

SECOND MEDICAL INDICATIONS & THE SWISS- FORM CLAIM: TAMING FRANKENSTEIN'S MONSTER

(PART II – PUTTING THE PROBLEM IN CONTEXT)

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ABSTRACT

Few patent claim formats present more interpretative difficulties than that of the so-called Swiss-form. Taking shape as purpose-bound process claims – i.e. claims directed towards a manufacturing process applied for a particular end – the Swiss form was originally conceived as an attempt to navigate treacherous waters – waters bordered by two seemingly immutable prohibitions on patenting: the excluded; and the old. A jury-rigged solution to a thorny problem, the Swiss form claim promised to extend patent law’s incentives to the discovery of new and useful functions of existing medicaments: repurposing the old to create the new. For inventions known in other fields, inventions with no prior medicinal purpose, a solution had already been given in statute; Art 54(5) of the European Patent Convention (EPC) 1973 allowed discovery of the first medical use of a known compound to be claimed as a purpose-bound product. Once, however, a first medical use was known: that was it. Secondary indications, arguably no less beneficial than the first, were left out in the cold. The Swiss-form was devised to bridge this gap: its purpose undoubtedly noble; its proposed effects glittering. However, this virtuous façade conceals a darker underbelly: an underbelly in which the text of the Convention was mutilated and warped, leaving knotty, perhaps intractable, problems in its wake. This then is the story of the Swiss-form: of its birth, its execution, and the more recent attempts to disentangle the legacy of its creation.

Part I of this series discussed the adoption of the Swiss-claim format within the jurisprudence of the European Patent Office and questioned the fundamental legitimacy of the circumstances of its hatching from Art 54(5) EPC 1973. This story forms the background for much of what is to come, and sets up significant elements of the criticism levelled at the *Warner-Lambert v Actavis* litigation that is made in Part III. This part (Part II) by contrast, begins by briefly outlining aspects of the regulatory framework for prescription medications in the UK – a topic that is necessary to understand a number of the issues that will be raised later on. Following this, the remainder of this Part is dedicated to the question of infringement and the problems raised by retro-fitting use-limitations into this arena.

...[CONTINUED FROM [2017] EIPR XXX]

IV MARKETING AUTHORISATION, LABELLING, PRESCRIPTION AND DISPENSATION PRACTICES OF PHARMACEUTICAL PRODUCTS – AN OUTLINE

In the EU, European Parliament and Council Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use (as amended)¹ governs the requirements for acquiring marketing authorisation for most² pharmaceutical products. As part of this process, the applicant is required to submit a summary of product characteristics (SmPC) and a copy of the package leaflet details (PL)³ both of which are required, among other things, to record the therapeutic indications for which the medicine may be used.⁴ Where authorisation is sought for the marketing of a generic version of an existing product then a streamlined process is available for the applicant under Art 10 of the Directive. This enables authorisation to be acquired without the submission of pre-clinical tests and clinical trials if the applicant can demonstrate their product is a generic of one that has already been authorised in the EU.⁵ A generic product is one that “has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.”⁶ Where this process is used, Art 11 then allows indications or dosage forms that are still covered by a patent at the time the generic medicine is to be marketed to be omitted, or “carved out”, from the generic medicine’s SmPC (and therefore also the packaging, PL and marketing authorisation itself).⁷ The resultant marketing authorisation is often referred to as a “skinny label”.

¹ A consolidated version, as of 16 Nov 2012 can be found here: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf.

² There are a small number of exclusions from the application of the Directive which include, for example, extemporaneous preparations, including both magistral and officinal formulas, supplied by a pharmacy directly to patients. See Article 3 of Directive 2001/83/EC.

³ Art 8 Directive 2001/83/EC.

⁴ Art 11 Directive 2001/83/EC lists the requirements for the SmPC. The PL is dealt with under Art 59. Art 59(1) requires that the package leaflet is drawn up in accordance with the SmPC and that it includes certain information in a prescribed order. Therapeutic indications are second on this list.

⁵ Art 10(1) Directive 2001/83/EC.

⁶ Art 10(2)(b) Directive 2001/83/EC.

⁷ Art 11 Directive 2001/83/EC.

Where marketing authorisation is granted on the basis of bioequivalence there can accordingly be no doubt that whatever the reference medicinal product can do, the generic can do just as well – to all intents and purposes they are, after all, the same thing just made by different parties. This would not be a problem for patent law if the marketing authorisation were a cast-iron diktat compelling obedience with its terms – in other words, if doctors were prevented from prescribing, pharmacists were prevented from dispensing, or patients were unable to take medicines for conditions outside of those mentioned in the marketing authorisation, SmPC and PL. However, they are not. Thus, while the marketing authorisation may be the starting point for prescription, doctors are also entitled to rely on their own clinical judgment. Indeed, the GMC-issued guidance on prescription practices in the UK notes that “unlicensed medicines” – i.e. medicines used outside of the terms of their UK licence or which have no UK licence – are commonly used in areas such as paediatrics, psychiatry and palliative care, and less commonly in other fields.⁸ Accordingly, while physicians should “usually prescribe licenced medicines”, prescription off-label is deemed permissible where a conclusion is reached that it is “necessary to do so to meet the specific needs of the patient.”⁹

This problem is compounded because doctors also face strong encouragement to prescribe generically.¹⁰ This pressure is fundamentally a product of the economics of the marketplace. Generic prescription gives more flexibility to the dispenser than prescription by brand name and also allows reduction in cost. The reason for this is self-evident: generics face direct competition whereas patentees (providing the patent is doing its job) do not – provision of monopoly is, after all, the way in which the patent works its magic. As a consequence there can often be significant differences between the originator and generic costs of exactly the same compound.¹¹ This

⁸ General Medical Council, *Good Practice in Prescribing and Managing Medicines and Devices* (GMC, London, 2013), at [67]. Available online here: http://www.gmc-uk.org/static/documents/content/Prescribing_guidance.pdf

⁹ Ibid. at [68].

