Spare Set of Claims

1. A medicament comprising:
(a) a solid generally cylindrical caplet with first and second ends;
(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.

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.

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.

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 band extending around the caplet to overlie the ends of the hard-shell gelatinous capsule halves.

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Abbreviations used

CGK = common general knowledge

PSIA = person skilled in the art

IC = inventive concept

SOTA = standard of the art

BVOD = by virtue of dependency

APMC = as per my construction

Y = feature present

N = feature not present

DA/DB/DC etc = document A/B/C etc

STP = standard patent term

API = active pharmaceutical ingredient

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CONSTRUCTION

1.1 A medicament comprising:

A medicament = a dosage form for oral delivery of medicine, containing an active pharmaceutical ingredient (API). Example API include but are not limited to medicinal ingredients presently

marketed over-the-counter or on a prescription basis, such as aspirin, paracetamol,

and ibuprofen (l4-6p4). Medicaments are available in a great variety of shapes and forms, such as coated compressed hard tablets, caplets, and filled gelatinous capsules (l7-8p3) thus this construction includes at least all of these forms but is not limited to them.

Comprising = STP, open term, indicates that the medicament has at least the following features and may have additional features too.

1.2 (a) a solid generally cylindrical caplet with first and second ends;

Solid = takes its usual meaning.

Generally cylindrical = at least a substantial portion of the caplet is cylindrical in shape, having a substantially circular cross-section

Caplet = solid, elongate, rounded-ended tablets, having a similar shape to a capsule (l14-15p3). Elongate shape provides for easier swallowing. Must be suitably sized to be swallowed by the patient.

First and second ends = the caplet two ends, as shown by first end 13 and second end 15 in figure 1, p7. In accordance with the above definition of caplet (and at l14-15p3), the ends are rounded in at least one plane, also as shown in Fig 1p7. The use of "a" in this

claim wording indicates the first and second end are the two opposing ends of the same caplet.

1.3 (b) a first hard-shell gelatinous capsule half secured on the second end of the caplet;

first hard-shell = implies there is more than one hard shell. Shown in figure 1, p7 as a pair of capsule halves 14 and 16 (also l9p4). Shell indicates this part goes around the core. There are two hard –shell gelatin halves, both substantially in intimate contact with the core 12 (l10p5). The hard –shell gelatin halves are separate portions to the tablet core in that they are formed from a different material (fig1p7).

gelatinous = describes the nature of the material making un the first capsule half. Gelatinous, by its usual definition, includes gelatin itself, and as indicated at l8-9p4, but the term gelatinous in the claim is not limited to gelatin and is construed to include other materials having similar physical properties which would be obvious to the PSIA. Whilst gelatinous capsules were originally formed from hard-gelatin, the term is now used to refer to any composition having the same physical properties as hard gelatin capsules (l11-13p3) and the PSIA would know this as part of their CGK. Gelatinous capsules are easy to swallow (l10p3).

capsule half = shaped like half a capsule, bisected through its longitudinal axis – ie the axis congruent with the longest dimension of the capsule, fig1p7, l9p4. Half implies there are two. The diameter and lengths of the halves are selected to allow a medicinal caplet to fit within the capsule halves (l27-28p3). fig1p7 shows the size is such to allow an end 13 or 15 of the table core (12) to be inserted inside the capsule half 14 or 16, respectively. the capsule half comes together with another capsule half to form a substantially whole capsule (fig 2p7), which has a length of no more than the length of the tablet core 12.

secured on = attached to. Capsule halves 14, 16 remain in place on the ends 13, 15 (l7p5). the capsule ends need to be such that the caplet shaped core can be inserted inside of them, but once the core is inserted, it is desirable that the capsule halves do not come off, that is the are fixedly secured to the core. May be secured using a dot of liquid gelatin, which holds the shell onto the core (l18-21p4) to form a first half-shell/core combination. If liquid gelatin is used and a hot-water based shrink wrapping method is employed, the liquid gelatin needs to have a melting point greater than that of the hot water bath used during the shrink wrapping, to prevent the the gelatin dot melting during further capsule processing and so the capsule halves 14,16 remain in place on the ends 13,15.

End = distal end, one end on each extremity of the longest axis of the capsule. Fig1p7 ends are 13, 15.

the second end of the caplet = it is a little strange that the claim is worded to secure the first capsule half to the second caplet end, and vice versa. As indicated by fig 1 and 2, p7, it is understood that the ends are substantially the same, that is the caplet is symmetrical. Thus the first and second ends are substantially the same in shape and the used of "first" and "second" merely distinguishes one from the other. In construing first/second, I do not think it matters which end is which, they are substantially the same. This is further supported by l28p3-l1p4 which states that the capsule halves have the same diameter, which implies that the two ends of the table core and the ends of the capsule itself also have the same diameter.

