EXTRACTING THE PRICE OF A PATENT: ENABLEMENT AND WRITTEN DESCRIPTION

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I INTRODUCTION

The patent is a somewhat curious legal creation. It provides exclusivity in an information source – the invention – that is, in economic terms, both free and public. The patent system creates a framework within which this information can be controlled, and this, in turn, enables limitations to be placed upon its supply and use. Information is itself a wayward thing: difficult to tame and coax into proprietary regimen. Economically speaking, it is a non-wasting asset; one whose utility is not lessened by widespread use. Consequently, arguing for the artificial imposition of personal control once information has transitioned from the secret to the public realm requires some forceful justification. As Hermann Rentzsch once noted, it is meaningless for a person to argue theft of an idea (or by extension any other informational good) as this is to complain "that something has been stolen which he still possesses, and he wants something back which, if given to him a thousand times, would add nothing to his possession."¹ The only element that will have been eroded in such a situation is the exclusivity of the originator.

The perils of making an invention public (a necessary and obvious consequence of marketing the vast majority of products that could be covered by patents) whilst failing to contain the inventive information and reduce it to one's possession, are further highlighted when one considers other economic consequences that flow from its definition as an information good. Classical theory would explain that once information has been created there are no further economic costs associated with its use (and, accordingly, its misuse), beyond those of communication and learning.² Therefore, returning to the subject-matter of the patent: once implemented or otherwise disclosed, the invention can (in the absence of legal protection) be freely, and relatively costlessly, copied by others. It is the patent's job to control this secondary use of information, to impose scarcity, and to provide reason to invest in the creation of the subject-matter in the first place.

Structurally speaking, therefore, the patent grant facilitates the formation of property in the subject matter that it protects. As such, it cannot be justified on the basis that invention is inherently someone's property: without the patent system property in an invention simply does not exist. The invention is only property *because* it is protected by a patent, because this imposes a structure of scarcity, and not *vice versa*.

The patent is accordingly not to be thought of lightly. The grant of exclusivity takes from the public a freedom that they were previously at liberty to enjoy. If nothing more, it removes the possibility of exploring and commercialising the selfsame pasture – developing the same

¹ Rentzsch H., 'Geistiges Eigenthum' in *Handwörterbuch der Volkswirtschaft* (Leipzig, 1866) at 334; Quoted from Machlup F., *An Economic Review of the Patent System*, Study No. 15 of the Sub-Committee on Patents, Trademarks and Copyrights of the Committee on the Judiciary, US Senate 85th Congress, 2nd Session, (Washington, 1958) at 22.

² See further the discussion of free and public goods given in Taylor C.T. & Silberston Z.A., *The Economic Impact of the Patent System* (Cambridge, Cambridge University Press, 1973) at 24; Quoting from Arrow K., 'Welfare Economics and Inventive Activity' in *The Rate and Direction of Inventive Activity* (Princeton, NBER, 1962).

prospect³ – that the patentee now asserts as their own.⁴ A price must therefore be paid: the public must be compensated for the inconvenience that the grant of exclusivity imposes upon them. Within a framework that has been developed on an international basis over many hundreds of years, the agreed toll has been standardised. Ignoring the financial, essentially administrative, costs that the patentee must meet in order to secure their grant – bureaucratic costs not fundamentally associated with public inconvenience – the real price of the patent is disclosure. Informing the world of your invention and, critically, providing them with instructions which enable one skilled in the art to replicate it without undue burden.

The remainder of this article considers the birth and development of the specification (the chosen vessel for communicating the invention to the public) and the interpretation of the standards to which is it now held. It briefly examines the genesis of the English patent custom, a system whose roots extend further than any other extant patent regime,⁵ and that in the U.S. – a system grown from an English seed, but which rapidly evolved from its anglicised beginnings. Finally, it discusses the more recent developments in the law concerning enablement, sufficiency and written description concentrating on U.K. and U.S. jurisprudence in this area.

First, however, the context.

II THE FRAMEWORK

In order to gain patent protection in the U.K., U.S. or indeed any of the other national or international patent systems that comply with the TRIPs framework,⁶ an invention must satisfy certain criteria relating to patentability: thus, amongst other things, it must be new, possess inventive step (i.e. be non-obvious) and be capable of industrial application (i.e. have utility).⁷ In addition, Article 29 of the TRIPs agreement requires that:

"an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application."

³ Utilising the nomenclature of Edmund Kitch – Kitch E., 'The Nature and Function of the Patent System', 20 *Journal of Law & Economics* 265 (1977).

⁴ History tells us that this cost is more important than one might otherwise presume. There are numerous examples of inventions, discoveries and breakthroughs being made by independent parties at or around the same time. Probably the most famous example of this phenomenon concerns the tale of the electric telephone, with both Alexander Graham Bell and Elisha Gray independently applying to patent the device on the same day. However, there are many other similar coincidences: Ogburn & Thomas provided what is possibly the first relatively comprehensive study into such 'multiples' in 1922 – see Ogburn W.F. & Thomas D., 'Are Inventions Inevitable? A Note on Social Evolution', 37 *Political Science Quarterly* 83 (1922)– in which they list 148 cases distilled from the fields of mathematics, astronomy, chemistry, physics medicine, biology, psychology and practical mechanics.

⁵ Readers might note that at the time of the genesis of the English patent custom both the potato and tobacco were new 'inventions' within the contemporary understanding of this term. It is important to note, however, that the English custom was not the first patent system: it is generally accepted that the city-state of Venice can lay claim to this accolade. See further, Mandich G., 'Venetian Patents', 30 *Journal of the Patent Office Society* 166 (1948).

⁶ Trade Related Aspects of Intellectual Property Rights (nobody mentions the missing 'A' in the acronym), which came into effect on 1 January 1995 following the Uruguay Round of negotiations under GATT. Ratification of TRIPs is a pre-requisite to membership of the World Trade Organization. TRIPs provides certain minimum standards that a country's intellectual property protection must attain.

⁷ See Article 27 of TRIPs.

The overlaying and interweaving of the patentability requirements creates a rich blanket in which to wrap worthy creations, protecting them from the incurse of others. Together these elements form the foundations of the patent system, their combination underpinning the genesis of the patent *right*: the notion that the applicant is *entitled* to protection from unauthorised competition provided their invention objectively satisfies the agreed criteria and fees are paid. This concept of fair and objective judgment allows separation from the "discretionary and quixotically granted monopolistic privileges"⁸ sometimes awarded in the past, and forms an element of the social contract into which the patentee may be notionally considered to enter with the State upon filing. Thus, bureaucratic property vests in the patentee's application⁹ on the basis of their offer of new and inventive teaching, with a full (although geographically and temporally limited)¹⁰ property right being conveyed upon the invention successfully passing formal examination.

Scarcity is maintained, and property policed, by the textual boundaries formed by the patent's claims – words of the inventor's choosing that demarcate the extent of the patent's protective sphere. In the 38 Member States that contract to the European Patent Convention (the EPC), this is mandated by Article 69 EPC, which explains that the extent of protection shall be determined by the claims as interpreted in light of the description and drawings. Article 84 then adds that the "claims shall define the matter for which protection is sought." In the U.S., a similar provision is found within 35 U.S.C. §112, which states that the "specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

In terms, then, of the protective nature of the patent, the claims are everything. It is only permissible to enclose subject-matter within their embrace that is both patentable, in the sense of being new, inventive, etc.,¹¹ and which gains support from the teaching of the broader specification, supplemented, as and when necessary, by the common general knowledge of the person skilled in the art (the notional skilled addressee, or person having ordinary skill in the art (PHOSITA) at they are sometimes known).¹² Thus, whereas sufficiency is a fundamentally

⁸ Silbey J., "The Mythical Beginnings of Intellectual Property' available at http://www.escholarship.org/uc/item/3gf7h2nz.pdf, the quote is found on p.14. The published version, 15 *George Mason Law Review* 319 (2008), omits "and quixotically granted" from this sentence, which is a shame: some were. See also Bracha O., "The Commodification of Patents 1600-1836: How Patents Became Rights and Why We Should Care' 38 *Loyola of Los Angeles Law Review* 117 (2004).

⁹ In the U.K. by virtue of s30(1) Patents Act 1977 (PA 1977). The European Patent Convention (EPC) deals with this concept within Part II, chapter IV of EPC 2000, i.e. Arts 71-74 EPC 2000. 35 U.S.C. §261 makes similar provision for US patents.

¹⁰ The patent right is evidently limited geographically by the territoriality of the state granting protection. Multiple applications must be made in order to gain protection in multiple states. The temporal limit on the patent is imposed by statute. Accordingly, Art 33 TRIPs provides that the "term of protection available shall not end before the expiration of a period of twenty years counted from the filing date". In the U.K., and all other states contracting to the European Patent Convention, the term of protection is understood as being a *maximum* of 20 years from filing – see, e.g. s25 PA 1977, Art 63 EPC 2000 – patents may, in practice, expire sooner due to the patent holder's failure to pay the relevant renewal fee. There is, however, possibility for limited extension of this term for medicinal or plant protection products if supplementary protection certificates have been issued. See Reg 469/2009 (EC) of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (codified version), and Reg 1610/96 (EC) of the European Parliament and of the Council of a supplementary protection certificate for plant protection products. The US position is dealt with under 35 U.S.C. §154 (term) and §§155 and 156 (extension).

¹¹ The intricacies of the exclusions from patentability are, for the purposes of this article, conveniently forgotten.

¹² See, for example, Arts 83 and 84 EPC 2000, which in turn are based on Arts 5 & 6 of the Patent Cooperation Treaty 1970 (as amended). Similar provisions are found within s14 PA 1977 and 35 U.S.C. §112.

internal, structural, element of the patent, both novelty and inventive step are restrictions imposed upon the claims by external forces. The integrity of the patent, the extent of the claims, will necessarily be influenced by the combination of all of the elements taken together.

Hence the majority of patents will be judged from two distinct points of view: internally on the basis of the sufficiency of disclosure and from an external perspective on the interwoven elements of patentability. Judgments on both will be made in light of the scope of exclusivity adopted by the patentee in their choice of claim language.

III THE RATIONALE AND ITS HISTORICAL DEVELOPMENT

The rationale behind the requirements of sufficiency and enablement, that the patentee must place the public in possession of the teaching that forms the core of their invention, is evidently the consummation of the patentee's bargain with the state. The specification fulfils this requirement by clothing the invention in words of instruction that one skilled in the art may follow. There is evidently an economic, perfectly rational, and natural disincentive to make such a disclosure if it is not explicitly demanded, as describing the invention in a manner clear enough and complete enough for it to be performed will also effectively teach third parties how to compete. Disclosure must therefore be extracted by making it a condition of grant. Accordingly, when the patent's exclusivity expires, and thereby the patentee's monopoly comes to an end, this teaching becomes a legacy for future generations of technologists to enjoy and exploit for themselves. Such is the accepted mantra, arrived at following many hundreds of years of development.

A. Early English Development

The underlying rationale of the system – that the patentee must enrich the state in return for their monopoly – has a very long pedigree indeed. One of the earliest examples of such considerations impacting upon the formulation of state policy towards invention can be found in the approach adopted by the English Crown in the mid-1500s. When the institution of a concerted policy of stimulating domestic industry by the award of letters patent took root in England during the reign of Elizabeth I, the Crown's primary aim was to make the technologically backward State self-sufficient.¹³ Central to the success of this plan was the acquisition of superior technology and know-how from England's Continental neighbours – it being a far more reliable prospect to simply steal another state's technological secrets than to develop one's own from scratch. Accordingly, those areas that had previously "figured most prominently on the list of imports – viz. alum, glass, soap, oils, salt, saltpetre, latten, etc"¹⁴ – were targeted for 'development' in this fashion. The Crown set about, through Elizabeth's First Minister, William Cecil (Lord Burghley),¹⁵ to incite the importation of foreign teaching and expertise by the offer of monopoly power.

