Examiner's Report 2024
FD4 – Infringement and Validity

Patent Examination Board

Introduction

This report is intended to give an overview of candidates' performance in the 2024 FD4 examination. It should be considered in conjunction with the question paper and the published mark scheme.

Almost all answers included a meaningful attempt at all sections of the question paper. Whilst there was a lot to cover to produce a full answer, and time management was important, there is no clear indication that the paper caused unreasonable time pressure for candidates. In the round, answers that failed to achieve the pass mark did so because their substance did not meet the necessary standard and not because large parts of the paper were not properly attempted.

The question paper this year related to medicament dosage forms. The technology was relatively straightforward and appeared to be understood by the vast majority of candidates.

Overall, candidates appeared to understand the requirements of the question paper and seemed to have a technique in place to work through each section of the paper in a systematic way.

Generally, those candidates who adopted a reasonable and justified construction and applied it consistently to their analysis of infringement and novelty did well. Those who provided only a limited justification of their construction points or reverted to the claim language alone when analysing infringement and novelty did poorly.

The mark scheme indicates where marks could be awarded and provides guidance on points that should attract marks. It does not set out prescriptively the only points for which marks can be awarded (especially for later sections). It is not an exemplar answer. To be awarded high marks, points made in an answer needed to be (a) clear, (b) reasonable in view of the source material and (c) fully justified. Those answers which included a liberal application of words like "because", "thus" and "therefore" almost invariably scored higher than those which did not. Where many candidates lost marks was not evidencing their points where evidence was available.

It was observed that many candidates who dropped marks in construction were nevertheless able to score well on the novelty and infringement sections by applying their adopted construction properly and consistently.

Many candidates used tables to format parts of their answer. It is recognised that this formatting can help candidates to formulate their answer. Tables are not prohibited nor their use prevented by the Word Answer document used in the examination. However, candidates should be aware that the use of tables can be detrimental to the clarity of their final answer and is therefore not encouraged.

For instance, many candidates presented their novelty section as a single table including the claim language, their construction and their novelty analyses of both documents C and D. The necessarily narrow columns of such tables in some cases lead to difficulty in understanding a candidate's novelty analysis (for example where a meaningful line break cannot be distinguished from text wrapping).

Candidates are also strongly discouraged from repeating parts of their answer (for example copying a construction into a novelty table). Not only can this lead to readability issues as explained above, but any discrepancy between the copies (for example due to copying mistakes or later revisions to a construction not being propagated to all occurrences) can make it extremely difficult to assess an answer.

Finally, candidates are reminded of instruction 4 on the question paper frontsheet: "Do not attempt to change the font style, font size, font colour, line spacing or any other pre-set

formatting". Some candidates adjusted the font sizing and/or page orientation of their script, which led to formatting issues in the copies used for marking. Whilst best efforts will be made to mark all scripts submitted, changing these formatting settings can lead to parts of answers being lost.

The pass rate for this year's examination was in line with recent years.

Construction

Most candidates appeared to appreciate the principles of construing patent claims according to UK law and sought to adopt a purposive construction of the claim features rather than a purely literal interpretation of the words of the claim.

Most candidates were able to identify passages of the patent that provided useful guidance for what the skilled person would have understood the patentee to be using each integer of the claims to mean. However, some candidates did no more than this when seeking to justify their conclusion. The best answers included well-reasoned explanations as to *why* the content of relevant description passages meant that certain interpretations would be adopted.

Much of the challenge in construction this year was due to the fact that the patent described many of the claimed features only in the context of how the medicament was made. This was particularly significant because both the alleged infringement and the relevant prior art disclosures used a different method of manufacture. The best answers clearly identified that the claims were directed to a completed medicament and made appropriate decisions for each claim integer in this context.

A full mark was available for explaining fully the possible combinations of claims permitted by the indicated dependencies. Many candidates missed out on this by providing only a cursory discussion that did not unambiguously identify all possible claim combinations.

Claim 1

Claim 1 was generally construed well. For, instance, many candidates were able to identify the definitions of "gelatinous" and "caplet" given in the description, and that "generally cylindrical" should be interpreted as encompassing at least those caplets illustrated in the figures of the patent. Most candidates were also able to recognise that the capsule halves could be in contact without overlapping.