1.4 (c) a second hard-shell gelatinous capsule half secured on said first end of said caplet,

Similar to 1.3. Together 1.3 and 1.4 are taken to mean there one of each of a pair of hard-shell gelatinous capsule halves is inserted on each end of the caplet.

l9p4 describes a pair of hard-shell gelatin capsule halves which indicates that the first and second hard-shell gelatinous capsule halves are a pair in that they are substantially similar and there are two of them.

Hard-shell gelatinous = same construction as for 1.3.

capsule half = same construction as for 1.3.

secured on = same construction as for 1.3.

said first end of said caplet = the second capsule half is secured to the opposite end to the first capsule half of 1.3. As noted above, it does not matter which end is which, as long as one of each of the first and second capsule halves is secured to both ends.

1.5 wherein the second hard-shell gelatinous capsule half does not overlap the first hard-shell gelatinous capsule half,

second hard-shell gelatinous capsule half = same as for 1.4.

first hard-shell gelatinous capsule half = same as for 1.3.

does not overlap = both capsules have the same diameter so that the end of one capsule half cannot be inserted into the other end (l28p3-l1p4) and this prevents overlap (l12p4). The annular (non-rounded) ends of the capsule halves may contact each other (l15p4) but do not overlap, or the annular ends may not be in contact (l12p5 and fig2p7). Preferably the ends may be in contact about midway 11 along the core 12 (l15-16p4), but the construction is taken to include alternative points of contact along the tablet core, not limited to midway, because this is only a preferred embodiment. Construction of 1.5 is taken to include the ends being in contact or not being in contact (also due to repercussive effect of 3.2 meaning 1.5 must be broader).

1.6 and wherein the first and second hard-shell gelatinous capsule halves have substantially the same diameter.

first and second hard-shell gelatinous capsule halves

substantially the same = need not be identical but are close enough in diameter that the annular end of one capsule half cannot be inserted into the annular end of the other capsule half (l28p3-l1p4). Overlapping of the ends is also prevented since capsule halves 14 and 16 are of the same internal diameter (L12-13p4). In order to achieve the effect of not overlapping, the tolerance for being substantially the same size is understood to be relatively small.

Due to the repurcussive effect of 3.2, the two half capsules may be in contact with each other or may leave a gap which is also acceptable in some cases (l15p5)

2.1 A medicament as claimed in claim 1, wherein

The medicament of claim 2 has all of the features of claim 1, as well as the following features. Combination of features 1+2.

2.2 the first hard-shell gelatinous capsule half is shrink-wrapped on the second end of the caplet; and;

the first hard-shell gelatinous capsule half = as construed for 1.3

is shrink-wrapped on = does the method of shrink-wrapping affect the end product? This is a method step which, unless the resulting effect of the shrink wrpaaing imparts an identifyable property to the resulting coating, the method step cannot be limiting.

The first half shell/core combination is dipped into a tank of hot water for a period of time sufficient to cause the hard gelatin shell to hydrate and plasticize (become flexible). Once removed from teh hot water, the gelatin dries which causes the hard-shell gelatin capsule to shrink to take substantially the form of the second end 15 of the core (l21-26p4). The hard-shell capsule half is substantially in intimated contact with the core 12 (L10p5). See also fig 2 which does not indicate an air gap between the capsule halve 14 or 16 and the perimeter of the respective end of the core 12.

2.3 the second hard-shell gelatinous capsule half is shrink-wrapped on the first end of the caplet.

As construed for 2.2 but understood to refer to the other end of the capsule.

3.1 A medicament as claimed in claim 1 or 2,

The medicament of claim 3 has all of the features of claim 1 or 2, as well as the following features. Combination of features 1+3 or 1+2+3.

3.2 wherein the second hard-shell gelatinous capsule half is in contact with the first hard-shell gelatinous capsule half.

The annular (non-rounded) ends of the capsule halves are in contact with each other (l15p4) but do not overlap. The annular ends butt up against each other. Limits feature 1.5. does not include the embodiment drawn in fig2p7 because this figure indicates a small gap between capsule halves 14 and 16. Preferably the ends may be in contact about midway 11 along the core 12 (l15-16p4), but the construction is taken to include alternative points of contact along the tablet core, not limited to midway, because this is only a preferred embodiment and because of the repercussive effect of 4.2. When the annular ends are in contact, the tablet core is entirely enclosed and no part of the table

core is visible which facilitates the simulation of a gelatin capsule medicament (l16-17p5).