¹⁰ As in the UK where NHS guidance and pressure from Clinical Commissioning Groups and Health Boards all suggests prescription of the lowest cost solution. See further the discussion in *Warner Lambert v Actavis* [2015] EWHC 72 (Pat) at [28] to [33].

¹¹ In a 2011 study commissioned by the EU Parliament’s Committee on Environment, Public Health and Food safety Kavanos, et al notes that “Generic prices average about 25% of the originator price, 12 and 24 months following patent expiry.” The author’s concede however, that this average masks a number of differences between Member States of the EU. See Kavanos. P, Vandoros. S, Irwin. R, Nicod. E & Casson. M, *Differences in Costs of and Access to Pharmaceutical Products in the EU*, (2011, European Parliament, Brussels). Available online at:

difference will be particularly acute where the market for a drug is fragmented by patents on a second medical use. Here some of the market will be under free competition, but a proportion should be ring-fenced for the benefit of the patentee on the second indication. Prices for the ring-fenced indication will naturally be higher than those for which there is competition. If, however, the prescriber has knowledge of bioequivalence then, without more, there is nothing within the regulatory framework to prevent them deviating from the marketing authorisation and prescribing the cheaper, generic, alternative.

This problem is magnified when dispensing practices are also brought into the equation. Pharmacists, for their part, “may not sell or supply a prescription only medicine except in accordance with a prescription given by an appropriate practitioner.”¹² Accordingly, where a prescription is written by reference to a branded product then the branded product itself must be supplied to the consumer.¹³ However, where a prescription is written generically then the pharmacist is at liberty to supply either the branded or the generic drug. Once more there will evidently be an economic incentive to supply the drug for which the pharmacist pays the lowest unit cost and this incentive will be enhanced where the NHS drug tariff, by which the reimbursement to the pharmacist is calculated, is pegged at a higher value than the cost of the generic.

A final layer of complexity is added by the fact that prescriptions do not usually specify the condition for which the drug is being prescribed. This is primarily for reasons of patient confidentiality – to take a blithe example, a requirement for a prescription to specify the ailment is unlikely to be greeted warmly by the patient suffering from an aggressive case of haemorrhoids, let alone if the condition is more serious. The pharmacist is therefore not often able to ascertain from the face of it the condition for which the prescription has been written. Obviously they may ask the person presenting the paperwork, but this may be impractical for a number of reasons, not least because the person presenting the script may not be the person for whom the prescription has been prepared. While it would in theory be possible to contact the person that had written the prescription and to gain this information from them, this would add

[http://www.europarl.europa.eu/RegData/etudes/etudes/join/2011/451481/IPOL-ENVI_ET\(2011\)451481_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/etudes/join/2011/451481/IPOL-ENVI_ET(2011)451481_EN.pdf)

¹² Reg. 214(1) Human Medicines Regulations 2012/1916

¹³ The pharmacist would also be open to a claim of passing off and/or trade mark infringement if they supplied generic medicines where the prescription was by brand.

an extra layer of complexity to the process that would be unworkable in practice. Accordingly, there will be “a strong commercial incentive to dispense the generic version of the drug against all generic scripts.”¹⁴

Given the combination of these factors, it is likely that off-label prescription forms a significant proportion of dispensed medicine in the UK.¹⁵ This alone gives rise to a clear problem for any patented indication that lies in the lee of a generic’s carve out. However, as we shall see, when added to the questions of construction that over-hang the claim, matters are made even worse. The irregularity of the Swiss-form’s introduction into EPO jurisprudence, and the lack of firm (dare we say ‘any?’) support within the Convention or its drafting history for the protection of its subject matter, provides additional uncertainty: uncertainty that is further amplified by the EPO’s own seeming indifference to the question of scope.

The core of the problem is this: if patents on second medical use were not catered for in the legislation, but were added as a judicial afterthought, then should we extend them the same courtesy of support as we would other, more legitimate, claims? Should we reward the underlying invention’s contribution to society, or should the claim-form’s limited birth right be reflected in the scope such patents are to enjoy? We do not, for example, entertain providing protection to subject matter explicitly excluded from the patent regime; no matter how great the advance heralded by innovation in such areas would be. Yet, while the distinction between a method of treatment¹⁶ and the novel use of a compound in medicine is a fine one, it is a distinction nevertheless. It is not therefore possible to say that a second medical use was fundamentally and irretrievably excluded per se under EPC 1973. Instead it falls into an uncomfortable middle ground: subject matter not explicitly prohibited, but also not embraced by that legislation. Moreover, matter which is incapable of survival within the patent system without specific assistance. How then to interpret such a claim: a claim which the Enlarged

¹⁴ [2015] EWHC 72 at [3].

¹⁵ Vrancken recently asserted that “The amount of off-label prescription can be estimated at 21 per cent of all drug prescriptions”, see Vrancken, I., ‘Off-label Prescription of Medication’, (2015) 22 *European Journal of Health Law* 165, at 168. However, this figure is provided with no geographical bounds and appears to have been derived from a series of US studies in some of which unsubstantiated assertions are piled upon conjecture. The figure should therefore be treated with caution.

¹⁶ Excluded under Art 53c EPC 2000 / Art 52(4) EPC 1973.

Board admits was a praetorian creation,¹⁷ “an adequate but exceptional solution” to the problem of second medical use, and one that could not be maintained under EPC 2000?¹⁸

In order to fully understand this issue and the challenges it presents, it is first necessary to take a step back and to consider some fundamentals of patent infringement that have distinct bearing on the matter in hand. It is therefore to these issues that we now turn our attention.

