy, while conversely facilitating agency and power in patent systems.

Keywords: Patent law, Rhetoric, Legitimacy, Claims, Examination Guidelines, Diagnostic Methods, Swiss-type claims, industrial application, European Patent Office.

---

* Associate Professor, Law Department, London School of Economics. I am grateful for helpful comments received on a draft of this paper from participants at an Oxford Intellectual Property Research Centre seminar on 19 February 2015; and at a Royal Literary Fund writing retreat in July 2014. I am particularly grateful to RLF fellows Marina Benjamin and Tina Pepler for their time and insight into the writing process.

In the land of Gibberish, the man who makes sense, the man who speaks clearly, clearly speaks nonsense.
Jarod Kintz, *This Book Has No Title,* Kongolibrary.com 2013

Tigers eat meat. Meat is a word. Therefore tigers eat words.

Clearly there must be an error in this argument. It occurs because "meat" is being used differently in the two premises. In the second premise what is being discussed is not the substance meat, but the name of the substance. These are two different things, and the usual way of distinguishing them is to put the name in quotation marks. For a famous but more complicated example of this kind of wordplay see Lewis Carroll's "Through the Looking Glass (and What Alice Found There)", search expression, "The name of the song is called". In such a complicated situation it is easy to confuse names or descriptions and the things they refer to.
G3/08 (Programs for Computers) [11.2.3]

INTRODUCTION

Patent law is rife with apparently inexplicable outcomes. Animals are patentable even though 'animal varieties' are an excluded category;[1] there is a barely discernible difference between computer program methods (patentable) and computer programs (not patentable);[2] and methods of obtaining diagnostic information from a living human or animal body can be patented despite the explicit non-patentability of 'diagnostic methods'.[3] These are just some of the many difficult to understand standards in patent law. As is usual in legal methodology, these outcomes are accepted as the settlement of legal controversy through conventional reasoning. A preoccupation solely with the final product of

[1] T 0315/03 Transgenic Animals/Harvard. The Biotechnology Directive (98/44/EC) and the European Patent Convention 1973 (EPC) (Art 53(b)) use the term 'animal variety'. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) allows for the exclusion from patentability of plants and animals (other than those produced by non-biological or microbiological processes) in Art 27(3). 'Animal variety' does not correspond to a recognised scientific taxonomic category.
[2] The law explicitly excludes computer programs as such from patentability, but does not define what that may be (EPC, Art 52(2) and Patents Act 1977, s 1(2)). In T 0424/03 Clipboard formats 1/MICROSOFT, the Technical Board of Appeal (TBA) of the European Patent Office (EPO) held that 'the claim category of a *computer-implemented method* is distinguished from that of a *computer program*. Even though a method, in particular a method of operating a computer, may be put into practice with the help of a computer program, a claim relating to such a method does not claim a computer program in the category of a computer program' (italicisation added).
[3] EPC, Art 53(c) and EPO Examination Guidelines 4.2.1.3, which state that 'Accordingly, methods for merely obtaining information (data, physical quantities) from the living human or animal body (e.g. X-ray investigations, MRI studies, and blood pressure measurements) are not excluded from patentability under Art 53(c)'.

these decisions and the standards they result in, however – such as what is patentable or what is not patentable – makes some of the more unconventional institutional processes that lead to those outcomes, invisible. [4]

Understanding the terms in which an invention is claimed is not merely a question of understanding conventional language because Examination Guidelines often comprise cipher-like texts where meanings are constructed,[5] abstracted and compacted. These heuristics go beyond mere complexity of language and are formed deliberately while attempting to account for a great number of legal or factual requirements. The incremental nature of some of these developments can lead to perversion in the meaning or purpose of the patent standard.

The purpose of this paper is to shed much needed light on claim formats within patent Examination Guidelines and through these texts on the legitimacy of patent law. Implementing Guidelines or patent Examination Guidelines are texts formulated by patent offices, which are often summative of a particular jurisdiction's patent standards and are an intermediary legal product of statutory interpretation and judicial reasoning, as re-cast by patent offices. As per Article 10(2)(a) of the European Patent Convention (EPC), the patent Examination Guidelines are drafted under the power to 'take all necessary steps to ensure the functioning of the European Patent Office (EPO), including the adoption of internal administrative instructions and information to the public'. The preliminary remarks to the Guidelines also state that these will be updated regularly to 'take account of developments in European patent law and practice, and refer to these as 'binding'.

These are generally designed to aid patent applicants to draft the text of the patent, while claim formats are aimed at helping patent applicants describe their inventions in legally significant or appropriate terms. While conventions around claim formats may be seen as one aspect of the formalism and registration requirements in patent law, in reality the structure and terminology of claim formats have an extraordinary impact on the substance of the law itself.

---

[4] Institutional approaches to patent law are uncommon with some notable exceptions. Drahos' work on patent offices shows how it has grown to be a strong agent of change (P. Drahos, *The Global Governance of Knowledge: Patent Offices and Their Clients* (Cambridge University Press, 2010)). Parthasarathy's paper on the 'Expertise Barrier' shows how processes around expertise can lead to closed and opaque understandings that go on to populate legal doctrine (S. Parthasarathy, 'Breaking the Expertise Barrier: Understanding Activist Challenges to Science and Technology Policy Domains' (2010) 37 *Science and Public Policy* 5, 355-367). A different vein of work shows how historical or institutional particularities have shaped the development of legal doctrine. For instance, J. Silbey in 'Harvesting Intellectual Property' ((2011) *Notre Dame Law Review*86, 2091) uses cultural narratives of creation, discovery, incentive and labour to interrogate their counterparts in intellectual property statutes and legal cases, and A. Pottage and B. Sherman's *Figures of Invention: A History of Modern Patent Law* (Oxford University Press, 2011) looks closely at how the text of the patent came to be the centrepiece of the patent bargain.

[5] Meanings are constructed based on context and circumstances of the invention in a process that is not dissimilar to the construction of terms of a contract. Meaning may be drawn from conventional uses of terms or from context that is specific to a patent application. Sometimes the description of the invention in a patent application functions as a dictionary for the terms used in the claims, but only when the meaning is not clear from the claims themselves. On occasion contested terms may be judicially constructed based on expert and technology-specific evidence. For more, see *Kirin-Amgen, Inc. v Hoechst Marion Roussel Ltd* [2004] UKHL 46.

This paper positions patent Examination Guidelines as products of larger structures of meaning and power[6] through which patent law is constituted, organised and enforced. By paying attention to the textual elements through which persuasive influence is derived, we can better understand how narrative and the power to persuade are intrinsic to the working of the law. [7]

There are others who have grappled with the relevance of texts in patent law. Pottage and Sherman, for instance, draw out the conceptual difference between the intangible invention and the text of the patent that is 'generated and sustained by real world acts of representation, interpretation and argumentation'.[8] This intermediated text becomes a conduit between the social world and third parties, and over time generates an epistemic community. Burk and Reyman also observe and argue that the patent system is largely text-based and that patents are fundamentally rhetorical.[9] In doing so they rightly proceed to ask what the rhetorical features of patent documents reveal about the workings of the patent system and the underlying ideologies of the patent community.[10]

Both of these approaches are improvements in contextualising patents in the social world and bringing attention to the process by which patents as texts are created. However, both sets of commentators diffuse meaning-making and agency amongst the entire patent system or patent community, which avoids the possibility that many of these dynamics are deliberate and driven by unique institutional forces that have set out precisely to create and replenish epistemic communities that go on to hold extraordinary power. By contrast, focusing on the process of textualisation[11] as implementing patent offices are engaged in, we are able to better understand the purpose and direction of meaning-making and rhetorical power in the patent system.

