

Paper Ref	Sheet	Percentage Mark Awarded
FD4	1 of 23	52%

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use only

Spare Set of Claims

1. A medicament comprising:
 - (a) a solid generally cylindrical caplet with first and second ends;
 - 5 (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, wherein the second hard-shell gelatinous capsule half does not overlap the first hard-shell gelatinous capsule half, and wherein the first and second hard-shell gelatinous capsule halves have substantially the same diameter.
- 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.
- 15 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.
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.
- 20 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.
6. A medicament as claimed in any preceding claim, further including a gelatinous
 - 25 band extending around the caplet to overlie the ends of the hard-shell gelatinous capsule halves.

[Instruction to Candidate: Save your Answer document to your computer as a Word document. Convert the Answer document to a PDF. Check and then Upload the PDF-ed Answer document to the PEBX system.]

Construction

Doc A, filing date 6 June 2014.

Claims	integer	Construction
1.1	A medicament comprising	Independent product claim. Medicament taken to mean a medicinal agent/drug, P3L9-10. Intended to cover all prescription/over counter drugs –P4L4-6. Contains but is not limited to
1.2	(a) a solid generally cylindrical caplet with first and second ends;	Solid takes its usual meaning, not liquid or gelatinous, generally cylindrical is a longitudinal axis with rounded opposing ends, see figures. “generally” taken as able to take a slight deviation from perfect cylinder.

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		Caplet is “solid, elongate, round ended tablet – similar shape to capsule” P3L14-15	1
1.3	(b) a first hard-shell gelatinous capsule half secured on the second end of the caplet;	Hard shell gelatinous capsule half – “any composition which has the same physical properties as hard gelatin capsules”, P3L11-13. “Secured on” taken as meaning covering the end, purpose to allow medicinal caplet to “fit within” capsule halves.	1
1.4	(c) a second hard-shell gelatinous capsule half secured on said first end of said caplet,	As above, the other capsule half fits the other end of the caplet, see Figures also.	
1.5	wherein the second hard-shell gelatinous capsule half does not overlap the first hard-shell gelatinous capsule half	The ends of the capsule halves may touch, but not overlap P4L10-14. May also not touch, P5 L13-17, Fig 2, repercussive effect of claim 4 also.	1

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1.6	and wherein the first and second hard-shell gelatinous capsule halves have substantially the same diameter.	“Substantially same diameter” taken to mean for the purpose of preventing insertion of one capsule half into the end of the other (overlapping), internal diameter – P3 L29-P4L1, L12-13. That is, they would abut each if of touched. Also has to “allow medicinal caplet to fit within the capsule halves” P3L26-28.
2.1	A medicament as claimed in claim 1,	Comprises all the features of claim 1, plus the following
2.2	wherein the first hard-shell gelatinous capsule half is shrink-wrapped on the second end of the caplet; and	hard gelatin shell hydrated and plasticized, then dried to cause the hard-shell gelatin capsule half to shrink to fit the form of second end to form a first shrink-wrap gelatin hard-shell covering/core combination – P4 L17-26 therefore shrink wrap taken the mean the described process.

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2.3	the second hard-shell gelatinous capsule half is shrink-wrapped on the first end of the caplet.	The same as above, for the other end. Both must be shrink wrapped by use of “and”.
3.1	A medicament as claimed in claim 1 or 2,	Contains all the features of claim 1, or claim 1+2, plus the following
3.2	wherein the second hard-shell gelatinous capsule half is in contact with the first hard-shell gelatinous capsule half.	This is the annular ends of the caplet halves that touch, P4L13-16
4.1	A medicament as claimed in claim 3	Contains all the features of claim 1+3, or 1+2+3, plus the following
4.2	wherein the first and second capsule halves are in contact with each other at about a midway point of the caplet.	As above, Around the centre of the longitudinal axis of the caplet. “about” taken to mean doesn’t necessarily have to be the exact centre point.

