

**SECOND MEDICAL INDICATIONS & THE SWISS-  
FORM CLAIM: TAMING FRANKENSTEIN'S MONSTER  
(PART III – THE FRANKEN-CUCKOO COMES HOME TO ROOST)**

Matthew Fisher\*

University College London

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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.

Parts I and II of this series of articles have provided a picture of the birth of the Swiss-claim format and outlined some of the difficulties inherent in any attempt to bring it to heel. This final part (Part III) concentrates on the litigation in *Warner Lambert v Actavis*, the case in which the EBA’s Franken-cuckoo finally came home to roost.

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

## **VI THE FRANKEN-CUCKOO COMES HOME TO ROOST**

### **The Dispute in Warner Lambert v Actavis**

Based on the discussion in Parts I and II of this series, it may surprise the reader to learn that the core factual background to the infringement dispute in *Warner-Lambert v Actavis* is, in patent law terms, capable of relatively straightforward summary. Complexity arises, however, from the manoeuvres of parties before the issue reached the courts and the processes and procedures that

accompany the dispensing of prescription medication in the UK. The dispute revolves around the drug pregabalin. Pregabalin is manufactured by Warner-Lambert (a subsidiary of Pfizer) under the trade mark “Lyrica”. Warner-Lambert owned a product patent on pregabalin (“the first patent”) that expired in May 2013.<sup>1</sup> Pregabalin was initially known to be useful in the treatment of epilepsy and generalised anxiety disorder (GAD). Subsequent to the filing of the first patent Warner-Lambert also discovered that pregabalin was unexpectedly useful in the treatment of pain. Accordingly in May 2003 it was granted a second patent with claims in the Swiss form that was directed to the use of pregabalin for this new indication (“the second patent”).<sup>2</sup> Consequently, Lyrica gained marketing approval for the treatment of epilepsy, GAD and neuropathic pain. So far, so good.

The market for Lyrica was extensive. In 2013 IMS Health placed the compound at number 14 in its list of the top 20 global pharmaceutical products with sales of US\$5.123 billion.<sup>3</sup> UK sales in the same year are said to have amounted to approximately \$310 million.<sup>4</sup> Unsurprisingly, as the Court of Appeal was to remark, this was “a market of considerable interest to generic pharmaceutical manufacturers both for the existing medical indications and the new.”<sup>5</sup>

Evidently, once the first patent had expired others were free to manufacture and sell pregabalin for those indications not covered by the second patent<sup>6</sup> – i.e. for anything other than the treatment of pain. Accordingly, Mylan and Actavis made preparations to launch generic pregabalin products for the treatment of GAD and epilepsy. Such should not be contentious – the point of the patent, after all, is to provide shelter from competition for a limited period of

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<sup>1</sup> EP No. 0 641 330, “Gaba and L-Glutamic Acid Analogs for Antiseizure Treatment”.

<sup>2</sup> EP No. 0 934 061, “Isobutylgaba and its Derivatives for the Treatment of Pain”. The patent claimed a priority date of 24 July 1996.

<sup>3</sup> [http://www.imshealth.com/files/web/Corporate/News/Top-Line%20Market%20Data/Global%20Prescription%20Sales%20Information1Top\\_20\\_Global\\_Products\\_2013.pdf](http://www.imshealth.com/files/web/Corporate/News/Top-Line%20Market%20Data/Global%20Prescription%20Sales%20Information1Top_20_Global_Products_2013.pdf).

Global sales figures carried through the judgments are somewhat lower, at US\$4.6 billion for 2013. See e.g. [2015] EWHC 72 (Pat) at [19] (Arnold J, interim stage), [2016] EWCA Civ 1006, at [2] (CoA, full trial). It is, however, unclear from where this latter figure was derived.

<sup>4</sup> [2016] EWCA Civ 1006, at [2]. No UK breakdown is given in the IMS Health dataset, *ibid*. Given the difference in the global market figures between the judgments and the IMS Health data is US\$500 million, it is probable that at least a proportion of this would be attributable to the UK market.

<sup>5</sup> [2016] EWCA Civ 1066, at [2].

<sup>6</sup> Subject, of course, to marketing authorisation.

time in consideration for the disclosure of the patented invention.<sup>7</sup> The core idea of patent protection being that this information enters into the public domain at the point of expiry of the grant. Thus, once the patentee's monopoly has ended others may enter the market and competition will drive the price down – this is all part of the life-cycle of a patent, and indeed is one of the fundamental limitations that enables the justification of the patent system itself. Without this latter step the social bargain that forms the basis of the patent grant would not be complete.<sup>8</sup> However, where patents for second (or subsequent) medical indications are concerned, things are not quite as straightforward: the downstream (post-initial-patent) market is effectively split when the new indication gains protection and this fracture remains for as long as any subsequent patent lasts. New fences are therefore erected: fences based not purely on the physical subject-matter of the grant, but rather on the use to which that subject-matter is put. Such boundaries are inherently harder to police than those surrounding traditional products or processes – especially where, as with claims in the Swiss form, the patent is directed to the manufacture of a compound that may be used by a third party for a variety of purposes: some permitted and some not.

Rational business decisions are based on a cost-benefit analysis of risk versus reward, and therefore uncertainties in the definition and scope of a patent's protection create economic volatility. In the absence of any determination of the scope of a claim in the Swiss form, it is therefore perhaps unsurprising that competitors seeking to capitalise on the space recently released by a patent's expiry might also want to clear the area around it as much as possible. A dead patent is, after all, a far more certain prospect than one in which the extent of the claims is, effectively, unknown. Accordingly, in the latter half of 2014, Mylan and Actavis commenced separate actions seeking revocation of the second patent on grounds that it was insufficient and lacked inventive step. In December of the same year, Warner-Lambert, for its part, commenced

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<sup>7</sup> Whether this is in the form of a reward for disclosure or an incentive to innovate and disclose the fruits of this innovation is for the time being irrelevant. The point is simply that the patent cannot be justified if it locks the subject matter of the grant away from the public in perpetuity.

<sup>8</sup> This concept of the patent as a bargain between the inventor and the state can be traced back to the insertion of “working clauses” into early-Elizabethan patent grants in the mid-16<sup>th</sup> century. Indeed, recognition of the time-limited nature of the exclusive rights provided was one of the elements that protected patents of invention from condemnation under the Statute of Monopolies 1623, under which all monopolies were declared to be “altogether contrary to the laws of this realm, and so are and shall be utterly void and of none effect.” See s1 of the Statute of Monopolies 1623, 21 Jac I, cap. 3. See further, discussion in Fisher, M., *Fundamentals of Patent Law: Interpretation and Scope of Protection*, (Hart, 2007), esp. chs 2 and 3.

infringement proceedings against Actavis seeking an interim injunction to restrain the sales of the latter's generic pregabalin product, branded Lecaent. On the one hand it would appear that Warner-Lambert felt it had legitimate monopoly of the pregabalin pain market that it wished to protect: it did, after all, have a patent on this very indication. On the other, Actavis also felt that it had a legitimate right to sell pregabalin for the (now) non-patented indications (i.e. anything except for pain). Had the on-patent and off-patent formulations been separate chemicals then the case would have been straightforward. However, as Lecaent and Lyrica were, by definition, the self-same molecules, the situation was evidently more complex. This complexity was amplified by the fact that, as Arnold J commented in his first judgment on the matter: "not only are about 83% of prescriptions written generically, but also about 95% of prescriptions do not state the indication for which the drug has been prescribed."<sup>9</sup> With the foregoing in mind, it is therefore simple to see why the situation presenting itself had the potential to cause problems for the parties.

Actavis had applied for, and been granted, marketing authorisation for a skinny label product which referred exclusively to its use in the treatment of epilepsy and GAD. Thus, while there was no mention of the treatment of pain in either the packaging leaflet or the SmPC for Lecaent, it will be evident from the foregoing discussion that this would not of itself prevent prescription or dispensing of the product for this indication. Therefore while Actavis had not actively targeted the treatment of pain (indeed had not manifested any intention that Lecaent would be used for this purpose)<sup>10</sup> it was practically inevitable that there would be some off-label use for the patented indication. This factor obviously posed a threat to the patentee's market for their patented use – one that if left unchecked could potentially fatally undermine the grant. The possibility of off-label use was enhanced by the fact that the market for treating pain was significantly larger than that for the other, patent-free, uses.<sup>11</sup> Furthermore, if a dispensing

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<sup>9</sup> [2015] EWHC 72 (Pat), at [3].

