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## The House of Lords Clarifies “Biogen Insufficiency”

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### Abstract

*The author considers the recent House of Lords’ jurisprudence on “Biogen insufficiency”, arising from its 1997 decision in Biogen Inc v Medeva Plc, which holds that unless claims in the patent specification correspond to the teachings of the patent, the patent will be invalid.*

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## 1. Setting the Scene

In *Biogen Inc v Medeva Plc*,<sup>1</sup> the House of Lords seemingly accepted that unless claims in the patent specification correspond to the teachings of the patent, the patent will be invalid. This is known as “*Biogen* insufficiency”. Although the House of Lords was there dealing with a complicated “product by process” claim, its statements were also applied to simple product claims, to the extent that many academics and lower courts accepted that this was the *ratio* of the case. In *Generics (UK) Limited v H Lundbeck A/S*,<sup>2</sup> Kitchen J, at first instance, found that although the patent was novel and non-obvious, it was invalid on the basis of insufficiency. The leading judgment in the Court of Appeal decision<sup>3</sup> was delivered, surprisingly, by Lord Hoffmann, the acknowledged patent law expert in the House of Lords, who accepted the finding of Kitchen J on novelty and inventive step, but disagreed with him on the insufficiency point - the issue that had formed the basis of discussion in *Biogen*. As a result of this decision, the House of Lords finally settled the issue that had plagued the courts<sup>4</sup> and academics<sup>5</sup> since its seminal decision in *Biogen*.<sup>6</sup> The Lords found, firstly, that the statements of Lord Hoffmann in *Biogen* do not apply to simple product claims in which the technical contribution of the invention is the product itself, even when only one method to create it is disclosed in the patent specification; and, secondly, that the provisions of the *Patents Act 1977* and the corresponding articles of the *European Patent Convention* do not lead inexorably to the conclusion that simple product claims must also support all methods of creating the product.

## 2. The Factual Background

In *Lundbeck*,<sup>7</sup> the House of Lords considered the scope of patent protection for the drug citalopram, which alleviates the symptoms of depression. Citalopram is a racemate, consisting of equal numbers of two molecules called enantiomers, which are mirror images that cannot be completely superimposed on each other and are conventionally designated as (+). Lundbeck successfully resolved the racemate in 1987 and subsequently discovered that the therapeutic effect was caused solely by the (+) enantiomer, escitalopram, which it then patented. Subsequent research showed that the (-) enantiomer actually slowed down the inhibitory effect, so that the (+) enantiomer works better without it. The patent, entitled “New enantiomers and their isolation”, claimed, *inter alia*, as follows: (a) claim 1 was for the enantiomer; (b) claim 3 was for a pharmaceutical composition using the enantiomer; and (c) claim 6 was for a method of preparing the enantiomer.

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<sup>1</sup> *Biogen Inc v Medeva Plc* (1997), RPC 1.

<sup>2</sup> *Generics (UK) Limited v H Lundbeck A/S*, [2007] EWHC 1040.

<sup>3</sup> *Generics (UK) Limited v H Lundbeck A/S*, [2008] EWCA Civ 311.

<sup>4</sup> *Kirin-Amgen v Roche Diagnostics* (2002), RPC 1.

<sup>5</sup> M Spence, “Patents and Biotechnology” (1997) 113 *Law Quarterly Review* 368-374.

<sup>6</sup> *Kirin-Amgen v Roche Diagnostics* (2002), RPC 1.

<sup>7</sup> *Generics (UK) Limited v H Lundbeck A/S*, [2009] UKHL 12; [2009] 2 All ER 95.