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5.1	A medicament as claimed in any preceding claim	Contains all the features of claim 1, 1+2, 1+3, 1+2+3, 1+3+4, or 1+2+3+4 plus the following
5.2	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.	Both halves are different colours to “facilitate the simulation of a capsule medicament” P4L2-3. Typically, red, white yellow and blue.
6.1	A medicament as claimed in any preceding claim,	Contains all the features of claim 1, 1+2, 1+3, 1+2+3, 1+3+4, 1+2+3+4, 1+3+4+5, or 1+2+3+4+5 Dependencies = x 1
6.2	further including a gelatinous band extending around the caplet to overlie the ends of the hard-shell gelatinous capsule halves.	A gelatinous “belly” band added. Around caplet taken to mean the smaller axis, not the longitudinal, as purpose is to “cover the gap between capsule halves” which is left from when the halves are shrink wrapped and they pull back from the centre of the core. P5L15-18 MARKS AWARDED: 9.5

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Construction total = 9½

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1.4	(c) a second hard-shell gelatinous capsule half secured on said first end of said caplet,	As above, coating on opposing end.
1.5	wherein the second hard-shell gelatinous capsule half does not overlap the first hard-shell gelatinous capsule half	Present – coatings do not contact or overlap one another, separated from one another to create gap P9L2-4.
1.6	and wherein the first and second hard-shell gelatinous capsule halves have substantially the same diameter.	Present, see figures, coatings appear the same diameter as tablet looks symmetrical.
Claim 1 would be infringed by selling, manufacturing and importing KC.		
2.1	A medicament as claimed in claim 1,	present
2.2	wherein the first hard-shell gelatinous capsule half is shrink-wrapped on the second end of the caplet; and	Not present, no mention of shrink wrap process.
2.3	the second hard-shell gelatinous capsule half is shrink-wrapped on the first end of the caplet.	Not present, no mention of shrink wrap process.

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Claim 2 not directly infringed.		
3.1	3. A medicament as claimed in claim 1 or 2,	Present when depend on claim 1, not when dependent on claim 2
3.2	wherein the second hard-shell gelatinous capsule half is in contact with the first hard-shell gelatinous capsule half.	Not present, “gelatinous coatings 24a, 24b do not meet, and in fact form a gap or band 16” P9L12-15, fig 2.
Claim 3 not directly infringed when dependent on claim 1 or claim 2.		
4.1	A medicament as claimed in claim 3	Not present as features of claim 3 not present.
4.2	wherein the first and second capsule halves are in contact with each other at about a midway point of the caplet.	Not present, “gelatinous coatings 24a, 24b do not meet, and in fact form a gap or band 16” P9L12-15, fig 2.
Claim 4 not directly infringed no matter on the dependency.		
5.1	A medicament as claimed in any preceding claim	Present only for claim 1

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5.2	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 – “The colours on each end may be the same or <u>different</u> from one another, such as red and white, or blue and yellow” P9 L7-8
Claim 5 directly infringed when dependent on claim 1 (directly or indirectly), not when dependent on other claims, by manufacture, sale, import of Kc.		
6.1	A medicament as claimed in any preceding claim,	Present when dependent on claim 1 or claim 5+1
6.2	further including a gelatinous band extending around the caplet to overlie the ends of the hard-shell gelatinous capsule halves.	Not present – band 22 is outer surface of core 10. The belly band of Kc. When covered with coatings 24a, 24b is not circumferential, would be longitudinal. Also does not overlie the coatings to cover the gap.
Claim 6 is not directly infringed.		

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In summary, claim 1, and claim 5 when dependent on claim 1, are directly infringed by the manufacture and sale of Kc in the UK, and its import into the UK by the TAB subsidiary.

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No actions by TAB or the subsidiary are considered to infringe via S60(2) contributory infringement.

No actions or products are considered to infringe via equivalents under Actavis v Lily.