There were several marks available for discussing the hard-shell gelatinous capsule halves recited in Claim 1. Most candidates correctly refrained from interpreting "secured on" to be limited to the specific use of gelatin dots discussed in the patent. Whilst many candidates identified that the patent describes the capsule halves being of the same internal diameter so as to prevent overlapping, few recognised that this refers to the capsule halves *prior* to the shrink wrapping and did not discuss the impact of this on their construction.

Claim 2

Claim 2 presented more difficulty. A notable number of candidates found that for a capsule half to be "shrink-wrapped" it must have been subject to the specific shrink-wrapping method described in the patent (or at least a method having broadly analogous steps). This overlooked the product nature of the claim. Better constructions determined that "shrink-wrapped" limited the structure of the end product, and most candidates who recognised this came to the expected conclusion that the capsule halves must be in intimate contact with the caplet.

Claim 3

Generally, this claim was discussed only briefly. Few candidates considered whether the capsule halves needed to be in complete contact, i.e. leaving no part of the caplet exposed, or if any type of contact was acceptable. A minority of candidates explained whether the embodiment of Figure 2 was excluded or not and why.

Claim 4

Few candidates put clear boundaries on "about a midway point", with many electing to simply substitute "about" for synonymous words in their construction (for example "near"). A better approach was to identify that contact at about the midway point was the result of the capsule halves being the same length.

Claim 5

Most candidates identified the example colours given the patent and sensibly decided that the claim was not limited to these examples. Fewer candidates recognised that the colours likely needed to be sufficiently different to look like a conventional two-colour capsule, or that each capsule half needed to be *only* one colour to achieve the desired effect. Several candidates decided that the halves needed to include *pigments* to attain the first and second colours, although it wasn't apparent from the patent that this was the only way to achieve the colouring.

Claim 6

Better candidates recognised and clearly explained that the band was an additional element due to the use of "further including" and the proscription of overlapping capsule halves by Claim 1. Because the belly band is introduced in the patent as an option for covering a gap between the capsule halves, it needed to be discussed whether Claim 6 was limited to such cases and the possible dependency on Claims 3 and 4 was an error, or vice versa.

Infringement

Infringement was generally handled well, although some candidates reverted to assessing infringement with reference to the claim wording rather than their construction. This was unlikely to attract marks.

Many candidates provided minimal reasoning for their findings that claim features were present or not present in the Kwikcap product, providing only a page and line reference alongside the present/not present conclusion. Whilst this may be appropriate for a very limited number of features where the justification of the present/absent conclusions is immediately apparent from the referenced passage, it is emphasised that bulk of the marks available in the infringement are for explaining how and why a feature of the adopted construction is present or not present in the alleged infringement.

It was expected that the Kiwkcap would be found to be within the scope of claims 1, 2 and 5, although different conclusions were possible depending on how the claims were construed. It seemed unlikely that claims 3 and 4 would be infringed, given that a primary goal of the Kwikcap product is to have a gap between the coatings to aid dissolution, unless a broad construction was adopted that allowed for small gaps.

Candidates were expected to pick up on the fact that only some versions of the Kwikcap might fall within the scope of claim 5.

Equivalents

There were three marks available for considering infringement by equivalence. Marks were awarded for accurate, reasonable **and justified** application of the three Actavis questions. Most candidates found that Claims 3 and 4 were not infringed on a normal meaning due to the gap in the Kwikcap product, and this provided a good opportunity to discuss whether there was nevertheless infringement by equivalence.

Some candidates who decided that Claim 2 required the medicament to be made with a specific method of manufacture found that activities in relation to the Kwikcap did not infringe this claim on a normal interpretation, but that it was infringed by equivalence. In such cases it might have been desirable to consider the impact of this conclusion on the validity position and whether a *Formstein*-type defence could be applicable, although this degree of analysis was not expected.

Novelty

25 marks were available for novelty this year, and some candidates scored very highly.

As with infringement, some candidates adopted a very minimal approach to assessing novelty. Answers which provided only a line and page reference in combination with a conclusion were rarely awarded all possible marks unless the reasoning was unambiguously self-evident. Candidates were instead expected to provide an explanation of **why** a feature of the adopted construction was disclosed as part of a prior art embodiment, although it should be emphasised that in most cases a satisfactory explanation does not need to be very long.