V INFRINGEMENT AND SOME PATENT LAW FUNDAMENTALS

At their most basic, the essential questions of construction and infringement are always ones of balance – balance essentially between the legitimate interests of a patentee in enforcing their monopoly and those of third parties in being able to operate freely in the territory of the public domain. The fulcrum upon which this weighing of freedoms rests is formed by the language of the claims, and in most instances the difference between a patented, and thereby exclusive, and a freely-appropriable indication (in other words, between something falling within and without those claims) is one of substance. The claims of the patent are compared to the thing that the alleged infringer has done, made or dealt with to see if the latter falls within the zone marked out by the former. A competitor will avoid infringement, falling outside of the scope of the patent’s exclusivity, not because of their desire to produce something different, but because the product or process in question is simply not the same as the claimed invention. While debate could be had about the latitude that is, or should be, given to elements falling outside of the strict language of the claim – in particular where substitutions of functionally equivalent means have been made – this is an issue for another day. For present purposes it is sufficient to note that the second party’s intention to infringe, the guilt or innocence of their mind, is, and should be, irrelevant.¹⁹ And so it is for most²⁰ acts of primary infringement.

¹⁷ “Praetorian law ... is that which in the public interest the [judges] have introduced in aid or supplementation or correction of the [civil law].” Cockbain & Sterckx attribute this definition to Roman jurist and Praetorian Prefect AEMILIUS PAPIANUS (PAPINIAN) (142 to 212 CE), *Definitions*. See Cockbain, J., and Sterckx, S., ‘Is the Enlarged Board of Appeal of the European Patent Office Authorised to Extend the Bounds of the Patentable? The G5/83 Second Medical Indication/EISAI and G2/08 Dosage Regime/ABBOTT RESPIRATORY Cases’, (2011) 42 *IIC* 257, at p.257.

¹⁸ G_02/08 *ABBOTT RESPIRATORY/Dosage Regime* [2010] OJ EPO 456, at Point 7.1.1 of the Reasons for Decision; [2010] EPOR 26, at [133].

¹⁹ The fact of infringement must, obviously, be separated from the remedies that may be imposed in such circumstances. “Innocence” under s62 PA 1977, for example, operates to exclude the possibility of damages or an

The infringement of a patent is a composite action: an act of infringement must be committed and this act must take place in relation to the subject matter that is circumscribed by the patent's claims – said claims must also be valid. Section 60(1) and (2) of the Patents Act 1977 (PA 1977) lay down the acts of infringement for a UK patent.²¹ These provisions derive, respectively, from Articles 29 and 30 of the ill-fated Community Patent Convention (CPC) 1975.²² The CPC was originally intended to complement the European Patent Convention: the two standing side-by-side to support European patent law.²³ At the signing of the EPC, the EC delegations formally expressed “their intention of depositing instruments of ratification of ... [the EPC] in such a way that it enters into force with respect to them simultaneously with the ... [CPC].”²⁴ To this end, the text of the Community Patent Convention that was agreed and signed off by the Member States of the EC in 1975 had annexed to it a “Declaration on the Adjustment of National Patent Law”. This declaration, which was stated to be effective “[u]pon signature of the Community Patent Convention” – i.e. without requiring ratification of the text – obliged the Community Member States to align their domestic patent provisions with those of the CPC, EPC and Patent

account of profits being awarded against the infringing party. It does not, however, preclude a finding of infringement per se.

²⁰ With the exception of offering a process for use under s60(1)(b) PA 1977. See further below.

²¹ Including both national (GB) patent grants and those European patents that designate the UK (EP(UK)) and have entered the national stage. According to s130(7) PA 1977, s60, among other sections, is “so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of the Community Patent Convention”. For this purpose, s130(6) adds that references to, inter alia, the CPC are references “to that convention as amended or supplemented”.

²² Convention for the European Patent for the Common Market (Community Patent Convention) of 1975 (76/76/EEC). The CPC was redrafted in the late 1980s when an attempt was made to reinvigorate the process. See Council Agreement Relating to Community Patents of 15 December 1989 (89/865/EEC). Like the 1975 draft, this also failed to enter into force, but that is another story. Articles 29 and 30 Draft CPC 1975 were carried over verbatim into Articles 25 and 26 of the 1989 Draft.

²³ See comments by Bossung for example who explains that “it was ... [never desired] to set up an EPC without the CPC.” Bossung, O., ‘The Return of European Patent Law to the European Union’, (1996) 27 *IIC* 287, at 290. Bossung was a judge of the Bundespatentgericht in Germany at the time of the drafting of the EPC and was present as “Adviser” to the German delegation at the Munich Diplomatic Conference that witnessed the signing of the Convention. See the List of Participants in the *Minutes of the Munich Diplomatic Conference*, (Munich, 1973) Doc No. M/PR/K/2, at p.212.

²⁴ See *Minutes of the Munich Diplomatic Conference*, (Munich, 1973) Doc No. M/PR/K/2 Point 14, at p.200.

Co-Operation Treaty.²⁵ Accordingly, despite the CPC never having been ratified by sufficient states to bring it into force, the infringement laws of a number of countries that are currently members of the European Patent Organisation (including the UK, France, Germany and the Netherlands) are directly derived from CPC provisions.

Primary Infringement

In the UK, section 60(1) PA 1977 deals with acts of primary (or direct) infringement and is subdivided according to whether a patent claims a product or a process. Product patents are dealt with under s60(1)(a), which specifies that it is an act of infringement if anyone not having the consent of the patent owner “makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise.”²⁶ Process patents find protection under s60(1)(b) against “use” simpliciter and “offering for use” in bad faith – i.e. where there is knowledge that use in the UK is prohibited.²⁷ Process patents also gain protection under s60(1)(c) against any third party not having their consent who “disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such

²⁵ The text of the Declaration reads: “THE GOVERNMENTS OF THE MEMBER STATES OF THE EUROPEAN ECONOMIC COMMUNITY,

Upon signature of the Community Patent Convention ...

HAVE DECIDED to commence the work, as soon as the Convention has been signed, to adjust their laws relating to national patents as soon as possible so as to permit ratification of the Strasbourg Convention on the unification of certain points of substantive law on patents for invention, and so as to bring their laws into conformity, as far as practicable, with corresponding provisions of the European Patent Convention, Community Patent Convention and the Patent Cooperation Treaty.” See ‘Resolutions, Declarations and Decision annexed to the Final Act’, in *Records of the Luxembourg Conference on the Community Patent 1975* (1982, Office for Official Publications of the European Communities, Luxembourg), at p.332.

