Suggested Answers to the Questions in Chapter 18

1. Why is the definition of 'making' in patent infringement not as straightforward as it sounds? What guidance have the courts given on interpreting this term?

The good answer will:

- Demonstrate knowledge of direct patent infringement under s.60 Patents Act 1977, which refers to a number of different ways that an infringer can infringe, including by 'making'. Note that although it might be thought the word 'makes' is a common term and needs no further explanation, in fact this not the case - as noted by the UK Supreme Court in *Schütz v Werit.*

- Discuss the fact that in *Schütz* the defendant supplied replacement plastic bottles to fit the patented cages of the claimant intermediate bulk carriers — yet it was held not to amount to infringement under s.60 because the bottles were a subsidiary part of the patented item. Therefore, what amounts to 'making' does not have a precise meaning — whether an activity amounts to 'making' is a matter of fact and degree.

- Conclude by reflecting on whether the ambiguity inherent in this term and its analysis by the courts is likely to benefit the patentee or the alleged infringer.

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2. Does the UKSC *Actavis v Eli Lilly* case present a useful clarification of the law on equivalents or a needless complication?

The good answer will:

- Begin by discussing *Actavis v Eli Lilly.* This case concerned whether drugs manufactured by Actavis infringed a European Patent owned by Eli Lilly. The case began when Actavis sought declarations of non-infringement under s. 71 of the Patents Act 1977 that its products did not infringe Eli Lilly's patent. Eli Lilly counter-claimed that Actavis' products infringed their patent directly and indirectly.

- Relate the fact that Eli Lilly's central argument was that Actavis' products infringed their patent, reasoning that the Actavis product—a pemetrexed salt (or the free acid) with vitamin B12— represented the key essence of the invention within the claims of the patent. Actavis argued that their acts were not infringing because the claims of the patent were limited to a specific pemetrexed salt, i.e. the one named in the patent: pemetrexed disodium. (Actavis' drug contained different pemetrexed salts e.g. the dipotassium salt.)

- Note that the UK Supreme Court held for Lilly, dismissing Actavis' cross-appeal. The reasoning of the UKSC is worth considering in detail. First, the SC had to construe the meaning of the patent's claims. The SC stated that 'as a matter of ordinary language' the claims only covered the disodium salt. Nonetheless, the SC stressed the need to take into account the Protocol on the Interpretation of Art. 69 (as amended in EPC 2000).

- In light of the Protocol, the UKSC decided that it had a duty to take account of non-literal infringement – in this case an infringing product that did not fall under the scope of the claims as written but was nonetheless 'equivalent' to the invention covered by the patent. The UKSC was satisfied that the Actavis products infringed the Eli Lilly patent, holding that Actavis' products achieved: (i) substantially the same result in substantially the same way as the patented invention, and (ii) this would have been obvious to the person skilled in the art at the priority date.

- Finally, conclude by noting that the UKSC held that in light of the Protocol the interpretation of the claims is not the same task as assessing the scope of protection—in the present case, this meant that although the patent's claims were limited to the disodium salt, this did not mean that the patentee did not intend other pemetrexed salts to infringe. This moves the UK away from the purposive approach stated in *Kirin-Amgen*, and towards the 'doctrine of equivalents'. We do not know as yet the full consequences of the ruling—there appears to be some confusion about the impact of

the decision on novelty, as shown by recent orbiter comments in the High Court case of *Mylan v Yeda*—but on infringement UK patent law is now more in line with the German and wider European approach. Here reference to academic commentary (Fisher, Laddie, etc.) would be welcome.

Suggested Answers to the Questions in Chapter 18

3. What are the positives and negatives of the territorial scope of patent infringement in European jurisdictions such as the UK? Will the proposed Unified Patent Court system provide a better option for patentees?

The good answer will:

- Focus on the fact that although the (non-EU) European Patent Office grants patents centrally, such patents do not have unitary effect and must be validated nationally, which means that patentees must decide which European jurisdictions to protect their inventions in. These validations often come at a price – indeed, in some countries this can be quite costly for the patentee as the (required) translation of the patent into e.g. Spanish or Italian can be expensive. For this reason, patent holders typically decide to validate their patents strategically – thus, many European Patents do not cover the entire EU: the majority are validated only in the major EU markets (Germany, France, the UK, Italy, the Netherlands, etc.).

- Explain that there are further complexities inherent in the current system – although the EPO has the final say on validity via its patent opposition service, it can take several years to get to a final decision on validity. In the meantime, national courts in the UK, Germany, France, etc. will often make decisions on validity of those patents as part of national litigation. Furthermore, questions of patent infringement are territorial, and thus national courts in the UK, Germany, France, etc. can make decisions that contrast with one another. The end result is fragmentation of litigation outcomes concerning the same essential patent, in different European jurisdictions.

- Discuss the fact that the EU has since 2012 been making preparations for reform of the European patent system. Along with the new European patent with unitary effect ('UP'), the most important reform is the setting up of a new Unified Patent Court ('UPC'), common to participating EU member states. The UPC will have jurisdiction to hear patent disputes and issue remedies to litigants that are binding within an area covering almost the entire EU single market (Spain, Poland and Croatia are at present not taking part). Refer to academic commentary (e.g. McDonagh) on topic.

- Conclude by noting that the ongoing Brexit process has put the entire package of reforms in doubt – will the UK be able to participate, post-Brexit? An ongoing German constitutional challenge could also derail the entire project. So for the moment, the current, fragmented system, remains in place.