Most candidates identified the need to analyse both documents C and D for novelty, although some candidates seemed to struggle to separate the different embodiments described in Document D. Few marks could be awarded for a novelty analysis that referred to different embodiments of Document D when analysing different integers of the claims. The best answers clearly identified which embodiment was being assessed, and explained any inferences about this embodiment that were being made in view of the rest of Document D.

It was important for candidates' novelty analysis to be consistent with their assessment in infringement. For instance, where candidates found that immersion processes described in the Kwikcap product description created hard-shell gelatinous capsule halves it was expected that the same conclusion would be reached about the dipping process described in Document C.

There were a few points where the disclosure of Documents C and D was ambiguous, and this required discussion. For instance, the description in Document D of coating pills by dipping did not identify explicitly whether the resulting coatings overlapped or were in contact. Some reasoned discussion of what could be inferred about these issues from surrounding passages of Document D was desirable.

Only a minority of candidates recognised that the mention of "bicoloured" or "two-tone coloured capsules" in Document D was not an unambiguous disclosure of two capsule halves having different colours.

Inventive Step

Most candidates made a reasonable attempt at assessing inventive step using the Windsurfing/ Pozzoli approach, although many candidates slipped into a EPO-style problem-and-solution analysis.

Most candidates suggested reasonable inventive concepts for at least some claims, although many fell into the trap of equating the inventive concept with a broad problem addressed by the

patent or an overall aim of the inventor, rather than a précis of the core technical insight that is actually provided by the claim.

Moreover, many candidates then went on to disregard the inventive concept they had proposed when applying the later steps of the Windsurfing/Pozzoli approach. Instead, candidates would revert to identifying specific differences between the words of the claim or their construction and the prior art (i.e. more akin to the EPO's problem-and-solution approach to assessing inventive step).

For those claims that were found to lack novelty, it was generally still possible to apply the Windsurfing/Pozzoli framework to assess inventive step and this is encouraged. Some candidates constructed an inventive step analysis based on an assumption that their lack-of-novelty conclusion was incorrect (for example "I will assume that feature X is not present in Doc C"). This approach is acceptable and was rewarded where the inventive step analysis provided was reasonable and evidenced.

Sufficiency

There were no sufficiency issues identified or implied by the provided documents, and one mark was available for recognising this. Some candidates asserted that minor errors or inconsistencies in the claims led to issues with sufficiency, but these were not accompanied by convincing reasons why the skilled person would thus not be able to carry out the claimed invention and so could not be rewarded.

Amendment

It was expected that the Kwikcap would be found to infringe at least some of the claims on a normal or equivalent basis, but that these claims would be invalid. The patent potentially provided support for an amendment to specify that the capsule halves were not in contact. This was not disclosed in the prior art but was a key feature of the Kwikcap and so represented a promising route for amending the patent. The best candidates noted that making this amendment would, however, exclude embodiments in which the capsule halves were in contact and that this may not be desirable.

Suggestions to amend to claims found to be invalid or non-infringed were generally not rewarded with marks.

Advice

In general, candidates scored relatively poorly in the advice section. Some candidates might have benefitted from allocating more time to their advice section, given that there were ten marks available and many of these were for relatively simple recommendations.

Some straightforward but good points of advice were identified by many candidates, including recommending to check whether the necessary renewals fees had been paid for the patent to be in force. However, many candidates neglected to explain **why** it was necessary to check this (i.e. because the patent was sufficiently old).

Many candidates also usefully corrected the client's misapprehension that the patent covers a process of producing gel caps.

Some candidates also correctly highlighted that it was not TAB but a subsidiary that was acting in the UK, which was a particularly important point to note if infringement proceedings were

envisaged. Better candidates identified the benefit of putting the subsidiary on notice as soon as possible to remove an innocent infringement defence.

Fewer candidates recognised that the product description was relatively old and recommended obtaining and analysing samples of the actual Kwikcap product on the market.

Those candidates who identified the possibility of requesting an interim injunction tended to apply the correct principles when assessing the likelihood of obtaining one (for example balance of convenience, damages being an inadequate remedy). However, discussion of these points often lacked substance, for example with candidates identifying no actual reasons why damages would not be an adequate remedy in this situation.