### **3. The Statutory Provisions**

Before examining the arguments made by the parties, it is necessary to identify the statutory basis for revocation of a patent on the ground of insufficiency. This is found in s 72(1)(c) of the *Patents Act 1977*: a court...may...revoke a patent [on the ground that] the specification of the patent does not disclose the patent clearly enough and completely enough for it to be performed by a person skilled in the art. A similar prerequisite forms the basis for sufficiency of disclosure in the patent specification. S 14(3) provides that the specification of an application shall disclose the invention in a manner that is clear enough and complete enough for the invention to be performed by a person skilled in the art.<sup>8</sup> Thus, if a patentee does not comply with the requirement of sufficiency of disclosure, it may open itself to objection before grant, and for revocation of the patent after grant. This requirement is labelled “enabling disclosure” and is claimed to be central to the law of patents.<sup>9</sup>

### **4. Clarifying the Reach of Insufficiency**

#### **4.1 The Arguments**

The claimants, who applied for revocation of the patent under s 72(1) of the *Patents Act 1977*, argued that, based on *Biogen*, the patent was insufficient because the technical contribution of the invention lay in finding a way to carry out that resolution. Lundbeck discovered one way of creating the (+) enantiomer, but claims 1 and 3 claimed the (+) enantiomer, however obtained. Consequently, the claims were considered too broad on the grounds of insufficiency.<sup>10</sup> The defendant, however, argued that the technical contribution of the patent was the discovery and realisation of a new and non-obvious compound, the (+) enantiomer. The issue to be resolved was whether a claim to a product, namely, escitalopram, was supported by the description in the patent specification.

#### **4.2 Decision at First Instance**

Kitchen J applied the new test for novelty, as defined by the House of Lords in *Synthon BV v Smithkline Beecham Plc*:<sup>11</sup> firstly, the matter relied upon as prior art must disclose subject matter which, if performed, would necessarily result in an infringement of the patent; and, secondly, the disclosure must have been enabling, that is to say the ordinary skilled person would have been able to perform the invention if he attempted to do so by using the disclosed matter and common general knowledge. On these criteria, Kitchen J held that the prior art did not anticipate the

<sup>8</sup> European Patent Convention 2000, Art 83.

<sup>9</sup> *Application of Asahi Kasei Kogyo KK* (1991), RPC 485, at 531-532; *Biogen Inc v Medeva Plc* (1997), RPC 1, at 46-51; *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* (2005), RPC 169.

<sup>10</sup> *Lundbeck*, [2007] EWHC 1040, at [252].

<sup>11</sup> *Synthon BV v Smithkline Beecham Plc*, [2005] UKHL 59; (2006), RPC 323.

isolated enantiomer.<sup>12</sup> In relation to the issue of obviousness, he concluded that the reaction schemes described in the patent would not have been obvious to the skilled person in 1988, stating that it was only with hindsight that it was possible to explain the outcome of a reaction which would otherwise have been unexpected.<sup>13</sup> The Court of Appeal agreed with both conclusions.<sup>14</sup>

On the question of sufficiency, Lundbeck argued that since the separation of the enantiomer of citalopram was not an obvious goal, no one had produced or tested it before the priority date, and because they had shown a way of making it, the patent was sufficient.<sup>15</sup> However, Kitchen J accepted that “if a patentee describes a new and non obvious compound which has a beneficial effect and describes a way by which it can be made then he is entitled to a patent for the compound.”<sup>16</sup> He continued that, moreover:

*[T]he technical contribution lies in the provision of the new and useful compound. Others might find different ways of producing it. But this does not render the original patent insufficient because in each case they are making use of the technical contribution – the knowledge they are making the new and useful compound.*<sup>17</sup>

Kitchen J stated that the first person to find a way of achieving an obviously desirable goal was not permitted to monopolise every other way of doing so. He concluded that the claims were too broad, because they extended beyond any technical contribution made by Lundbeck<sup>18</sup> and covered all ways of making the (+) enantiomer of citalopram.<sup>19</sup> The focus of the decisions of the Court of Appeal and the House of Lords was therefore on the vexed question of insufficiency. It is not therefore surprising that the various judgments of the lower courts<sup>20</sup> and the House of Lords<sup>21</sup> have been subject to commentary in academic journals.