²⁶ Art 29(a) CPC 1975, from which the provision was derived contained arguably clearer language: “... from making, offering, putting on the market, or using a product which is the subject matter of the patent, or importing or stocking the product for these purposes”.

²⁷ ‘Offering a process for use’ is the one act of primary infringement where there is an explicit knowledge requirement in the statute. This can be seen more clearly if s60(1)(b) PA 1977 is contrasted with the much clearer wording of Art 29(b) CPC 1975, upon which the former is based. The CPC prohibits anyone not having the consent of the patentee “from using a process which is the subject matter of the patent or, when the third party knows, or it is obvious in the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent, from offering the process for use in the territories of the contracting states”.

product whether for disposal or otherwise.”²⁸ In the case of s60(1)(a) and (b) the “product” or “process” so protected is that specified in the claims of the patent.²⁹ For s60(1)(c) the process must also obviously be that claimed: infringement under this section is evidently contingent upon something having been done (i.e. use of the patented process) which, if done in the UK by a third party not having the patentee’s consent, would prima facie be an act of infringement under s60(1)(b). Accordingly, in all cases under s60(1) the prohibited acts must take place in respect of something that satisfies (or is derived from something that satisfies) all material elements of the invention claimed. However, s60(1)(c) offers a clear extension of the protection otherwise available under a process patent where, to borrow language from a principle advanced under the 1949 Act in the UK, the acts of a third party deprive the patentee of the “profit and advantage” of their invention.³⁰

Of these acts, the mental state of the infringer is irrelevant to all but one: offering a process for use. When originally proposed, the text of what was to become Art 29(b) CPC 1975 did not contain any such restriction: offer without more would have been sufficient to trigger liability. However, this original language was considered by a number of the delegations at the Luxembourg Conference responsible for drafting the CPC to be too broad.³¹ An amendment was therefore proposed by two non-governmental entities, UNICE³² and CIFE,³³ which suggested restricting the application of the provision to offers by third parties acting in bad

²⁸ This language was derived from Art 29(c) CPC 1975, however protection for products obtained directly from patented processes is also required under Art 64(2) EPC. Art 29(c) CPC 1975 was, once more, arguably better drafted than the provision in PA 1977 intended to convey the same meaning.

²⁹ s125(1) PA 1977 and Art 69 EPC.

³⁰ See further the discussion in Blanco-White, T.A., *Patents for Inventions*, (4th Ed, 1974, Stevens & Sons; London), pp.96-8 discussing a line of cases stretching at least from *Von Heyden v Neustadt* (1880) 50 L.J. Ch. 126 (CA).

³¹ See, for example, the comments of the UK delegation found in Preparatory Document No. 11; and the Netherlands, Preparatory Document No. 19; as well as those of EIRMA (The European Industrial Research Management Association), Preparatory Document No. 34. Various others suggested that the provision could do with some redrafting, but did not make specific points about breadth. See, for example, the comments of the Danish delegation, Preparatory Document No 16; and that of CEEP (The European Centre of Public Enterprises), Preparatory Document No. 30. All can be found in *Record of the Luxembourg Conference on the Community Patent 1975*, (1982; Office for Official Publications of the European Communities, Luxembourg).

³² Union des Industries de la Communauté Européenne.

³³ Council of European Industrial Federations. Both UNICE and CEIF were also instrumental in the discussions that led to the European Patent Convention.

faith.³⁴ This was adopted by the Committee of the Whole.³⁵ It is therefore clear that the introduction within this provision of the knowledge requirement was a deliberate attempt to narrow the scope of infringement in certain, very limited, circumstances. For all others, therefore, the mental state of the infringer is irrelevant – offering of a process for use being the exception that proves this rule.

Secondary Infringement

Section 60(2) PA 1977, by contrast, which deals with secondary (or indirect) infringement, contains a distinct knowledge requirement within the section. Infringement under this provision essentially occurs where a party performs an act that does not fulfil the requirements of primary infringement by itself but which nevertheless facilitates infringement by others. Thus if a person not entitled to work the invention is supplied (or an offer is made to supply them) in the UK with means relating to an essential element of the invention (“means essential”) (said elements being required to put the invention into effect, again in the UK) then this can constitute an act of infringement under this section provided, that is, that certain knowledge requirements are met. The standard of knowledge was explained by the Court of Appeal in *Grimme v Scott*³⁶ as being satisfied if at the time of supply or offer of supply the supplier knows, or it is obvious in the circumstances, that some ultimate users (disregarding what the Court referred to as “freak use”)³⁷ will intend to use, adapt or alter the means essential so as to put the invention into effect. Evidently therefore, there must be some sort of interaction of the ‘means’ with the invention as claimed in order for there to be infringement. This interaction must also occur solely in the UK – both supply and the spectre of putting into effect are territorially bound by the statutory provision itself. However, it is not necessary to show that anyone has actually put the invention into effect to trigger the provision; all that is necessary is that there is knowledge that some will intend to do so at some point.³⁸ Importantly, there is no requirement that the supply be in bad

³⁴ LUX/15, 19 November 1975. Found in Record of the Luxembourg Conference on the Community Patent 1975, (1982; Office for Official Publications of the European Communities, Luxembourg), at p.172.

³⁵ See Minutes of the Conference; Committee of the Whole, in *Record of the Luxembourg Conference on the Community Patent 1975*, (1982; Office for Official Publications of the European Communities, Luxembourg), at p.234.

³⁶ *Grimme Landmaschinenfabrik GmbH & Co KG v Scott* [2010] EWCA Civ 1110; [2011] FSR 7 – knowledge is discussed at [105] to [133].

