Examiner's Report 2014
P4 – Amendment of Specifications

Patent Examination Board

Introduction

The present invention relates to a balloon catheter, a simple mechanical device but one the examiners hoped would not be intimidating to candidates practising in the life sciences. The balloon is inflated manually to a predetermined extent set by the user, so that it fits the diameter of the tube (e.g. an ETT) into which the catheter is inserted. The catheter also has a suction tube to assist in the removal of fluids, but this is a side issue.

The candidates were expected to amend claim 1 to both match the commercial area of interest of the client, but also to limit the claim to restore novelty and inventive step. It was surprising that although there were some excellent answers to the paper, a disappointing number of candidates only looked at one aspect or the other. Then the candidates needed to provide a reasoned response to the examination report and explain their actions and the implications to the client.

The better performing candidates picked up an even spread of marks over all areas of the paper – in particular they tended to have a well laid out response to the examination report and a coherent memo to their client. It was noticeable that the poorer candidates tended to miss a lot of marks in the memo to the client and the examiners would like to remind all candidates that the memo can attract up to 30 marks and therefore it should not be neglected.

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Questions

Claim 1

There are two pieces of prior art, D1 and the plunger-type syringe described in the application itself. Claim 1 at issue is distinguished from the plunger-type syringe by the presence of the releasable latch. Although the description did not explicitly mention an abutment, arguably an ordinary syringe does have an 'abutment', viz. the end of the syringe, against which the plunger abuts if one pushes it to the end. D1 also has an 'abutment' in a similar way, namely the base 26 of the clip. Not many candidates discussed these points. Of course, the IPO examination report does not make this objection, so there is perhaps no need to argue it in the response, but it should be noted in the report to the client, observing that the possible objection has already been headed off at the pass. Whether the ratchet teeth, on the other hand, can also be considered to present an 'abutment' was a matter inviting plentiful discussion and divergence of views.

The client considered the difference between his invention and D1 to lie in the fact that D1's is a sealed system, and therefore to vary the volume of fluid is difficult, involving emptying and refilling the bulb, or using a different bulb, whereas the device of the invention merely requires the user to move the slider to a different position.

A broad way of encompassing the advantages of the invention would be to say that the abutment is freely movable as to vary the limit volume of air expelled, as set out in the description on page 7 lines 18-19 and page 8 lines 19-21. Some candidates were slightly more specific, including a slider attached to the abutment, perhaps movable in a slot, and some were more specific still, saying that the actuator had wings pivoting towards each other, the sliding of the actuator being towards and away from the pivot. While these limitations were felt to be unnecessary in clam 1 (though making good material for sub-claims), claims incorporating an amendment of this kind attracted some marks.

Significantly, this was not, however, the only amendment to make to clam 1. In the first place, the client wants to cover balloon catheters for use in cleaning other 'medical tubes' (the reference by the client to 'catheters' is perhaps a trifle confusing). It was therefore expected that candidates broaden the reference in claim 1 from ETTs to 'medical tubes' or similar, since there is plenty of support for such a broadening. Most candidates dealt well with this point.

Secondly, and still more importantly, it was expected that the device claimed be broadened to an inflation device, without the catheter/inflation lumen/balloon, since the client says that he will be supplying just this device. Again, there is ample support, such as the opening of the description and the summary of the invention. Many candidates spotted the point – though a good many did not – but many that identified it did not deal with it very well. A particular issue was where claim 1 still apparently retained the catheter/ balloon elements even when the heading of the claim was broadened to an 'inflation device'. The marks could not be awarded here where the end result did not meet the objective.

Some candidates left claim 1 as directed to a cleaning device, but then added a separate independent claim to an inflation device without the balloon catheter. While this might be a good strategy in the US, the examiners could see no justification for it in the UK.

Dependent claims

In the dependent clams, a claim or two could be added to details of the slider / slot / wedge / scale, to provide backup positions. It was also expected that, claim 1 being broadened to an inflation device alone, there should be a claim near the end incorporating this device and the balloon catheter. A claim could then be included to the vanes of Figure 3. Some marks were also given for those candidates suggesting alternative claims such as the use of the device to clean medical tubes.