MARKS AWARDED: 6.5

Infringe total = 6½

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1.3	(b) a first hard-shell gelatinous capsule half secured on the second end of the caplet;	Present- P12 L6-17 and 18-25 describes the application of gelatinous material to each end of the caplet, which is dried (hard). Covers both ends “coated ends”.	Present – P17L31-33, describes dipping one half then the other into gelatinous solution (which will harden)
1.4	(c) a second hard-shell gelatinous capsule half secured on said first end of said caplet,	Present- P12 L6-17 describes the application of gelatinous material to each end of the caplet, which is dried (hard).	As above
1.5	wherein the second hard-shell gelatinous capsule half does not overlap the first hard-shell gelatinous	Present, lack of seam 300 or 302 in Fig 4a shows a non-overlapping embodiment. Also mentions a caplet “substantially covered in gelatin” P12 L27-30, so not fully covered in which there would be no overlap.	Not present, body fits over cap, overlaps P16L19-27

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	capsule half		
1.6	and wherein the first and second hard-shell gelatinous capsule halves have substantially the same diameter.	Present, caplet is symmetrical, both ends when coated and dried will have around the same diameter, which is the diameter of the caplet.	Not present, one fits in the other, slightly different diameter. Not present, body fits over cap, overlaps P16L19-27
Claim 1 lacks novelty over Doc C.			
Claim 1 is novel over Doc D.			
2.1	A medicament as claimed in claim 1,	present	Not present
2.2	wherein the first hard-shell gelatinous capsule half is shrink-wrapped on the second end of the caplet; and	Not Present – P12L18-30 describes coating process, but not shrink wrapping process of Doc A – no heat treatment and shrinkage.	Not present, only mentions dipping into solutions.

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2.3	the second hard-shell gelatinous capsule half is shrink-wrapped on the first end of the caplet.	As above	As above
Claim 2 is novel over Doc C.			
Claim 2 is novel over Doc D.			
3.1	A medicament as claimed in claim 1 or 2,	Present when depend on claim 1, not present when depend on claim 2	Not present
3.2	wherein the second hard-shell gelatinous capsule half is in contact with the first hard-shell gelatinous capsule half.	Present – figure 4 shows the colours in contact with each other, forming the seam also technically means the halves are in contact as they “overlap”	Not present

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Claim 3 lacks novelty over Doc C when dependent on claim 1, but is novel when dependent on claim 2.

Claim 3 is novel over Doc D via all dependencies

4.1	A medicament as claimed in claim 3	Present when depending on claim 1+3, but not when dependent on claim 1+2+3.	Not present
4.2	wherein the first and second capsule halves are in contact with each other at about a midway point of the caplet.	Present – see fig 4b-c and P13 L11-15, seam is at or about midway	Not present

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Claim 4 lacks novelty over Doc C when dependent on claim 1+3, but is novel when dependent on 1+2+3.

Claim 4 is novel over Doc D via all dependencies

5.1	A medicament as claimed in any preceding claim	Present when dependent on claim 1, 1+3, or 1+3+4, but not when dependent on claim 1+2 or 1+2+3, or	Not present
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		1+2+3+4	
5.2	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.	Two or more colours – p11L25-26, P12L15-17, each end can be different colour, 2-piece, figures 4b- c. Green and yellow examples P13L8-10	Present – “two-colour capsule dosage forms are preferred” P17L25-27
Claim 5 lacks novelty when dependent on claim 1, 1+3, or 1+3+4, but not when dependent on claim 1+2 or 1+2+3, or 1+2+3+4. Claim 5 is novel over Doc D, only via its dependencies.			
6.1	A medicament as claimed in any preceding claim,	Present when dependent on claim 1, 1+3, 1+3+4, 1+3+4+5, but not when dependent on 1+2, 1+2+3, 1+2+3+4, or 1+2+3+4+5	Not present, due to dependencies

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6.2	further including a gelatinous band extending around the caplet to overlie the ends of the hard-shell gelatinous capsule halves.	Not Present, 4b-c seam, overlapping gelatinous coatings, around the non- longitudinal axis, but mixed colouring shows that there was no gap/ends between the capsule halves exposed – the seam is filled in during the initial coating.	Not present, no band mentioned.
Claim 6 is novel over Doc C via all dependencies Claim 6 is novel over Doc D via all dependencies.			

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MARKS AWARDED: 18

Novelty total = 18

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Inventive step

Using Pozzoli

Both Doc C and Doc D are full prior art for the reasons outlined above.