<sup>10</sup> Actavis was stated by the judge at first instance to have been "unequivocal that ... [it] did not intend and had never intended its skinny label pregabalin to be used for the treatment of pain." Further, the judge concluded that there was "no proper basis for inferring that Actavis intended Lecaent to be dispensed for the treatment of pain". See [2015] EWHC 2548 (Pat), at [592] and [595] respectively.

<sup>11</sup> IMS data put before the court suggested that at least 54% of sales in the first nine months of 2014 were for the treatment of pain. Another 32% was classified as sales to treat "unspecified other diseases". Although not certain, it is arguable that this latter figure may also have included sales for the treatment of pain. See the judgment of Arnold J in *Warner-Lambert v Actavis* [2015] EWHC 72 (Pat) at [20] and that of Floyd LJ in *Warner-Lambert v Actavis* [2015] EWCA Civ 556, at [8]

chemist has no idea what a compound has been prescribed for then they have no reason to go behind the words on the prescription itself. Obviously if a drug was prescribed by brand then they would have to follow this instruction, but equally clearly a generic prescription could be fulfilled by whatever manufacturer's medication the pharmacist saw fit. The combination of these factors meant that it would be eminently foreseeable that the generic version of the drug would be dispensed for "patients who have in fact been prescribed the drug for treating the patented indication, unless positive steps are taken to prevent this."<sup>12</sup>

As Arnold J was to remark in his first judgment on the issue: it was "more or less common ground between all concerned that the best solution to the problem which arises in this case is to try to ensure that prescribing doctors prescribe pregabalin for the treatment of pain by reference to the brand name Lyrica rather than by reference to the generic name pregabalin."<sup>13</sup> However, this was not something that lay within the power of either of the parties in the case to guarantee. The actions of the prescribers were, to this extent, free actions of third parties. While we might bring such activities within the realm of patent law using the principles of joint tortfeasance or vicarious liability, neither was applicable here. On the facts, Actavis had not solicited prescription for pain in any way other than by the bare fact that it was producing a compound in a form that that could be used to treat this condition if so desired. Indeed, it had taken a number of steps to try and ensure that its generic pregabalin was neither prescribed nor dispensed for the treatment of pain.<sup>14</sup> It had therefore restricted its marketing authorisation to the off-patent indications and had prepared and packaged its product accordingly. It had also offered to write (and later did write) a series of letters to Clinical Commissioning Groups in England, Health Boards in Wales, superintending pharmacists and to the National Institute for Healthcare and Excellence (NICE), explaining that Lecaent should not be provided for the patented indication. Warner-Lambert for its part, however, wanted a more concrete assurance that its patent monopoly would not be undermined by off-label use of the generic product.

From before the commencement of proceedings, various non-patent solutions to this problem were being pursued. These included attempts to get the Department of Health (DoH), or NHS

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<sup>12</sup> [2015] EWHC 72 (Pat) at [3].

<sup>13</sup> [2015] EWHC 72 (Pat) at [73].

<sup>14</sup> The steps taken or proposed to be taken at the time of the interim judgment on the matter are listed in [2015] EWHC 72 (Pat) from [62] to [66]. By the time of the full trial in the matter additional steps had been taken. See [2015] EWHC 2548 (Pat) at [518] to [521].

England and NHS Wales to issue guidance, and asking prescription software suppliers to alter their software so it was easier to prescribe Lyrica by name for the treatment of pain.<sup>15</sup> Indeed, by the time the matter came to full trial (following its interim outings in the High Court and the Court of Appeal) Warner-Lambert (or its parent company, Pfizer) had written to over 35 different organisations and bodies, including NHS England, NHS Wales, the DoH, NICE, the GMC, GPhC, BMA and various prescription software providers in an attempt to prevent Lecaent being prescribed for the treatment of pain.<sup>16</sup> Actavis, the generic manufacturer of Lecaent, had also taken various steps to attempt to prevent their compound being dispensed for the patented indication – admitting that the skinny label alone would be insufficient in this regard.<sup>17</sup> However, these solutions, while they would arguably be more effective than those offered by patent law<sup>18</sup> cannot supplant the essential question: “whether, in such circumstances, the generic supplier will infringe the second medical use patent unless the supplier takes positive steps to prevent its generic version of the drug being dispensed for patients who have been prescribed the drug for the patented indication.”<sup>19</sup> If infringement was likely then a supplementary question presented itself: what steps could be taken to defend against that claim? In order to answer the first of these questions, the scope of the Swiss-form claim had to be considered, and this was to prove more problematic than might have been hoped.

### **Interpretations in the Interim – Pinning the Tail on the Donkey**

The Swiss form claim, it will be recalled, takes the general form “use of substance or composition X for the manufacture of a medicament for a specified new and inventive therapeutic application”. Before the court at first instance in the interim hearing, the parties had agreed that the adoption of the use limitation meant that the standard patent law construction of the word “for” as “suitable for” was simply not possible. By definition in the context of claims for the new use of an existing medication any condition treated by one compound would also be “suitable for” treatment by one of its biogeneric clones. Accordingly, if the standard definition of “for” were to apply, all generic manufacturers would find themselves marked out as infringers.

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<sup>15</sup> See discussion of these matters at [2015] EWHC 72 (Pat) [73] to [77].

<sup>16</sup> See further [2015] EWHC 2548 (Pat), at [459] to [505].

<sup>17</sup> See discussion in [2015] EWHC 2548 (Pat), at [516] to [521].

<sup>18</sup> The predominantly non-patent matters are dealt with by Mr Justice Arnold in *Warner-Lambert v Actavis, the National Health Service Commissioning Board & Ors* [2015] EWHC 485 (Pat).

<sup>19</sup> [2015] EWHC 72, at [4].

This could not be correct. It was therefore common ground before the judge that “for” could not take its standard meaning, and should instead be interpreted as “suitable and intended for”.<sup>20</sup>

This exact position was not, however, maintained in the remainder of the litigation; a point made explicit by Floyd LJ in the Court of Appeal’s first judgment in the matter.<sup>21</sup> Nevertheless, by this time a degree of damage had already been done. By casting the initial investigation in the language of intention, the real issue of the purpose of the limitations within the claim was, to an extent, obscured. The word “intention” evidently does not appear in the claim itself; it was only ever imported as an act of initial construction. Therefore, concentrating on this issue over and above the idea of ‘purpose’ and the broader question of the character of the mental element it imports into the use-limited claim only serves to distract from the key nexus between manufacture and eventual use. This focus therefore offered little in the way of clarity and, in many instances, simply served to confuse. Indeed, one of the main criticisms that can be levelled at the judgments in this case is the imprecision with which these mental elements of liability were, on occasion, deployed. The language of the mental state therefore became embedded in a thick soup of intention, foresight and knowledge. While acknowledging that a search for the appropriate meaning of intention by hunting around in various other parts of the law was “likely to throw one off the scent”,<sup>22</sup> the spectre of this mental state was nevertheless to haunt the remainder of the proceedings.

In addition to the above, however, understanding that intention is not the sole consideration underpinning the claim does not actually progress us that far. Construction of the claim and its consequent relation to the acts of infringement still requires determination of the manner in which the employment of “use” as a functional and limiting element changes the landscape. Therefore, pinning the tail on this particular donkey is not the most straightforward of party games even in ideal circumstances. For the Swiss-form, and its addition of the requirement of manufacture, matters are further complicated. There are, after all, a number of actors involved within the envelope of the second medical use claim – the manufacturer, intermediate suppliers (doctors and pharmacists) and the eventual end-user – each of whom potentially possess mental states that might be relevant to the question of infringement. In addition, the relationship between each of these parties, in particular, what each knows, foresees or desires of the actions

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<sup>20</sup> [2015] EWHC 72 (Pat) at [97].

<sup>21</sup> [2015] EWCA Civ 556, at [114].

