

FD4 Infringement and Validity

FINAL Mark Scheme 2024

This mark scheme is a guideline. Examiners may give marks for answers that do not follow this exactly but still address the necessary points

Construction

		Marks
1. A medicament comprising:	a product for administering a medicinal agent to a patient, P3L7-11, P4L4-6	1
(a) a solid generally cylindrical caplet with first and second ends;	“caplet” defined as solid, elongate, round-ended tablet (i.e. have a similar shape to a capsule) P3L14-15 Some discussion of “generally cylindrical”	1
(b) a first hard-shell gelatinous capsule half secured on the second end of the caplet;	Capsule is term of art -P16L9: completely enveloping the drug. “Half” suggests a divided capsule or capsule formed from two parts. P4L13-16 suggests they do not have to have the same length. “gelatinous” defined in patent P3L11-13 “hard-shell” both before and after shrink wrapping P4L23-26 “secured” – patent mentions the use of gelatin dots to secure, but claim doesn’t appear to be limited to this P4L19-21	1
(c) a second hard-shell gelatinous capsule half secured on said first end of said caplet,		1
		1
		1
wherein the second hard-shell gelatinous capsule half does not overlap the first hard-shell gelatinous capsule half, and	touch/contact, P4L14 or small gap P5L15 Nothing to suggest specific limit to size of gap	1
wherein the first and second hard-shell gelatinous capsule halves have substantially the same diameter.	“internal” diameter “substantially the same” suggests that diameter only needs to be similar enough to prevent overlapping P4L12-13 effect is discussed before shrinkage but claim is to medicament and not limited to this process so must be determined from final product not intermediate. Because caplet core is generally cylindrical it seems that internal diameters will be the same after shrinking too.	1 1 1

	Total for claim 1	10
2. A medicament as claimed in claim 1, wherein the first hard-shell gelatinous capsule half is shrink-wrapped on the second end of the caplet; and the second hard-shell gelatinous capsule half is shrink-wrapped on the first end of the caplet.	Shrink wrapped = process step so explain how this limits the structure “the two hard-shell gelatin capsule halves 14 and 16 are substantially <u>in intimate contact with the core 1</u> ” P5L9-11	1 1
	Total for claim 2	2
3. A medicament as claimed in claim 1 or 2, wherein the second hard-shell gelatinous capsule half is in contact with the first hard-shell gelatinous capsule half	“in contact with” in finished product (after shrink fit) Do the halves need to be in contact all the way around the core, or can there be some gaps? Halves are not in contact with each other in Fig 2 P5L11-13 due to shrinkage. Explain if this still falls within the scope of the claim or not, and why	1 1
	Total for claim 3	2
4. A medicament as claimed in claim 3, wherein the first and second capsule halves are in contact with each other at about a midway point of the caplet.	in contact at about midway point is the result of the two halves having the same length P4L13-16 Reference 11 to “midway” in Figure 1 is clearly not near a midway point. Is this an error or does it suggest more flexibility in “midway”?	1 1
	Total for claim 4	2
5. A medicament as claimed in any preceding claim, wherein the first hard-shell gelatinous capsule half has a first colour, and the second hard-shell gelatinous capsule half has a second colour different from the first colour.	Different colours P5L18-20 Each half seems to need to be (only) a single colour to achieve the desired effect of looking like a conventional two-colour capsule	1
	Total for claim 5	1
6. A medicament as claimed in any preceding claim, further including a gelatinous band extending around the caplet to overlie the ends of the hard shell gelatinous capsule halves.	“Belly” band 17 of Figure 2, P5L15-17 Fig 2 shows band to be a separate element. Claim 1 requires no overlap, so decide if claim 6 is limited to separate band or if band can be integral with one or other capsule half? “ <u>the ends</u> ” of the capsule halves are not introduced earlier.	1 1

	Explain if claim limited to case where there is a gap as only described in this context – is possible dependency on claim 3/4 an error?	1
	Total for claim 6	3
	Dependencies – unambiguous identification of all possible combinations required	1
	Total for Construction	21

Infringement

The comments below identify relevant passages in Document B. A candidate must effectively analyse how each identified feature maps onto their construction to receive full marks.