The instruction of a native workforce was considered critical to the success of such a plan, and the idea that consideration must move from the patentee to the state was also clearly ingrained

¹³ See Walterscheid E.C., 'The Early Evolution of the United States Patent Law: Antecedents (Part 2)', 76 *Journal of the Patent and Trademark Office Society* 849 (1994) at 855 and Getz L., 'History of the Patentee's Obligations in Great Britain', 46 *Journal of the Patent Office Society* 62 (1964) at 69-71.

¹⁴ Hulme E.W., "The History of the Patent System under the Prerogative and at Common Law', 12 LQR 141 (1896), at 152; also MacLeod C., *Inventing the Industrial Revolution: The English Patent System 1660 – 1800*, (Cambridge, Cambridge University Press, 1988) at 12.

¹⁵ See Walterscheid, 'Antecedents (Part 2)', n13 above, at 855; and MacLeod, *Inventing the Industrial Revolution*, n14 above, at 11.

within the nascent system. Accordingly, clear and distinct expectations were placed on the patentee, which, although the specifics varied from grant to grant, were "nonetheless consonant with the basic premise of developing new trade and industry within the Realm."¹⁶ Nowadays the price extracted by the state for the provision of the monopoly is evidently the requirement for written instruction to teach the populace of the invention and thereby to demonstrate its merit. Elizabethan practice, by contrast, was generally far more direct.

1. 'WORKING' AND 'REVOCATION' CLAUSES – A DOCTRINE OF INTRODUCTION

Clauses were often worked into grants, especially those of foreign artisans, to ensure the enrichment of native industry following the grant of a patent monopoly.¹⁷ The most basic of which were those that required the patentee to 'work' the new art, trade or industry within the kingdom.¹⁸ Strict time limits were often imposed, with the grant being void for lack of consideration if they were not adhered to.¹⁹

As time went on, however, and the policy became more established, the 'working' clause was gradually phased out in favour of a general revocation clause. This allowed the Crown to revoke grants on grounds of their being "generally inconvenient", a simple, but all encompassing, concept easily applicable to a failure to introduce the patented industry within the specified time period.²⁰ The power arose from the fact that the grant of a patent was, at this time, inherently a matter of Royal grace – and the hand that gave could also take away. Despite the potential breadth of the clause, it was mostly exercised in cases of non-use, cases where the grant was made on a false suggestion of novelty, and where the true inventor was discovered to be other than the patentee.²¹ It can be found in patents granted for the next two hundred years.

2. FROM 'INTRODUCTION' TO 'EXPLANATION' AS THE PRICE OF MONOPOLY

The transition from introduction to explanation (or, more accurately, a written disclosure) as the price of monopoly occurred at some point during the eighteenth century in England. Despite a number of potential precursors,²² it is generally accepted that the first enrolment of a true specification of an invention covered by a patent was performed by John Nasmith in 1711.²³

¹⁶ Walterscheid, 'Antecedents (Part 2)', n13 above, at 856-7.

¹⁷ See discussion in Hulme E.W., 'On the Consideration of the Patent Grant, Past and Present', 13 *LQR* 313 (1897), at 314. It was a well-known axiom of English law, relating to all forms of Royal grant, that the "King must not be deceived in his grant", the penalty for contravention of this rule being annulment – for a number of authorities that state this rule see Davies D.S., 'The Early History of the Patent Specification', 50 LQR 86 (1934), at 100. Given the whole point of the patent grant was to see the institution of the relevant manufacture within England, it was taken as given that failure to work the invention within the Realm would lead to annulment. However, as Walterscheid notes (Walterscheid, 'Antecedents (Part 2)', n13, above, at 857) foreigners were "apt to plead ignorance of the English common law!" It was therefore considered expedient to explicitly work such a clause into the grant.

¹⁸ As opposed to merely introducing it.

¹⁹ Other clauses with much the same end took the form of requirements obligating the patentee to employ and train native artisans to practice the trade covered by the grant. See Walterscheid, 'Antecedents (Part 2)', n13, above, at 857, who explains that this type of requirement was usually only applied to foreign patentees in order to safeguard the continuance of the industry should they abscond before the term of their patent expired.

²⁰ Davies, 'The Early History', n17 above, at 102. Also Walterscheid, 'Antecedents (Part 2)', n13, above, at 857.

²¹ Davies, 'The Early History', n17 above, at 103-4.

²² The earliest being an agreement between the Crown and Gerard Honricke, a German sea captain, in which he promised that in return for £300 he would "teache perfectlie by demonstraĉon and practice with the hand without all manner of decipte and falsehood the said arte of makinge salte peter in the moste perfect sorte." This he did,

Nasmith's precise motivation in providing a written description of his invention can only be guessed at. Some commentators have suggested that the most likely explanation was that he sought to make his grant more secure.²⁴ The fear of inventive theft was well grounded, and the path towards the specification had already been tentatively explored in the courts²⁵ and elsewhere in society.²⁶ However, others suggest that because its first mention appears in the report of the law officer dealing with Nasmith's petition it may be deduced that the initiative came from the Crown; the officer requiring a better disclosure before he would issue a favourable report.²⁷ Nevertheless, and whichever holds the greater grain of truth, it would be incorrect to suggest that with Nasmith's patent came a modern approach to assessing the sufficiency of the disclosure. It did not. Indeed for the remainder of the eighteenth century, most of the specifications submitted for enrolment were hopelessly vague by any, let alone modern, standards.²⁸ Accordingly, at this point in time, and for many years after "it is doubtful whether patentees had any clear idea what the function of a specification was or how full and accurate it ought to be."²⁹

However, even though the quality of the disclosures contained in these early specifications was very much in doubt, the practice soon took root, becoming customary in about 1734.³⁰ Four

²⁵ See, for example, *Garill's Case*, a dispute heard in the Privy Council in 1664. For a full account of Garill's dispute see Davies, 'The Early History', n17 above, at 274.

²⁶ In publications such as Sturtevant's *Treatise of Metallica*: Sturtevant, S., *Metallica: or The Treatise of Metallica*, (London, George Eld, 1612) reprinted in Woodcroft, B., (ed) *Letters Patent and Specifications of Letters Patent for Inventions*, (London, Eyre & Spottiswodde, 1858) at 1-40.

²⁷ See Walterscheid, 'Antecedents (Part 3)', n23 above, at 788; and Gomme, n23 above, at 33. The role played by the law officers in the grant at this time was significant. Hulme E.W., 'The History of the Patent System under the Prerogative and at Common Law – A Sequel', 16 LQR 44 (1900), states, at 53, that their influence in deciding patent grant policy began around the beginning of the 17th century. MacLeod, *Inventing the Industrial Revolution*, n14 above, at 48 suggests that in the century after 1660 all modifications in the patent system were made by them in the course of reporting on inventors' petitions. Walterscheid, 'Antecedents (Part 3)', n23 above, at 779 states that by the 17th century the participation of the law officers in deciding patent policy was becoming standard practice.

²⁸ See Adams & Averley, n23 above, at 161; also MacLeod, *Inventing the Industrial Revolution*, n14 above, at 49, who states that the specification, at this time, could be as informative or evasive as the patentee saw fit.

²⁹ MacLeod, *Inventing the Industrial Revolution*, n14 above, at 50.

and it is this document, reproduced in the State Papers for 1561 under the title of "The trew and perfecte arte of the making of Saltpeter to grow in Cellars, Barns, or in Lyme or Stone quarrees" (State Papers (Domestic), Eliz., XVI, 29-31) that Hulme contends is the first example of a specification. See discussion in Hulme E.W., "The History of the Patent System under the Prerogative and at Common Law', 12 *LQR* 141 (1896), at 145, also Hulme, "The Early History of the English Patent System', 3 AALH 117 (1909), at 142. However, as Davies notes, Honricke's claim to the first specification is dealt a fatal blow by the fact that he was never granted a patent, indeed he never asked for one – he just offered to sell his knowledge. See Davies, "The Early History', n17 above, from whence the above quote comes, at 263-4.

²³ In disputes akin to *Garill's case* in the Privy Council in 1664 – see discussion in MacLeod, *Inventing the Industrial Revolution*, n14 above, at 49; Dutton H., *The Patent System and Inventive Activity During the Industrial Revolution 1750-1852*, (Manchester, Manchester University Press, 1984), at 75; Gomme. A.A., *Patents of Invention: Origin and Growth of the Patent System in Britain* (London, Longmans, Green and Co., 1946) at 27; Davies, 'The Early History', n17 above, at 87; Adams J.N. & Averley G., 'The Patent Specification – The Role of Liardet v Johnson', 7 *Journal of Legal History* 156 (1986) at 158; and Walterscheid E.W., 'The Early Evolution of the United States Patent Law: Antecedents (Part 3)', 77 *Journal of the Patent and Trademark Office Society* 771 (1995), at 782.

²⁴ See Hulme, 'On the Consideration of the Patent Grant', n17 above, at 317.

³⁰ Hulme E.W., 'On the History of the Patent Law in the Seventeenth and Eighteenth Centuries', 18 LQR 280 (1902), at 283, states that the first requirement for a specification can be found in a patent of 1716, but that the practice was not uniform until about 1740; Davies, 'The Early History', n17 above, at 89 states that the practice was made customary in 1734 but that there are examples of the requirement being made in 1712, three times in 1716, twice in 1718 and that between 1720 and 1733 a further 15 specifications were required; Gomme, n23

decades later, at least by the time of the decision in *Liardet v Johnson*³¹ in 1778, the courts had clearly acknowledged the death of the doctrine of introduction, requiring instead the enrolment of a specification as the price of the patentee's monopoly.

Liardet v Johnson is a case described by some as a "landmark in the history of English patent law"³² and dismissed by others as insignificant.³³ Whichever view is held, it is certainly noteworthy as "one of the earliest statements by an English judge of the modern requirement that a specification must be enabling."³⁴ Lord Mansfield, charging the jury, famously explained that:

"...[T]he condition of giving encouragement is this: that you must specify upon record your invention in such a way as shall teach an artist, when your term is out, to make it – and to make it as well by your directions: for then at the end of the term, *the public shall have benefit of it*. The inventor has the benefit during the term, and the public have the benefit after... [Where the invention is a composition] the specification must state... the proportions; so that any other artist may be able to make it, and it must be a lesson and direction to him by which to make it. If the invention be of any other sort, to be done by mechanism, they must describe it in a way that an artist must be able to do it."³⁵ (emphasis supplied)

Irrespective, therefore, of whether the case was the first in which the importance of the disclosure was stressed – and as Walterscheid notes, there is at least one earlier case in which Mansfield discussed the adequacy of the specification³⁶ – *Liardet v Johnson* is, at least, evidence of an important step having been taken in the development of patent law. It stresses the importance of consideration moving to the public and firmly reflects the grant's status as a contract with the state in which temporary monopoly is exchanged for benefit accruing from the inventor's knowledge entering the public domain.

By the end of the eighteenth century, *Liardet v Johnson* was settled law, and the patent could finally be said to have started its separation from grants of Crown favour. It had entered the market economy as an item of commerce, and the price demanded for its existence was disclosure.³⁷ By the dawn of the 1800s it had become settled law that this meant the patent should teach the

above, states, at 34, that between 1711 and 1734 (when the practice became customary) 29 of 158 grants had a specification enrolled.

³¹ Reports of the first trial were published in the *Morning Advertiser* and the *Daily Post* on 23 February, 1778, and in the *London Chronicle* and the *Daily Advertiser* the following day. The second trial is reported in the *Morning Post and Daily Advertiser*, *The Gazetteer* and the *New Daily Advertiser* on 20 July, 1778. See Adams & Averley, n23 above, at 174. The case is reported at (1780) 1 Y & CC 527.

³² Hulme, 'On the Consideration of the Patent Grant', n17 above, at 317.

³³ Adams & Averley, n23 above.