---

[6] As seen in Foucault's work, see S. Cornell 'Splitting the Difference: Textualism, Contextualism and Post-Modern History' (Spring 1995) 36 *American Studies* 1, 57-80.

[7] This paper is based on the European patent system, but with a little care, the arguments and processes ought to be transposable to other jurisdictions that exercise agenda-setting power, notably the US legal system.

[8] A. Pottage and B. Sherman, *Figures of Invention*, n 4 above. See also K. Murray, *A Politics of Patent Law: Crafting the Patent Participatory Bargain* (London: Routledge, 2014).

[9] D. Burk and J. Reyman, 'Patents as Genre: A Prospectus' (2014) 26 *Law and Literature* 163. The authors use genre theory methodology to draw out the social role played by patents: 'We begin by sketching the general outline of the patent as a document, its distinctive characteristics, the unique community that drafts and processes the document, the agencies and institutions that have developed around the document, and the other features relevant to genre analysis. We discuss both linguistic characteristics of the patent document as well as its social character as the product of a community of patent practitioners. In doing so, we trace the connections between the production of patents and the development of the patent community, concluding that this interaction is key to understanding the unique role of patents.'

[10] This view fits in with new institutionalism's recognition of the transformative power of rhetoric when it comes to understanding the relationship between law and politics. See, for instance, S. Burgess, 'Beyond Instrumental Politics: The New Institutionalism, Legal Rhetoric and Judicial Supremacy' (Spring 1993) 25 *Polity* 3, 4445-459.

[11] I borrow the general perspective of Latour on 'textualisation' as he recasts the scientific article as a rhetorical vehicle that gives agency to technoscience (B. Latour, *Science in Action* (Harvard University Press, 1987).

I define textualisation here as a system of persuasion that does not use semantic meaning to communicate and influence, relying instead on rhetorical modalities to frame and prevail. Specifically, the focus here is on the intertextual and intergenerational heuristic of textualisation as it plays out in the process of converting complex legal standards into claim formats. Intertextual[12] because claim formats in Examination Guidelines often draw on previous texts and are the result of complex legal and technical compromises struck along the way, and intergenerational because often these compromises refer to historic arrangements, which although devoid of current substantive significance continue to have an impact on the contours of the claims. Textualisation, thus conceived, is the predominant constitutive element of persuasive power in patent law, and as such is an appropriate tool to interrogate the politics and legitimacy of patent law.

THE ORIGINS OF TEXTUALISATION

Claims denote the invention and police the borders of the right to exclusive use of the patented invention. Frequently, patent applicants are required to claim particular kinds of inventions in specific ways.[13] The stipulation of 'claim types' is often, but not always, detailed in patent office Examination Guidelines.[14] Claim types are sometimes borne out of convention or expediency but can also stem from or be modified under judicial review.

While what can be patented and what can be claimed is by law the same thing, in fact, there can be considerable differences. Misalignment commonly arises when what is claimed is closely aligned with what is not patentable in the law. The most recent US interim Examination Guidelines on eligibility capture the critical role played by the Guidelines in the following way:

At some level all inventions embody, use, reflect, rest upon or apply a law of nature, natural phenomenon, or abstract idea [*added* – all of which are judicial exceptions to patentability under US law]. To properly interpret the claim, it is important to understand what the applicant has invented and is seeking to patent.[15]

---

[12] As used in D. Burk and J. Reyman, n 9 above.

[13] An example of a claim format is the two-part claim, seen in Rule 43(1)(a) of the EPC Examination Guidelines that must be used 'wherever appropriate'. The first part details the prior art, and the second part details the features that the invention adds to the prior art. Also known as a Jepson claim, this sort of claim can be a double-edged sword for patent applicants – they are easy to write but are tantamount to an admission of closest prior art, which may work against patentability of the claim.

[14] The EPO is the implementing body under the EPC and the Guidelines under the EPC are available here: http://www.epo.org/law-practice/legal-texts/guidelines.html. The UK Intellectual Property Office (UKIPO) publishes Guidelines called the Manual of Patent Practice that implement the Patents Act 1977 and largely but not always mirror the EPC. These are available here: http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-manual/p-manual-practice/p-manual-practice-pat1977.htm. (URLs last accessed 16 February 2015.)

[15] Federal Register Vol 79, No 241 16 December 2014, 74622.

This statement of intent shows how knowing the law (which stipulates that laws of nature, natural phenomenon or abstract ideas are not patentable) is inadequate. In order to know what is patentable you need to know how to write and interpret the claim and claim format. This proposition strongly suggests that the process of translation or textualisation that follows in the Guidelines is legally appropriate even if not entirely uncontroversial.

In European patent law the struggle to avoid characterising all computer-implemented inventions as 'computer programs', which is excluded of patenting, has led to the acceptance of a number of descriptions short of this term in claim language. Thus, both 'computer program products' and 'computer program methods' are valid claims for computer-implemented inventions[16] that fall short of being 'computer programs as such'.[17] This work of 'translating' statutory interpretation, sometimes based on decisions either by courts or patent offices themselves is an important element of the implementing power that patent offices have. This power is not meant to be 'legislative' in any way, rather it is a rule-making power that exists because patent offices are tasked with guiding applicants about what they can (and equally importantly, cannot) patent. When judicial precedents are broadly worded, for instance, this power becomes particularly critical. [18]

As the examples and observations in this paper will demonstrate, far from playing a mere editorial role that faithfully transposes the meaning of the law, textualisation that is an inherent part of 'Guidance' on claim language is the very nub of patent law, and as such deserves much greater critical scrutiny and oversight. While textualisation can materialise in other areas of the law,[19] what makes it particularly relevant to patent law is the ubiquity of 'technolaw'[20] – an intermediate product in action of law and technology.

---

[16] 'Claim directed to a computer-implemented method is distinguished from that of a claim directed to a computer program corresponding to that method' (G3/08 (Programs for computers) [11.2.7]).

[17] Excluded as per Article 52(2) of the EPC. Inventions involving programs for computers can be protected however, in different forms of a 'computer-implemented invention', an expression intended to cover claims which involve computers, computer networks or other programmable apparatus whereby *prima facie* one or more of the features of the claimed invention are realised by means of a program or programs. Such claims have included the computer program itself as well as the physical media carrying the program (See T 1173/97 and T 424/03).

[18] The latest Interim Examination Guidelines drafted by the US Patent and Trademark Office (USPTO) is driven by the need to guide patent applicants following three recent Supreme Court decisions (*Alice Corporation v CLS Bank* 134 S.Ct 2347, *AMP v Myriad Generics Inc* 133 S Ct, 2107 and *Mayo Collaborative Serv v Prometheus Labs Inc* 132 S Ct 1289). The Guidelines carry the following disclaimer: 'It is recognized that under the controlling legal precedent there may be variations in the precise contours of the analysis for subject matter eligibility that will still achieve the same end result. The analysis set forth herein promotes examination efficiency and consistency across all technologies' (Federal Register Vol 79, No 241 16 December 2014, 74620).

[19] For instance the growing textualisation of the common law where similar although not identical processes may manifest. See P.M. Tiersma, 'The Textualisation of Precedent' (2013) 82 *Notre Dame Law Review* 1187.

[20] Mirroring Latour's technoscience, n 11 above.

Take inventiveness[21] for instance. An important threshold criterion of patentability, it controls when an invention is inventive enough to become patentable. The answer lies in what an average person skilled in that particular art would make of the invention – based on what she already knows, would she consider the invention to be an obvious development? If yes, then it will not merit a patent. In order to understand how these decisions are made we need to know what can be considered 'average' knowledge and skill in the field. These are often expressed as technical facts: '*the average person already knew that x causes y, and also that y is closely related to y1*'. The patentability of x for y1 will therefore pivot on how easily the average person skilled in the art would associate y and y1. A decision on inventiveness leading to patentability here will almost certainly involve technical or expert evidence that will give context to what is ultimately a legal standard.