Claim	Doc B Kwikcap	Marks
1. A medicament comprising:	Present P9L1 P8L5-11 does not describe the Kwikcap product	1
(a) a solid generally cylindrical caplet with first and second ends;	Present P8L24-25. Figure 1 shows core of Kwikcap product shown in Fig 2	1
(b) a first hard-shell gelatinous capsule half secured on the second end of the caplet; (c) a second hard-shell gelatinous capsule half secured on said first end of said caplet,	Possibly Present P9L2-4 Discuss whether dip coatings meet construction. Does dip coating form a hard-shell gelatinous capsule half? Document D P16L4-5 and L16-19 suggests yes Are the results of dip coating “secured”?	1 1 1
wherein the second hard-shell gelatinous capsule half does not overlap the first hard-shell gelatinous capsule half, and	Present P9L3-5 and L20-22, Fig 2	1
wherein the first and second hard-shell gelatinous capsule halves have substantially the same diameter.	Not explicitly disclosed but will be the case because dipping process P9L9-15 means that core 10 defines the inner diameter of the coatings which must therefore be the same P9L17-19 says that there is no detectable transition between core and ends.	1

	Total for claim 1	7
2. A medicament as claimed in claim 1, wherein the first hard-shell gelatinous capsule half is shrink-wrapped on the second end of the caplet; and the second hard-shell gelatinous capsule half is shrink-wrapped on the first end of the caplet.	No explicit mention of shrink wrapping Dipping would appear to provide intimate contact (possible to discuss in Actavis section) so does dipping result in a “shrink-wrapped” half?	1 1
	Total for claim 2	2
3. A medicament as claimed in claim 1 or 2, wherein the second hard-shell gelatinous capsule half is in contact with the first hard-shell gelatinous capsule half	Explicitly states ends do not contact or overlap P9L2-3 P9L22 suggests that gap is needed for improved dissolution If construction allows for small gap due to pull back, is this met by smallest gap 26 in doc B (2 mm - 3mm)?	1 1 1
	Total for claim 3	3
4. A medicament as claimed in claim 3, wherein the first and second capsule halves are in contact with each other at about a midway point of the caplet.	P9L20 states that gap 26 can be centred Conclusion same as cl 3	1
	Total for claim 4	1
5. A medicament as claimed in any preceding claim, wherein the first hard-shell gelatinous capsule half has a first colour, and the second hard-shell gelatinous capsule half has a second colour different from the first colour.	Present P9L3-7 But P9L6-7 says that this is only in some versions of the Kwikcap	1 1
	Total for claim 5	2
6. A medicament as claimed in any preceding claim, further including a gelatinous band extending around the caplet to overlies the ends of the hard shell gelatinous capsule halves.	Not present. Differentiate bellyband of Doc B from bellyband of Doc A	1
	Total for claim 6	1

Conclusions (may be found in advice section, give marks here)	Conclusions including consistency and dependencies	1
	For claims not infringed on normal meaning, how does Actavis change outcome? For all marks to be awarded, candidate must present a reasoned analysis of whether one or more specific equivalents nevertheless infringe with reference to the three Actavis questions.	3
	Total for Infringement	20

Novelty

Award up to 25 marks from the following

Date for assessing novelty: Filing Date

1

Prior Art: CGK Doc D (There are several products described in document D. Candidates must analyse whether the document discloses a single embodiment meeting their construction); Doc. C

1

The comments below identify relevant passages of the prior art documents. A candidate must effectively analyse how disclosures in the prior art map onto their construction to receive full marks.