³⁷ Jacob J, as he then was, put this another way in *Chapman v McAnulty*, unreported, February 19, 1996, BL SRIS C/20/96, Pat Ct when he referred to disregarding “maverick or unlikely uses of the thing”. See *Grimme v Scott*, *ibid.* at [116].

³⁸ See *Grimme v Scott*, note 36, above, at [90]. Also see *KCI v Smith & Nephew* [2011] FSR 8, esp at [53] to [54].

faith – it is just as much an infringement if the person making the supply believes that it is lawful to do so as if they understand that it is not.³⁹

In addition to the above elements, Article 30 CPC 1975 also introduced a limited exception to secondary infringement where the things supplied are “staple commercial products”⁴⁰. This shield was incorporated in the UK as s60(3) PA 1977. Thus, it is not an act of infringement to supply or offer to supply ‘means essential’ provided both that these means are ‘staple commercial products’ and also that the supply or offer is not made with the purpose of inducing the person supplied to infringe. This saving provision was added to the CPC at a relatively late stage in the negotiations following concerns being expressed about the breadth of the infringement provision without it.⁴¹ It is simple to see why: transformation of legitimate commerce into something that infringes based solely on the whims and perceived intention of a party further down the chain of supply is obviously an unpalatable proposition without more. Nevertheless, the scope of the defence is narrow and does not prevent legitimate provision of a ‘means essential’ being transformed into something illegitimate under s60(2) where the commercial product supplied is not ‘staple’. The border between staple and non-staple commercial products has, however, never been fully explored in the courts.

³⁹ *Kennametal v Pramet* [2015] RPC 2, esp at [90] and [95].

⁴⁰ There is no definition of “staple commercial product” within the CPC or PA 1977. However, in *Nestec v Dualit*, it was accepted that a good working definition would be “products that are of a kind which is needed every day and can be generally obtained”. Moreover, such a “product must ordinarily be one which is supplied commercially for a variety of uses.” See [2013] EWHC 923 (Pat); [2013] RPC 32 at [179] and [182] respectively.

⁴¹ See, for example, the comments of CNIPA – The Committee of National Institutes of Patent Agents – in the *Record of the Luxembourg Conference on the Community Patent 1975*, (1982; Office for Official Publications of the European Communities, Luxembourg). CNIPA’s submission, Preparatory Document 27, stated that there should be a limitation imposed on Art 30 to the extent that “the mere supply of materials or components well known for other purposes” should not be considered infringement, unless these were “accompanied by instruction or other inducement to infringe the patent.” Other delegations also submitted similar observations – see e.g. UK Delegation, Preparatory Document 11. The draft published in 1973 (Preparatory Document 28) contained new text that included the ‘staple commercial product’ provision.

No definition of staple commercial product is given in either piece of legislation, and the only guidance on the interpretation of the provision found in the travaux préparatoires (apart from the comments of CNIPA above) come from the minutes of the Committee of the Whole. Here it was stated that the Federal Republic of Germany had insisted that the phrase “must be interpreted in such a way as in no event to include products specifically adapted for exploiting the patented invention.” See Minutes of the Conference: Committee of the Whole, in *Record of the Luxembourg Conference on the Community Patent 1975*, (1982; Office for Official Publications of the European Communities, Luxembourg), at p.235.

Fundamentally, therefore, within the context of infringing acts, the concept of knowledge as a precondition of liability adopts two distinct roles for standard product and process claims. Seen from the perspective of primary infringement, knowledge is introduced into s60(1)(b) as a limiting element – to prevent an excessively broad application of the offering of a process for use. Accordingly, while bona fide offers evade the patentee’s web, those made in bad faith become entangled in its threads. For secondary infringement, by contrast, the concept of knowledge serves fundamentally to expand the zone of protection. This occurs through enabling liability to be constructed based upon what others might do with the elements supplied – adding an extra hand to the infringement tiller over which the supplier of the ‘means essential’ ostensibly has no control. An erstwhile legitimate supply of elements can therefore be rendered infringing moving forward from the point the supplier learns that an end user will utilise them to put the invention into effect. Nevertheless, this expansion of liability is not unbounded. Limited constraint is first of all placed upon the exercise of the provision by requiring a definite mental link between the act of supply and the third party’s intention to put the invention into effect. The double territoriality element of s60(2) – supply or offer to supply in the UK where it is known or obvious that the invention will be put into effect in the UK – and the specific defence in respect of staple commercial products both also operate to constrain the provision.

Construction of Claims

For standard product or process claims the technical subject-matter (and hence the scope of the patentee’s monopoly) relates to the product or process claimed as such. The words of the claim are interpreted in the context of the rest of the specification⁴² and we ask what the person skilled in the art would consider the patentee to have used the language of the claim to mean.⁴³ A suggestion that a product or process is to be “used for” a particular purpose is not usually considered to be limiting. It is commonly accepted within English patent jurisprudence that the word “for” in a patent claim should be interpreted as “suitable for” rather than “when used for”

⁴² s125(1) PA 1977 which is itself based on Art 69 EPC – for this purpose the text of EPC 1973 and EPC 2000 are functionally identical.

⁴³ *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2005] 1 All E.R. 667; [2005] RPC 9. While this article was awaiting publication, the Supreme Court decided *Ely Lilly v Actavis* [2017] UKSC 48. This fundamentally altered the UK’s approach to the construction of a patent’s claims, specifically embracing the inclusion of equivalents in the determination of scope.

(or any other variant thereof).⁴⁴ In other words: “The use of such phrases in claims is usually a sign that the draftsman of the claim set out to describe the invention and not delimit it.”⁴⁵

Accordingly, in all standard cases the question of knowledge or intention falls outside of the issue of construction – relegated to an indication of preference rather than a limiting factor. Indeed, it is only when the jigsaw of infringement is made complete, and the claim as construed is married with the infringing acts, that we see knowledge and intention taking any role whatsoever in the proceedings.