Technolaw as an intermediary between legal and technical standards allows the operationalisation of legal doctrine within a given technological context. It is material to a number of standards, such as novelty, disclosure and infringement. Decisional outcomes are often presented in terms of the difficulties of dissociating mixtures of law and technical fact. Since the language of the law and language of technology are not designed to be in easy concert, technolaw involves a greater degree of constructed meanings than other kinds of law. This is particularly true in rapidly moving technologies where technical facts are prone to revision or where new terminology is emerging. The opportunity for manipulation in meaning is therefore considerable. It is the inevitability of technolaw that makes textualisation such a riveting and potentially distorting process here.

While textualisation can become part of the patent itself, put there by the 'patent community' that is engaging in interpreting and re-interpreting the law,[22] the implementing patent office is the original source of this heuristic. In being so, the patent office may well be implicitly and explicitly taking into account the 'needs' of any one part of the constituent patent community, but as I hope this paper will demonstrate, the key driver of textualisation remains patent office agency and choice. [23]

Empirical reflection on three very different kinds of subject matter dealt with under the EPC (diagnostic methods, Swiss-type claims for new medical uses and the industrial application of gene patents) and how they are claimed manifests

---

[21] Defined in Article 56 of the EPC (and similarly in section 3 of the Patents Act 1977) as: 'An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.'

[22] As seen in the work of both A. Pottage and B. Sherman, n 8 above, and D. Burk and J. Reyman, n 9 above.

[23] Alvesson's institutionalist grounding of rhetoric as being closely tied to agency, knowledge and ambiguity, is particularly helpful here in exploring how textualisation may allow actors like patent examiners and judges to give accelerated directionality to the law (M. Alvesson and D. Karreman, 'Taking the Linguistic Turn in Organizational Research: Challenges, Responses, Consequences' (2000) *Journal of Applied Behavioral Science* 36, 136-158, and M. Alvesson 'Organizations as Rhetoric: Knowledge-Intensive Firms and the Struggle with Ambiguity' (1993) *Journal of Management Studies* 30, 997–1015. Also see S.E. Green Jr and Y. Li 'Rhetorical Institutionalism: Language, Agency and Structure in Institutional Theory Since Alvesson 1993' (November 2011) 48 *Journal of Management Studies* 7.

textualisation in legal standards in patent law. In each of these cases a close reading of the text of the Examination Guidelines is essential to understand the requirements of the law, even as they lead to opaque, distorted or hyper contextualised outcomes.[24]

Claim formats or claim guidance are often constructed defensively where potential objections are usually anticipated through use of references and citations to stage and frame the path to uncontroversial positions. Latour terms the defensive use of language in this way to weaken disagreement as 'stratification' of previously linear prose.[25] Using the metaphor of the black box,[26] he details how a dissenter who faces one has only three recourses open to him – 'giving up (the most likely outcome), going along, or working again through what the author did'[27] to begin building up contrary evidence to support a dissenting view. The third option is a resource-intensive process of re-examining how controversial positions are settled, the costs of which can contribute to making such positions de facto legitimate. Patent law, specifically the language in which the invention is claimed and denoted, is suffused with black boxes – accepted axioms constructed from a set of commands that are too complex to work with routinely, are presented as uncontroversial legal facts, yet are also deeply opaque. In order to understand these signifiers of legitimacy fully, therefore, we need to look at patent law as it is being made – before the box closes and becomes black.

---

[24] In doing so I am following the lead of a number of modern legal scholars who are turning towards institutional perspectives to predicate their empirically validated observations on different aspects of legal systems. M.C. Suchman and L.B. Edelman, 'Legal Rational Myths: The New Institutionalism and the Law and Society Tradition' (1996) 21 *Law & Soc. Inquiry* 903 (available at: http://scholarship.law.berkeley.edu/facpubs/475) make the classic case for new institutionalism to merge with the law and society in aid of debunking the myths of legal rationality. Professor Lacey, for instance, makes the case for historical and institutional conditions of the existence of legal concepts to be studied as a way to illuminate doctrinal analysis within particular jurisdictions at particular times (N. Lacey, The Jurisprudence Annual Lecture 2013 - Institutionalising Responsibility: Implications for Jurisprudence, (2013) 4 JURISPRUDENCE 1, 1–19). Professor Black consolidates and strengthens the case for looking at institutional processes in the exercise of legal discretion (J. Black, 'New Institutionalism and Naturalism in Socio-Legal Analysis: Institutionalist Approaches to Regulatory Decision Making' (January 1997) *Law and Policy* 51).

[25] Using the scientific article as a vehicle, Latour shows how stratification can weaken and mute disagreement (n 11 above, 48).

[26] A term from Cybernetics that denotes a piece of machinery or set of commands that are too complex to work with routinely – a piece of kit denoted only by input and output.

[27] n 11 above, 63.

DIAGNOSTIC METHODS

Diagnostic methods for humans and animals have a long history of being prohibited from patentability.[28] Strong socio-economic policy reasons for the exclusion have facilitated statutory inclusion in a number of jurisdictions.[29] Yet Examination Guidelines based on the Enlarged Board of Appeal's decision (Enlarged Board) in *Diagnostic Methods* G1/04 set out a rigid framework for assessing whether an invention is excluded from patentability, achieving as a result a very narrow interpretation of the exclusion. They state that the term 'diagnostic methods' does not cover all methods related to diagnosis; and that '*accordingly, methods for merely obtaining information (data, physical quantities) from the living human or animal body (e.g. X-ray investigations, MRI studies, and blood pressure measurements) are not excluded from patentability under Art. 53(c)*'. In other words, many of the methods that an ordinary person would regard as contributing towards a 'diagnostic method' are in fact patentable. The guidelines appear to reserve the entire weight of the scope of this exclusion only to the most unskilled patent applicant.[30]

Here, the claim language is a direct result of the decision of the Enlarged Board and it could be said that the EPO's guidelines are nothing but a representation of the position taken there. While acknowledging this important aspect, there are several remarkable characteristics of the language of the Examination Guidelines on diagnostic methods that further extrapolate the decision in G1/04[31] – including the two trends of incrementalisation and stratification. In presenting the controversial position as final outcomes, the Guidelines paper over the intense disagreements that preceded this final position.[32] One of the ways in which this is done is by expressing the final position – namely that a number of different kinds of diagnostic methods are in fact patentable – in bite-sized increments, that direct you methodically towards the final outcome. The increments themselves go either towards or away from patentability,[33] although taken as a whole, there can be no doubt that the position is one that makes it fairly easy to obtain a patent on a diagnostic method.

---

[28] It mirrors the history of the exclusion of methods of medical treatment. See T. Piper, 'A Common Law Prescription for a Medical Malaise' in C. Ng, L. Bently and G. D'Agostino, *The Common Law of Intellectual Property: Essays in Honour of David Vaver* (Hart Publishing, 2010).

[29] TRIPS Agreement, Art 27, Patents Act 1977, s 4A(1), EPC, Art 53(c).

[30] G1/04 OJ 2006, 334. The decision on appeal to the Enlarged Board (EBA) usually indicates the need to reconcile divergent interpretations coming from the Technical Boards of Appeal (TBA).

[31] ibid.

[32] In making the case for the referral on appeal, the President of the EPO extensively sets out a number of conflicting decisions of the TBA (G1/04 OJ 2006, 334). The decisions most recent to G1/04 were T385/86 (BRUKER/Non-invasive measurement) which interpreted the diagnostic exclusion narrowly, and held that a method was excluded only if its result makes it immediately possible to decide on a particular course of medical treatment; and required the claimed method to contain all the steps involved in reaching a medical diagnosis; and T964/99 (CYGNUS/Diagnostic method) which in contrast gave a broad interpretation and held that a method was excluded if it contained at least one step which was of diagnostic character and which was practiced on a living human or animal body.