³⁴ Walterscheid, 'Antecedents (Part 3)', n23 above, at 797. Although see Adams & Averley, n23 above, at 171 who suggest that the novelty of the case lies in its reliance on the testimony of expert witnesses.

³⁵ Quoted from Hulme, 'On the History of the Patent Law', n30 above, at 285.

³⁶ Walterscheid, 'Antecedents (Part 3)', n23 above, at 797, citing Hulme E.W., 'Privy Council Law and Practice of Letters Patent for Invention from the Restoration to 1794 (continued)', 33 LQR 180 (1917), at 192, for the proposition that Mansfield had previously held a Mr Brand's Patent invalid in 1771 owing to the fact that the patentee had omitted certain material information from his specification

³⁷ Buller J was therefore able to definitively state in 1795 that the "specification is the price that the patentee is to pay for the monopoly." *Boulton & Watt v Bull*, 2 H BL 463, 126 English Reports 651 at 654.

operation of the invention without further experimentation,³⁸ defective teaching being grounds for avoiding the grant.³⁹ Working of the invention was no longer enough.

3. THE SPECIFICATION AS A MARK OF EVOLUTION

Uncertainties concerning the scope and substance of patent rights in England had been evident since before the passage of the Statute of Monopolies 1624, and were to continue for many decades after the advances marked by Nasmith's patent. They were, in many senses, the inevitable result of an evolution within both the patent sphere and society. When the system was conceived during Elizabeth I's reign all grants were semi-contractual agreements between the patentee and the Monarch whereby protection was offered in return for the introduction of new manufacture. The system was relatively parochial, certain industries were targeted by the Crown for development, and the link between petition, grant and enforcement of the patent and the working of the manufacture within the realm was eminently clear. The overall small number of patents, minute by today's standards, and the clear connection that the patent maintained with the exercise of royal favour meant that it was possible to keep an eye on individual patentees to ensure that they continued to uphold their end of the bargain. By the mid-eighteenth century, however, the patenting process had evolved into something altogether different. Whereas "patents originally represented royal privileges issued under the royal prerogative to achieve royal policy goals"40, numerous legal advances, beginning with the decision of Darcy v Allin in 160241 and following on through the Statute of Monopolies 1624,⁴² had made significant steps towards curtailing the Monarch's power in this area. The Civil Wars (1642-51) had also obviously impacted upon the Crown's freedom to dispense favours under the exercise of the prerogative. The combined effect of these developments was to necessitate a shift away from patents being seen as royal privileges and towards their being viewed in the context of the common law and legal rights. The separation from the Crown was further enhanced by the increasing formalisation of the disclosure requirement.

Accordingly, patentees in the post-Nasmith period began to take a far more active role in the definition of their own scope of protection because they were the ones in charge of the drafting of the specification. Suddenly they were the authors of their own fortunes, and this, in turn, allowed focus to be switched from the issuing body to the petitioners themselves. The specification can therefore be seen to have assisted in the disengagement of the patent from its prerogative steeped roots by grafting it onto a bureaucratic, proprietorial, system the like of which we are all familiar. The increasing distance that this placed between the Crown and the grant is significant, as it enabled opponents of the system to begin to voice their complaints, and competitors to challenge the grants, without this being viewed as criticism of the Sovereign *per se.* This, in turn, eventually led to wholesale reform of the U.K. patent system following a bitter struggle against a strong abolitionist movement in the mid-to-late-nineteenth century.⁴³

³⁸ See, for example, *Turner v Winter*, 1 TR 601, 99 English Reports 1274 at 1276.

³⁹ It should be noted that a specification could equally be defective if it included too much as if it disclosed too little. This was especially the case if the superfluous material was thought to be included for the purpose of misleading the public – see Walterscheid, 'Antecedents (Part 3)', n23 above, at 802 where he discusses R v Arkwright, 1 Web. P. C. 64 (1785, Common Pleas).

⁴⁰ Mossoff A., 'Rethinking the Development of Patents: An Intellectual History, 1550 – 1800', 52 Hastings Law Journal 1255 (2001) at 1274.

⁴¹ For a discussion of the case and its legacy see Fisher M., 'The Case that Launched a Thousand Writs, or All that is Dross? Re-conceiving Darcy v Allen: The Case of Monopolies', [2010] *Intellectual Property Quarterly* 356

⁴² Statute of Monopolies 1624, 21 Jac. I cap 3.

⁴³ See further, Fisher M., 'Classical Economics and Philosophy of the Patent System', [2005] Intellectual Property Quarterly 1.

Central to the anti-abolitionists' cause was the idea of the patent as a contract between the inventor and the state. Three of the main treatises extant at the beginning of the crisis, those of Carpmael,⁴⁴ Hindmarch,⁴⁵ and Spence,⁴⁶ went to lengths to emphasise the nature of this bargain. Carpmael, for example, states that the possibility of gaining a patent was:

"...a great incentive to the exertion of ingenuity; as the... [patentee] found themselves rewarded for their labour... and the public were ultimately benefited by being made acquainted with the means of producing the invention, which became public property at the expiration of the term of the grant, or earlier."⁴⁷

As Coulter explains, this view of the patent as a bargain accorded with both the common law and the "exchange" arguments of the classical economists. "Any restrictions that the patent placed upon use of the new manufacture … were temporary ones acceded to by the public in return for the information contained in the written specification."⁴⁸

Hindmarch reiterated this point, rationalising that the only way in which the patentee could have exclusive property in his invention, once it was made public, was by the application of some positive law made with the actual or implied consent of the whole community.⁴⁹ Such consent was deemed to exist because of the benefits that would accrue to society from the publication of the invention; information that, absent the patent system, might have remained secret.⁵⁰ In essence, therefore, the only relevant question to be asked of a particular specification to see if it was worthy was whether it was "such that a mechanist can make the machine from the description there given."

In terms of justifications, this 'exchange theory' enabled the pro-patent lobby to side-step any difficult questions concerning the nature of invention and the inventive process and to claim they were supporting a system that encouraged the dissemination of knowledge. The patent was no longer a privilege meted out by a benevolent/capricious⁵² monarch, it was a simple bargain whereby the inventor agreed to tell the world of his invention in return for a temporary monopoly.⁵³ As John Farey was to state before the 1829 Select Committee charged with

⁴⁴ Carpmael W., The Law of Patents for Inventions, Familiarly Explained, for the use of Inventors and Patentees (London, G. Wightman, 1832).

⁴⁵ Hindmarch W.M, *Treatise on the Law Relating to Patent Privileges for the Sole Use of Inventions*, (London, V&R Stevens, G.S. Norton, and W. Benning & Co., 1846).

⁴⁶ Spence W., *A Treatise on the Principles Relating to the Specification of a Patent for Invention*, (London, V&R Stevens, and G.S. Norton, 1847).

⁴⁷ Carpmael, n44 above, at 3. Quoted from Coulter M., *Property in Ideas: The Patent Question in Mid-Victorian Britain*, (Kirksville, Thomas Jefferson University Press, 1991), at 78.

⁴⁸ Coulter, n47 above, at 78. For a more modern appreciation of the information function patents see Beier F.K. & Straus J., 'The Patent System and its Information Function – Yesterday and Today' (1977) 8 *IIC* 387. Also see, 'The Disclosure Function of the Patent System (or lack thereof)' (2005) 118 *Harvard Law Review* 2007.

⁴⁹ Hindmarch, n45 above, was at pains to point out that patents, regardless of their social utility, were not a natural right of the inventor, rather they were a "matter of favour".

⁵⁰ See Hindmarch, n45 above, at 1; see also Coulter, n47 above, at 79.

⁵¹ See the arguments of Romily and Scott (for the plaintiff) in *Harmer v Plane*, (1807) 14 Ves. (Jun) 130, at 131, who attribute the quote to Lord Eldon, "when Lord Chief Justice", in *Cartwright v Eamer*, (unreported).

⁵² Depending upon which side of the fence you happened to be standing in respect of any given grant.

⁵³ See further, Machlup F. & Penrose E.T., 'The Patent Controversy in the Nineteenth Century', (1950) 10 Journal of Economic History 1, at 26; Dutton, n33, above, at 22, Machlup F., An Economic Review of the Patent System, Study No. 15

investigating the patent system: "The first applicant who is able, and willing, to make disclosure of the secret, ought to have the patent, that is to be given as the price of such disclosure."⁵⁴

B. The Early Position in the U.S.

The development of patent law in the U.S. tells a similar story. Although early custom was heavily based on English practice, the Constitutional mandate provided by Article 1, §8, clause 8 ("to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the Exclusive Right to their respective Writings and Discoveries"), and the creation of a nationwide patent system in the early days of the first Congress⁵⁵ soon took the system in its own direction.

From the outset, the U.S. legislation emphasised the need for a written specification detailing the invention. Section 2 of the Patents Act 1790 accordingly required a

"...specification in writing, containing a description... of the thing or things, by him or them invented or discovered, and described as aforesaid, in the said patents; which specification shall be so particular... as not only to distinguish the invention or discovery from other things before known and used, but also to enable a workman or other person skilled in the art or manufacture, whereof it is a branch, or wherewith it may be nearest connected, to make, construct, or use the same, to the end that the public may have the full benefit thereof, after the expiration of the patent term".⁵⁶

Substantially identical requirements were subsequently made in both the 1793 Act and that of 1836. However, throughout the lives of these three enactments the specification was not only the source of the teaching, it also performed a public notice function warning third parties of the extent of the patent's protective influence. As Justice Story explained in *Evans v Eaton*,⁵⁷ the:

"specification... has two objects: one is to make known the manner of constructing the machine... so as to enable artizans to make and use it.... The other object of the specification is, to put the public in possession of what the party claims as his own invention, so as to ascertain if he claims anything that is in common use, or is already known, and guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented..."58

However, at this point in time, there was not yet any requirement for the patentee to include separate claims within their application; these were only introduced with the Patents Act 1836.⁵⁹

⁵⁵ Patent Act of 1790, ch. 7, 1 Stat. 109 (10 Apr., 1790).

⁵⁸ 20 U.S. 356 (1822, Sup Ct) at 433.

of the Sub-Committee on Patents, Trademarks and Copyrights of the Committee on the Judiciary, U.S. Senate 85th Congress, 2nd Session, (Washington, 1958) at 24; and Coulter, n47 above, at 94-5.

⁵⁴ John Farey in his evidence before the 1829 Select Committee: Report of the Select Committee on the Law Relative to Patents for Inventions, Parliamentary Papers III, 1829 (Command Paper No. 332), at 22.

⁵⁶ Ibid.

⁵⁷ The case reached the Supreme Court in 1818 (16 U.S. 454 (1818, Sup Ct)), and was the first time that a substantive patent issue had done so. The Court remanded the issue for a new trial and it returned to the Supreme Court in 1822 - 20 U.S. 356 (1822, Sup Ct). It is this latter case in which the practice was formally established.

⁵⁹ Readers will note that it was to take another 47 years for a similar requirement to be made in the U.K.. See s5(5) of the Patents Act 1883, which required for the first time that "a specification, whether provisional or complete, must commence with the title, and in the case of a complete specification must end with a distinct summary of the invention claimed."

Thus, when Justice Story was examining the issue in *Evans*, the specification inevitably fulfilled this definitional function – short of directly examining the physical embodiment of the invention itself,⁶⁰ there was nothing else that could do so. Furthermore, even when the 1836 Act made claims a requirement,⁶¹ they initially did little more than serve as guardians of novelty. Indeed it was not until almost 35 years later that they came to occupy their current position and to determine the patents' extent of protection. Accordingly, until the passage of the Patents Act 1870,⁶² infringement was determined by reference to the description in the specification and the drawings alone – the patent being deemed to cover all forms of invention that embraced the principle or mode of operation disclosed in the patent documentation and which gave the same effect.⁶³ The claims were simply signposts utilised to indicate the invention's prominent features and to point out what was novel about the patentee's creation.⁶⁴ With no claims to police the boundaries of protection and constrain the invention, the concept of sufficiency encompassed what would nowadays be considered questions of patentability simpliciter – including whether the patentee had succeeded in distinguishing the old from the new.⁶⁵

Nevertheless, throughout the life of the 1836 Act a slow but inexorable shift in the importance attributed to claim language became evident in the patent jurisprudence. Courts and patentees sought more certainty in the scope of the patent's reach, and claim language became the focus of much debate.⁶⁶ The final act which clearly signalled the claims' ascendance to their current status as the guardians of the patent's boundaries occurred with a subtle change in wording introduced under the 1870 Statute; section 26 of which required that the inventor:

"shall particularly point out *and distinctly claim* the part, improvement, or combination which he claims as his invention or discovery"⁶⁷ (emphasis supplied).