<sup>12</sup> *Lundbeck*, [2007] EWHC 1040, at [64].

<sup>13</sup> *Ibid*, [179].

<sup>14</sup> *Lundbeck*, [2008] EWCA Civ 311, at [13] (novelty) and [25] (obviousness).

<sup>15</sup> *Ibid*, [264].

<sup>16</sup> *Ibid*, [265].

<sup>17</sup> *Ibid*.

<sup>18</sup> *Ibid*.

<sup>19</sup> *Ibid*, [267].

<sup>20</sup> High Court: B Whitehead, S Jackson and R Kempner, “Patents and Enantiomers: *Generics v Lundbeck*” (2007) *Journal of Intellectual Property Law & Practice* 801-808. Court of Appeal: P Inman, “Biogen Insufficiency: Does it Still Have Teeth?” (2008) *Journal of Intellectual Property Law & Practice* 491-493; S Moore and D Ribbons, “The Court of Appeal Clarifies the Law on Sufficiency” (2009) *Journal of Intellectual Property Law & Practice* 347-352.

<sup>21</sup> P Inman and S Spink, “House of Lords Addresses ‘Biogen Insufficiency’” (2009) *Journal of Intellectual Property Law & Practice* 459-461; J Pila, “Chemical Product Patents and Biogen Insufficiency before the House of Lords” (2009) 125 *Law Quarterly Review* 573-578.

#### 4.3 Relationship between Sufficiency and Inventive Step

The question for determination was essentially whether the contribution to the art should be defined solely by the inventive step of the invention or whether it should rest with the product itself. In the Court of Appeal, Lord Hoffmann noted that Lundbeck's inventive idea was not discovering that the enantiomer existed and had a medicinal effect, but rather their discovery of one way of making it. He observed, however, that this did not entitle them to monopolise every way of making it.<sup>22</sup> Nonetheless, he claimed that he understood and sympathised with the instinctive reaction of the Judge to the inherent breadth of a product claim, noting that Kitchen J was not the first to have registered such a protest. He went on to say that there was nothing in s 72(1)(c) of the *Patents Act 1977* that connected the requirement of sufficiency to the inventive step. It was the invention, as defined by the claims, that needed to be disclosed sufficiently to enable it to be performed, and that remained the same irrespective of the inventive step.<sup>23</sup> Although the inventive concept merely provided one way of making the product, the important point was that the method claimed by Lundbeck was the first discovery of a way of making the (+) enantiomer – consequently, the patentee was entitled not only to a patent for this new method of making the product, but also to the product itself. Although intuitively this sounds incredulous, the product, although known, was novel as defined by the House of Lords in *Synthon*. As a result, the reasoning of the Court of Appeal suggested that the patentee need only provide one way of making a new product, even if other ways may be subsequently discovered. Noting that the term “inventive concept” and “technical contribution to the art” do not mean the same thing, Lord Walker clarified that “[n]either expression is a statutory term of art.<sup>24</sup> He also observed that, although the terms are connected, it was not “helpful (either in considering Lord Hoffmann’s opinion [in *Biogen*], or generally) to treat them as having precisely the same meaning.”<sup>25</sup> He then clarified that:

*“Inventive concept” is concerned with the identification of the core (or kernel, or essence) of the invention—the idea or principle, of more or less general application (see Kirin-Amgen [2005] RPC 169 paras 112-113) which entitles the achievement of the inventor to be called inventive. The invention’s technical contribution to the art is concerned with the evaluation of its inventive concept—how far forward has it carried the state of the art? The inventive concept and the technical contribution may command equal respect but that will not always be the case.<sup>26</sup>*

In other words, the “inventive concept” is concerned with determining what the invention is; and the “technical contribution” relates to the advancement of the

<sup>22</sup> *Lundbeck*, [2008] EWCA Civ 311, at [26].