Some corrections needed to be made in the existing claims – claim 4 would need to depend on the restored claim just mentioned, to the cleaning device as a whole. Claim 5 cannot depend directly on claim 1 since it mentions the frame and bellows, appearing first in claim 2 (though some candidates put these items into claim 1 – an unnecessary but not a drastic limitation – and thus solved the problem in passing).

The existing omnibus claim should probably be amended to an 'inflation device', though there is plenty of scope for other adjustments, including of course the exclusion of reference to Figure 1. If this claim is directed to an inflation device, it is then reasonable to exclude claims 3 and 6 from its purview, as they show only parts of the catheter, but no weight was laid on this.

Response

A portion of marks in the response are set aside for explaining the support and basis for the amendments to the claims. The examiners are looking for more than a bare page and line reference for this section, and full marks could not be awarded in those cases where only a reference to the specification was given. This applies in particular for the broadening amendment to claim 1, where it was necessary to explain why the broadening did not add any subject matter.

With respect to novelty, it was possible to contest the Examiner's point that the ratchet teeth 33-35 constituted an 'abutment'. Although they stop the pressure strip 29 from being pushed back (i.e. with liquid returning into the syringe bulb), they do not stop it from being pushed forward, to inflate the balloon catheter – the end of the strip rides over the teeth, the curved strip 31 bending outward as necessary. Even if one were to concede this point (as the client says), and to deem one of the ratchet teeth as an 'abutment', this 'abutment' is not movable so as to move the end point of travel of the actuator (pressure strip): it can only move outwardly, so as to get out of the way. Some candidates said that the ratchet teeth were not movable at all, which is not strictly true, and the point needs to be made more clearly that the teeth cannot be moved (say) along the curved strip 31, as they would have to in order to anticipate a revised claim 1.

Many candidates argued that D1 did not enable 'precise setting' of the amount of fluid dispensed. Again, this argument usually needed to be made more carefully. D1 allows precise filling of the balloon, in that one fills the syringe with the required amount of fluid and then squeezes all of it into the balloon. Furthermore, the ratchet teeth could be placed in manufacture at particular points. What D1 does not do is allow the **user** at the point of operation to set a freely adjustable amount to be dispensed. Even if one were to take the ratchet teeth as 'abutments', they cannot be adjusted so as to vary the end point of travel of the actuator.

There was a small point as to whether it mattered that D1 used a liquid in the bulb, while the device in the invention specified air. Since the device of D1 could presumably be filled with air it

was not seen that much hung on this point, and those candidates who discussed it generally came to this conclusion.

The examiners apologise for the slight discrepancy between the claims of the application and the 'spare set', which some candidates noted, and hope that it did not cause too many worries. Certainly no marks were lost or gained if either the text as provided was used, or if it was amended for conformity with the application set.

Report

Some candidates produced rather indifferent responses to the examination report, but saved themselves by a good memo explaining why they had taken the action they did, which was enough to convince the examiners that they had a reasonable grasp of the issues and what amendments were necessary even if they hadn't found the perfect amendment in the claims submitted.

As to a divisional, there is a clear steer towards looking for protection for the spacer idea, though this is easier said than done. It is improbable that a claim could be justified to a spacer on its own, even having perhaps a few indicia, as this amounted to little more than a tube. A claim to a cleaning device roughly as the present claim 1, further including a spacer as in claim 4, would be going in the right direction. Many candidates did pick up good marks in this area with a reasonable attempt at a claim. Furthermore, it was acceptable to refer to the original claims (e.g. a device as specified in claim 1 further comprising…) to save time.

Some candidates proposed a new application to the plumbing idea. This raises the question of whether the present application is already published, or whether the inventor has already disclosed the invention at least in its medical form. In any event, a point of novelty would be needed, and a device on its own 'suitable for' plumbing purposes might not be such. A method of unblocking a drain would be new, but the examiners felt that this was going beyond the bounds of the present paper and that a mention to the client of the possibility was enough.

Finally, when discussing the broadening of claim 1 to the device alone, it was expected that the candidates would pick up on the difference between who would infringe a claim to the inflation device alone, vs. who would infringe a claim to the cleaning device including a catheter etc. The good candidates were able to pick up several marks from a good discussion in this section.