4.1 A medicament as claimed in claim 3,

The medicament of claim 4 has all of the features of claim 3, as well as the following features. Combination of features 1+3+4 or 1+2+3+4.

4.2 wherein the first and second capsule halves are in contact with each other at about a midway point of the caplet.

Refers tot eh preferred embodiment described at l13-16p4. The hard shell capsule halves 14 and 16 have substantially the same length, equal to about half of the overall length of the caplet, so that the annular ends of each hard shell capsule half meet and are in contact at a point about midway 11 along the long axis of the core 12.

About midway = need not be exactly half way but needs to be substantially close to half way to create the look of a conventional two part capsule (l19p5), to meet the aim of satisfying the consumer acceptance of the well known capsule (l17-18p3).

When the hard-shell halves are in contact, there is no gap between the capsule halves 14, 16 which facilitates the simulation of a gelatin capsule medicament (l16-17p5).

5.1 A medicament as claimed in any preceding claim,

The medicament of claim 5 has all of the features of any of claims 1-4, as well as the following features. Combination of features 1+5, 1+2+5, 1+3+5, 1+2+3+5, 1+3+4+5 or 1+2+3+4+5.

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.

Each of the gelatinous hard-shell capsules halves 14 and 16 is a different colour, created by including different colour pigments in the material of each half. Gives the final product the look of a conventional two-colour capsule. Suitable colours are understood to include red, white, yellow and blue but the construction of 5.2 is not limited to these colours and includes all colours (l18-20p5).

6.1 A medicament as claimed in any preceding claim,

The medicament of claim 6 has all of the features of any of claims 1-5, as well as the following features. Combination of features 1+6, 1+2+6, 1+3+6, 1+2+3+6, 1+3+4+6, 1+2+3+4+6, 1+2+5+6, 1+3+5+6, 1+2+3+5+6, 1+3+4+5+6 or 1+2+3+4+5+6

6.2 further including a gelatinous band extending around the caplet to overlie the ends of the hard-shell gelatinous capsule halves.

further including = open term, may include additional features too.

a gelatinous band = includes a 'belly' band made of gelatin (l15p5), but construction may include additional gelatinous materials, in line with the construction of gelatinous in 1.3. Understood to be a separate portion of gelatinous material.

extending around the caplet = around the latitudinal circumference of the elongate capsule, perpendicular to the longest axis, ie the 'belly' l15p5. Extending indicates it goes all the way around. As shown in fig2p7, which is a cross section indicating the band goes all the way around. Needs to go all the way around to cover the gap formed between the two halves (l15-17p5).

to overlie the ends of the hard-shell gelatinous capsule halves = arrange such that the gelatinous band overlaps with each of the annular ends of the two hard-shell gelatinous capsule halves 14,16, as show in fig 2. The band covers the gap between capsule halves

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14 and 16 to facilitate the simulation of a gelatin capsule medicament (l15-17p5) and satisfy the consumers acceptance of the well-known capsules (l17p3). Their claim covers the embodiment shown in fig2p7.

MARKS AWARDED: 15

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INFRINGMENT

DB contains two embodiments, the gel cap depicted in fig 1 and the kwickcap depicted in fig 2p10 – refered to GC and KC going forward, respectively.

Claim 1

	GC	KC
1.1 A medicament comprising:	Y –because L5p8 describes capsules of the invention as being preferred dosage for for oral delivery of active ingredients and l1p9 indicates the active ingredients may be pharmaceutical, ie API, APMC. Applies to both embodiments.	Y –because L5p8 describes capsules of the invention as being preferred dosage for for oral delivery of active ingredients and l1p9 indicates the active ingredients may be pharmaceutical, ie API, APMC. Applies to both embodiments.
1.2 (a) a solid generally cylindrical caplet with first and second ends;	Y Galcap is a type of tablet (l22p8) and tablets are solid forms (l20p8). Fig1,p10 depicts a generally cylindrical shape. The crosss section is not entirely circular but is at least substantially	Y The core 10 is said to be inserted into a holder in order to form gelatinous coatings 24a and 24b (l9-10p9) and in order for this to work, the core must be solid or it would fall out of the holder.