	Doc C	Marks	Doc D	Marks
1. A medicament comprising:	Present P11L3-5	1	Present P16L4-12 discloses that pharmaceuticals in dosage forms are known. P17L12-14 also discloses a specific coated tablet.	1
(a) a solid generally cylindrical caplet with first and second ends;	Present Figs 2 & 3. P12L18 says that the dipped caplet is solid	1	Possibly Present P17L12-14, 29-32. Is "oblong" generally cylindrical?	1
(b) a first hard-shell gelatinous capsule half secured on the second end of the caplet; (c) a second hard-shell gelatinous capsule half secured on said first end of said caplet,	Present P12L18-29 Discussion of capsule halves must be consistent with infringement analysis.	1	Possibly Present p. 17, ll. 29-33. Discussion of capsule halves must be consistent with infringement analysis.	1

wherein the second hard-shell gelatinous capsule half does not overlap the first hard-shell gelatinous capsule half, and	Present Fig 4a	1	Not explicit, no basis to say implicit or inherent	1
wherein the first and second hard-shell gelatinous capsule halves have substantially the same diameter.	Present, not explicitly disclosed but dipping P12L7-11 means that core defines inner diameter so both are therefore same. Discussion of capsule halves must be consistent with infringement analysis.	1	Possibly present Dipping p. 17, ll. 29-33 therefore same. Discussion of capsule halves must be consistent with infringement analysis.	1
	Sub-total	5	Sub-total	5
			Total Claim 1	10
	Doc C	Marks	Doc D	Marks
2. A medicament as claimed in claim 1, wherein the first hard-shell gelatinous capsule half is shrink-wrapped on the second end of the caplet; and the second hard-shell gelatinous capsule half is shrink-wrapped on the first end of the caplet.	Possibly Present. Dipped but not shrink-wrapped. Discussion of “shrink-wrapped” must be consistent with infringement analysis	1	Possibly Present. Dipped but not shrink-wrapped. Discussion of “shrink-wrapped” must be consistent with infringement analysis. Half shells disclosed for filling with powder later P16L16-27, but this is a separate embodiment to that described at P17L29-33	1 1
	Sub-total	1	Sub-total	2
			Total Claim 2	3
	Doc C	Marks	Doc D	Marks
3. A medicament as claimed in claim 1 or 2, wherein the second hard-shell gelatinous capsule half is in contact with the first hard-shell gelatinous capsule half	Present Fig 4a. Not explicit in description so explain why. P13L2-3, L7-10 mention overlapping and thus contacting but these embodiments do not seem to meet the	1 1	Not explicit. Does disclosure at P17L31-33 of immersing “half” and then the “other half” suggest that the resulting coatings contact?	1

	"does not overlap" requirement of claim 1			
	Sub-Total	2	Sub-total	1
			Total Claim 3	3
	Doc C	Marks	Doc D	Marks
4. A medicament as claimed in claim 3, wherein the first and second capsule halves contact each other at about a midway point of the caplet.	Present Fig 4a Not explicit so explain why	1	Not explicit. Does disclosure at P17L31-33 of "half" and then the "other half" suggest that the resulting coatings contact about midway?	1
	Sub-Total	1	Sub-total	1
			Total Claim 4	2
	Doc C	Marks	Doc D	Marks
5. A medicament as claimed in any preceding claim, wherein the first hard-shell gelatinous capsule half has a first colour, and the second hard-shell gelatinous capsule half has a second colour different from the first colour.	Present, p. 12, ll 14-17, P13L1-6	1	p. 17, ll. 23-28 mentions bicolour/two-tone. This does not appear to be an unambiguous disclosure of the coated tablet product having halves with different colours.	1
	Sub-total	1	Sub-total	1
			Total Claim 5	2

	Doc C	Marks	Doc D	Marks
6. A medicament as claimed in any preceding claim, further including a gelatinous band extending around the caplet to overlie the ends of the hard shell gelatinous capsule halves.	Present/not present depending on construction. The caplets of Figs 4b, 4c have a seam 300, 302; p. 13, ll. 1-3, but these embodiments do not seem to meet the “does not overlap” requirement of claim 1	1 1	Not disclosed	1
	Sub-total	2	Sub-total	1
			Total for Claim 6	3
			Conclusions including dependencies	1
			Total for Novelty	25

Inventive Step

	Marks
Date for assessment of IS = Filing Date	1
PSA = e.g., an engineer or equivalent person skilled in the design and production of medicament dosage forms	1
CGK = Doc D, Doc A P3L7-18	1
State of the art = Doc C, with appropriate reasoning	1
	4