Subsequent Supreme Court decisions highlighted the importance of the claims as a separate and distinct part of the patent and emphasised the value of clear and concise language in order that

⁶⁰ A less than ideal situation given the invention's technical contribution would inevitably be broader than the precise embodiment created.

⁶¹ s6 Patents Act 1836 required that the patentee "particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery". See Hantman R.D., 'Doctrine of Equivalents', 70 *Journal of the Patent and Trademark Office Society* 511 (1988), at 517. Also Takenaka T., *Interpreting Patent Claims in the United States, Germany and Japan* (Munich, Max Planck Institute for Foreign and International Patent, Copyright and Competition Law, 1995) at 6; and Jessup W., 'The Doctrine of Equivalents' 54 *Journal of the Patent Office Society* 248 (1972).

⁶² Patent Act of 1870, ch. 230, 16 Stat. 198 (8 July, 1870).

⁶³ See, for example, the comments of Justice Curtis, delivering the opinion of the court, in *Winans v Denmead* 56 U.S. 330 (1853, Sup Ct) at 342, when he stated: "It is generally true, when a patentee describes a machine, and then claims it as described, that he is understood to intend to claim, and does by law actually cover, not only the precise forms he has described, but all other forms which embody his invention".

⁶⁴ Lutz K.B., 'Evolution of the Claims of U.S. Patents', 20 *Journal of the Patent Office Society* 134 (1938) explains, at 147, that during the period from 1836 to 1870 the claims "rarely, if ever, received consideration on the question of infringement".

⁶⁵ See further discussion in Lutz, n64 above, esp 147-56.

⁶⁶ See Prager, F., 'Trends and Developments in American Patent Law from Jefferson to Clifford (1790-1860)' 6 *American Journal of Legal History* 47 (1962) for a discussion of this trend. See also Prager F., 'The changing views of Justice Story on the Construction of Patents' 4 *American Journal of Legal History* 14 (1960).

⁶⁷ Patent Act of 1870, ch. 230, 16 Stat. 198 (8 July, 1870). Section 6 of the 1836 Act simply required the patentee to "particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery."

the public interest was not impeded.⁶⁸ The 1870 Act also maintained the requirement that the patentee:

"file in the patent office a written description of the [invention]..., and of the manner and process of making, constructing, compounding, and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same; and in case of a machine, he shall explain the principle thereof, and the best mode in which he has contemplated applying that principle so as to distinguish it from other inventions"⁶⁹

Although it may be noted that the language used to form the foundation of the requirement for an enabling disclosure had changed somewhat from that contained in the Act of 1790,⁷⁰ the essential principles were maintained. The specification had to be sufficient to enable a person skilled in the art to perform the invention: enablement was still the price of the patent. This said, with the claims now defining the invention for which protection was sought, and determining the extent of the resultant patent's influence, it might have been thought that the need for the specification to lay claim to, and demonstrate possession of, the inventive concept should either be tied to enablement, or transferred to the claims. This is not, however, what happened.

Accordingly, notwithstanding the changes wrought by the ascendance of the claims as the definitional medium for the patent's exclusive territory, the idea that the specification contributes to determination of the patentee's possession of the invention has been maintained even under a system of peripheral claiming.⁷¹ Notably, the Court of Appeals for the Federal Circuit (CAFC) declared relatively recently, in *Vas-Cath v Mahurkur*⁷², that:

"The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed."⁷³

As Lefstin notes, this might have made sense in the early stages of U.S. patent law but once concepts of "invention" and "claim" became synonymous the logic of possessing the invention under the description should have evaporated.⁷⁴ That it did not is a point to which we return in due course.

⁶⁸ See for example *Merrill v Yeomans*, 94 U.S. 568 (1876, Sup Ct). In which Justice Miller, giving the opinion of the Court states, at 570, that the language of the claim in the instant cases is: "far from possessing that precision and clearness of statement with which one who proposes to secure a monopoly at the expense of the public ought to describe the thing which no one but himself can use or enjoy".

⁶⁹ §26 of the Patent Act of 1870, ch. 230, 16 Stat. 198 (8 July, 1870)

⁷⁰ Reproduced in text accompanying note 56 above.

 $^{^{71}}$ i.e. a system where claims form the outer boundary of protection, as opposed to central claiming – as under the 1836 Act, where the claims simply point out what is new and inventive.

⁷² 935 F.2d 1555 (1991, CAFC).

⁷³ *Ibid.* at 1563-4.

⁷⁴ See Lefstin J.A., "The Formal Structure of Patent Law and the Limits of Enablement", 23 *Berkeley Technology Law Journal* 1141 (2008), at 1197-8.

IV THE MODERN LAW OF SUFFICIENCY AND SUPPORT IN THE U.K.

A. The Statutory Framework

Pre-grant issues of sufficiency and support are currently dealt with under s14 of the Patents Act 1977 (PA 1977). Accordingly, s14(3) requires that "[t]he specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art." Section 14(5)(c) then continues, requiring that the claim or claims shall be "supported by the description." In other words, an application should be rejected if the patentee attempts to claim more than she discloses in her specification. This evidently concurs with the notion that disclosure is the price the patentee pays for their patent. It would make a mockery of the pact between the inventor and the state if the former was able to gain broader protection from the latter than the area that they would bequeath upon expiry of their monopoly.

Any analysis of the sections of the PA 1977 that relate to sufficiency and support must take into account the provisions of the European Patent Convention (EPC) upon which these sections are based. Like so much else of the Act, these sections are "so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of the European Patent Convention".⁷⁵ The precise benefit of translating one overarching statutory provision into another and then proclaiming that it has the same effect as the language that the draftsman eschewed in favour of his own, is somewhat of a mystery – a point often made by Lord Justice Jacob when sitting in the English Court of Appeal.⁷⁶ Nevertheless, s14(3) finds reflection in Art 83 EPC and s14(5) in Art 84.

s14(3) PA 1977 is further reflected in the grounds for revocation of a patent found in s72 – itself based on Art 138 EPC. Accordingly, s72(1)(c) (equivalent to Art 138(1)(c) EPC) refers to a patent being invalid if the "specification... does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art." Thus, the grant can be revoked if the patentee has not provided the consideration required as their side of the social bargain that the patent represents. The issue of over-broad claiming, or lack of support, found within s14(5) has no clear analogue within the grounds of invalidity. This lies in stark contrast to the previous, pre-EPC, position wherein s32(1)(i) of the Patents Act 1949 (PA 1949) allowed objection on the basis that any claim was not fairly based on the matter disclosed in the complete specification. This was generally agreed to mean that the patentee was "not entitled to claim a monopoly more extensive than is necessary to protect that which he has himself (in his specification) said is his invention."77 Blanco-White noted that as well as encompassing claims that were wider than what was new and inventive, this also extended to "any case in which ... it appears that the inventor has not given adequate consideration for the grant."⁷⁸ We shall return to this subject in due course, however, for the present our concentration must rest on insufficiency proper.

⁷⁵ See s130(7) PA 1977

⁷⁶ "To this day I remain baffled, nay flabbergasted, by this convoluted and roundabout way of implementing the relevant provisions of the treaties." Per Jacob LJ in *Shiitz v Werit* [2011] EWCA Civ 303, at [39].

⁷⁷ Blanco-White, *Patents for Inventions* (5th Ed) (London, Stevens & Sons, 1983), at 4-801.

⁷⁸ Ibid.

B. Insufficiency Proper

Insufficiency proper, i.e. the requirement that the disclosure in the specification be adequate to enable the invention as claimed to be performed, now found within s14(3) and s72(1)(c) PA 1977, was also a ground of objection to the validity of a patent under the old U.K. legislation – see, e.g. s31(1)(h) PA 1949 – and had been explicitly so since the Patent and Designs Act 1932.⁷⁹ Prior to this point, the selfsame considerations that Lord Mansfield had laid down in *Liardet v Johnson* were applied directly by force law: a failure to adequately disclose the invention could therefore result in the grant being revoked at common law.⁸⁰ The rule for insufficiency first adopted under a U.K. statutory framework is, accordingly, warmly familiar: in *No-Fume v Pitchford* Romer LJ explained that:

"Specifications very frequently contain mistakes; they also have omissions. But if a man skilled in the art can easily rectify the mistakes and can readily supply the omissions, the patent will not be held invalid. The test to be applied ... [is] this: Can he rectify the mistakes and supply the omissions without the exercise of any inventive faculty? If he can then the description of the specification is sufficient."⁸¹

This approach was to continue practically unchanged under PA 1949 – as Blanco-White explained: "To be proper and sufficient, the complete specification as a whole … must in the first place contain such instructions as will enable all those to whom the specification is addressed to produce something within each claim "by following the directions of the specification, without any new inventions or additions of their own" and without "prolonged study of matters which present some initial difficulty."⁸² Disclosure of the best method of performing the invention was also required under PA 1949, although, as with invalidity for lack of support, this did not make it into the post-EPC statute.

1. CASE LAW ON SUFFICIENCY UNDER THE 1977 ACT

The leading decision in the U.K. on sufficiency of disclosure is that of the Court of Appeal in *Mentor v Hollister*,⁸³ decided in 1992. This was the first decision of a higher court under the 1977 Act in which it had been specifically required to consider the degree of clarity and completeness required of a patent specification. The facts are, thankfully, relatively simple. The patent in question related to a male urinary incontinence device – a one-piece device designed to be rolled over and adhered to the penis and which then drained into a collection bag. The advantage that this had over the prior art was that it was simpler to apply and remove; the prior teaching all pointed towards two-part devices employing separate adhesive tape. Mentor had originally brought an action against Hollister for patent infringement. At first instance, the defendants denied infringement and counterclaimed that the grant was invalid on grounds on obviousness and insufficiency. The judge, Aldous J, held the patent valid and infringed,⁸⁴ and the defendants appealed.

⁷⁹ See s25(2)(h) Patent and Designs Act 1932 – "That the complete specification does not sufficiently and fairly describe and ascertain the nature of the invention, and the manner in which the invention is to be performed."

⁸⁰ See, for example, R v Arkwright (1785) 1 Web. P. C. 64, at 66.

⁸¹ No-Fume v Pitchford (1935) 52 RPC 231, at 243.

⁸² Blanco-White, *Patents for Inventions* (5th Ed) (London, Stevens & Sons, 1983), at 4-502. Citations omitted.

^{83 [1993]} RPC 7.

^{84 [1991]} FSR 557

Before the Court of Appeal, the question of sufficiency was the only live issue – the defendants having conceded that the relevant claim was inventive and infringed. Lord Justice Lloyd, giving the judgment of the Court, explained that the requirement that "the specification should sufficiently and fairly describe the invention and the method by which it [could be]... performed [was]... the price which the inventor pays for his twenty year monopoly."⁸⁵ The Court noted that this had "always been a requirement of our patent law"; adding that disclosure of the best method of performance was no longer demanded of the patentee, this having been abandoned with the passage of PA 1977.