[33] Similar to Latour's positive and negative modalities (n 11 above).

The Examination Guidelines based on G1/04 state that for a 'diagnostic method' to be practiced on 'the human or animal body', direct physical contact with the body is not required. But it does so by saying that 'each of the multiple technical steps' in the diagnostic methods must be '*performed*' on a human or animal body, and that for each such step we must ascertain if there has been '*an interaction*' with the human or animal body. Such interaction is not determined by type and intensity, only by the *presence* of a human or animal body.[34]

Through language, the substantive statutory requirement of 'practiced on the human or animal body'[35] is overwhelmed by a successive dilution in terminology – *practiced* to *performed* to *interaction* to *mere presence* – such that no actual physical contact with the body is necessary. In effect, the type of interaction with the human or animal body is irrelevant to patentability such that visual observation, X-rays and invasive techniques would all equally qualify. Each of these terms is collated in G1/04 from a number of previous TBA decisions where least common denominators of '*interaction*' appear to have been set out in no particular coherent order. So framed, the stipulation that the diagnostic method be 'practiced on human or animal body' has the potential to filter out a greater number of methods than if the actual presence of a human or animal body were required. This increment therefore makes it more difficult to patent a diagnostic method.

The text of the Guidelines also exhibits stratification – an internal folding over of layers, where relatively simple straightforward ideas (diagnostic methods) are 'coiled back on themselves in a folded array of successive defense lines'.[36] As Latour says:

> The difference between a regular text in prose and a technical document is the stratification of the latter. The text is arranged in layers. Each claim is interrupted by references outside the text or inside the text to other parts, to figures, to columns, tables, legends, graphs. Each of these in turn may send you back to other parts of the same text or to more outside references. In such a stratified text, the reader once interested in reading it, is as free as a rat in a maze.[37]

The key question is whether a claim in a patent application is directed towards a diagnostic method. The Guidelines for Article 53(c) of the EPC state[38] (the bold highlighting is part of these Guidelines):

---

[34] Paragraph 4.2.1.3 of the Examination Guidelines. Available here: http://www.epo.org/law-practice/legaltexts/html/guidelines/e/g_ii_4_2_1_3.htm (last accessed 16 February 2015).
[35] EPC, Art 53(c).
[36] n 11 above, 48.
[37] ibid.
[38] n 34 above [4.2.1.3].

> The claim must include method steps relating to **all** of the following phases:
> (i) the **examination phase,** involving the collection of data,
> (ii) the **comparison** of these data with standard values,
> (iii) the **finding of any significant deviation**, i.e. a symptom, during the comparison,
> (iv) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary **decision phase** (diagnosis for curative purposes *stricto sensu*).

If features pertaining to any of these phases are missing and are essential for the definition of the invention, those features are to be included in the independent claim (see Example 9 in Annex II of F-IV). Due account should be taken of steps which may be considered to be implicit: for example, steps relating to the comparison of data with standard values (phase (ii)) may imply the finding of a significant deviation (phase (iii) – see T1197/02). The deductive medical or veterinary decision phase (iv), i.e. the "diagnosis for curative purposes *stricto sensu*", is the determination of the nature of a medical or veterinary medicinal condition intended to identify or uncover a pathology; the identification of the underlying disease is not required (see T125/02).

One of the ways in which stratification manifests in this paragraph is by the splitting up of a claim into several 'diagnostic method *steps*' itself not a term of art in the EPC. These 'phases' of diagnostic method claims are presented in technical language redolent of medical or veterinarian phraseology, even if many of these phases are implicit or embedded in how a physician or vet would approach the question of diagnosis.

As observed previously, each of the increments themselves can go towards or away from patentability. Thus, stipulating that the final phase does not need to relate to a disease, but must merely be *intended to uncover a pathology* appears to be strengthening the impact of this exclusion, by including within its ambit 'mere pathologies'. The reader is then directed towards citations to legal decisions which are supportive decisions of different Boards of the same tribunal[39] – the equivalent of repeating oneself to gain authority – while ignoring a similar number of Technical Board of Appeal decisions that lead to the opposite conclusion.

The overall directionality of stratification becomes clear in the first sentence – when the Guidelines stipulate that the claims must include *all* of these phases in order to be a true 'diagnostic method' (and therefore not patentable). There is a triple negative here that is also put to great use: '*If all the phases are not present, then it is not a diagnostic method, and is therefore not excluded*.' In other words, to patent a diagnostic method all you have to do is avoid these phases in sequence in the claims, which will not be hard to do as they are in fact a construct that can be side-stepped by the patent applicant either by showing that not all the stipulated phases

[39] See discussion of divergent case law in G1/04, n 32 above.

are reflected in his claim,[40] or by showing that even though all the phases are present in his claim, one or more of them are 'not practiced on/performed on/do not interact with a human or animal body'. The result is the creation of multiple loopholes in the law that can be exploited even by the most un-opportunistic patent applicant who seeks to monopolise a diagnostic method.

There are at least three observations one can make that contribute to both hyper-contextualisation and decontextualisation in this particular instance. Firstly, we see no allusion to the purpose or function of the exclusion of diagnostic methods on patentability. This has the effect of muting the long history of policy reasoning behind this exclusion. Secondly, these guidelines present as settled a deeply controversial area of the law, and one that was subject to opposite Technical Board of Appeal decisions not so long ago.[41] There is no hint of this controversy in the Guidelines. Thirdly, the law still says 'diagnostic methods' are excluded, and therefore potential dissenters are subdued if not silenced, except now we have a newly constructed meaning of 'diagnostic method' that has a life only in the Examination Guidelines of the EPO.

This particular example of textualisation is perhaps a result of the unique institutional position of the EPO – where the entity drafting the claim guidance and the body that is the final arbiter of interpretation are essentially the same. The overall impact, therefore, is of text that is staggeringly self-assured and persuasive. Reaching into the legal, policy and interpretational reasoning in order to place this text in the context of the disagreements it arose from requires the reader to be an insider – not just to the law, but also to the particularities of the technical language that forms the scaffold to the final interpretative position. The result is a text that is almost impervious to critical scrutiny.

SWISS CLAIMS

An understanding of Swiss-type use claims,[42] begins with an understanding of novelty in patent law. Generally only something that is new can be patented; it also needs to be inventive. When a patent is granted on a chemical product as a novel substance, the law generally assumes that all uses or other technical characteristics of that product have also '*been made available*'[43] – in other words, once a product is patented, all of its qualities and attributes become known, and are no longer novel.

---

[40] In G1/04, the Enlarged Board asserted that this kind of circumvention 'does not seem to pose a real risk having regard to well-established jurisprudence at the EPO in respect of Art 84, EPC, which requires, that in order to be patentable, an independent claim must recite all the essential features which are necessary for clearly and completely defining an invention' [6.2.4].

[41] See BRUKER/Non-invasive measurement and CYGNUS/Diagnostic method, n 32 above.

[42] First approved at the EPO in 1984 by G5/83 (Eisai/Second Medical Indication).

[43] An invention is anticipated (that is, it is no longer novel) as long as it has been made available to the public.

This is the case even if those qualities are not detailed in the patent application. The assumption is that it is possible (for an average person skilled in the art) to reverse engineer or analyse the product to obtain a great deal of information about that product.