<sup>22</sup> [2015] EWCA Civ 556 at [114].



of the others in the supply chain further clouds the issue, and arguably diverts attention from the core question of the nexus between the claim elements and the acts of infringement. Thus, even if we throw off the shackles of intention and look at things more broadly, questions still need to be answered concerning precisely what this question of purpose actually imports into the claim in such circumstances and how it can be satisfied. How too will it interact with the other elements of the claim – especially the manufacturing step? And who is required to hold it? Only after satisfying these queries would it be possible to begin to answer the essential patent law question of whether Lecaent was a product obtained directly by the use of pregabalin for the manufacture of a medicament intended for the treatment of pain. In other words, whether it infringed under s60(1)(c) PA 1977.<sup>23</sup>

On this latter issue, Arnold J at first instance, and Floyd LJ in the Court of Appeal, came to polar opposite conclusions based primarily on differing views of the mental state necessary to satisfy the claim. Nevertheless, despite this disagreement, both shared the view that the Swiss-form must be interpreted as a process claim – the weight of authorities on this point being insuperable<sup>24</sup> – and both also understood the claim to avoid touching the prescribing doctor by the use of a manufacturing step.<sup>25</sup> In respect of the mental element imported by the claim, Floyd LJ considered that there were effectively two: one of which was a necessary, but not sufficient, precondition of infringement. Accordingly, his Lordship was of the view that the use-element of the claim required the intentional application of the claimed compound for the patented indication. In the words of the Court: this was “at the heart of the invention.”<sup>26</sup> Nevertheless, the question of infringement would revolve around the mental state of another party – that of the manufacturer. In this latter respect, the judges agreed: Arnold J having explained that the claim ““is to a process of manufacture and ... is directed at the manufacturer.... It follows that the relevant intention is that of the person who carries out the process”.”<sup>27</sup> Clearly, if intention is to cloud the construction of the claim then this is an eminently sensible conclusion. The manufacturer is, after all, the person responsible for the creation of the drug and should therefore have some handle on their own destiny. Indeed, if the intention of someone further down the chain of supply were to be the fulcrum upon which infringement turned then the link

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<sup>23</sup> The act of manufacture had been carried out in Bulgaria, thereby rendering s60(1)(b) (which would require use of the process in the UK) redundant.

<sup>24</sup> See [2015] EWHC 72 (Pat), esp. at [11] and [93] (Arnold J); [2015] EWCA Civ 556 at [118] (CoA).

<sup>25</sup> [2015] EWHC 72 (Pat), at [96] and [99] (Arnold J); [2015] EWCA Civ 556, at [119] (CoA).

<sup>26</sup> [2015] EWCA Civ 556, at [121].

<sup>27</sup> [2015] EWHC 72 (Pat) at [99].

between manufacture and use would be all but severed. In such a situation, the manufacturer would be unable to tell if they had made use of the invention until perhaps long after they had disposed of the product. Rejection of such a construct must therefore be correct.

Nevertheless, a conclusion that the nexus between manufacture and use must be determined by looking at the mental state of the manufacturer does not get us very far on the question of liability. What, for example, will satisfy this requirement? Is it sufficient that the manufacturer simply suspects that their product is being applied for the patented indication, or do they need something more: constructive knowledge; actual knowledge; oblique intention or even a direct and subjective intention – an active desire to infringe? On this point the two judge’s opinions differed markedly.

Arnold J clearly rejected knowledge and foresight as the standards for liability, reasoning that they simply placed the bar for infringement at too low a level. If they were used to determine liability then an innovative party creating a compound for the first time might subsequently be held hostage by a second-comer who discovered a new use for that compound. “If foreseeability is enough, [a] first inventor will infringe the second patent *simply by carrying on doing* what he was doing before the second patent was applied for.”<sup>28</sup> (emphasis supplied) In the judge’s view this was evidently not an attractive outcome. Accordingly, “[n]othing less than a requirement of subjective intention” (i.e. a direct and aimed for purpose) was considered to protect the first inventor from infringement.<sup>29</sup> The problem with this construction, however, was that (in the claimant’s eyes at least) it robbed the claim of much of its enforceability. An unscrupulous manufacture of generic medications could therefore absorb much of the patented market as long as this was not their subjective (and provable) intent. Furthermore, manufacturers who were ambivalent as to whether their product was prescribed for the patented indication or the old, off-patent, uses would escape scot-free. This conclusion was clearly a bitter pill for Warner-Lambert to swallow and was one of the main elements that led to their appeal.

In the Court of Appeal, construction of the claim and the issue of infringement followed lengthy consideration of a multitude of authorities from the EPO,<sup>30</sup> UK,<sup>31</sup> Australia,<sup>32</sup> Germany<sup>33</sup> and the

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<sup>28</sup> [2015] EWHC 72 (Pat) at [109].

<sup>29</sup> Ibid.

<sup>30</sup> Discussed in [2015] EWCA Civ 556 from [51] to [60].

<sup>31</sup> Discussed in [2015] EWCA Civ 556 from [61] to [71].

Netherlands<sup>34</sup>, as a result of which Floyd LJ was able to conclude that the “law relating to both direct and indirect infringement of Swiss claims is far from settled.”<sup>35</sup> His Lordship therefore turned to the decision of the judge below, commending Arnold J on providing a “succinct judgment” on a “very difficult question”,<sup>36</sup> but nevertheless disagreeing with him on almost every issue of infringement.

Commencing by drawing the parameters of the invention, Floyd LJ noted that the Swiss-form was a process claim and that the skilled person would understand its technical features to extend beyond mere manufacture of the product and “yet fall short of including the step of actually using pregabalin for treating pain”.<sup>37</sup> Accordingly, a distinction was drawn between “use” in the claim and “use” as an act of infringement within s60(1)(c) PA 1977.<sup>38</sup> In the case of the former, “use” was a step in the claim – “use of compound X in the manufacture of a medicament...” – in the latter, the statutory question was considered to refer to use by some person of the process as a whole. The Court therefore concluded that the subject matter of the claim encompassed the manufacture of pregabalin for the class of patients for whom it will be intentionally administered for the treatment of pain. However, even with this conclusion reached, the question of how strong the connection between manufacture and eventual use should be, in other words “what is sufficient to constitute that link”,<sup>39</sup> remained a knotty problem. Evidently, the extreme protectionist view – that the requirement would be satisfied based merely on whether pregabalin was used for the claimed indication had to be rejected out of hand. Following similar lines therefore to those drawn by Arnold J at first instance, the Court concluded that there needed to be some sort of mental element attaching to the manufacturer themselves. Furthermore, the

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<sup>32</sup> *Warner-Lambert Company LLC v Apotex Pty Limited* [2014] FCAFC 59. Discussed at [2015] EWCA Civ 556 at [73].

<sup>33</sup> Including Case X ZR 236/01 *Carvedilol II* (decision of the BGH of 14 March 2013); Case 4A O 145/12 *Chronic Hepatitis C Treatment* (decision of the Landgericht Dusseldorf of 19 December 2006); Case I-2 U 54/11 *Cistus* (decision of the Oberlandesgericht Dusseldorf dated 31 January 2013); as well as Case 327 O 140/15 *Warner-Lambert Company LLC v Aliud Pharma GmbH* (decided by the Landgericht Hamburg at the same time as the case in the English Court of Appeal was being heard). See [2015] EWCA Civ 556 at [74] to [92].

<sup>34</sup> Including Case HA ZA 10-437 *Schering v Teva* (a decision of the District Court of the Hague dated 10 November 2010); and *Novartis v Sun* (a decision of the Court of Appeal of the Hague dated 27 January 2015). See [2015] EWCA Civ 556 at [93] to [97].

<sup>35</sup> [2015] EWCA Civ 556, at [98].

<sup>36</sup> [2015] EWCA Civ 556, at [99].

<sup>37</sup> [2015] EWCA Civ 556, at [118].

<sup>38</sup> i.e. use of a product directly obtained from a patented process.