<sup>23</sup> *Ibid*, [41].

<sup>24</sup> *Lundbeck*, [2009] UKHL 12, at [29].

<sup>25</sup> *Ibid*, [30].

<sup>26</sup> *Ibid* (emphasis in original).

invention in relation to the state of the art. Lord Neuberger agreed with Lord Walker's reasoning, stating that:

*"Inventive step" suggests how something has been done, and, in the case of a product claim at any rate, one is primarily concerned with what has been allegedly invented, not how it has been done. On the other hand where the claim is for a process or (as in Biogen [1997] RPC 1) includes a process, the issue of how the alleged invention has been achieved seems to be more in point.<sup>27</sup>*

In assessing the technical contribution, Lord Walker opined that the courts should have regard to the "lasting strategic importance of the invention to the art".<sup>28</sup> It is not clear how this requirement will be interpreted by lower courts when issues relating to insufficiency arise in future cases. This requirement is not mentioned in either the *Patents Act 1977* or the *European Patent Convention (EPC) 2000* and, if anything, its vagueness will create uncertainty and difficulties in the future.<sup>29</sup>

#### **4.4 Product Claims**

Lord Hoffmann claimed that, in his opinion, the reasoning of Kitchen J was justified neither by the statute nor existing authorities. In an ordinary product claim, he continued, the product is the invention and it is sufficiently enabled if the specification and common general knowledge enables the skilled person to make it – one method is enough.<sup>30</sup> He stated that the question as to whether the specification is sufficient cannot be answered until it is determined what the invention is, by reading and construing the claims.<sup>31</sup> He added that a product claim is sufficiently enabled if the specification discloses how to make it and that "there is nothing to say that it must disclose more than one way."<sup>32</sup> In *Biogen*, the invention concerned a class of products that was characterised by how they were made and what they did; whereas in *Lundbeck* the claim was simply for the product, without any reference to how it was made or what it did. The method of making the product was relevant only for satisfying the requirement of inventive step. It was not surprising, therefore, that the requirement for sufficiency would differ as between the two cases. After examining the history of product claims in English law, Lord Hoffmann concluded that it "is too late to have regrets about the breadth of the monopoly which such claims confer."<sup>33</sup> Since UK Patent law has a long history of allowing product claims, which gives patentees a monopoly over the product itself, a product patent would be infringed if someone produces that product by any method whatsoever. It is this wide monopoly - granted to a patentee who has discovered only one method of creating the new

<sup>27</sup> *Ibid*, [101].

<sup>28</sup> *Ibid*, [33].

<sup>29</sup> See generally, M Spence and T Endicott, "Vagueness in the Scope of Copyright" (2005) 121 *Law Quarterly Review* 657-680.

<sup>30</sup> *Lundbeck*, [2008] EWCA Civ 311, at [27].

<sup>31</sup> *Ibid*, [29].

<sup>32</sup> *Ibid*, [30].

<sup>33</sup> *Ibid*, [46].

product, even where other methods are subsequently discovered - that troubled Kitchen J. The Court of Appeal found that notwithstanding his concerns, UK patent law relating to the scope of claims remain principled, and cannot now be challenged in light of their ancient origins.

Lord Neuberger, who gave the leading judgment in the House of Lords, stated that the “appeal raises a point of principle relating to product claims in patents, and it also requires consideration of the ambit of the reasoning [in *Biogen*].”<sup>34</sup> He claimed that:

*[I]t is hard to discern any statutory provision (or, by the same token, any provision in the EPC) to support the proposition that, once it has been established that a product claimed in a patent is novel and non-obvious, and the specification sufficiently explains to the person skilled in the art how to make it, the claim can nonetheless be rejected because there may be other ways of making the product which owe nothing to the teaching of the patent.*<sup>35</sup>