Claim 1		Marks
Concept	e.g., Provide a caplet with the same appearance and feeling as a capsule by covering a solid caplet core with two hard-shell gelatinous capsule halves – P3L20-22	1
State of the art	Doc C	
Difference	As claimed: none. Fig 4a	1
Obviousness	The features and their effects and desirability are all found in Doc C	1

	Total for claim 1	3
Claim 2		
Concept	e.g., To provide a dosage form that has capsule half-shells in “intimate contact” with a solid core to simulate a capsule	1
State of the Art	Doc C	
Difference	Possibly none if dipping process in Doc C leads to “intimate contact”	1
Obviousness	If dipping leads to “intimate contact”, concept found in Doc C. If not, does not seem obvious as nothing in CGK which points toward this..	1
	Total for claim 2	3
Claim 3		
Concept	Depends on construction of “in contact”. E.g., have halves in contact to avoid gap and facilitate simulation of gel cap P5L11-17	1
State of the art	Doc C	
Difference	No explicit disclosure of halves being in contact	1
Obviousness	CGK Doc D P17L12-17 identifies anti-tampering and swallowing benefits of entirely coating caplets, seems obvious to try to avoid gap in coatings of Doc C	1
	Total for claim 3	3
Claim 4		
Concept	Provide a medicament coated with capsule halves of the same length	1
State of the art	Doc C	
Difference	None, Fig 4a	
Obviousness	Concept known from Doc C	1
	Total for claim 4	2
Claim 5		

Concept	Provide a medicament coated with capsule halves having different colours to simulate appearance of a conventional two-colour capsule	1
State of the art	Doc C	
Difference	None, Doc C P11L13-15, 24-26, P12L14-17	
Obviousness	Concept known from Doc C. CGK also discusses “strong preference” for bicoloured or two-tone coloured combinations P17L23-28	1
	Total for claim 5	2
Claim 6		
Concept	cover gap and simulate standard capsule P5L15-17	1
State of the art	Doc C	
Difference	No band in Doc C, just one end overlying the other	1
Obviousness	No gap mentioned in Doc C or Doc D. Doc C avoids gap by over-dipping one end (Figs 4b, c). Doc D mentions fitting one end of a capsule into the other P16L19-24. Band covering both ends not obvious from either of these	2
	Total for claim 6	4
	Total for Inventive Step	21

Sufficiency

No sufficiency issues

Total for Sufficiency**1 Mark****Amendment**

Any amendment with basis and reasoning to address novelty/inventive step and infringement.

For example:

Amendment based on:

P5L11-13: "the shrink-wrapped capsule halves 14 and 16 sometimes are not in contact at a point about midway along the core" could capture infringement.

Also needs to present argument why belly band 17 not essential

Novel because not disclosed in Doc C or D

Possibly inventive because Doc C considers overlapping to be desirable

Excludes "contacting" embodiment so needs discussion of how desirable amendment might be (see also Advice)

Total for Amendment

2 Marks

Advice**10 Marks**

award up to ten marks for relevant points of advice.

Patent older than 4 years - confirm renewal fees paid up to date so that patent is still in force (1)

Patent does not protect a specific process as client believes P2L9-10 (1)

Outline of options for enforcing patent: IPEC, HC, sale, manufacture, importation (1)

Damages or account of profits may be available given client's lost contracts (1)

Injunctive relief available if successful but timings suggest interim relief unlikely (1)

Could agree licence with TAB subsidiary, but seems unlikely (1)

Need to amend before enforcing due to validity issues or apply to amend when bringing infringement action (1)

(must discuss validity issues when advising how to enforce, no credit for advising to enforce invalid patent)

Outline further information needed:

Appears that subsidiary is the one acting in UK, so TAB inc. itself may not be an infringing entity (1)

How big is gap in client's Fig 2 embodiment? Does it correspond to any of the gap sizes disclosed in Doc B? (1)

How important is "contacting" embodiment? (1)

Doc B four years old. Does it describe current Kwikcap product? Recommend to obtain samples. (1)

Put TAB subsidiary on notice to remove innocence defence to damages claim (1)

Advise client on threats issues – may need to be careful around dialogue with customers (1)