	circular, APMC, because a larger proportion of the cross section is circular than flat. Has two opposing ends, 12a and 12b in fig 2	Therefore the coated core is also solid. Fig2,p10 depicts a generally cylindrical shape. ✓ The crosss section is not entirely circular but is at least substantially circular, APMC, because a larger proportion of the cross section is circular than flat. Has two opposing ends, 12a and 12b in fig 2
1.3 (b) a first hard-shell gelatinous capsule half secured on the second end of the caplet	N No capsule or coatings present or indicated on fig1p10. Formed from compressed powder l20p8.	Y 24a of fig2,p10. Described as gelatinous ✓ coatings, which must be in intimate contact with the core 22. The core is depicted as being inside the coatings, and so the coatings are capsule halves APMC. ✓

		The term gelatinous is used to refers to any composition having the same physical properties as hard gelatin capsules, so hard-shall gelatinous capsule halves are present. Shaped like a half capsule because shown to be the same shape as capsule 22 as if bisected through the longitudinal axis.
1.4 (c) a second hard-shell gelatinous capsule half secured on said first end of said caplet	N No capsule or coatings present or indicated on fig1p10. Formed from compressed powder l20p8, there is no gelatinous material present.	Y 24b of fig2p,10. Remaining features of 1.4 present as set out above for 1.3.
1.5 wherein the second hard-shell gelatinous capsule half does not overlap the first hard-shell	N – not present	Y A gap is shown 26 in fig 2p10. L4p9 – the coatings 24a, 24b are separated from each other so as to form a

gelatinous capsule half		gap. If there is a gap, the two capsule halves 24a and 24b cannot be overlapping. Gap width 06mm-4mm l16p9.
1.6 and wherein the first and second hard-shell gelatinous capsule halves have substantially the same diameter	N	Y Can be seen on fig2p10. Capsule halves have substantially the same diameter as the core 10. Core has substantially uniform length along its long axis, therefore coatings on each end must have substantially same diameter. The annular end of one capsule half cannot be inserted into the annular end of the other capsule half, APMC.
Claim 1 conclusion	Not infringed	Infringed

Claim 2

	GC	KC
2.1 A medicament as claimed in claim 1, wherein	N – features of claim 1 are not present.	Y – features of claim 1 are present as described above.
2.2 the first hard-shell gelatinous capsule half is shrink-wrapped on the second end of the caplet; and	N No hard-shell gelatinous capsule, so cannot be heat shrunk.	Y Coating 24a has substantially the same form as the end of the core (fig2,p10). By definition, coating is in intimate contact with the core and there must be no air gap between the core and the coating. This gives rise to the same medicament features as shrink wrapping. The method by which this is achieved is not limiting.
2.3 the second hard-shell gelatinous capsule half is shrink-wrapped on the first end of the caplet	N As for 2.2, no hard-shell gelatinous capsule, so cannot be heat shrunk.	Y As for 2.2, but with reference to coating 24b.

Conclusion	Not infringed	Infringed

Claim 3

	GC	KC
3.1 A medicament as claimed in claim 1 or 2	N Requires features 1+3 or 1+2+3	Y Requires features 1+3 or 1+2+3
3.2 wherein the second hard-shell gelatinous capsule half is in contact with the first hard-shell gelatinous capsule half.	N Fig 1p10 – no hard-shell gelatinous capsule halves are present, so cannot be in contact with each other	N There is a gap 26 between coatings 24a and 24b through which the outer surface of the core can be seen – fig2p10 and l14-16p9
Conclusion	Not infringed	Not infringed

Claim 4

	GC	KC
4.1 A medicament as claimed in claim 3	N – for all dependencies Requires features1 +3+4 or 1+2+3+4.	N Requires features1 +3+4 or 1+2+3+4.

4.2 wherein the first and second capsule halves are in contact with each other at about a midway point of the caplet	N – Fig 1p10 – no hard-shell gelatinous capsule halves are present, so cannot be in contact with each other, let alone at a midway point.	N As for 3.2, the first and second capsule halves are not in contact, therefore cannot be in contact at a midway point. In contrast, the gap may be at the midway point (l20p9).
Conclusion	Not infringed	Not infringed