This assumption creates a difficulty in the case of pharmaceutical products with known therapeutic effects, which yield other, explicitly unpatented therapeutic uses. This is a common occurrence as once a product has been used for a therapeutic purpose it is deemed safe, making the potential benefits of experimentation much higher than in an untested product. Largely in response to demands by the pharmaceutical industry, the EPC incorporated a provision that allows new medical uses of patented products to be protected with a separate and limited patent on the newly discovered medical use, which for the purposes of the grant of the patent is deemed to be novel.[44]

This is an extraordinary provision that essentially negates the conventional meaning of novelty of products, to provide a limited exception for a perceived policy reason. This is, of course, within the remit of what a legitimately established legislature can do. There arose, however, the problem of further 'new' medical uses that became apparent as more and more research was done on the same tried and tested products.[45] These uses came in a number of forms – for example, they related to new diseases, or to new dosage regimes with fewer side effects or where increased efficacy was experienced.

As a general principle, if a statute specifies one thing (here, first medical use) and does not specify it as an example of a particular class of things, then everything except the specified thing is deemed to have been expressly excluded. In *Eisai/Second Medical Indication*, the Enlarged Board ruled that *expressio unius est exclusio alterius* (the expression of one subject, object, or idea is the exclusion of other subjects, objects, or ideas)[46] did not apply here. In other words, bestowing patent protection to the first medical use of a known (not new) substance, did not exclude the possibility of second and further medical uses also becoming eligible for patent protection. This dramatic decision meant that an old or known product could now potentially leach novel medical uses indefinitely.

The Swiss-type claim format is fashioned by a combination of this history of second and subsequent medical uses with another important exclusion in patent law. Methods of medical treatment of humans or animals, in parallel with diagnostic methods, have a long history of being excluded, dating back to the professionalisation of medicine when it was deemed important to remove the snake oil merchants and their sales talk from the ambit of what a credible and self-regulated body of professional men should be free to do without the pressures of

---

[44] EPC, Art 54(4).

[45] Not the only development, as the patentability of novel purpose patents with non-medical uses was recognised soon after by the EPO. See G2/88 (Friction reducing additive).

[46] n 42 above. See C. Williams, 'Expressio Unius Est Exclusio Alterius' (1931) 15 *Marquette Law Review* 4, 191.

commerce.[47] Until recently, this exclusion was expressed as follows: '*Methods of medical treatment are not industrially applicable.*'[48] In other words, methods of medical treatment are deemed not to belong in the commercial sphere and so are excluded.[49]

The methods of medical treatment exclusion presented a conundrum to the EPO that had to follow up on its promise of patent protection to second and subsequent medical use, granted in the *Eisai/Second Medical Indication* decision. If we denote the product as x, and y as the first medical use and y1 as the second medical use, here is the problem and solution, in claim language:

> *x for the use of y* – is already patented.
> *x for the use of y1* – cannot be patented as the statute only allows for the first use to be patented.
> *x for the treatment of y1* - is not appropriate because this form of claim is a method of medical treatment, which is excluded.

Enter the artifice of the Swiss-type use claim, which was set up in the form of:

> *use of compound x in the manufacture of a medicament for the treatment of the disorder y1* – can be patented.

The Swiss-type use claim in this form is a version of the 'method of medical treatment claim' except that the addition of *manufacture of medicament* allows these claims to escape the explicit exclusion because it alludes to an industrial use. If it has industrial use, it cannot be a method of medical treatment because methods of medical treatment do not have industrial application. This coiled reasoning opens the way for one of patent law's black boxes.

What about the novelty of this kind of claim? The manufacture of the medicament itself does not have to be a new method of manufacture because the novelty of the Swiss-type claim here is, in the words of the EPO 'derived by analogy from the new therapeutic application rather than the process of manufacturing the medicament.'[50] Novelty by analogy, or a notional novelty that

---

[47] See generally T. Piper, n 28 above.
[48] Art 52(4) was replaced by Art 53(c) in EPC 2000.
[49] In itself a controversial conclusion. Prior to the EPC 2000 amendments, a number of commentators have noted that often 'the evil sought to be avoided – a monopoly on a healing art – is a necessary pre-condition for the good sought – the specific advance in medical science' (G. F. Burch, 'Ethical Considerations in the Patenting of Medical Processes' (1987) 65 *Texas Law Review* 1139, as cited in T. Martin, 'Patentability of Methods of Medical Treatment: A Comparative Study' (2000) 82 *Journal of the Patent and Trademark Office Society* 381).
[50] Enlarged Board in G5/83 (second medical indication) [21]. Further, 'it is to be clearly understood that the application of this special approach to the derivation of novelty can only be applied to claims to the use of substances or compositions intended for use in a method referred to in Art 52(4) EPC'. In other words, a notional concept of novelty 'that could not be transposed' (G2/08 (Dosage regime/ABBOTT Respiratory) [III.4]).

cannot be transposed,[51] is in effect a way of saying in the patent world and in patent language, that we now treat certain kinds of old things as new.

In the aftermath of *Eisai/Second Medical Indication* and the acceptance of Swiss-type claims, something remarkable trickled through. Follow-up decisions began to accept '*mere distinguishing features'* other than treatment of a different disease as constitutive of novelty. Thus a new dosage regime, new class of patients being treated, new modes and routes of administration of a known substance[52] have all been considered to be 'distinguishing' enough to confer novelty. Swiss-type use claims thus prised open the door for claims which were based on nothing more than new information (sometimes of the kind that may be obtained by a doctor in the course of administration of a drug) about known things.

What is the net effect of this type of subject matter in the real world? The cost of finding out more about something that has already been tested for safety is marginal compared to the cost of inventing and testing a completely new chemical product. Pharmaceutical companies can now claim multiple layers of property rights over the same thing, in a process that admits usurious rent-seeking behaviour.

Swiss-type use claims, particularly those that allowed new dosage regimes to be protected[53] were proving difficult to justify in judicial reasoning and given the understandable difficulties in using a nonsensical method of claiming for commercial prospects, the EPO was forced to contemplate a resolution. In a move that heralded the death of the Swiss-type use claim, they adopted a two-step process – one of which was immensely more justifiable than the other but taken together formalised the textualised version of law detailed here.

The first step involved changing the exclusion of methods of medical treatment from being excluded on the grounds of not being industrially applicable, to just being excluded in the revised EPC 2000. Thus '*methods of medical treatment are not patentable*.'[54] This was sure to be welcomed by national courts as it had become difficult to reason this exclusion as though it were a matter of legal interpretation rather than direct policy.[55] Rather disingenuously, this change was denoted as 'a mere editorial change' without substantive legal content.[56]

---

[51] ibid.

[52] See list of TBA cases in G2/08 (Dosage Regime/Abbott Respiratory). In particular see T102/03 (Method of administration of IGF-I/GENENTECH INC) and T2003/08 (Dilated cardiomyopathy/EDWARDS) as cited in Suleiman Ali 'Swiss-type Claims and Double Patenting: Of Opportunities and Anomalies', available here: http://ipkitten.blogspot.co.uk/2014/05/Swiss-type-claims-and-double-patenting.html (last accessed 16 February 2015).

[53] Since *Wyeth* [1985] RPC 545 and *Bristol-Myers Squibb v Baker Norton* [2001] RPC 1, Swiss claims have been accepted in the UK although the UK has stopped short of accepting dosage claims as novel. In *Actavis v Merck* [2008] EWCA Civ 444, the Court of Appeal reversed its previous binding decision to accept new dosage regimes as being novel for the purposes of a Swiss claim.

[54] EPC, Art 53(c).

[55] In *Eli Lilly's and Co's Application* [1975] RPC 438, the court stated that 'the reasons for such an exclusion appear to us to be based in ethics rather than logic'.