Claim 1

- The person skilled in the art is a manufacturer of pharmaceuticals. Their common general knowledge is the use of hard gelatin capsules for the containment of pharmaceuticals that have “been known for years”, and the standard capsules with a body and cap, described in Doc D P16-L27. 1
- the inventive concept is to provide a simulated capsule medication to with improved consumer acceptance, and ease of swallowing. 1
- the state of the art is Document C, which also addresses the need to improve swallowability of capsule medication.
- There is no difference between the inventive concept and the state of the art, which discloses the features of claim 1. Claim 1 is therefore obvious over the state of the art. 1

Claim 2

- The skilled person and their CGK is the same as above.
- the inventive concept is to provide a medicament in which the two gelatin capsule halves are in intimate contact with the core, to prevent tampering 1
- the state of the art is Document C, which also addresses the need to improve compliance of capsule medication and tampering

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- The claim is not obvious, as Doc C alone or combined with the CGK does not teach or suggest shrink wrapping a caplet in gelatinous material.

1

Claim 3

- The skilled person and their CGK is the same as above.
- the inventive concept is to provide a medicament in which the two gelatin capsule halves are contact with each other, to improve anti-tampering activity.
- the state of the art is Document C, which has many features in common with the claim.
- There is no difference between the inventive concept and the state of the art, which discloses the features of claim 3. Claim 3 is therefore obvious over the state of the art.

Claim 4

- The skilled person and their CGK is the same as above.
- the inventive concept is to provide a medicament in which the two gelatin capsule halves are contact with each other around a midway point, to provide uniformity.
- the state of the art is Document C, which has many features in common with the claim.
- There is no difference between the inventive concept and the state of the art, which discloses the features of claim 4. Claim 4 is therefore obvious over the state of the art.

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Claim 5

- The skilled person and their CGK is the same as above.
- the inventive concept is to provide a medicament which will look like a conventional two-colour capsule, to improve patient compliance and allow identification of a specific product..
- the state of the art is Document C, which also addresses this need.
- There is no difference between the inventive concept and the state of the art, which discloses the features of claim 5. Claim 5 is therefore obvious over the state of the art.

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Claim 6

- The skilled person and their CGK is the same as above.
- the inventive concept is to seal the gap between capsule halves to facilitate the simulation of a typical gelatin capsule medicament, and prevent
- the state of the art is Document C, which also addresses this need. The difference between Doc C and the inventive concept of claim 6 is inclusion of a gelatinous band around the caplet to overlie the ends of the halves and seal off the caplet from the outside.
- The claim is not obvious as Doc C achieves this in a slightly different manner, by joining each half in a seam whilst coating.

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MARKS AWARDED: 12

Inv. step total = 12

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MARKS AWARDED: 1

Sufficiency/amendment

Suff. total = **1**

- No clear sufficiency issues visible.
- Amend to introduce the shrink wrapping features of claim 2 into claim 1? Cant extend scope, only narrowing.
- Amend to include dependent claim which further defines the shrink wrapping process described. Have basis P4L17-30

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MARKS AWARDED: 1

Amend total = **1**

Advice?

- Can enforce patent (check renewals paid)
- Can make TAB aware of the patent, also permitted communication to threaten legal action, as manufacturing and importing. Can contact subsidiary who manufacture separately, two infringers?
- Can request delivery up of Kc or destruction, or damages/account of profits.
 - o Seems damages/account of profits appropriate if have lost contracts and sales.
 - o Injunction not likely for this reason - no status quo and damages may be appropriate
- Can request a declaration of infringement.
- Could offer a licence to TAB
- Check if there is any pending patent for Kc? Set up a watch service, potentially could be patentable as it has the benefit of quicker dissolution. If so, cross licence?

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- Claim 1 and 5 infringed, but likely invalid. Claim 6 appears valid but not infringed.
 - Add dependent claim to further define features which could further limit the product by its process, the gelatin dots?
 - Do this quickly before making TAB aware of intention to enforce, as they can oppose the amendment S75.
 - Delete invalid claims also
- Noted client thinks they have a patent to the process, not true, no real process claims.

1

MARKS AWARDED: 4

Advice total = 4

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