Claim 5

	GC	KC
5.1 A medicament as claimed in any preceding claim	N Requires all features of 1+5, 1+2+5, 1+3+5, 1+2+3+5, 1+3+4+5 or 1+2+3+4+5.	Y – when dependent on claim 1 or 2, N for all other dependencies. Requires all features of 1+5, 1+2+5, 1+3+5, 1+2+3+5, 1+3+4+5 or 1+2+3+4+5.
5.2 wherein the first hard-shell gelatinous capsule half has a first colour, and the	Y – l6p9 the colours on each end (understood in reference to coatings 24a and 24b, which are hard-shell	Y – l6p9 the colours on each end (understood in reference to coatings 24a and 24b, which are hard-shell

second hard-shell gelatinous capsule half has a second colour different from the first colour	gelatinous capsule halves APMC) may be different colours from one another. Choice of colour is not relevant APMC.	gelatinous capsule halves APMC) may be different colours from one another. Choice of colour is not relevant APMC.
Conclusion	Not infringed	Infringed when dependent on claim 1 or 2. Not infringed when dependent on claims 3 or 4.

Claim 6

	GC	KC
6.1 A medicament as claimed in any preceding claim	N Requires features 1+6, 1+2+6, 1+3+6, 1+2+3+6, 1+3+4+6, 1+2+3+4+6, 1+2+5+6, 1+3+5+6, 1+2+3+5+6, 1+3+4+5+6 or 1+2+3+4+5+6.	Y when dependent on claim 1,2 or 5. N when dependent on claim 3 or 4. Requires features 1+6, 1+2+6, 1+3+6, 1+2+3+6, 1+3+4+6, 1+2+3+4+6, 1+2+5+6, 1+3+5+6, 1+2+3+5+6, 1+3+4+5+6 or 1+2+3+4+5+6.

6.2 further including a gelatinous band extending around the caplet to overlie the ends of the hard-shell gelatinous capsule halves	N Belly band 14 occurs along the longitudinal circumference, not the latitudinal circumference APMC. Further belly band 14 is formed from the same compressed powder material as the core because it forms when the core comes in to contact eith the walls of the press (l26-27p8). Thus the belly band is not a separate portion of gelatinous material APMC.	N Belly band 14 occurs along the longitudinal circumference, not the latitudinal circumference APMC. Further belly band 14 is formed from the same compressed powder material as the core because it forms when the core comes in to contact eith the walls of the press (l26-27p8). The belly band is partially coated by coatings 24a 24b as seen in fig2p10, but it remains a coated feature of the core itself, not a separate portion of gelationous material APMC. Thus the belly band is not a separate portion of gelatinous material APMC.
Conclusion	Not infringed	Not infringed.

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Actavis

Consider if the overlapping band of DC be variant to the additional gelatinous band of claim 6

- Does the variant achieve substantially the same effect in the same yea? Same effect yes in that it covers the whole of the tablet core and the core is no longer visible, but does not achieve this in the same way because the band is due to overlap in DC but is a separate component in claim 6.
- Remaining Actavis question not relevant because there would not be infringement by the variant.

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NOVELTY

Novelty is assessed at the filing date, 6 june 2014.

DC was published on 3 september 2009, which is before the filing date of DA. Therefore DC is citable for novelty and inventive step against DA. The method described in DC implicitly discloses the resulting product.

DD is an excerpt from "one of the most common text books in this field" as described by the client at l26-27p2. DD was published in 1998 and os had been around a long time at the time of filing DA. Therefore DD forms part of the CGK and will be referred to as CGK going forward. The CGK also includes l7-16p3.

	DC	CGK
1.1 A medicament comprising:	Y Described as a coated medicament l3p11 so it is a medicament	Y Containment of pharmaceuticals l5p16, so is a medicament APMC.
1.2 (a) a solid generally cylindrical caplet with first and second ends;	Y Solid cores such as caplets, l16p11. Described as for swallowing so must be suitably sized for swallowing. Generally cylindrical because has elongate shape with rounded ends as shown in figs	Y Caplets described at l12p17. Caplets are very popular and are solid, elongate, rounded end tablets (l14-15p3). Caplets are therefore well known in the CGK.

	2 and 3 p14. Ends are rounded in at least one plane, as shown in figs 2 and 3 p14. Has two ends as shown in figs 2 and 3 p14.	
1.3 (b) a first hard-shell gelatinous capsule half secured on the second end of the caplet	Y Gelatinous coating to provide simulated capsule like medicaments (l17p11), so a gelatinous capsule shell is present APMC. The first end is coated with gelatinous material by dipping l811p12. A coating must be in intimate contact with the core, and secured to the core, APMC. The coating is a gelatinous material which is understood to be a different material to that of the tablet core.	N Capsule halves are formed from gelatin l17-19p16. Caplets may be coated with a material such as cellulose (l14p17). May be gelatin coated l32-33p17. Capsules are sold assembled but empty, and filled later. Thus the glatin capsule half is not secured to a caplet.
1.4 (c) a second hard-shell gelatinous	Y	N – as for 1.3