<sup>39</sup> [2015] EWCA Civ 556, at [122].

only “realistic candidates” for this element that would satisfy the nexus between the intentional administration of the compound and the act of manufacture were either foreseeability or subjective intention.<sup>40</sup>

Disagreeing with the judge at first instance, however, Floyd LJ explained that he could “see no reason why the skilled person would conclude that the word “for” implied subjective intent.”<sup>41</sup> Indeed, there would, his Lordship explained, be significant difficulties with the application of the test for infringement if subjective intent were required. The patentee would have to show that it was the defendant’s active desire to commandeer a proportion of the patented market: “How does the patentee go about establishing this wish or desire if it is not enough to show that it is known or foreseeable that some of their [the defendant’s] product is intentionally being used for pain?”<sup>42</sup> Requiring such a standard would, in the opinion of the Court of Appeal, have “rob[bed] Swiss claims of much of their enforceability.”<sup>43</sup> This point of policy was therefore considered to swing the balance. Accordingly, “the skilled person would understand that the patentee was using the word “for” in the claim to require that the manufacturer knows [(and for this purpose constructive knowledge is enough)] or can reasonably foresee the ultimate intentional use for pain.”<sup>44</sup> It was therefore not necessary that the manufacturer have that specific intention or desire themselves. Having dropped down on this side of the fence, the Court noted that the test proposed has “structural similarities to that under s60(2)”. While not being considered to provide a reason for adopting the formulation suggested, Floyd LJ did, however, note that it provided confirmation that the test was “a workable one”.<sup>45</sup>

Nevertheless, progressing down the path of foresight did bring with it a number of potential problems – most notably when dealing with what the Court referred to as a number of “hard cases” that had been canvassed before it.<sup>46</sup> Thus where a manufacturer had commenced sales before the priority date of the patent on the second indication, the Court was asked whether it would be fair if that party was made an infringer simply because it had seen its sales increase simply as a result of uptake of the old product for the new use? In such a case, Floyd LJ

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<sup>40</sup> [2015] EWCA Civ 556, at [122].

<sup>41</sup> Ibid. at [127].

<sup>42</sup> Ibid at [126].

<sup>43</sup> Ibid.

<sup>44</sup> [2015] EWCA Civ 556, at [127].

<sup>45</sup> [2015] EWCA Civ 556, at [126].

<sup>46</sup> See discussion at [2015] EWCA Civ 556, at [130].

considered that the answer to any perceived unfairness (avoided entirely, it may be noted, if Arnold J's formulation had been adopted) would be to tailor the relief to be granted, withholding an injunction from the patentee but otherwise progressing as normal.<sup>47</sup> National rules – whether relating to the damages payable in such circumstances (whether on a royalty or loss of profits basis) that might make otherwise legitimate generic competition unprofitable, or in relation to the prescription drug market itself – should not, in the Court's opinion, be allowed to dictate the scope of the claim. Accordingly, although these were “justifiable concern[s]” they were not considered to lay a “basis for adopting the narrow claim construction” that had been applied in the Court below.<sup>48</sup>

The fundamental point of concern for the Court of Appeal would therefore appear to be the policy argument that adopting the construction advocated by the judge at first instance would simply have crippled the Swiss-form claim: robbing it of all incentive value. With the greatest of respect to Floyd LJ, this argument entirely misses the point. Swiss-form claims, as should now be clear to the reader, are fundamentally crippled entities. To treat them as other, dare we say ‘more legitimate’, patent claims and to expect that they should carry the same scope of protection and be subject to the same latitude of interpretation is to misunderstand the creature that the EBA created. The approach taken by the judge at first instance may indeed offer narrow prospects for demonstrating infringement, but it would not rule them out. The adoption of subjective intention as a standard would not therefore gut the Swiss-form claim entirely, but would reflect that the nature of the patentee's contribution under patent law is correspondingly narrow.

The argument that adopting a narrower interpretation of the Swiss-form would rob it of all enforceability is also troubling from a pure policy perspective. If, for example, we take the view that the patent is fundamentally justified on the basis that it provides incentive for the creation and dissemination of invention<sup>49</sup> – in other words, that investment in the process of invention will not be carried out, or will be carried out at a sub-optimal level, in the absence of the offer of some sort of reward – then we immediately hit problems with claims in the Swiss-form. To begin, the original claims to second medical indications were applied for at a time when patents

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<sup>47</sup> [2015] EWCA Civ 556, at [130].

<sup>48</sup> See *Ibid.* from [130] to [132]

<sup>49</sup> As Lemley notes: this “simple model” has “been the model for 200 years”. See Lemley, M.A., ‘Reconceiving Patents in the Age of Venture Capital’ (2000) 4 *Journal of Small and Emerging Business Law* 137, at p.139.

on a new use of a known medicament were routinely rejected by both European and national patent offices.<sup>50</sup> Accordingly, inventions in this field must have occurred in the absence of any patent incentive. Even if we accept, as we must, that such innovation may be occurring at a sub-optimal level in the absence of patent protection and that adding patents to the mix will only increase the occurrence of developments in this field, then we still have difficulty with this policy argument. As the Court of Appeal itself has stated, at the time of its interim decision no clear position had been adopted on the interpretation of the Swiss-form claim either in the UK or abroad.<sup>51</sup> In fact no cases had actually dealt with the substantive issue in a clear enough fashion as to give rise to any legitimate (or illegitimate) expectations at all. At this point in time, therefore, much like Schrödinger's potentially unfortunate cat, the claim format was both alive and dead – broad and narrow in scope. In other words, while the format may have been ostensibly valid, its construction was simply uncertain. Indeed, as the EBA has itself stated:

“There can be no ‘legitimate expectation’ that an interpretation of a substantive provision governing patentability given in a decision of the boards of appeal will not be overruled in the future by the Enlarged Board, since recognising such an expectation as legitimate would undermine the function of the Enlarged Board of Appeal.”<sup>52</sup>

Accordingly, if there could be no concrete supposition that the claim format created by the Enlarged Board would survive challenge before that Board then it is difficult to see how there could be any expectation whatsoever concerning its interpretation before any decision on that matter had been delivered by the courts. Thus, any judgment based on not upsetting the applecart and robbing patentees of their legitimate beliefs concerning the scope of their entirely uncertain claims is flawed from the start. At the time the litigation commenced it is hard to see that there could have been any expectations concerning the construction that would eventually be placed on the claim format at all.

Furthermore, as of the date of the commencement of proceedings in *Warner-Lambert* all of the patents containing Swiss-form claims that could ever have been applied for under the European Patent Convention must already have been filed. The ABBOTT decision<sup>53</sup> of the EBA had, after all, closed the doors firmly on the prospect of anything else following the expiry of the three-

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<sup>50</sup> See discussion in text accompanying notes 27 to 29 in Part I of this series of articles (CITATION).

<sup>51</sup> [2015] EWCA Civ 556, at [98].

<sup>52</sup> G\_02/07 *PLANT BIOSCIENCE/Broccoli* [2012] OJ EPO 130, see point 2.5 of the Reasons for Decision.

<sup>53</sup> G\_02/08 *ABBOTT RESPIRATORY/Dosage Regime*, [2010] OJ EPO 456; [2010] EPOR 26. See further the discussion of ABBOTT in text accompanying notes 16 to 22 of Part I of this series of articles (CITATION).

month transition period after publication of its decision. Therefore any policy argument that future patentees would need to have a broad interpretation so as to provide sufficient incentive to invest in the discovery of new and innovative uses for old medicines must also be void in as much as it relates to the Swiss-form. Claims to second medical indications under EPC 2000, by contrast, which can be claimed as use-bound products, would obviously receive different, broader, scope as they are unconstrained by the step of manufacture.

Thus, with the policy argument against Arnold J's interpretation upended, we are left with the argument that a subjective, 'aimed-for', approach would be impractical to implement. However, upon consideration we can see that this, once more, is unfounded. The issue of proving the infringement, of divining the defendant's intentions, would still be a matter of evidence – straightforwardly (although admittedly not readily) demonstrated if the court were to insist on the envelope of manufacture being explicitly extended to include the packaging and labelling of the product. This would have the effect of taking the initial manufacture of the active compound outside of the confines of primary infringement and placing it into the realm of the secondary. While this approach would arguably stretch the concepts under consideration – manufacture, for example, becoming manufacture for administration with all that this entails rather than simply creating the base product – it arguably does no greater damage than attempting to massage the protection offered by the Swiss-form so as to avoid robbing it of much of its enforceability vis-à-vis other forms of claim.