Concentrating solely on the question of insufficiency proper, the Court cautioned against adopting too strict a requirement of disclosure: "Disclosure of an invention does not have to be complete in every detail, so that anyone, whether skilled or not, can perform it."⁸⁶ Lord Justice Lloyd explained that the patent's teaching was addressed to the person skilled in the art, who inevitably approached the question of sufficiency armed with their own understanding based on their common general knowledge. The patent does not, he explained, therefore have to disclose what would be "self-evident" to this person. Nevertheless, then comes the difficulty – where do the boundaries lie between those things that the addressee is expected to do for herself and those things that she must be told? Place the bar too low and the requirement of sufficient disclosure would be robbed of all its significance and the specification turned into an enigma for the addressee to decrypt and solve. Place it too high, however, and the burden placed upon the patentee to minutely explain and instruct others in the performance of their invention becomes too burdensome and potentially renders patents invalid where only minor, easily surmountable, errors or omissions remain.

The Court cautioned itself over adopting any hard and fast rule on the matter, noting that the "language in which such a rule might be couched does not itself admit of precision".⁸⁷ Lord Justice Lloyd explicitly approved of the explanation of this point made by the Judge at first instance when he had noted that:

"In each case, it is a question of fact, depending on the nature of the invention, as to whether the steps needed to perform the invention are ordinary steps of trial and error which a skilled man would realise would be necessary and normal to produce a practical result."⁸⁸

Further, Lloyd LJ explained that there were a great many different words that could be used to describe the steps that the addressee might be required to take once departing from those explicitly laid down in the teaching of the patent. A continuum stretched from "mere practice at one end of the scale, through enquiry, trial, experiment and research at the other, until one reaches the threshold of a fresh invention."⁸⁹ However, the Court acknowledged that the lack of precise boundaries between any of these descriptors – they "shade into each other"⁹⁰ – rendered their utility as definitional markers somewhat dubious.

⁸⁵ [1993] RPC 7, at 9.

⁸⁶ *Ibid.* at 10.

⁸⁷ *Ibid.* at 11.

⁸⁸ Ibid. at 11. Quoting from Aldous J, [1991] FSR 557 at 562.

⁸⁹ [1993] RPC 7, at 12.

⁹⁰ Ibid. at 12.

Nevertheless, appreciating that a working definition was probably required, Lloyd LJ turned to an earlier judgment of the Court of Appeal in *Valensi v British Radio Corporation*,⁹¹ a decision explicitly relied upon in the court below. In the *Valensi* decision, Buckley LJ explained that the notional person skilled in the art, a hypothetical construction of the court, was "not a person of exceptional skill or knowledge", and moreover could not be expected to "exercise any invention not any prolonged research, inquiry or experiment." However, they must be "prepared to display a reasonable degree of skill and common knowledge of the art in making trials and to correct obvious errors in the specification if a means of correcting them can readily be found."⁹²

Notwithstanding that *Valensi* was decided before the passage of PA 1977, Lloyd LJ considered the test laid in the case was "as appropriate" under the current Act as it was before. Nevertheless, he noted that the Judge at first instance's classification of the sort of experiments that the addressee should be expected to conduct in light of this test – "routine trials" – perhaps provided "a surer test of what is meant by "clearly enough and completely enough" in section 72(1) of the Act than the negative test proposed in *Valensi*."⁹³ This approach has been summarised in subsequent decisions as essentially asking: "whether the patent imposes an undue burden on the skilled reader to arrive at a workable prototype of the invention."⁹⁴

On the facts of *Mentor*, the patentee's failure to provide (i) information concerning the adhesive used to affix the device to the body, and (ii) how to select a suitable material to release the adhesive as the sheath was unrolled, were not considered to render the specification insufficient. Both omissions could be remedied by simple trial and error experimentation. The fact that it would have taken significantly more time to create a commercially saleable product which could compete with the plaintiff's was not a relevant consideration. Lord Justice Lloyd noted that it was "only the work involved, and the time taken, in reaching a workable prototype that is relevant for the purpose of testing sufficiency."⁹⁵

Whether defects and/or omissions in the instructions contained in the specification will serve to render a disclosure insufficient is clearly a question of degree. As Floyd J has noted recently, in *Zipher v Markem*: "a specification may present the skilled team with such a combination of defects that, whereas individually no single defect would have stopped the team from being able to perform the invention, in combination they may do."⁹⁶ Furthermore, if the teaching in a document is such that a skilled person following it could find themselves at one of a number of possible end points, some within the scope of the claim and some without, then this is evidently not enabling.⁹⁷

C. The Broad Claim Problem in English Law

As noted, whilst being a valid objection at the pre-grant stage, the requirement in s14(5) that the claims be adequately supported by the description has no direct analogue in the post-grant arena. If mistakes are made, and an unsupported claim issued, what then is to happen following the grant? It is evident that s72 PA 1977 contains a closed list of grounds – such is clear from the

⁹³ Ibid. at 14.

⁹¹ [1973] RPC 337.

⁹² [1993] RPC 7, at 13.

⁹⁴ Per Floyd J in Zipher v Markem [2009] FSR 1 at [425].

^{95 [1993]} RPC 7, at 15.

^{96 [2009]} FSR 1, at [380]

⁹⁷ See Evans Medical Ltd's Patent [1998] RPC 517, at 536-7.

language of the provision on which it is based, and "so framed" as to have the same effect: Art 138 EPC. This states that a European Patent "may be revoked with effect for a Contracting State *only* [on the five grounds that follow]"; and lack of support is not one. Nevertheless, this has not prevented parties, and on occasion members of the judiciary, from attempting to shoehorn the old grounds of revocation into the post-EPC regime: a tactic which has generally been met by a rather stern response from the courts. Accordingly, efforts by the Judge at first instance to resurrect the 'lack of fair basis' as a post-grant objection in *Genentech's Patent*⁹⁸, were wholeheartedly rejected by the Court of Appeal – Mustill LJ noting, for example, that the Judge had "held these claims ... to be bad on a ground which, as all members of this court agree, was beyond his jurisdiction."

Notwithstanding these comments, the dissonance between the grounds of objection pre- and post-grant was the source of consternation for some time following the Court of Appeal's clear statement of principle in *Genentech*. This problem was compounded by a feeling that the European Patent Office (EPO), in particular, was apt to grant claims of very broad scope, especially in the field of biotechnology.¹⁰⁰ How best, then, to deal with these? Attempts to draw the breadth argument into the objection concerning insufficient disclosure under s72(1)(c) of the Act met with resistance in *Chiron v Organon (No. 3)*.¹⁰¹ Following EPO decisions on this matter,¹⁰² the court rejected arguments that the claimants' broad claims were insufficiently enabled by the description, as there was "no dispute that the skilled man could, using his general knowledge and the information in the specification make an embodiment within all the claims".¹⁰³ Mr Justice Aldous therefore considered that the section could not be the "vehicle for the judicial massage that the defendants would wish."¹⁰⁴

Further, inventive, attempts to circumvent the deficiencies in the grounds of invalidity were also met with resistance. Thus, the argument that "if a patentee "got away with" [to be understood as: "was mistakenly allowed"] a claim contrary to s14(5)(c), then that was a relevant matter or consideration when the court was exercising its discretion to allow amendment [of the patent]",¹⁰⁵ was roundly rejected in *Chiron v Organon (No. 5)*.¹⁰⁶ Mr Justice Aldous considered it inappropriate to raise the issue of support for a broad claim when a narrower claim in the patent was to be deleted: explaining that it was not "relevant or right to consider matters which have no nexus with the amendment nor with the cause for the amendment".¹⁰⁷

^{98 [1987]} RPC 553 (Whitford J).

⁹⁹ Per Mustill LJ, [1989] RPC 147 at 260.

¹⁰⁰ See, e.g., the discussion in Roberts T., 'Broad Claims for Biotechnological Inventions', [1994] EIPR 371, and Wibbelmann J., 'Broad Claims: A Nuisance? [1997] EIPR 515.

¹⁰¹ [1994] FSR 202.

¹⁰² Such as Decision T_292/85 GENENTECH I/Polypeptide expression [1989] EPOR 1.

¹⁰³ [1994] FSR 202 at 241. The quote continues with the words "except the vaccine and in vitro cell growth claims", however, these were challenged on the basis of insufficiency proper and not due to the fact of their broad scope. There was no requirement that the skilled man should be able to make all embodiments falling with the claims – see discussion in *Mölnlycke A.B. v. Procter & Gamble Ltd*, [1992] FSR 549, at 600.

^{104 [1994]} FSR 202, at 242.

¹⁰⁵ Chiron v Organon (No. 5) [1994] FSR 258, at 266.

¹⁰⁶ There were 14 cases in this series in total.

^{107 [1994]} FSR 258, at 267.

The broad claim problem therefore remained substantially unresolved until the decision of the House of Lords in *Biogen v Medeva*¹⁰⁸ almost 20 years after the promulgation of PA 1977. By this time, the EPO Boards of Appeal had clarified their understanding of the requirement of sufficiency.¹⁰⁹ Instrumental in this clarification was the decision of the Technical Board of Appeal (TBA) in T_409/91 *EXXON/Fuel Oils*, described by the editor of the European Patent Office Reports as reflecting a

"significant and (it is submitted) wholly desirable back-tracking from the excessively liberal view of Article 84 expressed previously by the Technical Board..."¹¹⁰

In the decision, the TBA held that in order to satisfy the requirements of Art 83 EPC (on which s14(3) PA 1977 is based), the specification must contain sufficient information to enable a person skilled in the art, utilising her common general knowledge, to carry out the invention across the whole area claimed.¹¹¹

Subsequent decisions of the TBA confirmed this approach; so by the time the House of Lords came to consider the issue of broad claims in *Biogen v Medeva*, it was settled that the Boards of Appeal had abandoned their erstwhile more lenient position. The established view was accordingly that, in order to be sufficient, a claim needed to be enabled across its breadth. Lord Hoffmann, providing the leading judgment in the *Biogen* case, took this as his starting point, referring directly to *EXXON/Fuel Oils* he noted that the TBA had held that:

"Article 84 EPC also requires that the claims must be supported by the description, in other words, it is the definition of the invention in the claims that needs support. In the Board's judgment, this requirement reflects the general legal principle that the extent of the patent monopoly, as defined by the claims, should correspond to the technical contribution to the art in order for it to be supported, or justified."

The key, his Lordship noted, was the generality of the claim and the disclosure. If the patentee was able to show that their teaching encompassed a beneficial effect shared in common by all of a class of products, then they would not be barred (on grounds of insufficiency at least) from claiming all within the class, even though they had made only one or two of them. On the other hand, if they "cannot demonstrate that there is a common principle by which that effect will be shared by other products of the same class, [they]... will be entitled to a patent for that product but not for the class, even though some may subsequently turn out to have the same beneficial effect."¹¹² Accordingly, depending on the technical contribution made to the art by the patent, it is not necessarily enough to simply disclose just one way of performing the invention.

On the facts: having invented and disclosed a perfectly good method of producing the hepatitis "B" virus antigen, the patentee had claimed "any method of making a DNA molecule which

¹⁰⁸ [1997] RPC 1.

¹⁰⁹ For the reader not versed in the intricacies of the European patent system, the House of Lords has explained, e.g. in *Merrell Dow Pharmaceuticals Inc v. H.N. Norton & Co. Ltd* [1996] RPC 76, at 82, that decisions of the EPO's Boards of Appeal are "of considerable persuasive authority."

¹¹⁰ [1994] EPOR 149, at 150.

¹¹¹ *Ibid.* at 152.

¹¹² [1997] RPC 1, at 48.

would achieve the necessary expression."¹¹³ Such a broad claim could not be left to stand as it clearly exceeded the patentee's technical contribution to the art. As Arnold J lucidly explained in a recent decision: "The breadth of the claim will exceed the technical contribution if the claim covers ways of achieving the desired result which owe nothing to the patent or any principle it discloses"¹¹⁴ In *Biogen*, this is precisely what had occurred.