capsule half secured on said first end of said caplet	A second gelatinous coating is applied to the opposing end to the first end (L12p8).	
1.5 wherein the second hard-shell gelatinous capsule half does not overlap the first hard-shell gelatinous capsule half	Y Once both ends have been dipped, the caplet is substantially covered in gelatin. There is no disclosure of there being any gap between the coatings or the caplet core being visible. Figs 4a p15 shows the two coatings touching but not overlapping. Figs 4b and 4c show overlapping coatings, p15.	N Cap and body are mated by the body part fitting over the the open end of the cap portion (l19-24p16), therefore the two hard shell gelatin capsules must overlap.
1.6 and wherein the first and second hard-shell gelatinous capsule halves have substantially the same diameter	Y Coatings must have same diameter as caplet, caplet is shown as symmetrical in fig 2, thus the two coatings must have the same diameter at a given distance from teh centre.	N the body part must fit over the open end of the cap portion to form the capsule (l19-24p16), so they cannot have the same diameter.

Claim 1 conclusion	Not novel	Novel

Claim 2

	DC	CGK DD
2.1 A medicament as claimed in claim 1, wherein	Y Requires features 1+2.	N Requires features 1+2.
2.2 the first hard-shell gelatinous capsule half is shrink-wrapped on the second end of the caplet; and	Y Solid caplets are dipped into a gelatinous material (l18p12). The steps by which the coating is applied are not relevant but the end result is a caplet with substantially in intimated contact with the core and therefore the resulting coated caplet is the same as that formed by heat shrinking.	N Capsule halves are formed by dipping rows of stainless steel pins into solutions of gelatin material (l16-18p16). No mention of shrink wrapping and not formed directly on the caplet, rather on a steel pin.
2.3 the second hard-shell gelatinous capsule half is shrink-	Y As for 2.2 but the other end of the caplet – the two ends are	N – same reasoning as 2.1.

wrapped on the first end of the caplet	dipped separately and consecutively in the gelatinous coating (l12-13p12).	
Conclusion	Not novel	Novel BVOD.

Claim 3

	DC	CGK
3.1 A medicament as claimed in claim 1 or 2	Y Requires features 1+3 or 1+2+3	N Requires features 1+3 or 1+2+3
3.2 wherein the second hard-shell gelatinous capsule half is in contact with the first hard-shell gelatinous capsule half	Y Fig 4a, 4b, 4c indicate the coatings 304 and 306 are at least in contact with each other, if not overlapping.	Y The body and cap portions are fitted together to form a capsule l22-25p16 so they must be in contact.
Conclusion	Not novel	Novel BVOD.

Claim 4

	DC	DD CGK
4.1 A medicament as claimed in claim 3	Y Required features of 1+3+4 or 1+2+3+4	N Required features of 1+3+4 or 1+2+3+4
4.2 wherein the first and second capsule halves are in contact with each other at about a midway point of the caplet	Y Figd 4a, 4b, 4c p15 show the contact and overlap portions are about midway along the capsule. Seam circumscribes the medicament at about a midway point of longitudinal access l13-14p13. ✓	Y Capsules described to have halves l19p16. Understood to be substantially the same size, so must meet substantially in the middle of the constructed capsule.
Conclusion	Not novel	Novel BVOD

Claim 5

	DC	DD CGK
5.1 A medicament as claimed in any preceding claim	Y Requires features 1+5, 1+2+5, 1+3+5, 1+2+3+5, 1+3+4+5 or 1+2+3+4+5.	N Requires features 1+5, 1+2+5, 1+3+5, 1+2+3+5, 1+3+4+5 or 1+2+3+4+5.

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	Y Colour scheme can be bifurcated l1p13, understood to mean each half is different colour. ✓	N not present
Conclusion	Not novel	Novel BVOD

Claim 6

	DC	DD CGK
6.1 A medicament as claimed in any preceding claim	Y Requires features 1+6, 1+2+6, 1+3+6, 1+2+3+6, 1+3+4+6, 1+2+3+4+6, 1+2+5+6, 1+3+5+6, 1+2+3+5+6, 1+3+4+5+6 or 1+2+3+4+5+6	N Requires features 1+6, 1+2+6, 1+3+6, 1+2+3+6, 1+3+4+6, 1+2+3+4+6, 1+2+5+6, 1+3+5+6, 1+2+3+5+6, 1+3+4+5+6 or 1+2+3+4+5+6
6.2 further including a gelatinous band	N	N – not present

extending around the caplet to overlie the ends of the hard-shell gelatinous capsule halves	Figs 4b and 4c p15 depict a band around the latitudinal circumference of the elongate capsule. However,t eh band is formed by overlap of the coatings l12p13, and is not a separate portion of gelatinous material APMC.	
Conclusion	Novel	Novel BVOD