Furthermore, the analogy that the Court of Appeal draws between its proposed test and that applicable under s60(2) to demonstrate that the former is “workable” also fails to appreciate the critical differences that exist between the two sections and the degrees of protection that they offer. Fundamentally, s60(2) PA 1977 is a very different beast to s60(1)(c) on a number of levels. Functionally, the latter carries with it cascading liability for any products that are deemed infringing – any subsequent dealing in these elements will therefore also be an act of primary infringement on a strict liability basis.<sup>54</sup> The same cannot be said of the means supplied for the purpose of s60(2).<sup>55</sup> Moreover, the extended protection given under s60(2) is traded against both knowledge and the double territoriality requirement within the section as well as having the specific defence available under s60(3) for staple commercial products. Notwithstanding that there will be few pharmaceutical formulations that one would consider fall into this latter

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<sup>54</sup> See further the discussion of s60(1)(c) above.

<sup>55</sup> Infringement under the section always being contingent upon the possession of the relevant mental element.

category, there are some that are arguably so ubiquitous that they would satisfy the requirements of the section – aspirin<sup>56</sup> and paracetamol<sup>57</sup> for two. By extending protection under s60(1)(c) to functionally overlap with that under s60(2) in the manner proposed by the Court of Appeal, the differences are ignored and the safeguards applied to the latter section are effectively jettisoned. The elision of principles in this manner is no more legitimate than the EBA’s structural reorientation of the text of the EPC in *EISA* that led to the Swiss-form in the first place.

### **The Saga Continues: Decision at Full Trial (Part I – the High Court)**

By the time the case came to full trial, as noted above, Warner-Lambert and its parent company, Pfizer, had written to over 35 different organisations in an attempt to prevent Actavis’ product being dispensed for the patented indication. Guidance had been issued by NHS England, NHS Wales and NHS Northern Ireland,<sup>58</sup> and changes had also been made to clinical software.<sup>59</sup> Actavis had also taken various steps. These included writing to over 7,500 pharmacists and to every Clinical Commissioning Group in England, every Health Board in Wales and Scotland and every Trust in Northern Ireland. In addition, they had emphasised in their marketing literature and promotional materials that Lecaent was not to be used to treat pain, and had briefed their sales and telemarketing teams to the same end. However, Pfizer complained that these steps were both inadequate and late: they wanted more.<sup>60</sup> In the absence of further security for the maintenance of a partition between the on- and off-patent uses of the compound Pfizer therefore maintained that Actavis would still infringe. By the time the matter came to trial, Pfizer had also expanded their assault to include allegations that Actavis intended Lecaent to be dispensed for the treatment of pain.<sup>61</sup> This argument was, however, dismissed by the judge on grounds that there was “no proper basis” for inferring that Actavis had actively and subjectively intended to supply Lecaent for the treatment of pain,<sup>62</sup> and neither were there grounds to impute such intention as the natural and probable consequence of their acts.<sup>63</sup> Nevertheless, having

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<sup>56</sup> Acetylsalicylic acid, or 2-acetoxybenzoic acid, to provide its proper chemical name.

<sup>57</sup> Properly known as N-(4-hydroxyphenyl)ethanamide, or N-(4-hydroxyphenyl)acetamide.

<sup>58</sup> Detailed at [2015] EWHC 2548 (Pat) from [511] to [513].

<sup>59</sup> *Ibid.* [514] to [515].

<sup>60</sup> A list of some 11 additional elements is provided in the High Court’s judgment, not all of which were pursued in the claimant’s closing arguments. Arnold J describes some of these as “bizarre” suggestions. See [2015] EWHC 2548 (Pat) at [522] to [549].

<sup>61</sup> See [2015] EWHC 2548 (Pat) at [590].

<sup>62</sup> [2015] EWHC 2548 (Pat) at [595].

<sup>63</sup> [2015] EWHC 2548 (Pat) at [596] to [597].



dispensed with this point, the court still had to consider infringement under the standard laid down by the Court of Appeal at the interim stage in the proceedings. We therefore return to the question of the scope that was to be accorded to the claims of the second patent: i.e. the claims in the Swiss-form. And on this issue, the judge had a number of concerns.

Following relatively extensive discussion of the Court of Appeal's construction of the relevant elements within the Swiss-form claim, Arnold J concluded that they were, strictly speaking, obiter dicta and therefore non-binding on his court.<sup>64</sup> However, given the decision of the senior court was unanimous and had been reached following full argument on the matter, the judge conceded that it was highly persuasive and should be followed unless he was convinced it was wrong. On this latter point, Arnold J expressed considerable doubts as to the correctness of Floyd LJ's construction, siding with counsel for Actavis and the Secretary of State (as intervener) who had argued that the interpretation adopted in respect of the word "for" "did not accord with its context or purpose" within the Swiss-form claim.<sup>65</sup> The insistence upon foresight as the trigger for infringement was criticised on the basis that it eroded the nexus between the manufacturer's acts and the ultimate intentional use of the compound for the patented indication.<sup>66</sup> In addition, concerns were raised about how well the principles espoused by the Court of Appeal could be applied in cases where a proportion of a manufacturer's product would be used for infringing purposes but most would not. In such cases, the judge asked rhetorically, "on what principled basis can one arrive at [an answer to the question of infringement]...?"<sup>67</sup> Notwithstanding these trenchant concerns, Arnold J was apparently not entirely convinced that the senior court's decision on the matter was wrong. He therefore relented and, in the words of the Court of Appeal "loyally decided to follow this court's decision on the legal issues which arose."<sup>68</sup>

In seeking to apply the Court of Appeal's test, however, Arnold J noted that, even on the assumption that the senior court's judgment was to be followed, the parties were "divided as to how it should be applied."<sup>69</sup> The essential debate between the sides once more revolved around the nature of the mental element that the use-limitation imported into the claim, and in

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<sup>64</sup> [2015] EWHC 2548 (Pat) at [617] and [618].

<sup>65</sup> [2015] EWHC 2548 (Pat) at [625].

<sup>66</sup> Ibid.

<sup>67</sup> [2015] EWHC 2548 (Pat) at [629].

<sup>68</sup> [2016] EWCA Civ 1006 at [186].

<sup>69</sup> [2015] EWHC 2548 (Pat), at [633].

particular, how the Court of Appeal’s “foresight test” could be satisfied. Was it sufficient that the manufacturer foresaw that some of their product would be used for the patented indication, or did they have to foresee that a given box of tablets would intentionally be put to this use?

The Court of Appeal’s test was, in the eyes of the judge, “plainly not a pure test of foreseeability.”<sup>70</sup> Intentional administration was said to be at the core of the invention – it was, after all, the element that conferred novelty, and therefore Arnold J was of the view that the word “for” had been used to provide a link between the manufacturer’s acts and this intention. Accordingly, there were two mental elements at play. A manufacturer would only infringe where they know or foresee that users will intentionally administer pregabalin for the treatment of pain. This was, in the view of the judge, something that could be distinguished from a “pure foreseeability” standard. Once more, therefore, intention was placed into the equation – albeit this time not that of the manufacturer themselves. The intention of the prescribing doctor was considered “highly relevant, if not exclusively so”.<sup>71</sup> This party would, after all, have the medical expertise necessary to produce the new therapeutic effect and would have the power to ensure that the manufacturer’s pregabalin was used to satisfy that purpose. In consort with the doctor, the pharmacist’s intention was also held, “[a]fter considerable hesitation” to be a relevant consideration.<sup>72</sup> Furthermore, the judge considered that “it would make no sense for it to be sufficient that the doctor intended pregabalin from any source to be administered for pain. Infringement must depend on what the manufacturer can foresee happening with the pregabalin it manufactures, not pregabalin made by others.”<sup>73</sup> The intention of the ultimate end user, the patient, was however considered irrelevant: they simply take what they are given. Therefore in order to satisfy the requirements of the Court of Appeal’s test, Arnold J held that there would have to be a combined and very specific intention at play. It would not be sufficient, for example, that a doctor merely prescribed and a pharmacist dispensed generic pregabalin for the treatment of pain. Rather, in the judge’s view, the relevant intention would be satisfied only where “the pharmacist dispenses Lecaent when he or she knows that pregabalin has been prescribed for pain.”<sup>74</sup> In other words: where the doctor prescribes generically for the treatment of pain and the pharmacist knows this and dispenses the generic manufacturer’s product in any

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<sup>70</sup> [2015] EWHC 2548 (Pat), at [634].

<sup>71</sup> [2015] EWHC 2548 (Pat), at [637].

<sup>72</sup> [2015] EWHC 2548 (Pat), at [638].

<sup>73</sup> [2015] EWHC 2548 (Pat), at [637].