The same cannot be said, however, for use-limited claims. These, whether for first or second medical indications and whether they are drafted as use-bound products⁴⁶ or use-bound processes,⁴⁷ are inherently more complex entities. Accordingly, placing functioning “use”-limitations within the context of patent infringement is not a simple exercise. Initial complexities arise for the very reason that the “use” must have some effect if the claim is to be valid. Such purpose is, after all, integral to the legitimacy of the claims’ existence; indeed, in patentability terms it is the new medical indication from which the otherwise old compound or substance derives fresh validity. Accordingly, even though it would be verboten if claimed explicitly, the novelty of the new use must somehow leach validity into the package as a whole. Despite, therefore, distinctions having to be drawn between “the technical subject matter of the claim, on the one hand, and the rights which a patent gives rise to in national law ... based on that technical subject matter, on the other”,⁴⁸ this cannot be used as a pretext to relegate the use-limitation to a mere sideshow attraction in infringement proceedings. If mere novelty of purpose is to be recognised as a key component in securing acceptance of such a claim then it must also take a central role in determining the extent of the patent’s influence upon others.

⁴⁴ See the discussion on this point in *Coflexip v Stolt* [2000] EWCA Civ 242 at [23] to [27]. *Adhesive Dry Mounting v Trapp* (1910) 27 RPC 341 is cited as authority for this point. The report of *Coflexip v Stolt* in the Reports of Patent Cases ([2001] RPC 9) inexplicably omits the relevant paragraphs.

⁴⁵ See Blanco-White, T.A., *Patents for Inventions Patents for Inventions*, (4th Ed, 1974, Stevens & Sons; London), at [2-213], p.69.

⁴⁶ Under EPC 1973 only claims to the first medical indication of a known substance or composition was allowed to be in this form (Art 54(5) EPC 1973). However, with the entry into force of EPC 2000, claims to both first and second (or subsequent) medical indications are able to be claimed using this format (Art 54(4) and (5) EPC 2000).

⁴⁷ Only claims to second or subsequent indications drafted under EPC 1973, or in the transitional window allowed under G_2/08 *ABBOTT RESPIRATORY* are entitled to adopt this claim format.

⁴⁸ *Warner-Lambert v Actavis* [2015] EWCA Civ 556, at [115].

Accordingly, while the general principles of construction are the same for all patents, in those that claim a medical use the phrase “used for” (or its equivalent) must adopt a different meaning such that it does in fact operate to constrain the scope of the claim. This should not be controversial. After all, to simply rely on the standard construction of “for” as meaning “suitable for” would render infringers of all generic suppliers of drugs on which there was patent for a second medical use: the drug, by definition, always being “suitable for” the new indication. Nevertheless, taking the purpose of use into consideration in the context of infringement does place an additional layer of complexity into the assessment of a claim’s scope of protection as well as clouding its relationship with the infringing acts. With this in mind, the first question for anyone seeking to understand the Swiss-form claim should be what precisely the phrase “use for” a particular purpose could mean if it cannot simply be construed in its usual manner. However, this is only the start of the process, as it is also clear that the introduction of a limiting use-element changes other factors within the infringement construct as well.

The Relationship between Infringing Acts and the Claims

a) Working from first principles: “standard” claims

In normal, non-use-bound, cases of infringement, the relationship between the primary prohibited acts and the claimed invention is clear and direct. There is no gap. Taking a simple example, if party X makes a product that falls within the scope of P’s patent, and X does not have the permission of the patent holder or have a valid defence, then they will infringe. Similarly, if X makes the product and sells it to Y, who sells it to Z who keeps it in stock for the purpose of further sale, then X will infringe under s60(1)(a) PA 1977 separately by “making” and “disposing”, Y will infringe by “disposing”, and Z by “keeping”. Each of the statutory acts infringes on a strict liability basis and causation therefore only runs one way, cascading from the top of the chain. Therefore, but for X the product would not exist and would not be infringing; but for Y selling the product to Z, Z would not have it in stock, etc. However, even though we have a causal relationship that cascades from the top of the chain, each of the acts committed stands by itself. In other words, none of the acts themselves (the disposal, keeping, etc.) is affected by the actions of the others above and beyond the fact that the product is illegitimate. Thus taking Y as an example, if they sell the product to Z then they will infringe irrespective of what Z does (or intends to do) with the product. This is the case even if Z’s endeavours are, in patent law terms, entirely legitimate. For example, if Z uses the product for experimental purposes (an act that would fall under s60(5)(b) PA 1977 and therefore be permitted under cover

of this defence) then despite Z having a defence, Y will still have denied the patentee a sale by disposing of the product to Z. Accordingly, Y will still infringe.⁴⁹

In the standard setting therefore, the fact of primary infringement cannot be affected by those further down the chain of supply. What anyone else intends, desires, or wilfully or accidentally does with the thing subsequently is simply irrelevant. Liability is locked in, subject to defence, at the point of performance of the relevant act, and then is based solely upon what the performer themselves does. The same is true where the patent concerns a process. Notwithstanding the extension of liability under s60(1)(c) for dealing in products obtained directly from a patented process, the chain of causation still only flows one way. Each of the acts of infringement also stands by itself – use of the process is infringement regardless of what the products that may be produced are used for by others. Equally, disposal, offering to dispose, keeping, importing, etc., the products obtained directly from a patented process will be acts of infringement irrespective of what any other party subsequently does.

When dealing with standard claims, the acts of other parties further down the supply chain only ever begin to matter to those further up it in cases of secondary infringement under s60(2) PA 1977. Here knowledge of the intention of these other parties will, indeed, be determinant of the issue. After all, as noted above,⁵⁰ supply or offer to supply of ‘means essential’ must be made in circumstances where it is known or it is obvious that those means are suitable and intended to put the invention into effect. Accordingly, the liability of individual X will be contingent upon their having foresight of what a person somewhere down the supply chain (Z) may intend to do.⁵¹ Such foresight must, according to the Court of Appeal in *Grimme*, be fixed at the point of supply/offer,⁵² but foresight of a future desire by another can be sufficient to ground liability.