He concluded that “the specification of the patent clearly sets out the diol method of manufacturing escitalopram, and therefore it plainly satisfies s 14(3).”<sup>36</sup> The appellants could not point to any provision in the *Patents Act*, or the common law of patents, to justify why a novel and non-obvious product claim cannot be validly granted notwithstanding the existence of other methods of creating the product. Their suggestion that there were two types of novelty in relation to product claims – one expressly mentioned in s 1(1)(a) and another implied in s 14(5)(c) of the *Patents Act 1977* – was rejected by Lord Neuberger who countered that this seemed like an unlikely proposition: either a product is novel or it is not.<sup>37</sup> He accepted that, at least as a general rule, the monopoly granted to the patentee should be assessed by reference to the “technical contribution” made by the teaching of the patent.<sup>38</sup> He found that, at its lowest, the respondent’s technical contribution was to make available, for the first time, a product which had been previously unavailable, namely the isolated (+) enantiomer of citalopram. It is the evaluation of the “technical contribution” that the patentee made which defines the scope of the monopoly he is to be granted for his invention. In *Lundbeck*, the technical contribution was the product itself, not the method of creating it, as claimed by the appellants. Therefore, the statutory provisions and the common law of patents compelled the conclusion that the claim was valid, which meant that the respondent was entitled to claim the enantiomer<sup>39</sup> unless precluded by the reasoning in *Biogen*.<sup>40</sup>

Lord Neuberger observed that in *Biogen* Lord Hoffmann had said that “if the claims include a number of discrete methods or products, the patentee must enable the

<sup>34</sup> *Lundbeck*, [2009] UKHL 12, at [58].

<sup>35</sup> *Ibid*, [80].

<sup>36</sup> *Ibid*, [81].

<sup>37</sup> *Ibid*, [82].

<sup>38</sup> *Ibid*, [83].

<sup>39</sup> *Ibid*.

<sup>40</sup> *Ibid*, [90].

invention to be performed in respect of each of them”,<sup>41</sup> but clarified that this did not apply to all claims. The claim in the instant case was however “to a single product, and it is clear that the product is enabled by the disclosure in the Patent.”<sup>42</sup> As a result, “the claim [in *Biogen*] was very different from a simple product claim as in the present case.”<sup>43</sup> He made it clear that:

*[I]n the context of a simple product claim such as the present (especially where the claim is to a single chemical product), the technical contribution is (at least in the absence of special factors) the product itself. As I have suggested, the technical contribution can often be equated with non-obvious novelty – what is new to the art and not obvious is really another way of identifying the technical contribution.*<sup>44</sup>

Where a claim is for a single product, one way of enabling it would suffice to give the patentee a monopoly over the product itself. As such, the subsequent discovery of any other method of creating the product is irrelevant for the purposes of determining sufficiency in this case, because the patentee claims only the product. It would be otherwise if the claim was to a method of making the product, in which case, any other newly discovered method would also be patentable. Product claims are therefore much broader than method claims. Lord Walker too stated that a single chemical compound was a product for the purposes of UK patent law, but accepted that it was a product of a special character, because as a chemical compound it can have only one embodiment.<sup>45</sup> He emphasised that “statements of general principle relating to inventions with many embodiments may be irrelevant to an invention which consists of a single chemical compound.”<sup>46</sup> Such statements of general principle, it is agreed, cannot apply to single product claims. The other question which troubled the UK courts was the extent to which statements of principle emanating from the decision of the House of Lords in *Biogen* are applicable to claims other than the one before the House of Lords in that case. It is to this issue that I now turn.

#### 4.5 Process Claims and Biogen

In *Biogen*, the House of Lords held that the claim, which was a product claim defined by how it was made (recombinant technology) and what it did (its capacity to express hepatitis B antigens), was not sufficiently supported. It applied the principle enunciated in the decision of the Technical Board of Appeal (TBA) of the European Patent Office (EPO) in *EXXON/Fuel oils*<sup>47</sup> - that “the extent of the patent monopoly

<sup>41</sup> *Ibid*, [92], citing *Biogen Inc v Medeva Plc* (1997), RPC 1, at 48.