<sup>74</sup> [2015] EWHC 2548 (Pat), at [666].

case. When the requirement of the manufacturer’s foresight is added to the equation then the result borders on the absurd. In terms of tests for infringement, it does not come much narrower.

Accordingly, what we essentially see here is a gutting of the Court of Appeal’s test under the guise of implementation: Hell apparently has no fury like a first instance judge scorned. The result is paradoxically narrower than Arnold J’s original test of subjective intention, as now the fulcrum upon which infringement rests is not simply the view of the manufacturer but rather the knowledge that person possesses of the intentions of at least one, maybe two, third parties. Arguably, therefore, even if a generic manufacturer actively desires that their compound be dispensed for the patented indication and produces sufficient quantity to far exceed the off-patent market, they will only infringe where they also foresee:

- (1) a doctor writing a generic prescription for pain **and**
- (2) a pharmacist, possessed of knowledge that that the prescription was written for pain, dispensing the specific generic product in satisfaction of it in any case.

It is therefore not unsurprising that the Court of Appeal was once more to disagree with the judge’s conclusions when the matter again came before it.

### **Taming the Franken-Cuckoo: Decision at Full Trial (Part II – Back to the Court of Appeal)**

When the case landed back in the Court of Appeal, Lord Justice Floyd accepted that his comments concerning the scope of the Swiss-form in the Court’s first decision were, strictly speaking, unnecessary for the determination of the case and were therefore obiter.<sup>75</sup> In the meantime, Arnold J had found the relevant claims of the patent invalid for insufficiency, a conclusion also supported by the Court of Appeal. In Floyd LJ’s words, therefore: “the infringement claim fails.”<sup>76</sup> There was, strictly speaking once more no need for the Court to consider the interpretation of the Swiss form or any of the issues of infringement contingent upon this. However, given the importance of this issue and its “great difficulty”, not to mention the “profound reservations about the law” expressed by the judge at first instance, Floyd LJ explained that it would not be right to leave the case without considering the principal arguments on the matter. Accordingly, we see further elucidation and explanation of the points laid down in the interim decision.

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<sup>75</sup> [2016] EWCA Civ 1006, at [186].

<sup>76</sup> [2016] EWCA Civ 1006, at [184].

The fundamental issue, his Lordship explained, was that the law was:

“[S]truggling on the one hand to give the patentee a proper reward for his contribution to the art by elucidating the new use for the drug, whilst at the same time not excluding the competing manufacturer from making and marketing the drug for its known purpose.”<sup>77</sup>

This matter was complicated by the interaction with the law and practices of the market in prescription medicine outlined above.<sup>78</sup> Accordingly, the approach taken by the Court of Appeal in the interim stages of the dispute was said to be an attempt to strike the appropriate balance. By enabling liability to be founded upon a manufacturer’s constructive knowledge/reasonable foresight of the ultimate intentional use for the patented indication, the Court considered that it was avoiding placing “insuperable obstacles” in the path of the patentee. On the other side of the coin, Floyd LJ noted that it was also recognised “in very clear terms that the remedies available for infringement will have to be moulded so as to achieve fair and proportionate relief to the very special circumstances of this type of case.”<sup>79</sup>

While it cannot be denied that the case is indeed non-standard, it is less clear that this therefore requires a bespoke approach to the remedies to be applied. We could instead simply accept that we are dealing with subject-matter at the very edges of patentability and treat the claim accordingly. This would not necessarily require pandering to its limitations but could be achieved by the straightforward acknowledgement that it is compromised. Indeed, having already witnessed the EBA ride roughshod over the EPC 1973 in order to allow such inventions space to germinate, it would seem to add insult to injury to require the remedies to be applied to be twisted in a similar fashion in order to allow for the claim’s enforcement. The Court’s reliance upon securing the patentee adequate reward for their contribution is also misplaced. Surely, if we are considering reward due to the patentee then we have to respect the contribution not just to humanity but rather within the confines of patent law. After all a brilliant new method of treatment per se is, at least under the EPC,<sup>80</sup> outside of the realms of protection and

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<sup>77</sup> [2016] EWCA Civ 1006, at [187].

<sup>78</sup> See text accompanying notes 1 to 18 in Part II of this series of articles (CITATION).

<sup>79</sup> [2016] EWCA Civ 1006, at [187].

<sup>80</sup> Excluded by Art 53(c) EPC 2000, ex-Art 52(4) EPC 1973.

therefore receives no patent reward irrespective of how bounteous and beneficial it may be. Thus, even if we accept the validity of the Swiss-form second medical use claim, it remains separated from the excluded method of treatment by a meniscus so thin that it is practically undetectable in the majority of cases: a fact acknowledged by the EBA itself in both *EISAI*<sup>81</sup> and *ABBOT RESPIRATORY*.<sup>82</sup> The *patentable* contribution that such an invention brings is accordingly narrow, and it would seem to flow that the eventual scope of its protection should be similarly constrained. To attempt to place the Swiss-form claim on an equal footing with other patentable contributions one might make therefore appears, with the greatest of respect to Floyd LJ and the rest of the Court, to place nonsense upon stilts.<sup>83</sup>

Seeking perhaps to defer criticism of his approach to the interpretation of the Swiss-form, Floyd LJ once again turned to look at the tactics adopted in other EPC member states and in doing so traversed much of the same ground that had been explored in the Court's decision on the interim injunction. Once more, his Lordship noted that a number of different methods of dealing with the claims were evident in different EPC states and that no uniform approach had yet emerged.<sup>84</sup> Some, like Germany, appeared to require an outward manifestation of intention in the manufacture itself. Accordingly, a compound would be considered to have been manufactured for a particular indication where there was some direction provided in its packaging to direct the end user to that use. This, according to Floyd LJ, represented too narrow a view: one that while it has "obvious advantages of practicality", does not provide adequate protection for the patentee.<sup>85</sup> A middle ground was said to be occupied by those states, including Spain, where a broader view of encouragement is taken. Accordingly, a decision of the Madrid Court of Appeal was said to have held that infringement could be forthcoming if the defendant had at least "performed ...[a] procedure directed at strengthening the use of the [generic compound for the patented indication]."<sup>86</sup> The French approach was said to complete the spectrum, requiring that the generic manufacturer seek to actively prevent the use for the patented indication. In other words, liability would appear to be automatic where the compound

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<sup>81</sup> G\_05/83 *EISAI/Second Medical Indication* [1985] OJ EPO 64; [1979-85] EPOR B241.

<sup>82</sup> G\_02/08 *ABBOTT RESPIRATORY/Dosage Regime* [2010] OJ EPO 456; [2010] EPOR 26.

<sup>83</sup> To borrow from Bentham. See Bentham, J., *Rights, Representation, and Reform: Nonsense upon Stilts and Other Writings on the French Revolution*, in Schofield P., Pease-Watkin C., and Blamires C. (eds), *The Collected Works of Jeremy Bentham*, (2002, OUP; Oxford), pp.317-401.

<sup>84</sup> [2016] EWCA Civ 1006, at [189], and [201].

<sup>85</sup> [2016] EWCA Civ 1006, at [190] to [191].

<sup>86</sup> *Ibid.* at [192].

created is “suitable for” treating the claimed indication unless the generic manufacturer has actively taken steps to discourage this. While straightforward, such an approach – you’re liable unless you can prove that you are not – does not seem to accord with either notions of natural justice or provide any real certainty. What steps, for example, are appropriate and also how effective they must be in order to avoid liability? How much is enough?

A final alternative, rejected by the Court of Appeal essentially because it was seen to be predicated upon overly “technical distinctions”,<sup>87</sup> had been adopted by the Maritime and Commercial High Court in Denmark.<sup>88</sup> Here the court is stated to have treated the application of the dispensing label by the pharmacist as the final stage in the process of manufacture: it being a requirement in Denmark to label the dispensed product with the condition for which it was to be taken. Accordingly, a pharmacist could be held liable for primary infringement as someone who uses the process of manufacture – effectively treating the label as the cherry on top of the cake. However, the party producing the medication could then also be considered to have supplied “means essential” under the Danish equivalent of s60(2) PA 1977 and therefore to potentially infringe upon a secondary basis. While, as the English Court of Appeal was to state, it may be “unfortunate that the patentee’s right to a return for his contribution to the art should turn on such technical distinctions”,<sup>89</sup> it is not necessarily also the case that this would be an incorrect approach to take. It does, after all, have the benefit of preserving an avenue to s60(2) for the patentee without doing further violence to the primary infringement provisions by stretching their ambit through the medium of claim construction.