⁴⁹ See e.g. *Hoffman-La Roche v Harris* [1977] FSR 200.

⁵⁰ See the section on Secondary Infringement, above.

⁵¹ As explained above, the standard applied in such cases satisfied if at the time of supply or offer of supply the supplier knows, or is obvious in the circumstances, that some ultimate users (disregarding what the Court referred to as “freak use”) will intend to use, adapt or alter the means essential so as to put the invention into effect. See *Grimme Landmaschinenfabrik GmbH & Co KG v Scott* [2010] EWCA Civ 1110; [2011] FSR 7 at [116].

⁵² *Grimme Landmaschinenfabrik GmbH & Co KG v Scott* [2010] EWCA Civ 1110; [2011] FSR 7, at [131]: “[T]he knowledge and intention requirements of Art. 26 and section 60(2) are satisfied if, at the time of supply or offer of supply, the supplier knows, or it is obvious in the circumstances, that ultimate users will intend to put the invention into effect. That is to be proved on the usual standard of balance of probabilities. It is not enough merely that the means are suitable for putting the intention into effect (for that is a separate requirement), but it is likely to be the

Therefore, under s60(2), in contrast to primary infringement, legitimate acts of supply can be turned into something illegitimate based on nothing more than knowledge of what a third party may intend to do with it once it enters their possession. In this respect, protection is evidently offered that is far broader than that of s60(1). However, as already noted, liability under the section is not unbounded. The double territoriality requirement of section 60(2) – supply in the UK and foresight that another will put the invention into effect in the UK – and the presence of s60(3), which exempts from liability the supply of staple commercial products unless used to induce the infringement of another, both serve to restrict the scope of secondary infringement.

Bringing “use” into the mix

By its very nature, including “use” as an operative and limiting principle within a claim changes the landscape of infringement. Therefore while the infringing acts under s60(1) must still maintain their disinterest in the mental state of the protagonist (offer of a process under s60(1)(b) obviously excepted), the inclusion of “use” brings a mental element within the claim itself. This inevitably causes complications. Taking the most straightforward example, where a claim encompasses the use of a product for a particular purpose then the product itself is neutral within the context of the use-bound claim. The existence of the product is a necessary, but not sufficient, element of liability. Instead satisfaction of the claim hinges upon the question of whether or not the subject of the use is directed towards the claimed purpose. In other words, in the absence of active utility for a defined purpose (i.e. that which is claimed), or the credible threat thereof, there can by definition be no infringement. If this were not the case then “use” would simply cease to be limiting.

When trying to seek a viable construction of such a claim the skilled person would inevitably understand that which distinguishes the new from the old is the desire to use the compound in the new way and the revelation that this has unexpected benefit when compared to the teaching of the prior art. In such circumstances they would also appreciate that the administration of the old compound or substance for the new indication (in therapy, diagnosis, etc.) must become an integral part of the claim, at least at some level of generality. From the perspective of the infringement of such a patent, the skilled addressee would also realise that accidental, or unintentional, use should not fall within the scope of the claim. This is perhaps most easily seen

case where the supplier proposes or recommends or even indicates the possibility of such use in his promotional material.”

in respect of claims to the first medical use of a compound known in another field.⁵³ Here, both in terms of the regulatory framework that it must satisfy⁵⁴ and also the formulation that it must adopt⁵⁵ there is little chance of overlap between the old and new markets for the substance in the absence of conduct that intentionally and actively places the old product into the new arena. In terms, therefore, of securing adequate reward to the owner of this new patent, manifest intention to supply the relevant compound for the new purpose would seem to be sufficient to protect such a patentee's interests.

While the same general approach must be taken in relation to second and subsequent indications – it is, after all, the intentional use of the compound for the new indication that differentiates the old from the new in patentability terms – for these claims the matter is not quite so clear cut. Indeed, the border between conduct that satisfies the claim and that which does not may be razor thin. In contrast to cases of first medical use, the outward manifestation of intent is likely to be less: the compound evidently already exists in a medically active form and therefore detection of infringement may be more difficult. Furthermore, all that potentially separates the old and new markets for the substance is the private intent of the end user; patented and prior art indications in theory being identical in all but this factor. How best then to reflect this element within the construction afforded to the claim?

Whatever the standard to be applied, the incorporation of intention into the claim itself brings additional complications to the question of infringement. Again, this is perhaps most straightforwardly demonstrated in cases of use-limited product claims such as those allowable for first medical indications. To take “making” under s60(1)(a) as an example: in the abstract, the act of making itself may be perceived as an ongoing enterprise or may be seen at the level of the individual quanta of things made. For the standard (i.e. non-use-bound) patent claim this distinction is unimportant: liability is strict and therefore those things made that fall within the scope of the patent's claims will infringe. In the absence of any determining factor that transforms non-infringing into infringing conduct (or vice versa) part way through a production run (for example the removal or provision of consent by the patent holder) the situation is clear.

⁵³ And thereby made legitimate by Art 54(4) EPC 2000, ex-art 54(5) EPC 1973.

⁵⁴ Marketing authorisations must be gained before the sale of any pharmaceutical product can be undertaken. See European Parliament and Council Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use (as amended).

⁵⁵ It being unlikely, at the very least, that a non-medicinal product would be packaged and formulated in exactly the same manner as the same product for use in medicine.

The entire run will be an infringement. As soon as the use-limitation is added, however, then things necessarily become more complicated. The addition of “use” adds an element of choice to the equation such that we are forced to view the act of manufacture at the level of the individual quanta of things made. The same is true of the other acts of primary infringement. Under s60(1)(a) therefore, things ‘made’, ‘disposed of’, ‘offered’, ‘used’, ‘kept’, and ‘imported’ will only fall within the claims if these acts are done not only in relation to the physical subject matter of the claim, but also if they are to be put to the patented use.