MARKS AWARDED: 10.5

deps/conds 1

NOV 10.5

INVENTIVE STEP

Inventive step is assessed at the filing date of DA, 6 june 2014. ✓ ✓

DC is citable for inventive step.

Applying the Pozzoli test.

The PSIA is the designer of solid medicament dosage forms. ✓

CGK is as described in document D, ✓ which is an excerpt from "one of the most common text books in this field" as described by the client at l26-27p2. DD was published in 1998 and so had been around a long time at the time of filing DA and must form part of the CGK.

The CGK also includes l7-16p3, document A, ✓ the use of gelatinous capsules for the encapsulation of medicinal agent sis described as a popular method in the introduction of the patent A and so must have been CGK at thte time of filing. Further, capsules are described as being popular at l15p3 of patent A and so caplets were part of the CGK at the time of filing A.

Claim 1

Claim 1 was found not novel over DC. However, in the event a judge disagreed with my construction of the hard-shall gelatinous capsule halves, claim 1 may be found novel and inventive step will be assessed on this assumption.

The IC of claim 1 is that the medicament combines the shape and convenient solid dosage form of a caplet with the gelatinous capsule exterior of a gelatin capsule, which are more widely accepted by consumers than uncoated caplets (l15-16p3). ✓

The SOTA is DC because it describes coated medicaments and processes for providing coated medicaments and therefore has the greatest number of features in common with DA.

The difference with DC is that DC describes a method by which the solid cores are dipped into gelatinous material, first one end and then the other, to create a gelatinous coating on each end. In contrast, DA describes the insertion of a solid core into hard-shall gelatinous capsule halves, which are shrink-wrapped onto the solid core to create a gelatinous coating on both ends. While the methods described are different, the resulting coated caplets are the same. As noted above, if a judge disagrees on my construction of the hard-shell gelatinous capsule halves, there could be a difference here, but ultimately the end result coated caplet is the same in that it is coated with a gelatinous material on both ends.

The CGK provides for gelatin capsule which may be filled with drug or medicament (l27p16) and also provides for coated pills or tablets whereby the tablet is dipped into a gelatin solution and immersed half way, before being inverted and dipped on the other end to create a gelatin coating.

The PSIA would learn from DC a method of coating solid cores with gelatinous material. The PSIA would know of hard-shell gelatin capsules from their CGK, and know that it is common to coat tablets in gelatin. Caplets are known to be tablets of capsule-like shape which are easier to swallow. It would be obvious to employ a capsule-shaped tablets to aid swallowing, and based on the CGK it would also be obvious to provide a caplet with a gelatin coating, for example a hard gelatin coating like that employed in the known and widely accepted two part gelatin capsules.

Claim 1, if found novel, is therefore not inventive.

Claim 2

Claim 2 has been found not novel. However, in the event that a judge disagrees with my construction and finds claim 2 novel, I will also consider inventive step.

The features claim 2 adds to claim 1 are method steps. As discussed above, it does not appear that shrink wrapping the hard-shell gelatinous capsule imparts any special technical features on the coating. he IC of claim 2 is therefore the same as claim 1.

SOTA is DC because it has the most features in common.

Claim 2 is obvious and non-inventive for the same reasons as claim 1.

Claim 3

Claim 3 has been found not novel. However, in the event that a judge disagrees with my construction and finds claim 3 novel, I will also consider inventive step.

The IC of claim 3 is that the caplet is substantially covered with the gelatin coating because the two capsule halves are in contact with each other and there is no gap between the two halves and so the tablet core is not exposed. ✓

The SOTA is document C. whilst DC has a different aim of providing tamper evident capsules, it also seeks to provide a medicament having a faster dissolution time relative to commercially available gelatinous-coated tablets (l15-16p8). Overall DC has a large number of features in common with DA.

There is substantially no difference between the coated caplet of DC and claim 3 because both provide a medicament that is fully coated and does ✓ not expose the tablet core. This can be seen in figs 4a, 4b, 4c on page15.

Claim 3 is obvious and non-inventive.