[56] According to point 6 of the explanatory remarks concerning 'transitional provisions' the shifting of the former provisions of Article 52(4) of the EPC 1973 to the new Article 53(c) of the EPC 2000 'does not change the actual legal position' (OJ EPO 2001).

Once this had been done, it frees up patent applicants from the straightjacket of the Swiss-type use claim format, because now there is no need to claim it in the form of 'manufacture of a medicament'. Another amendment was introduced to explicitly allow 'use' claims. Article 54(5) states:

> Paragraphs 2 and 3 [of Article 54 of the EPC] shall also not exclude the patentability of any substance or composition referred to in paragraph 4 [any substance or composition, comprised in the state of the art] for any specific use in a method referred to in Article 53(c) [methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body], provided that such use is not comprised in the state of the art.

To put this provision in other words, the exclusion of methods of medical treatment from patentability will not prevent the further patentability of specific uses of already known substances, because these have now been formalised as 'new'. Taken together, the two amendments pave the way for claims on new uses of known (patented) substances in the form '*Use of x for use in medical treatment of y*' – now called the medical use claim.[57]

Art 54(5) effectively culls the Swiss-type use claim, but like the dragon serpent hydra that produces two new heads for each that is decapitated, it has produced two legislative changes that confirm what the textualisation through claim format intended to achieve. Interestingly, now that this consequence has been confirmed in the EPC, the UKIPO has moved to express how unworkable Swiss-type claims were in the first place. Thus:

> Specifically, Swiss-type claims are considered to be unclear because, although they define a method of manufacturing a medicament, the invention does not in fact relate to the method of production but instead relates to the intended use of the medicament. As stated in G02/08, there is no functional relationship between the feature conferring novelty (the intended use) and the claimed manufacturing process. As Section 4A(4) now allows a simpler and clearer form of second medical use claim, there is no longer a reason to allow the more ambiguous Swiss form of claim.[58]

In other words, the novelty of the claim comes from the intended use of the product and not the method of manufacture. Everyone knows therefore that there is no logical link between the novelty feature and the manufacturing process that is claimed. This is an admission that such claims were hard-to-justify anomalies.

---

[57] See Examination Guidelines [7.1].
[58] UKIPO Practice Note 26 May 2010.

The Swiss-type use claim, despite its convoluted history and text, is a successfully textualised outcome. Several jurisdictions allow such claims and others have recently introduced them including Singapore in 2011[59] and New Zealand in 2009.[60] In Thailand following a decision to reject Swiss-type use claims in 2011[61] such claims are no longer entertained, and more recently new Examination Guidelines from the Indian patent office appear to take a skeptical view of new uses of known substances.[62]

The irregularity of the Swiss-type use claim is highlighted by two recent developments that potentially go to the very heart of access to affordable drugs. In *Warner-Lambert v Actavis*,[63] the claimant's patent on Pregabalin for treatment of neuropathic pain was in a Swiss form, being the third medical use of the pharmaceutical in question. Meanwhile, the use of the same substance for the earlier two medical uses had fallen into the public domain and several generic versions of this drug were available on the market.

Warner-Lambert wanted the scope of its Swiss claim patent to extend to preventing the use of the generic version in the public domain for treating neuropathic pain. The only way to effectively do this would be to constrain the pharmacist or the prescribing doctor from encouraging the use of the cheaper generic drug for the purpose covered by the patent. Arnold J rejected the injunction and saw the claim 'use of [Pregabalin] for the preparation of a pharmaceutical composition' as being directed to the manufacturer such that a prescriber or dispensing pharmacist could not be forced to take positive steps to prevent another non-patented version being used for treatment of neuropathic pain.

A recent EPO decision however may spell the end of the limitation to the scope of the Swiss use claim Arnold J sought to achieve in *Warner-Lambert*. An Enlarged Board of Appeal has held that Swiss-type medical use claims are not directed to the same subject matter as the new medical use claim, as a result of which an applicant can have two European patents covering the same use. This is an odd position given that the new medical use claim was in fact introduced to replace the old Swiss-type use claims. This potentially opens up the possibility of

---

[59] The Singapore Patents Act is closely related to the Patents Act 1977. See Examining Guide from the Intellectual Property Office of Singapore. Available here: https://www.ipos.gov.sg/Portals/0/Patents/Examination%20Guidelines%20for%20Patent%20Applications%20at%20IPOS_Feb%202014.pdf (last accessed 16 February 2015).

[60] See Intellectual Property Office of New Zealand Guidelines available here: http://www.iponz.govt.nz/cms/patents/patents-act-1953/patent-topic-guidelines/5.-examination-of-patent-applications/5.2-guidelines-for-the-examination-of-Swiss-type-claims (last accessed 16 February 2015).

[61] Available here: http://www.mirandah.com/pressroom/item/309-the-end-of-Swiss-type-use-claims-in-thailand (last accessed 16 February 2015).

[62] 'Further, it should be borne in mind that finding the new property of an already known substance does not make the substance novel and/or inventive.' Available here: http://ipindia.nic.in/iponew/draft_Pharma_Guidelines_12August2014.pdf [6.2] (last accessed 16 February 2015).

[63] [2015] EWHC 72 (Pat).

the same invention being covered by two patents – one claiming a Swiss-type use claim, and a newer patent using the new medical use claim.

In a move that further suggests the foreclosing of the lack of coverage identified by Arnold J in the old Swiss-type claim, the Enlarged Board in G2/08[64] appears to indicate that the rights conferred by a medical use claim are 'likely broader than those conferred by a Swiss-style claim' and 'could, in particular lead to possible restrictions on the freedom of medical practitioners to prescribe or administer generics.'[65] In a concession however, the Enlarged Board goes on to say that:

> in view of the clear provisions of Art 53(c) second sentence, and 54(5) EPC the intention of the legislator, the Enlarged Board has no power to broaden or reduce in a *praetorian way* [emphasis added] the scope of these provisions.[66]

This statement perhaps is an accurate indication of the new direction the medical use claim can be expected to take. Decisions like that in *Warner-Lambert* are merely likely to hasten this development.

Textualisation seen through the lens of the Swiss-type use claim highlights the role of the EPO as quasi-legislator, interpreter and enforcer all in one – leading to extraordinary power to direct and implement far-reaching changes through a process of textualisation of substantive claims. Ideally, textualisation can be used to give effect to legal standards in a benign and neutral manner that does not either add or take away from the substance of the law. The history and evolution of the Swiss-type claim to the medical use claim is an example of how institutional agents, here the EPO, can use textualisation to give velocity to particular versions of contested legal standards.

INDUSTRIAL APPLICATION

The third example of textualisation demonstrates both multiplicity of terms as a tool of persuasion and institutional agency directing convergence in meaning. We start with the patentability criterion of 'use' – what is the invention useful for? In the Patents Act 1977 and the EPC, the term that is used is 'industrial application'. This patentability criterion has recently undergone a transformation, driven in part

[64] Dosage Regime/ABBOTT RESPIRATORY G2/08.
[65] [6.5] In contrast, Jacob LJ in *Actavis v Merck* observed that the Swiss use claim 'is not aimed at and does not touch the doctor – it is directed at the manufacturer', n 53 above [75].
[66] [5.9].

by the human genome project and by the textualisation that accompanied efforts to find a resolution.[67]

Prior to the human genome project industrial application was the provincial equivalent of a quiet night in – it was relatively easy to fulfill as most inventors had a use for their inventions that they were then required to disclose in clear and unambiguous terms to be understood by a person skilled in the art. Industrial application most often caught out fantastical inventions like perpetual motion machines, that could not be made to work and therefore had no 'use' that could be satisfactorily disclosed.[68]

Gene sequence patents opened a Pandora's box because it became possible to claim or attempt to claim genetic material that only had speculative uses, disclosed in some cases as a list of unverified possible uses, or uses that draw on an established use on the basis that the invention is credibly related to that established use, or a use that it is to become the subject of further study (the research use). These kinds of uses challenged conventional parameters of 'industrial application'.[69]

Unprecedented subject matter usually presents an opportunity for renewed legal reasoning or reasoning based on workable analogies or purposive implementation of the law. A functional approach to the law would ask whether speculative uses fit, or could ever fit, the purpose of patent law – to reward inventors who contribute something useful to society.