The House of Lords revisited the issue in *Generics (U.K.) v Lundbeck* in 2009.¹¹⁵ Lundbeck was the proprietor of a patent for escitalopram, the (+) enantiomer of citalopram (a known antidepressant). The isolated enantiomer had superior properties, and less side effects, than the known racemic mixture. The patent claimed the (+) form of the molecule however it was made, but disclosed only two routes to manufacture in the specification. At first instance the Judge held that this was insufficient, citing *Biogen* as his authority. This conclusion was overturned in the Court of Appeal, a view subsequently endorsed by the House of Lords.

Their Lordships considered it to be a question of identifying the correct technical contribution of the patent in question, and it was a mistake to equate this with the inventive concept. Here, the contribution made by the patent was the provision of the isolated enantiomer – a product – and not the process by which it was made. This was the case "even though the inventive step lay in finding a way to make the product."¹¹⁶ Where the technical contribution was the product itself, it was settled law that the patentee need only explain one route by which it could be made in order to be sufficient. The claim was accordingly not too broad.

Another recent case to discuss the interface between sufficiency and over-broad claims is that of *Novartis v Johnson & Johnson*¹¹⁷ in the Court of Appeal. The facts of the case are admirably summed up by Jacob LJ, giving the judgment of the Court:

"The reader might be forgiven for initially supposing that this apparently detailed list of elements would lead to a monopoly of reasonably defined scope, that each of the elements actually meant something by way of delineating the monopoly. But the reader would be wrong. Upon analysis it turns out that the elements are mostly meaningless and what is left is no more than a claim to a [contact]lens made from two types of polymer, provided it works."¹¹⁸

Not only were the criteria for choosing the constituent components of the substance from which the lens was to be created "extremely wide", but each was also described as having "woolly

¹¹³ Per Lord Hoffmann, [1997] RPC 1, at 40.

¹¹⁴ Per Arnold J in MedImmune v Novartis [2011] EWHC 1669, at [469].

¹¹⁵ [2009] UKHL 12, [2009] RPC 13. The case is not the easiest decision from which to extract a rational consensus. As Arnold J has explained in a recent judgment of the patents court: "The principal speeches were given by Lords Walker of Gestingthorpe, Mance and Neuberger of Abbotsbury. Lord Phillips of Worth Maravers said that they reached the same conclusion for the same reasons, and agreed with all of them. Lord Scott of Foscote agreed with Lord Neuberger. Lord Walker said he understood his reasons to be essentially the same as those of Lords Mance and Neuberger said that he understood that his reasons to be effectively the same as those of Lords Walker and Mance. In these circumstances, it is not easy to quote particular passages from just one opinion as representing the reasoning of at least a majority of the panel." See *MedImmune v Novartis* [2011] EWHC 1669, at [474].

¹¹⁶ Per Arnold J, discussing the case in *MedImmune v Novartis*, [2011] EWHC 1669, at [475].

¹¹⁷ [2010] EWCA Civ 1039.

¹¹⁸ *Ibid.* at [10].

limits" as well. There was, according to the Court, "a lot to be said for the view that the claim should never have been allowed as not complying with Art. 84 of the EPC" – i.e. the requirement for clarity and support. Nevertheless, as Jacob LJ explained, such "[u]ndue width" could be remedied using either non-obviousness, or insufficiency, or a combination of the two.¹¹⁹

The Judge at first instance had found that the skilled person would only know whether they had succeeded in creating something falling within the claims if they conducted "a small scale test on actual people". However, as Jacob LJ explained, it was unclear what effect the failure of such a trial would have. Accordingly:

"...[W] come to an astonishing conclusion. Although the claim has a number of elements, hardly any of them have any significance... In substance the claim amounts to this: 'if you try any pair of polymers, to see if they work (perhaps only after surface treatment) and find anything that does, we claim it."¹²⁰

Moreover, the teaching of the patent was held to give the skilled reader hardly any assistance in determining whether any given combination of polymers would "work" at all – and this notwithstanding that it stretched to 422 paragraphs over 53 pages. "Something fishy", said the Court, had gone on.¹²¹

Being unable to predict from the patent documentation whether any of the examples therein 'worked' or not, the addressee was left with a vexing question: what was he to do? Trial and error would be a major enterprise: the patent suggested selection of two polymerisable materials from two vast classes, with little guidance on proportions and no advice on how to assess if the blend would be successful short of actual trial. If a selection 'worked' then this was all "well and good – but that would tell you nothing about the remainder of the vast ambit of the claim.... If it does not 'work' then the Patent does not help you as to what to do next."¹²²

In essence, therefore, Novartis' patent "did no more than to invite the reader to perform a research program where, if he succeeded, the patent claimed the fruits of his research." This, according to Jacob LJ, was "a long way off from satisfying the sufficiency test".¹²³

This case, perhaps more than any other in recent years, illustrates the difficulty of assessing the quality of the specification without intensively probing the facts and calling for expert evidence on the matter. Indeed, as Jacob LJ noted,¹²⁴ this was a European Patent issued by the EPO and the selfsame specification had survived challenge in at least three other European states, as well as before the TBA. All assumed that the examples given in the patent did, in fact, work; however, this was not actually the case.

In summary, therefore, it would appear that the requirement for support under s14(5) PA 1977 can lay foundation to an invalidity action on grounds of insufficiency where the breadth of the

- ¹²⁰ *Ibid.* at [50].
- ¹²¹ *Ibid.* at [44].
- ¹²² *Ibid.* at [70] and [71].
- ¹²³ Ibid. at [77] and [72].
- ¹²⁴ Ibid. at [62].

¹¹⁹ *Ibid.* at [19].

claim exceeds the invention's technical contribution to the art. As Arnold J explained, following an exhaustive review of the authorities, in *MedImmune v. Novartis*, this may occur in at least two ways:

"[First] where the patent claims results which it does not enable, such as making a wider class of products when it enables only one and discloses no principle to enable the others to be made, and [second] where the patent claims every way of achieving a result when it enables only one way and it is possible to envisage other ways of achieving that result which make no use of the invention."¹²⁵

This is the case notwithstanding that lack of support (or rather lack of fair basis) is no longer a freestanding ground of invalidity under the Act. Nevertheless, by adopting such an approach, the dissonance between pre-and post-grant objections to patentability in this respect has been ameliorated, preserving the integrity of the underlying justifications for the requirements whilst sidestepping the lapse in statutory wording. As such, it is a pragmatic, and eminently more palatable, solution to the broad claim problem than the "judicial massage" suggested in the Act's formative years.

V THE MODERN LAW OF ENABLEMENT & WRITTEN DESCRIPTION IN THE U.S.

The provision within modern U.S. patent law that governs issues of sufficiency and written description is §112 of the 1952 Act (as amended). Paragraph 1 of which requires that:

"(a) IN GENERAL – The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention."

The jurisprudence of the CAFC and its predecessor, the Court of Customs and Patent Appeals (CCPA), has established¹²⁶ that there are three separate requirements contained within this section: (1) enablement; (2) written description; and (3) best mode.¹²⁷ While there will inevitably be a degree of overlap between the three, the CAFC has nevertheless been at pains to note that each is distinct, and none are subsumed within the others.¹²⁸ In terms of their underlying rationales, the three requirements have certainly been supported by the courts on different bases. Whereas the requirement for an enabling disclosure appears predicated upon provision of consideration for the patent grant,¹²⁹ written description has been stated to be a broader concept – requiring the patentee to "convey with reasonable clarity to those skilled in the art that, as of

¹²⁵ [2011] EWHC 1669 at [469].

¹²⁶ Although not without some significant dissent – see e.g. the judgment of Rader J, dissenting from the court's refusal to rehear the case en banc, in *Enzo Biochem v Gen-Probe*, 323 F.3d 956 (2002, CAFC).

¹²⁷ See, for example, *Ariad Pharmaceuticals v Eli Lilly*, 598 F.3d 1336 (2010, CAFC) and *In re Ruschig*, 379 F.2d 990 (1967, CCPA).

¹²⁸ See, for example, the categorical statement of the majority in the en banc decision in *Ariad Pharmaceuticals v Eli Lilly*, 598 F.3d 1336 (2010, CAFC), considered below.

¹²⁹ See comments to this end in *Genentech Inc v Novo Nordisk* A/S, 108 F.3d 1361, at 1366 (1997, CAFC), where Judge Lourie, giving the judgment of the court, explained that "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

the filing date sought, he or she was in possession of the invention."¹³⁰ It has been noted that this rationale was once thought to apply only where the patent's claims had been amended after filing, where there were questions of entitlement to priority from an earlier application, or "where a party asserted that counts in an interference were supported in a specification."¹³¹ However, in more recent years the standard has been found to apply to all claims, whether original or amended.¹³² Best mode is relatively self-explanatory, and relates to a robust understanding of the bargain the patentee strikes with the state. Not only, therefore, must she disclose a method of performing the invention, she must disclose her best.

A. Enablement Proper

As may now be anticipated, the approach taken to the issue of enablement under modern U.S. law is strikingly similar to the formulations adopted under previous statutes. Its core, that the patent is only justifiable if it contributes to society by teaching the invention to those skilled in the art, is immediately familiar. So too is the standard by which enablement is judged: the CAFC *In re Wands*,¹³³ for example, explained that:

"Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation." 134

Notwithstanding, therefore, that the term "undue experimentation" does not feature in the statutory language, it is now well established that this is the standard to be applied. What precisely amounts to undue experimentation will inevitably vary from case to case and will depend on the weighing of a number of factual considerations, having regard to both the nature of the invention and the state of the art.¹³⁵

Judge Newman explained the rationale of enablement in her, part concurring part dissenting, judgment *In re Wands* in the following terms:

"The premise of the patent system is that an inventor, having taught the world something it didn't know, is encouraged to make the product available for public and commercial benefit, by governmental grant of the right to exclude others from practice of that which the inventor has disclosed. The boundary defining the excludable subject matter must be carefully set: it must protect the inventor, so that commercial development is encouraged; but the claims must be commensurate with the inventor's contribution. Thus the specification and claims must meet the requirements of 35 U.S.C. § 112."¹³⁶

¹³⁰ Vas-Cath v Mahurkur, 935 F.2d 1555 (1991, CAFC), at 1563-4.

¹³¹ See Janis M.D., 'On Courts Herding Cats: Contending with the "Written Description" Requirement (and Other Unruly Patent Disclosure Doctrines)', 2 *Washington University Journal of Law & Policy* 55 (2000), at 59-60.

¹³² See comments to this end in Regents of the University of California v Eli Lilly & Co, 119 F.3d 1559 (1997, CAFC), at 1567.

¹³³ 858 F.2d 731 (1988, CAFC)

¹³⁴ *Ibid.* at 736-7.

¹³⁵ *Ibid.* at 736-7

¹³⁶ *Ibid.* at 741.

Thus we see once more that enablement is strongly tied to the scope of the claims, it being settled that one cannot claim more than one teaches.¹³⁷ The notion of avoiding undue experimentation also meshes well with the concept of only allowing routine trial and error experiment to supplement the specification's teaching under U.K. jurisprudence. The policy goals of each system are clearly cut from the same cloth. Both seek to enrich the state of the public domain with the patent's teaching following its expiry, both require instruction of the hypothetical person skilled in the art, and both allow leniency in respect of minor, easily surmountable, errors or omissions.

Nevertheless, the extent of the enablement doctrine's reaches in the U.S. is worthy of further comment. The language found within §112 is important: not only does it require instructions to "make" the patented subject-matter, but it also demands instructions to "use". The nexus between enablement and utility¹³⁸ is accordingly very strong – a point made clear in *re '318 Patent Infringement Litigation*.¹³⁹ The case concerned a patent for a method of treating Alzheimer's disease with a particular (known) compound, galanthamine. Judge Dyk, giving the judgment of the Court, explained the problem that had arisen:

"The specification for the '318 patent was only just over one page in length, and it provided almost no basis for its stated conclusion that it was possible to administer "an effective Alzheimer's disease cognitively-enhancing amount of galanthamine.""