These issues evidently make the construction of the claims of a use-bound patent, and the subsequent determination of infringement, significantly more difficult than for those of standard, use-unlimited, cases. However, while all patents claiming a medical indication share complications over the nature of the relationship between the eventual use of the substance or compound, the remainder of the claim, and the acts of infringement, this complexity is amplified for patents containing claims in the Swiss-form. It is to this topic that we now direct our attention.

Further problems for the Swiss-form Claim

As the reader should by now have gathered, Swiss-form claims were created in the form of a compromise – following what Arnold J rather kindly referred to as “piece of judicial lawmaking which fudged some of the difficult issues.”⁵⁶ They are claims that, albeit for arguably valiant and noble reasons, have been forced into what was a non-existent shadow-space between statutory prohibitions on the patenting of medical processes of treatment, diagnosis and surgery, and the requirement that an invention be new. To do this, the claim format piggy-backed on the concessions given to the first medical use of known substances under the EPC 1973 and cloaked itself in the same fiction of novelty that such inventions were able to derive from the use to which the compound was to be put. However, in contrast to cases of first medical use,⁵⁷ in the Swiss-form claim the nexus between the use of the product and the act of infringement was further fractured by the addition of an extra step: manufacture.

Twinning use with manufacture evidently imposes an additional functional relationship between these two elements which must be respected in order that liability for infringement can be

⁵⁶ [2015] EWHC 72 (Pat) at [11].

⁵⁷ And indeed those patents drafted under EPC 2000 for second medical indications that are now allowed to make use of the same use-bound product claim format.

justified. Bizarrely, however, in many respects manufacture is functionally redundant within the Swiss-form claim. Therefore even though the claim is directed to the manufacture of a compound – “the use of chemical/compound X in the manufacture of a medicament for a specified (and new) medical use” – this process appears all but irrelevant to the claim’s eventual validity in anything other than the most tangential manner: a simple magician’s trick designed to distract attention while a rabbit is placed in a hat. Indeed, the manufacturing process may, as the Enlarged Board itself noted in *EISAI*, be one in which the “medicament resulting ... is not in any way different from a known medicament.”⁵⁸ In other words, an old compound may be produced in an old way and may be intended to be supplied to a known group of patients in precisely the same form and dosage as is indicated in the prior art, and yet because the purpose for which the drug is administered is new (and non-obvious) then a patent may be granted afresh. The only functional limitation that is placed upon this latter patent derives from the use itself, in that it must be constrained to the new purpose. Thus, for a claim in the Swiss-form, it is tempting to see ‘manufacture’ as nothing more than a disguise designed to smuggle the invention past the methods-of-treatment police, and to conclude that it may therefore be discarded once their attention is elsewhere.

However, logically this temptation must be resisted. True, it is difficult to see the EBA’s invention of protection for second medical use in *EISAI* as anything other than a well-intentioned but unorthodox and ultimately unsupportable judicial extension to a statutory text: a move that was fundamentally offensive to the supposed sanctity of the Convention. Nevertheless, having gone down this path, the utility of a mechanism for incentivising the investigation of new uses of old medicaments cannot be doubted. Accordingly, the time for any such fundamental objection to claims in the Swiss-form has unfortunately long passed. Now, standing as we do at the bottom of the rabbit-hole we can only try to make sense of the surroundings in which we find ourselves. Within this Wonderland it would seem sensible, if indeed there is any sense left, to force both manufacture and use to share a degree of responsibility for the protection that the claim is to enjoy. Excluding one or the other would, after all, only compound the problem of the claim’s existence. While the honest approach to such patents may once therefore have been to decry their very existence, a more pragmatic line of argument must now be deployed. Such reasoning would appreciate the claims’ limitations and bring this into consideration when their scope is placed in question. Therefore, notwithstanding

⁵⁸ G_05/83 *EISAI/Second Medical Indication*, [1985] OJ EPO 64; [1979-85] EPOR B241, at Point 20 of the Reasons for the Decision.

the circumstances of the Swiss-form's birth and that the EBA's use of 'manufacture' within the claim is little more than a smoke and mirror trick within this construct, to further cast off the mantle and allow the patent to progress unrestrained would simply add insult to injury. It would also fundamentally change the character of the claim. Accordingly, despite agreeing that it would have been better all-round if, instead of *EISAI* having been decided the way that it was, "doctors had been provided with a defence, or the restriction on methods of treatment repealed altogether"⁵⁹, it is argued that it would be impermissible to attempt to reverse engineer such results by further meddling with the claim format.

If truth be told, the construction of the Swiss-form claim was never going to be a simple exercise. Wading through the morass of use, intention and manufacture that is required to make sense of this unnatural oddity was a safari reserved for the brave or reckless only. The circumstances of the claim format's birth and development arguably placed it in a position where no strand of logic would lead to an answer that satisfied both the claim's wording and its promise as a vehicle to foster innovation. Fundamental concepts of incentive, reward and freedom to operate all jostle for dominance in the quest to tame the Franken-cuckoo birthed in *EISAI*. Part III of this series is therefore dedicated to investigation of the landscape into which Arnold J. in the High Court, and (subsequently) Floyd LJ (among others) in the Court of Appeal, found themselves thrust in the *Warner-Lambert* litigation.⁶⁰ How best to wend a path through these problems and make sense of the Swiss-form?

⁵⁹ [2015] EWCA Civ 556 at [55].

⁶⁰ At first instance see *Warner-Lambert v Actavis* [2015] EWHC 72 (Pat) (Arnold J; interim injunction), [2015] EWHC 2548 (Pat) (Arnold J; full trial) as well as a number of other related decisions in the case (all before Arnold J): [2015] EWHC 223 (Pat); [2015] EWHC 249 (Pat); and [2015] EWHC 485 (Pat). The Court of Appeal's decision on the interim matter was handed down in May 2015 - [2015] EWCA Civ 556 (CoA), and the decision at full trial in October 2016 - [2016] EWCA Civ 1006. Related matters concerning the same patent formed the basis of *Warner-Lambert Company LLC v Sandoz GmbH & Ors* [2015] EWHC 3153 (Pat).