The UK Supreme Court (SC) had the opportunity to consider a solution proposed by the EPO – the adoption of the *specific*, *credible* and *substantial* standard, itself borrowed from the US law of 'utility'. The SC explicitly rejected this standard, observing that it was not suitable for the statutory term applicable here – industrial application – although it accepted that there may in practice be considerable similarity. Thus:

> The analyses in the US cases deserve great respect, and it is interesting to note that, in *Fisher* 421 F 3d 1365, the US Court of Appeal referred to a requirement that 'an invention is useful to the public as disclosed in its current form' as opposed to 'prov[ing] useful at some future date after further research', and that the invention 'can be used to provide a well-defined and particular benefit to the public.' *However, there are obvious risks in relying on US jurisprudence when considering the precise nature of the requirements of Article 57* [emphasis added] in relation to a claim for a patent for biological material under the EPC.[70]

---

[67] I examine the development of this multiplicity of terms in US law here, although at the time I did not call it 'textualisation' - S. Thambisetty, 'Legal Transplants in Patent Law: Why Utility is the New Industrial Applicability' (2009) *Jurimetrics* 155-201.

[68] UKIPO examination guidelines [4.05.1].

[69] n 67 above.

[70] *Human Genome Sciences v Eli Lilly and Co* [2011] UKSC 51 [38]-[41].

Conversely, having said this, the court then went on to confirm multiple terms that echo *specific*, *substantial* and *credible* derived from EPO Technical Board of Appeal decisions, ignoring the fact that the EPO has used the US terms for a number of years.[71] The SC did not ask questions about the provenance of the terms in the EPO's usage but accepted them as a given – refusing in effect to entertain the 'deeply flawed'[72] nature of such reasoning or 'obvious risks' in use of such terms without statutory grounding in European law.[73] Remarkably, the SC lists fifteen different 'general' principles derived from EPO case law that can be used to support 'industrial application' in a patent application. With some paraphrasing, here then is a list of terms that would meet the requirement of patentability:[74]

> A practical application;
> Plausible use;
> Reasonably credible use;
> Educated guess will suffice;
> Some profitable use that can be expected to lead to some commercial benefit;
> A concrete benefit derivable from the description;
> A real as opposed to a purely theoretical possibility of exploitation;
> Plausible and specific possibility of exploitation can be at the biochemical, the cellular or the biological level;
> Merely speculative use will not suffice;
> Vague and speculative indication of possible objectives that may or may not be achievable will not do;
> The absence of any experimental or wet lab evidence of activity of the claimed protein is not fatal;
> Disclosure is 'important to the pharmaceutical industry'; the disclosure of the sequences of the protein and its gene may suffice, even though its role has not 'been clearly defined'.

In this particular case the multiple ways in which a patent applicant may clothe his claims using varying degrees of speculation is the equivalent of playing musical chairs with more chairs than players. For the patent applicant, the chances of acquiring the cover of one or the other term are very high. Yet, the compilation, loosely held together, tells us very little about how each term fulfills the requirement of 'industrial application' in UK and European law. Each of the relevant terms in this list is supported by a number of citations to Technical Board

[71] Since the 2002 T1191/01 (V28 receptor/ICOS).
[72] n 67 above.
[73] above para.
[74] Wording from the fifteen 'principles' listed in *Human Genome Sciences v Eli Lilly and Co* [2011] UKSC 51.

of Appeal decisions. This appeal to 'higher'[75] and more numerous allies is an *argument from authority*[76] – it pits authority of a multitude of supportive citations, against reasoned or purposive analysis of legal standards.

Given that there are different bodies interpreting the same statute, but no clear hierarchy amongst them, UK courts have increasingly relied on the desirability of harmonising positions with the EPO.[77] Here too, the SC justifies the principles because they stem from the same statute. But rather than satisfy itself of this fact, all that the court establishes is that these principles emanate from the EPO's decisions. To know whether they are genuinely borne of principled reasoning from the statute, one has to unpack each of the decisions cited to support the fifteen principles. There is a hub and nodes at the end of the spoke but the spokes themselves are missing. A classic black box has thus been created.

Crucially, and perhaps to temper the artifice of harmonisation, the SC reserved the right to disagree with the weight of evidence that is presented under each term:

> Thus, the EPO (or another national court) and a national court may come to different conclusions because they have different evidence or arguments, or because they assess the same competing arguments and factual or expert evidence differently, or, particularly in a borderline case, because they form different judgments on the same view of the expert and factual evidence. Further, while national courts should normally follow the established jurisprudence of the EPO that does not mean that we should regard the reasoning in each decision of the Board as effectively binding on us.[78]

This process of reserving a sliver of discretion mutes the possibility of strong disagreement. Here, institutional processes have created a strong pull towards mimesis and converged meanings are achieved through the textualisation of the law. In terms of rhetoric and persuasion, it uses a positive and a negative modality to strengthen the argument for the multiplicity of terms now introduced into UK patent law. The highest appellate judicial authority has been forced to act, I would argue, uncharacteristically, leaving large swathes of the judgment unreasoned and propelling textualised versions of industrial application in good faith that these principles are appropriately derived from the statute.

---

[75] Clearly there is no de jure hierarchy between the TBA and the SC, but the push to harmonise positions with the EPO has resulted in higher appellate courts in the UK deferring to legal positions stated by the EPO, even against their own better legal judgment in some cases. For instance see *Actavis v Merck* (n 53 above), and *Symbian v Comptroller General of Patents* [2008] EWCA Civ 1066.

[76] n 11 above, 31.

[77] In a number of recent decisions of the House of Lords, attention has been drawn to 'the importance of UK patent law aligning itself, so far as possible, with the jurisprudence of the EPO (and especially decisions of its Enlarged Boards of Appeal)', to quote Lord Walker in *Generics (UK) Ltd v H Lundbeck A/S* [2009] UKHL 12; [2009] RPC 13 [35].

[78] n 70 above [85].

THE POLITICS OF TEXTUALISATION

Language both constrains and enables institutional choice, and textualisation as a process demonstrates how those choices are expressed and prevail. Examination Guidelines are drafted in order to reflect and give effect to legal standards, but because these texts emerge from mostly invisible institutional processes it can become a pliable medium giving specific direction to contested legal standards.[79] The rhetorical processes described here are not isolated instances; several of these play out simultaneously and staged transformations of contested positions to legal axioms are occurring all the time.

The three examples here are all controversial matters of deep public relevance. The increased patentability of diagnostic methods, pharmaceutical claims and patentability of gene sequences are active spheres of contention between patent offices, national courts, emerging economies with newly introduced patent systems, civil society activists and policy makers. Monopolisation of such subject matter through patents often translates to control over price and therefore access to affordable health care or life-saving or life-enhancing technologies. Patents that are perceived to be unjustifiably granted and to fall outside the purposive grant of such rights are increasingly seen as beacons of income inequality. Some degree of artifice in reasoning is common in the law, but constructed meanings that only make sense within the hyper-contextualised domain of technolaw create genuine predicaments for law and reason.