Nevertheless, following this European tour, Floyd LJ reiterated his conclusions from the interim stage of the proceedings: “From an objective standpoint one would normally regard a person to intend what he knows or can reasonably foresee will be the consequences of his actions.”<sup>90</sup> Accordingly, bringing together the other threads of argument, a presumption of infringement will arise where it is (or should be) obvious to the manufacturer in the circumstances that at least some of the generic medicament will be used for the patented indication.<sup>91</sup> Later in the

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<sup>87</sup> Ibid. at [197].

<sup>88</sup> *Warner-Lambert Company LLC and another v Krka d.d. and another*, a decision of the Maritime and Commercial High Court dated 25 June 2015. See [2016] EWCA Civ 1006 at [196].

<sup>89</sup> [2016] EWCA Civ 1006, at [197].

<sup>90</sup> [2016] EWCA Civ 1006, at [206]

<sup>91</sup> This is the formulation suggested by Floyd LJ in the interim decision: “In my judgment, therefore, the skilled person would understand that the patentee was using the word “for” in the claim to require that the manufacturer

judgment, his Lordship refers to foresight of “intentional use for the new indication.” This is explained as being “distinguished from use where the drug is prescribed for a different indication and, without it in any sense being the intention of the treatment, a pain condition is in fact treated.”<sup>92</sup> This subsequent statement would seem to limit foresight to consideration of the prescribing physician’s intention. This is obviously narrower than requiring knowledge that the compound will ultimately be consumed for the patented indication.<sup>93</sup> Nevertheless, as noted above, the construction of such knowledge is, without more, already a practical inevitability of the market for prescription medicine in the UK. In which case, we are placed in the *de facto* position that a generic manufacturer will infringe unless they can demonstrate that they have taken sufficient steps to negate the existence of this intention: presumed guilty until proven innocent.

Discussing what will be sufficient to escape liability, Floyd LJ explained that a manufacturer must take “*all reasonable* steps within his power to prevent the consequences occurring”<sup>94</sup> (emphasis supplied). What is reasonable and what is not, and what limitation the requirement to take *all* reasonable steps might sensibly be considered to possess were, however, questions for another day. This said, the Court did note that where all reasonable steps are taken then the manufacturer’s “true objective is a lawful one, and one would be entitled to say that the foreseen consequences were not intended, but were an unintended incident of his otherwise lawful activity.” Apart from the implicit acknowledgement that steps need not be 100% effective at maintaining the partitioning of the market between old and new indications in order for the manufacturer to avoid liability, we are left none the wiser as to the precise relationship between reasonableness and effectiveness in this context.

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knows (in the above sense) or can reasonably foresee the ultimate intentional use for pain, not that he have that specific intention or desire himself.” See [2015] EWCA Civ 556, at [127]. It is further reiterated at full trial: “...the skilled person would understand that the patentee was using the word “for” in the claim to require that the manufacturer knows (and for this purpose constructive knowledge is enough) or can reasonably foresee the ultimate intentional use for pain.” [2016] EWCA Civ 1006, at [212].

<sup>92</sup> [2016] EWCA Civ 1006, at [216].

<sup>93</sup> The Guardian newspaper, for example, ran a story in June 2016 concerning “The cancer drugs in your bathroom cabinet” that detailed, among other things, how members of the public had used the biomedical database PubMed (<http://www.ncbi.nlm.nih.gov/pubmed>) to research repurposed drug treatments and to thereby construct their own treatment regime. See <https://www.theguardian.com/science/2016/jun/12/anti-cancer-drugs-medicine-cabinet-repurposed-aspirin-thalidomide-beta-blockers>.

<sup>94</sup> [2016] EWCA Civ 1006, at [208].

An additional problem with the reasoning of the Court stems from the fact that it is clear that when considering these elements, it was really only concerned with the situation in which the generic producer is a new entrant to the market. Accordingly, in justification of the “all reasonable steps” line of argument, Floyd LJ noted that this approach “recognises an obligation on the manufacturer to take steps if he is to *enter* the market where he stands to benefit from the patentee’s contribution to the art”<sup>95</sup> (emphasis supplied). This may be a relevant consideration for a fresh entrant to the market for the drug and who is newly trying to exploit the genericity of a recently exclusive compound. However, it is less clear that the same principles can be applied where, for example, the compound has been off patent for a long time, or where the “generic” manufacturer is actually the originator of the compound and the inventors of the secondary indication are themselves the new entrants. What “all reasonable steps” are in each of these contexts will likely be very different. We therefore end up with a level of clarity that is arguably no greater than that experienced when entering the litigation: murkiness over the construction of the claim having given way to murkiness over the steps needed to avoid liability. What is more, because the determination of infringement and the pronouncements on the scope of the claim are acknowledged by all as being unnecessary for the determination of the case, we are given no indication whatsoever as to whether the steps taken by the parties were at all sufficient in the eyes of the Court of Appeal. This is hardly an ideal outcome.

## **VII THE CUCKOO IS HOME TO ROOST, BUT HAS IT REALLY BEEN TAMED? SOME CONCLUDING COMMENTS**

Bossung, as noted above, claimed that Art 54(5) EPC 1973, which enabled the patenting of the first medicinal use of a compound known in other fields, was a “cuckoo’s egg”:<sup>96</sup> a provision disguised to look like it belonged in the nest of the European Patent Convention, but which he thought might nevertheless turn out to contain something unexpected. How right he was: although perhaps not quite in the manner prophesied. For as we have seen, the cuckoo was given some help to hatch. By taking the provision, extracting its essence, cannibalising, rebuilding and augmenting it so it could survive on different fodder, the European Patent Office’s Enlarged Board of Appeal played Frankenstein with Bossung’s egg. The chimeric Franken-cuckoo that hatched, resplendent in its plumage of the Swiss-form, may well have shared much of the DNA of its forbear, but was nevertheless a new species within patent law’s

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<sup>95</sup> [2016] EWCA Civ 1006, at [208].

<sup>96</sup> See Bossung, O., “Erfindung and Patentierbarkeit im Europäischen Patent recht” [1974] *Mitteilung der deutschen Patentblatt* 101, at 121.



fauna. A bird which for over 30 years following its emergence in the EISAI decision was to roam, unchecked, untamed and uninterpreted through the patent landscape: flexing its wings and expanding its territory, but never submitting to detailed scrutiny or construction. This latter fact alone marks out the significance of the Warner-Lambert litigation – the case in which the Franken-cuckoo finally came home to roost.

As we have seen, Warner-Lambert’s application for an interim injunction against Actavis formed the backdrop for what Arnold J accurately proclaimed the “first judgment in the UK which squarely addressed the issue of the mental element of Swiss form claims in the infringement context.”<sup>97</sup> Indeed, it was the first case to consider the problems created by the marketing of generic pharmaceuticals with skinny labels; the first to try and tame the Swiss-form. And in this latter respect, some might claim success. We do, after all, have the Court of Appeal’s view on the matter: a resolution of scope and an interpretation of the troublesome claim. A judicial sandwich of obiter with a filling of Arnold it may be, but nevertheless: two obiter statements expressed in terms as strong as these are likely to carry significant weight. We also have confirmation that the Swiss-form and its wedding of manufacture and purpose brings with it two distinct mental elements of differing value. In respect of the first, subjective desire has been rejected in favour of an objectively constructed question of knowledge and foresight on the part of the generic manufacturer. Furthermore, this element will be satisfied providing only that the manufacturer foresee that some of the drug that it makes will end up being applied for the patented indication. The second mental element – “intentional administration” of the drug for the patented indication – has been cast as a coarse filter intended only to exclude situations where the patentee’s claimed purpose is fulfilled by accident. However, while being in possession of a test undoubtedly places us closer to the goal than ever before, it is questionable whether the cuckoo has truly been tamed.