Whilst the specification did provide short summaries of a number of scientific papers in which galanthamine had been administered to humans or animals, in no case were these studies conducted on organisms that showed "physiological changes" similar to Alzheimer's disease. Experimental data suggesting that the compound could be a promising treatment for the disease were only obtained some 2 months after the patent had issued. It was settled that enablement was to be determined at the filing date of the patent's application,¹⁴⁰ and therefore the question before the Court was whether the specification contained sufficient evidence to suggest that the compound would work in the manner suggested. The issue of enablement was accordingly considered to hang on whether the patentee was in a position to prove utility at the filing date. Judge Dyk explained that:

"Allowing ideas, research proposals, or objects only of research to be patented has the potential to give priority to the wrong party and to "confer power to block off whole areas of scientific development, without compensating benefit to the public.""¹⁴¹ (citations omitted)

In the Court's opinion, the specification provided by the patentee, even read in light of the knowledge of those skilled in the art at the filing date, did "no more than state a hypothesis and propose testing to determine the accuracy of that hypothesis. That is not sufficient."¹⁴²

¹³⁷ See, similar conclusions *In re Fisher* 427 F.2d 833 (1970, CCPA).

 $^{^{138}}$ The requirement for which is found in 35 U.S.C. $\S101.$

¹³⁹ 583 F.3d 1317.

¹⁴⁰ Plant Genetic Systems, N.V. v DeKalb Genetics Corp., 315 F.3d 1335 (2003, CAFC), at 1339. See also In re Glass, 492 F.2d 1228 (1974, CCPA), at 1232.

¹⁴¹ 583 F.3d 1317, at 1324.

¹⁴² *Ibid.* at 1327.

B. Best Mode

The robustness of the enablement requirement, and its emphasis as a central doctrine of patent validity, is ostensibly further enhanced by the requirement of "best mode."¹⁴³ The basic principle is straightforward—as well as requiring the invention to be taught to the person skilled in the art, the specification must also disclose the best mode of operation (if any) that the inventor possessed at the time of filing. As such, the information necessary to satisfy this requirement potentially goes far beyond that demanded under sufficiency proper. As the CCPA noted in *In re Gay*:

"Manifestly, the sole purpose of [best mode]... is to restrain inventors from applying for patents while at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived."¹⁴⁴

Nevertheless, recent legislative changes,¹⁴⁵ although stopping just short outright slaughter of the provision, have emasculated this justification (and indeed the requirement of best mode *per se*) by ripping from 35 U.S.C. the effective means for enforcing the requirement post-grant.

Prior to the passage of the Leahy-Smith America Invents Act¹⁴⁶ (the AIA) in late 2011, §112's insistence on the provision of this preferred embodiment was further reinforced by §282. This gave the courts the power, notwithstanding a general presumption of validity, to declare a patent invalid or render it unenforceable for failure to disclose best mode. However, in much the same manner as the transition to a post-EPC statutory regime robbed the UK courts of the ability to hold a patent invalid for 'lack of fair basis' whilst still preserving the pre-grant requirement that the claims must be supported by the description, so too has the AIA neutered best mode. Following the enactment of the statute, §282 has been amended. The relevant part now reads:

"The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

...(3) Invalidity of the patent or any claim in suit for failure to comply with—

(A) any requirement of section 112, <u>except that the failure to disclose</u> the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable;" (emphasis supplied)

Accordingly, in any proceedings commenced on or after 16 September 2011, the effective date for the amendments made by the AIA in this respect, the courts are no longer in a position to enforce 112(1)'s third mandate. Nevertheless, as the first paragraph of 12 remains

¹⁴³ Found in the third paragraph of 35 U.S.C. §112. Although it may be argued that this enhancement is now little more than notional – see the discussion of the changes wrought by the Leahy-Smith America Invents Act ("the AIA"), below. The reader will recall that a similar requirement under U.K. law to disclose the 'best method' of performing the invention, required under the Patents Act 1949, was abandoned with the passage of the 1977 Act. It is not a requirement made of the patentee under the TRIPs agreement, and, prior to the AIA, had been the subject of a degree of criticism in the U.S. *See, e.g.*, Walmsley S.B., 'Best Mode: A Plea to Repair or Sacrifice This Broken Requirement of United States Patent Law', 9 *Michigan Telecommunications & Technology Law Review* 125 (2002).

¹⁴⁴ See In re Gay, 309 F.2d 769 (1962, CCPA), at 772.

¹⁴⁵ Ushered in by the AIA, considered below, in late 2011

¹⁴⁶ "An Act to amend title 35, United States Code, to provide for patent reform", to provide its long title. Pub. L. No. 112-29, 125 Stat. 284 (2011), which will be codified in various sections of 35 U.S.C.

substantially untouched (cosmetic titivation aside), the USPTO has confirmed that the AIA's changes do not, and will not, affect their examination practice in this area.¹⁴⁷

Therefore, even following the AIA's amendments in this respect, best mode remains a pre-grant requirement; the test for which is essentially two-pronged. The first question is subjective:¹⁴⁸ did the inventor possess a best mode of operation at the time the patent was filed?¹⁴⁹ Assuming that the answer to this first question is 'yes', the second stage is the objective enquiry: has the inventor 'concealed' the best mode from the public? As such, best mode stands distinct from enablement proper – which would not necessarily require the disclosure of anything approaching a marketable variant. Walmsley sums the position up with great clarity when he notes that:

"[T]he best mode requirement is a subset that represents the intersection of two larger sets—the written description and enablement requirements. Thus, the best mode requirement is not limited to just the "what" (description requirement) or the "how" (enablement requirement) of an invention. Rather, the best mode requirement may well be thought of as the "what best" and "how best" of an invention."¹⁵⁰

Evidently, therefore, complete failure to set forth any mode at all would be equivalent to nonenablement,¹⁵¹ while concealing the most advantageous method of operation known at the filing date of the application would fall foul only of this 'sufficiency-plus' best mode requirement. However, as the AIA has ensured, once granted, lack of best mode cannot any longer be used as an explicit ground of challenge to an otherwise healthy patent – mistakes of issuance in this respect cannot be remedied *post hoc*.

The practical effects of the amendments made by the AIA in this context are therefore difficult to assess. Whilst best mode has evidently not been entirely scrubbed from the patent landscape, it is now but a shadow of its former self – an old soldier: shell-shocked and broken. However, it is perhaps over-egging the pudding to claim, as some have done, that the changes wrought by the AIA have "effectively eliminated the best mode requirement from patent law".¹⁵² As we have seen with similar changes instituted under English law, the pre-grant requirements for support under s14(5) PA 1977 have become subsumed within general notion of sufficiency – effectively outflanking the deletion of 'lack of support' as a freestanding ground of invalidity in the transition from the old law. It is therefore hard to accept that inventive lawyers will be willing to let best mode simply fade away. To return to the justification for the requirement given in *In re Gay*, its continued relevance to prosecution would suggest, at the very least, the possibility of advancing defensive arguments of inequitable conduct where the inventor has intentionally concealed her preferred embodiment. Accordingly, the old adage may well prove to be true: Old soldiers never die.

¹⁴⁷ See the answers to "AIA Frequently Asked Questions", specifically questions BM2 and BM3, on the USPTO website: <u>http://www.uspto.gov/aia_implementation/faq.jsp</u> (last accessed 24 July 2012).

¹⁴⁸ As confirmed in Northern Telecom Ltd. v Samsung Electronics Co., 215 F.3d 1281 at 1286 (2000, CAFC).

¹⁴⁹ See U.S. Gypsum Co. v National Gypsum Co., 74 F.3d 1209, at 1212 (1996, CAFC).

¹⁵⁰ Walmsley, 'Best Mode', n143 above, at 132.

¹⁵¹ See comments to this end in The Application of Glass, 492 F.2d 1228 (1974, CCPA), at 1233.

¹⁵² See, for example, Petherbridge L. & Rantanen J., 'In Memoriam Best Mode', 64 *Stanford Law Review Online* 125 (2012), at 126-7.

C. Written Description

1. A SEPARATE REQUIREMENT FOR A WRITTEN DESCRIPTION

Finally we arrive at the requirement of 'written description'. This is undoubtedly one of the more controversial aspects of §112 paragraph 1, having spawned a great deal of discussion, both within the courts and without, on the merits or otherwise of separating this requirement from that of enablement proper.¹⁵³ Battle-lines are drawn between those who favour a clear divide, and those who consider written description should essentially be subsumed within enablement itself.

The former group believe that requiring a patentee to demonstrate possession of their invention, above and beyond teaching one skilled in the art how to make and use it, is a necessary demand with an extensive historical pedigree.¹⁵⁴ They explain that this function of the specification can be traced back at least to the Act of 1793, and point to Justice Story's classic statement in *Evans v Eaton*, noted above, as supporting this fact. It will be recalled that Story declared in this case that the specification had two objects. The first was to teach the invention. The other was:

"...[T]o put the public in possession of what the party claims as his own invention, so as to ascertain if he claims anything that is in common use, or is already known, and guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented..."¹⁵⁵

While this statement would appear to support the view taken, it must be recalled that the patent system at this point in time was a very different animal to that which we see today. Most critically: in 1822 claims, our modern-day notice-givers, custodians of the patent's extent of protection, the means by which we now define the invention itself, were simply not required. The task of demarcation, of definition, therefore fell to the specification. As Janis notes: "[r]ead in context, the "possession" language of *Evans* clearly is directed towards satisfying ...[the] notice function, one which the modern description does not require."¹⁵⁶

Sensing, perhaps, that putting too much weight on the historical leg might make the table collapse, proponents of a separate and distinct written description requirement under §112 also attempt to support their argument on broader policy grounds. They explain that whilst it might be imagined that there is little to differentiate describing an invention, on the one hand, and enabling someone skilled in the art to make and use it, on the other, this is not actually the case. There is a gulf of difference, especially in the chemical arts. Circuit Judge Rich attempted to maintain this distinction *In Re Hunter*, where he explained that: "[a] patent specification... may fortuitously enable those of skill in the art to make and use an invention that an applicant did not make before filing the patent"¹⁵⁷ (emphasis in original). Accordingly, "[a]lthough a specification

¹⁵³ Compare, for example, the comments of the majority and of those in dissent in *Ariad Pharmaceuticals v Eli Lilly*, 598 F.3d 1336 (2010, CAFC) (*Ariad II*). Similarly, *Enzo Biochem*, n126 above. Also compare Schroeder J.A., 'Written Description: Protecting the Quid Pro Quo Since 1793', 21 *Fordham Intellectual Property Media & Entertainment Law Journal* 63 (2010) with Janis, 'On Courts Herding Cats', n131 above.

¹⁵⁴ See, for example, the comments of Miller J, in the majority, in *Barker* 559 F.2d 588 (1977, CCPA), at 592-3. See also comments of Rich J in *Vas-Cath v Mahurkur*, 935 F.2d 1555 (1991, CAFC), at 1560-1.

^{155 20} U.S. 356 at 433.

¹⁵⁶ Janis, 'On Courts Herding Cats', n131 above, at 64.