<sup>42</sup> *Lundbeck*, [2009] UKHL 12, at [92].

<sup>43</sup> *Ibid*, [94].

<sup>44</sup> *Ibid*, [95].

<sup>45</sup> *Ibid*, [25]. Lord Walker noted that if it is used in a pharmaceutical preparation it can of course have numerous embodiments in terms of dosages and non-active ingredients, as in claims 3 and 5 of the patent in suit.

<sup>46</sup> *Ibid*, [25].

<sup>47</sup> *EXXON/Fuel oils* T 409/91 (1994), EPOR 653.

claims should correspond to the technical contribution to the art in order for it to be supported or justified.<sup>48</sup> The reasoning of the House of Lords was that where a claim embraces a class of products it will only be sufficiently enabled if the person skilled in the art was able to make all the members of the class.<sup>49</sup> Lord Hoffmann, speaking for a unanimous court, noted that the specification must enable the invention to be performed to the full extent of the monopoly claimed. If the invention discloses a principle capable of general application, the claims must be in correspondingly general terms. Where this happens, the patentee need not show that he had proved its application in every individual instance. If, however, the claim embraces a number of discrete methods or products and the patentee cannot demonstrate that there was a principle common to them all, he must enable the invention to be performed in respect of each of them.<sup>50</sup> Since the patent in *Biogen* only disclosed one way of making the product using recombinant technology, it was held to be insufficiently supported, because it taught no principle of general application, and there were other methods of making the product which owed nothing to the teaching in the patent specification.

In the Court of Appeal in *Lundbeck*, Lord Hoffmann noted that when “a product claim satisfies the requirements of s 1 of the *Patents Act*, the technical contribution to the art is the product and not the process by which it was made, even if that process was the only inventive step.”<sup>51</sup> He said that *Biogen* should therefore not be read as casting any doubt upon the proposition that an inventor who finds a way to make a new product is entitled to make a product claim, even if its properties could have been fully specified in advance and the desirability of making it was obvious.<sup>52</sup> In other words, the *Biogen* principle does not affect a claim for a new product. He concluded that the decision in *Biogen* was limited to the form of claim that the House of Lords was there considering and cannot be extended to an ordinary product claim in which the product is not defined by a class of processes of manufacture.<sup>53</sup> Similarly too, Lord Walker concluded that this was the fundamental reason why *Biogen* does not provide a direct answer to the issue for consideration in *Lundbeck*.<sup>54</sup>

Lord Mance noted that the second issue for consideration by the House of Lords was whether the claim in question can “be said to have been supported in its full width by the description given, in the sense identified as necessary by Lord Hoffmann [in *Biogen*]”.<sup>55</sup> He then examined *Biogen* and the statutory provisions and said that the disclosure in the description must enable a skilled person to make the patented product across its full width or to its full extent, but that did not mean that it must also enable the skilled person to make it by all possible methods.<sup>56</sup> He held that the claim

<sup>48</sup> *Ibid*, para 3.3.

<sup>49</sup> S Moore and D Ribbons, “The Court of Appeal Clarifies the Law on Sufficiency” (2009) *Journal of Intellectual Property Law & Practice* 347-352, at 349.

<sup>50</sup> *Biogen* (1997), RPC 1, at 48.

<sup>51</sup> *Lundbeck* [2008] EWCA Civ 311, at [36].

<sup>52</sup> *Ibid*, [40].

<sup>53</sup> *Ibid*, [35].

<sup>54</sup> *Lundbeck*, [2009] UKHL 12, at [26].

<sup>55</sup> *Ibid*, [41].