As has been seen, the test advanced by the Court of Appeal is potentially problematic in effect. When combined with the regulatory environment for the personal allocation and dispensation of prescription medication in the UK, it effectively returns us to a position where “for” means “suitable for”. Infringement under the Court of Appeal’s test is a *de facto* consequence of entering the market for the generic drug. After all, if off-label use is known generally to occur then the reasonable person in the shoes of the manufacturer of the generic compound must be in a position from the very commencement of their production where they would have reason to

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<sup>97</sup> [2015] EWHC 223 (Pat), at [43].

believe that their product will be used off-label as well. Given the generic product will, by definition, be suitable for the patented indication, the Court of Appeal's proposed test begins to resemble a strict liability standard – albeit one with defences that can be deployed where the court considers that “all reasonable steps” have been taken to avoid an infringing outcome. Desire to infringe and the active targeting of the market for the secondary indication are as irrelevant to this equation as indifference or a fervent wish not to infringe. Only true ignorance will avoid the patentee's zone of exclusion, and then only if objectively justified. In such circumstances, the nexus between manufacture and the eventual use for the novel therapeutic effect is fundamentally fractured, with infringement essentially becoming contingent upon the regulatory environment alone.

Furthermore, while liability can still be rebutted we are given no real guidance on what will suffice for a court to agree that the generic manufacturer has taken all reasonable steps within their power to prevent infringement from occurring. We are also not informed whether these steps need to be at all successful and, if they do, how successful they must be. As far as illuminating what may and may not be done, we are essentially left in the dark. While it may be too much to have asked that all aspects of the Swiss-form's construction be put to bed in one case, it is nevertheless frustrating that the *Warner-Lambert* decisions leave so many gaps unfilled: settling some uncertainties, but creating significant others.

The end result of this exercise is clearly a triumph for the holders of patents on second medical indications expressed in the Swiss-form. Not only is there a *de facto* presumption of infringement, but there is also as yet no clear indication of what might be sufficient for the manufacturer of a generic compound to escape the patent's clutches. In such circumstances the uncertainty of the situation clearly benefits the party holding the grant. Whether this strikes the correct balance between the interests of the patentee, those of third parties, and indeed of the public at large is evidently open to debate. The Court of Appeal's decision is ostensibly justified on the basis that Arnold J's alternative construction, which relied upon demonstration of subjective intent to infringe, risked robbing the patent of much of its enforceability. Despite this being true – although one should note that removing “much” of a patent's enforceability is not the same as saying that it is unenforceable – the Court of Appeal's argument does ignore the flip side of the patent's justifications. For while it is clear that the public interest not satisfied by an unenforceable patent, neither is it acceptable to use the grant to restrain the free competition of somebody that should not be so restrained.

The weight of this latter point is increased in the case of the Swiss-form, as here the underlying legitimacy of the claim format is itself open to question. After all, the format was applied from the outset in circumstances of compromise. Protection for secondary indications was derived under a judicially created annex to the deliberate language of the EPC 1973: an essentially unprecedented extension of patent protection with no explicit foundation in the Convention itself. To assert therefore that reward of the patentee requires a court to give a broad interpretation to a claim that, from the Convention's perspective at least, was fulfilling a function that should not have existed, is somewhat bizarre.

To an extent this questionable legitimacy of the Swiss-form is acknowledged by the Court of Appeal when it describes the format as “a fudge”<sup>98</sup> and notes that rather than the EBA creating a workaround: “It would have been better if doctors had been provided with a defence, or the restriction on methods of treatment repealed altogether.”<sup>99</sup> However, at the point that it was seeking to tread a fair and principled path through the questions of construction, the Court ignored, for better or worse, the pedigree of the claim it was attempting to construe. Gone were the concerns about the fudging of the issues; replaced by considerations of what would be fair in the circumstances to reward the patentee's investment. In this respect, it could be argued that the legal fiction of the Swiss-form claim is justification enough for putting the minutiae of patent law to one side and seeking a fair and balanced approach that rewards the patentee for their contribution. However, it should not be forgotten that throwing caution to the wind and ignoring the confines of the legislative language is how we got into this mess in the first place.

In addition, reward is a difficult peg upon which to hang a construction; particularly given the timing of the dispute in this case. Thus, even though it was still very much a developing area of law at the point that the Warner-Lambert litigation hit the courts, by this point the Swiss-claim was also neutered, withered and dying: the last of its kind having entered the patent office files by a point some five years before.<sup>100</sup> None of Arnold J's or the Court of Appeal's decisions could therefore possibly have had any effect on the incentives offered to subsequent patentees –

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<sup>98</sup> [2015] EWCA Civ 556, at [53].

<sup>99</sup> [2015] EWCA Civ 556, at [55].

<sup>100</sup> As explained in Part I of this series of articles, the last patent with claims in the Swiss form must have been filed before the end of the three month transitional period given in G\_02/08 *ABBOTT RESPIRATORY/Dosage Regime* [2010] OJ EPO 456; [2010] EPOR 26 – i.e. by 29 Jan 2011. See further, text accompanying notes 20 and 21 in Part I of the series (CITATION).

the claim format being a veritable cul-de-sac in this regard. Accordingly, the pre-patent uncertainty of having a claim whose construction was fundamentally indeterminate, one that no court had ever been called upon to construe but which was feared to pose “intractable problems”<sup>101</sup> should the day of reckoning arrive, was effectively over before the case was even commenced. Anticipated reward for the patentee was therefore also somewhat moot; by the time of the case all bets that could ever be laid had in fact been placed for some time and the bookmakers was closed. Securing a legitimate reward for a patentee that entered the game blind is a difficult goal to achieve. On what principled basis does one calculate the prize? If the framework of construction is unknown at the time that a patent is applied for then it cannot really be said that there is a legitimate expectation that needs to be fulfilled. It is accordingly no more appropriate to try and avoid robbing a patent of much of its enforceability by focusing on rewarding the investment in research that it represents, than it would be to use the same argument to save a patent from invalidity when faced with the prior art.

In addition, from the perspective of incentive (the flip-side of reward) all this uncertainty had evidently not prevented investment in the discovery of new uses for old medicaments. In actual fact, patents had proliferated: as we have seen, in the years following EISAI the Swiss-form had become replete with a vast array of new ‘uses’ with ever diminishing distinction between the old and the new.<sup>102</sup> Looked at in the cold light of day, it is difficult to see how the various parties to this process of expansionism could have considered that anything other than chaos would have erupted from this practice. Common sense would seem to dictate that one would need at least to determine the Swiss-form’s scope of protection before packing more and more patents into the inventive space surrounding any given compound. And yet this sashimi-slicing of the patent landscape was occurring despite the uncertainties that must have existed concerning the enforcement of any of these claims in litigation.

Of course, the answer to this concern over uncertainty could simply be an issue of belief. “Intractable problems” or not, the grant offered the opportunity to wield the promised exclusivity in defence of the underlying invention whatever shape this cudgel may have taken. The end goal being chased by the patent system was one that was clearly of benefit to society – the incentivisation of the discovery of new uses for existing medications. Parties believed that the patents that they were acquiring were worth something and therefore the detail and

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<sup>101</sup> *Bristol Myers Squibb v Baker Norton* [1999] RPC 253, at 272, per Jacob J.

<sup>102</sup> See text accompanying notes 69 to 75 in Part I of this series of articles (CITATION).

enforceability of individual grants was of less import than the fact of the patent itself. In such circumstances uncertainty in scope may actually have been of benefit to the patentee: an exploitable ambiguity perhaps offering all parties greater incentive to licence than to litigate.<sup>103</sup> However, if this is the case then the question of providing stronger protection so as to secure fair reward for the patentee based on their contribution also effectively falls away. Patentees, as noted, had entered the game blind. The risks of an unproven, un-litigated and un-construed claim format would have been obvious, but the die was cast in any case. Much like in respect of the Emperor's new clothes, we must therefore ask if the reliance upon the promise offered by the patent is, in this corner of the pharmaceutical field at least, somewhat more illusory than we have been led to believe.

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<sup>103</sup> Similar comments are made concerning uncertainty of scope in Fisher M., *Fundamentals of Patent Law: Interpretation and Scope of Protection* (2007, Hart), at p.111, where the author discusses interviews undertaken with a number of patent attorneys. One of whom states: "if you're wearing the hat of the patent holder, you want uncertainty, because that gives you effectively broader scope—particularly if you're a rich patent holder, if you're a poor patent holder, it means not a lot, but if you're a rich patent holder, yes, that uncertainty around the edge of your claim, if you can make it great enough, gives you a more powerful tool."