¹⁵⁷ In re Hunter, 59 F.3d 181 (Table) (1995, CAFC), at p.5 of the judgment.

that meets the written description requirement always satisfies the enablement requirement, the converse is not always true."¹⁵⁸

If this is the case, and enablement is always within written description, then one might wonder why we bother having two separate standards at all. Nevertheless, as Janis has noted, it is Rich's reference to 'fortuitous' enablement that is truly "startling", appearing, as it does, to be an invitation for "judges to distinguish between those inventors who deliberately provided information about how to make and use their invention, and those who "got lucky"."¹⁵⁹ Janis continues, asking "what justifies penalizing the inventor" in cases where their teaching enables one skilled in the art to perform an invention that falls within a claim, but has somehow not been demonstrated to have been possessed by them at the date of filing.¹⁶⁰

So there is controversy: but nevertheless the separate requirement of a written description now seems ensconced within U.S. patent law. Judge Linn made the point elegantly in his concurring opinion in *Ariad Pharmaceuticals v Eli Lilly* 560 F.3d 1366 (*Ariad P*), when he stated that:

"I join the opinion of the court because I concur that it is supported by our precedent. I write separately to emphasize, as I have before, my belief that our engrafting of a separate written description requirement onto section 112, paragraph 1 is misguided."¹⁶¹

2. DEVELOPMENT OF THE STANDARD

Whichever side of the fence one happens to be on, it seems uncontentious to state that the modern revival of the separate written description doctrine (or its invention, if you happen to hold that view)¹⁶² occurred in the CCPA's 1967 decision *In re Ruschig.*¹⁶³ In this case, Judge Rich explicitly distinguished written description from enablement, noting that:

"While we have no doubt a person so motivated would be enabled by the specification to make ... [the compound in question], this is beside the point for the question is not whether he would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented."¹⁶⁴

The case itself concerned an amended claim, and so essentially the court was faced with a question of priority. This might have conceivably been dealt with under §132 as an added matter issue,¹⁶⁵ but instead the Court considered written description best placed to deal with the shortcoming. Accordingly, whilst undisputedly enabled, there was still an issue of whether the patentee had shown that they were in possession of the invention at the filing date.

¹⁵⁸ Ibid.

¹⁵⁹ Janis, 'On Courts Herding Cats', n131 above, at 67.

¹⁶⁰ *Ibid.* at 67-8.

¹⁶¹ 560 F.3d 1366 (1973, CCPA).

¹⁶² See, for example, the comments of Judge Rader in *Enzo Biochem*, n126, above, esp. at 977.

¹⁶³ 379 F.2d 990 (1967, CCPA).

¹⁶⁴ *Ibid.* at 995.

¹⁶⁵ Some cases following *Ruschig* did just this – see, for example, *Barker* 559 F.2d 588 (1977, CCPA) – seeming to treat written description and added matter interchangeably. See further, Janis M.D., 'On Herding Cats', n131 above, at 64.

Cases subsequent to *Ruschig* not only heralded a tightening of the manner in which §132 was utilised – essentially relegating it to policing amendments to the specification; written description taking prominent place when the claims were redrafted¹⁶⁶ – but also saw the idea of a separate written description standard being fully embraced. Accordingly, by the time of the CAFC's en banc decision in *Ariad Pharmaceuticals v Eli Lilly* (*Ariad II*'),¹⁶⁷ Circuit Judge Lourie, speaking for the majority, was able to remark that:

"Since its inception, this court has consistently held that § 112, first paragraph, contains a written description requirement separate from enablement, and we have articulated a "fairly uniform standard," which we now affirm."¹⁶⁸

Furthermore, by the time of *Ariad II*, the written description requirement had ceased to be confined to cases in which the claims had been amended: it now applied to original claims as well. This transition to an "extended" written description standard, as some have called it,¹⁶⁹ occurred with the 1997 decision in *Regents of the University of California v Eli Lilly*.¹⁷⁰ The case's facts are strongly redolent of those before the House of Lords in *Biogen*.¹⁷¹ thus, at the time of patent's filing, the patentee, the University of California (UC), had developed and fully enabled a perfectly good method for producing rat insulin cDNA, but had nevertheless claimed far more broadly. Their patent accordingly encompassed methods for producing vertebrate, mammalian and human insulin cDNA within its scope.¹⁷² UC charged Lilly with infringement. Lilly responded, denying that it infringed and alleging, in any case, that the claims to mammalian, vertebrate, and human cDNA, were invalid for lack of an adequate written description.

The Court agreed. It explained that:

"Contrary to UC's argument, a description of rat insulin cDNA is not a description of the broad classes of vertebrate or mammalian insulin cDNA. A written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials."¹⁷³ (citations omitted)

As some have noted, the "fact pattern in *Eli Lilly* is similar to past Federal Circuit enablement determinations"¹⁷⁴, and it is therefore somewhat odd that the Court had chosen to create an additional requirement when enablement could have done the job just as well.¹⁷⁵ Nevertheless,

¹⁶⁶ See comments to this end *In re Rammussen*, 650 F.2d 1212 (1981, CCPA), at 1214-5. However, note the powerful dissent of Judge Rader in *Enzo Biochem*, n126 above, at 978, where he argues that the priority function of the written description requirement is redundant in the face of §132.

¹⁶⁷ 598 F.3d 1336.

¹⁶⁸ *Ibid.* at 1351.

¹⁶⁹ See, for example, Whitley G.M., 'A Patent Doctrine Without Bounds: The "Extended" Written Description Requirement', 71 University of Chicago Law Review 617 (2004).

¹⁷⁰ 119 F.3d 1559 (1997, CAFC).

¹⁷¹ [1997] RPC 1, discussed above.

¹⁷² See discussion of the patents: 119 F.3d 1559, at 1562-3.

¹⁷³ 119 F.3d 1559, at 1568.

¹⁷⁴ Whitley, 'A Patent Doctrine Without Bounds', n169 above, at 621.

¹⁷⁵ Judge Rader makes the point succinctly in his dissent *Enzo Biochem*, n126 above, when he notes, at 980, that: "the patent claimed vertebrate insulin cDNA a category ranging from fish to humans again claims whose scope far exceeds the patent's enabling disclosures."

the intention of the Court is clear: whether or not a patent contains an enabling disclosure, it may still be invalidated for lack of written description.¹⁷⁶

The decision in *Lilly* has attracted significant criticism; both from academic commentators¹⁷⁷ and from within the ranks of the CAFC itself, Judge Rader notably proclaiming not only that:

"A straightforward reading of the text of section 112 suggests that the test for an adequate written description is whether it provides enough written information for others to make and use the invention."¹⁷⁸

But also that the Court in Lilly had erred because:

"Instead of invalidating under the statutory test for adequacy of disclosure, i.e., enablement, the Lilly court purported to create a new doctrine for adequacy of disclosure that it labeled incorrectly "written description." As noted, from its creation through thirty years of application, WD had never been a free-standing substitute for enablement."¹⁷⁹

Nevertheless, with the en banc decision of the Court in *Ariad II*, any hope of resigning the separate written description requirement to the trashcan of history must surely now have withered and died. The majority's support for the enhanced standard is un-quavering:

"a separate requirement to describe one's invention is basic to patent law. Every patent must describe an invention. It is part of the quid pro quo of a patent; one describes an invention, and, if the law's other requirements are met, one obtains a patent. The specification must then, of course, describe how to make and use the invention (i.e., enable it), but that is a different task."¹⁸⁰

VI IN CONCLUSION

Parallels between the expanded written description standard under *Lilly* and the machinations undertaken by the House of Lords in *Biogen* in order to invalidate the overly broad claim, are easy to draw. Both, if one is being unkind to the courts, effectively resurrect a doctrine from a bygone era and apply it curtail the new upstart technology from running away with the show. The fact that *Lilly*, *Ariad II* and *Biogen* all hail from the ranks of biotechnology is not insignificant, as it demonstrates the inherent concern that courts seem to have with breakthroughs at the frontier of new fields of technology. Despite the patent system being all about progress and technological advancement, the history of its own development is littered with concerns about providing overly broad monopolies in the formative years of any given art. Accordingly, Morse's

¹⁷⁶ See comments to this end in 119 F.3d 1559, at 1567.

¹⁷⁷ See, for example, Mueller J.M., "The Evolving Application of the Written Description Requirement to Biotechnological Inventions', 13 *Berkeley Tech LJ* 615 (1998); Whitley G.M., 'A Patent Doctrine Without Bounds', n174 above; Janis M.D., 'On Herding Cats', n131 above; and Sampson, M., "The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology', 15 *Berkeley Tech LJ* 1233, (2000). See also, Burk D.L & Lemley M.A., 'Is Patent Law Technology Specific?' 17 *Berkeley Tech LJ* 1155 (2002), who, although generally discussing the requirement in positive terms, are critical of its application by the CAFC.

¹⁷⁸ Enzo Biochem, n126 above, at 976.

¹⁷⁹ Enzo Biochem, n126 above, at 980.

¹⁸⁰ Ariad II, n153 above, at 1345. This point is repeated at 1353-4.

broad claims were struck down using the sabre of enablement.¹⁸¹ So too was Arkwright's patent for his "water frame", which basically paved the way for mechanisation of the spinning industry, eventually felled;¹⁸² the court citing the patentee's attempts at obfuscation as one of the grounds of invalidation (elements in the specification being "of no use but to be thrown in merely to puzzle"¹⁸³). Biotechnology is the new frontier, and the courts' caution in this area is understandable. Nevertheless, the perils of requiring too much disclosure of prospective patentees are difficult to ignore.

The most enduring theories that are said to underpin the modern patent system are those that rationalise it on the basis of incentive: one commentator has even noted that this "simple model" has "been the model for 200 years."¹⁸⁴ Therefore, whether economically sound or not,¹⁸⁵ the popular conception is that the patent system provides monopoly power by creating a zone of exclusion as an incentive for investment in, or disclosure of the results of, innovative endeavour.¹⁸⁶ The system is predicated upon assumptions that technological progress is good for society and that the offer of a patent is justified as a means of extracting supra-normal levels of inventive teaching *from* the populace *for* the populace. This is view is encapsulated in the comments of Sir Donald Nicholls VC when he famously noted that one of the golden threads of the jurisprudence relating to patents is that:

"Patents exist today to reward and thereby encourage inventors; they are not intended to make it possible to take out of public use processes or products already made available to the public."¹⁸⁷

However, it is apparent that any such system for the reward and encouragement of innovative endeavour can only be legitimate if technological progress is actually obtained – in other words, if the knowledge the State gains as a result of extending legal protection to the patentee is something that its people did not have access to before. Novelty and non-obviousness patrol this requirement from the outside, making sure that the patentee does not monopolise things already in the state of the art (or minor, obvious, additions thereto). It is the task of sufficiency, and 'best mode' where demanded, to police from within, ensuring not only that the public does not lose out from the bargain, but in fact gains something new and valuable from their toleration of the monopoly so granted.

¹⁸¹ O'Reilly v. Morse, 56 US (15 How) 62 (1854).

¹⁸² R v Arkwright, 1 Web. P. C. 64 (1785, Common Pleas).

¹⁸³ *Ibid.* at 69

¹⁸⁴ Lemley M.A., 'Reconceiving Patents in the Age of Venture Capital', 4 *Journal of Small and Emerging Business Law* 137 (2000) at 139.

¹⁸⁵ Needless to say, the view of the patent as a monopoly does not go unchallenged. Despite the validity of Pretnar's assertion that "...this view can easily be verified by opening almost any textbook on economics or industrial organization." (see Pretnar B., 'The Economic Impact of Patents in a Knowledge-Based Market Economy', 34 *IIC* 887 (2003) at 887), some writers have questioned whether conventional thinking can, in fact, be said to be reflective of the true situation. Kitch, for example, argues that the patent only rarely confers monopoly power; more usually it provides a simple property right that is subject to diverse competitive market pressures. See Kitch E., 'Patents: Monopolies or Property Rights?', 8 *Research in Law and Economics* 31 (1986). See also Rich G.S., 'Are Letters Patent Grants of Monopoly?', 15 *Western New England Law Review* 239 (1993). He concludes that they are not.

¹⁸⁶ This is certainly the accepted justification for Elizabeth I's institution of a patent custom in the 16th Century, see above.

¹⁸⁷ Merrell Dow v Norton [1995] RPC 233, at 238.

Sufficiency – the requirement for teaching the invention – is the bedrock of the modern patent grant. As important as technological development is to the state, and as important as the need to offer inducement for innovators to invest in the process of invention, the patent system simply could not justifiably operate without payment of this price. Put simply, the patent system lives or dies by the quality of its disclosure: without disclosure there can be no bargain, and without a bargain there should be no patent. But bargain it is, and the scales of justice are finely balanced.