<sup>56</sup> *Ibid*, [51].

in *Biogen* was not regarded as a simple claim in respect of a novel product,<sup>57</sup> and that the Court of Appeal was not bound by the reasoning or result in *Biogen* to find the claims in *Lundbeck* invalid because they extended in scope to any method of making escitalopram other than that devised by Lundbeck.<sup>58</sup> The appellants' only inventive step involved no general or common principle that was used to produce the (+) enantiomer in competition with escitalopram.<sup>59</sup> Importantly, Lord Mance claimed that the:

*[P]assage quoted by Lord Hoffmann at p.49 in *Biogen* from the [TBA's] decision in *Exxon/Fuel Oils* has never been applied to a simple product claim such as the present, and a reading of the full text from which it is taken shows that it too was dealing with a situation where the description did not support all the inventions or all the embodiments of the invention in respect of which the patent claim was made.<sup>60</sup>*

Lord Mance stated that the appellants' approach cannot be accepted because, first, it "could well add in practice to the issues which may arise as to the validity or proper scope of patent claims to what under *Synthon* are novel products prepared by inventive methods"; and, second, and in his view conclusively, this was an area where there is clear EPO jurisprudence.<sup>61</sup> He noted that the TBA decisions considered only the issue of obviousness and that it "very significant" that no objection of insufficiency was raised.<sup>62</sup> He concluded that *Biogen* was not applicable to the instant case because it applied in light of the very unusual nature of the claims in that case.<sup>63</sup> Moreover, the claims in *Biogen* were altogether different from the one considered in *Lundbeck*. In the same vein, Lord Neuberger observed that Lord Hoffmann in *Biogen* was "discussing insufficiency and support in the normal sense" and that there is no indication that "in the case of a product claim, once it is decided that the product is novel, the technical contribution may not be the product itself, if it is a known desideratum."<sup>64</sup> Lord Neuberger stated that the claims in *Biogen* were almost a "process by- product-by-process claim",<sup>65</sup> whereas Lord Walker characterised them as "product by process claim".<sup>66</sup> This differentiation may sow the seeds of future uncertainty in this already complicated area of the law. Their Lordships were therefore all of the opinion that only if certain sections of Lord Hoffmann's judgment in *Biogen* were read out of context would it be possible to construe it as supporting the reasoning of Kitchen J.

<sup>57</sup> *Ibid*, [50].

<sup>58</sup> *Ibid*, [52].

<sup>59</sup> *Ibid*.

<sup>60</sup> *Ibid*, [55].

<sup>61</sup> *Ibid*, [54].

<sup>62</sup> *Ibid*.

<sup>63</sup> *Ibid*, [99].

<sup>64</sup> *Ibid*, [98].

<sup>65</sup> *Ibid*.

<sup>66</sup> *Ibid*, [24].

## 5. Conclusion

The validity of patents for chemical products has been confirmed. *Lundbeck* has clarified the law relating to insufficiency in the UK, aligning UK law with the EPO jurisprudence, whereby a single enantiomer will not be anticipated by the racemate and may be patentable so long as its resolution involved an inventive step. Lords Neuberger and Walker distinguished the “inventive concept” and “inventive step” from the necessary technical contribution that an invention must make for it to be patentable. In so doing, the House of Lords has confined *Biogen* to the nature of the claims considered in that case, explaining that where a patent claims a product, it will be sufficiently supported if the patent specification only describes one way of making it. The critical point emerging from *Lundbeck* is that in determining sufficiency one must be careful to properly determine and isolate the invention – for it is the invention that must be sufficiently enabled. By marrying the test for sufficiency to the invention as defined in the claims, the House of Lords in *Lundbeck* has fittingly come full circle. It recently pronounced in *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc*<sup>67</sup> that in determining inventive step, it is only necessary to consider the invention as defined by the claims, and not on the disclosure in the patent specification.

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<sup>67</sup> *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc*, [2008] UKHL 49; (2008), RPC 28. See also S Moore and D Ribbons, “The Court of Appeal Clarifies the Law on Sufficiency” (2009) *Journal of Intellectual Property Law & Practice* 347-352, at 352.