There are at least three significant and inter-related concerns about rule-making that emerge from the analysis in this paper. The first arises from acknowledging that a law that is not transparent cannot be scrutinised for legitimacy. Questions and concerns about legitimacy[80] of the law suffuse every stage of decision-making in all but the most acute positivists' world-view.[81] Clearly it is not possible to check or even necessary to establish legitimacy for every decision made in law, but it should be within the realm of possibility to undertake that enquiry. In order to keep open the possibility of enquiries into legitimacy, we need a law that is scrutinisable for method and content and that can be retraced to assess its source, contrivances and meaning. This scrutiny is manifestly difficult when the terminology used in a legal disagreement is itself opaque and its origin in

---

[79] Other subject matter that could be exposed to similar analysis includes synthetic biology claims, where opportunistic patent applicants seeking protection for unprecedented subject matter can be expected to pioneer broad claim formats (see S. Thambisetty, 'The Learning Needs of the Patent System and Emerging Technologies: A Focus on Synthetic Biology' (2014) *Intellectual Property Quarterly* 1, 13-39) and claims relating to 'essentially biological processes' that have been revised to include protection for an aspect of plant biotechnology that was hitherto considered unpatentable (Tomatoes/Broccoli II cases G02/12 and G02/13).

[80] I use this term to imply the outcome of processes that are constitutive of good law - one that comes from a legitimate source prescribed by statutory power, that is purposive, principled and proportionate; and above all that can be scrutinised for substantive content and methodological clarity.

[81] An interesting review of the role of legitimacy in legal positivism is in D. Priel 'The Place of Legitimacy in Legal Theory' (2011) 57 *McGill Law Journal* 1.

legal reason all but impossible to retrace. The ciphers that become a shorthand for legal reasoning, and constructed meanings that make up internal benchmarks of rationality[82] prevent critical theorists, legal philosophers and civil society activists from engaging with the content of patent law.

Secondly, what should we make of the agency of the actors that initiate, participate and perpetuate textualisation? Knowledge and ambiguity in language enable agents to make a choice between alternatives; and therefore change the distribution of power within a system.[83] Rhetoric or linguistic modalities can be used to construct the appearance of knowledge (for example, identifying 'phases' of diagnostic methods) or institutional myths (for example, the idea of notional novelty) in order to provide meaning and apparent legitimacy to organisational practices.[84] Textualisation centralises an agentic view of patent law that enables us to focus more productively on institutional processes (for example, how claim formats come to be) rather than outcomes (for example, is something patentable or not patentable). Others have noted the formation of an epistemic community in the patent system,[85] and the expertise barrier,[86] or how patent offices have moved to fulfill demand and supply in regulation;[87] but more work is urgently needed from critical theorists and empiricists to integrate institutional processes, including textualisation, in narratives of agency and power in the patent system.[88]

Patent offices, including the EPO, are not normally staffed by lawyers or judges with legal training, but by technically qualified examiners who commonly work with documentary evidence – texts. They do not generally interrogate the material or viewpoints through adversarial processes like cross-examination or evidence-weighting, where the push and pull of an argument becomes much more evident. It seems apt therefore that patent offices are familiar and skilled in the heuristic of textualisation as the preferred mode of persuasion.

A new frontline of concern is the Unitary Patent Court, which is expected to begin work sometime in 2016. The EPO is driving the many changes needed to

---

[82] An example of such an internal benchmark is 'certainty' or 'consistency', such that conforming to particular definitions itself becomes a test of rationality, irrespective of what that standard says or does in the law. Particularly relevant in this context are the insights of P.J. DiMaggio and W.W. Powell, 'The Iron Cage Revisited: Institutional Isomorphism and Collective Rationality in Organizational Fields' (April 1983) 48 *American Sociological Review* 2, 147-160.

[83] See Alvesson, n 23 above.

[84] M. Alvesson, 'Organizations as Rhetoric: Knowledge-intensive Firms and the Struggle with Ambiguity' (1993) *Journal of Management Studies* 30, 997–1015, at 1003.

[85] S. Thambisetty, n 79 above.

[86] S. Parthasarathy, n 4 above.

[87] C. Long 'The PTO and the Market for Influence in Patent Law' (2009) 157 *University of Pennsylvania Law Review* 1965.

[88] Indeed, a number of newly established patent offices do not have publicly available patent Examination Guidelines – a feature that is a manifestation of uneven power in the patent system (See M. Chon, 'Intellectual Property and the Development Divide' (2006) 27 *Cardozo Law Review* 2821-2912). The World Intellectual Property Organization website, for instance, shows only a handful of developing countries as having published patent examination guidelines. India recently made available pharmaceutical patent guidelines for public consultation. Undertaking the process of drafting such guidelines close to ten years after the introduction of pharmaceutical product patents may be seen as a coming of age of the Indian patent system, irrespective of the content.

establish and run such a court, including training workshops for putative judges.[89] It seems somewhat inevitable then that textualisation will leak into the judicial culture of the new court and, once set, will become increasingly difficult to shift, particularly given the complex court structure that, although unified, straddles vastly different legal and judicial systems and cultures. This is the single greatest threat to reason and purpose in European patent law within the context of the new court.

Other commentators have pointed out how the unitary patent package is 'schizophrenic'[90] (because of the push to remove the court from the EU legal framework) or those orchestrating it are 'the patent microcosm'[91] (referring to the narrow epistemic community that has formed at the European level led by the EPO). What this paper demonstrates is that those aspersions are not entirely off the mark, and must create pause for thought amongst jurists who understand the role and purpose of law, even patent law.

Thirdly, patent Examination Guidelines are now an important tool in taking advantage of international treaty flexibilities; they are consequently crucial to the de facto harmonisation of trade-related patent rights. The TRIPS Agreement prohibits the making of special standards for specific kinds of subject matter because it has a non-discrimination provision. This, however does not extend to 'differentiation', which is a more subtle process where legal standards are de facto applied in a technology-specific way.[92] Although differentiation in patent law is itself regarded as a legitimate and necessary to make the law operational, textualisation is one of the processes through which differentiation can be actualised. While the examples used in this paper all show heightened standards of protection, in the context of severe disparities in international norm-setting power,[93] a newly established patent office in a developing country could also use textualisation to lower or tailor standards of protection. The extent of differentiation that can be unveiled via textualisation will depend on the confidence of a patent office and as such will signal its negotiating position.

Patent law today seemingly exists in a sealed bubble of expertise that appears to successfully resist all attempts at critical, regulatory or civic oversight. Yet it has a significant role to play in any number of legal and political controversies such as the use of ethically problematic technologies, access to patented medicines and the

---

[89] A dedicated training centre for the Unified Patent Court has been established in Budapest (http://www.epo.org/news-issues/news/2014/20140313.html (last accessed 16 February 2015) and it is expected that the 'EPO, with its long experience in training patent specialists, will offer its expertise and knowledge to facilitate the creation of a new centralised jurisdiction for patents in Europe.'

[90] T. Jaeger, 'All Back to Square One? - An Assessment of the Latest Proposals for a Patent and Court for the Internal Market and Possible Alternatives' (2012) *International Review of Intellectual Property and Competition Law* (IIC) 286.

[91] 'An Inside View of the Patent Microcosm' (http://www.unitary-patent.eu/content/inside-view-patent-microcosm, last accessed 16 February 2015).

[92] See 'Declaration on Patent Protection: Regulatory Sovereignty under TRIPS' (http://www.mpg.de/8132986/Patent-Declaration.pdf, last accessed 16 February 2015).

[93] See M. Chon, n 88 above.

future of climate-ready technologies. Textualisation is a significant phenomenon that is designed to persuade and bind legal conduct, while marching to a distinct rhythm that is depreciative of substantive legal meaning and content. Understanding this phenomenon and resisting its pervasive force may go some way to salvaging the substance of patent law which is otherwise in danger of slipping out of its moorings in the real world.