Claim 4

As above, claim 4 is not novel but in the event that claim 4 is found novel, inventive step assessment is as follows:

IC = the first and second capsule halves are in contact with each other at the midpoint which may create the look of a conventional capsule and please the consumer.

SOTA is document C because it has the most features in common.

The difference with DC is that the layers of claim 4 overlap with other by means of one being shrink wrapped on top of the other, whereas in DC the layers are formed by dipping in gelatinous material and being overlapped. However this difference does not impart any special technical feature that can contribute to inventive step.

Document C sets out to achieve a different purpose of obtaining a tamper evident capsule medicament. However, the capsule of document C still retains the look and feel of a traditional gelatin capsule with which the consumer is very familiar. The PSIA also knows of transitional two-part gelatin capsules from their CGK - L19-24p16.

Document C provides the PSIA with motivation to form a capsule with the look and feel of a traditional gletain capsule and the PSIA already knows these are popular from their CGK. Therefore claim 4 is obvious and non-inventive.

Claim 5

Novel when dependent on claim 1 or 2.

The IC of claim 5 is that the two capsule halves have different colours, which makes them look like a conventional two-colour capsule (l19p5), with which consumers are already familiar.

Colour may not usually, in itself, be enough to provide a technical effect for inventive step but int eh context of medicaments, bicoloured capsules assure the consumer that they are getting a specific medication by brief visual examination and therefore the colour provides a valuable effect which may contribute to inventive step.

The SOTA is DC because it has the most features in common with claim 5.

DC also describes that the simulated capsule-like medicaments of DC may be provided having a coating in two or more colours (l24-26p11) and that the colour scheme may be bifurcated as depicted in the coatings 304 and 306 of fig4p15. As such, DC teaches the IC of claim 5 and claim 5 is obvious.

Further, the PSIA knowns from their CGK that there is a strong preference for bicoloured or two-tone coloured capsules and it would therefore be obvious to use coating halves having two different colours in the medicament of claim 5. Therefore claim 5 is not inventive.

Claim 6

Claim 6 is novel

IC = the medicament has an additional gelatinous band around its latitudinal circumference which ensures that none of the tablet core is exposed. This further simulates a gelatin capsule medicament (l14-16p5) because the consumer cannot see the tablet core and consumers prefer gelatin capsules for ease of swallowing.

SOTA = document C because it has the most features in common with DA.

DC does teach a core that is fully enclosed in gelatinous coating such that the consumer cannot see the surface of the core (figs 4a, 4b, 4cp15). Therefore DC teaches fully coating the core. However, DC does not teach or suggest a separate gelatinous band to

Examiner's use only

provide this effect. DC, not the CGK, provide any motivation to employ a separate gelatinous band to cover a gap left between the two capsule halves. Therefore claim 6 is non-obvious and inventive.

MARKS AWARDED: 10.5

1.5 10.5

Page sub-total

Examiner's use only

SUFFICIENCY

The specification appears to be sufficiently disclosed, no issues.

MARKS AWARDED: 1

Suff 1

AMENDMENTS

Insert features of claim 6 into claim 1 to restore novelty and inventive step over DC. This does not add matter because claim 6 is multiple dependent and so there is basis for the combination of amended claim 1 with claims 2-5. Also need to delete the aspect from claim 1 of the capsule halves not overlapping for the amendment to make sense. However, this amendment excludes the infringing embodiment of DB sp we should not make this amendment. ✓

We should amend to specify that the coating ✓ halves are not in contact with each other (basis at line 12 p5), which will be novel ✓ over DC and capture the infringement.

MARKS AWARDED: 1.5

amdt 1.5

Page sub-total

ADVICE

Infringement

You are correct that TAB's product uses the concept of non-overlapping coatings of your patent. Claims 1, 2, 5 (when dependent on claim 1 or 2) and 6 are infringed by TAB's kwickcap (KC).

TAB manufactures KC in the UK, which is an act of direct infringement of DA. TAB also imports KC into the UK after manufacture elsewhere which is also an act of direct infringement of DA. Activities are carried out without CAP's permission

Infringement through manufacture is being carried out by TAB's subsidiary ✓ manufacturing facility. We need to find out exactly who this is, for example if it is directly owned by TAB or if ti si a third party. Depending on the company structure or any manufacturing agreements in place, the subsidiary manufacturing facility or TAB may be liable for infringement proceedings. In seeking to find this out we must be very careful not to unjustifiably threaten TAB.

Import is said to be carried out by TAB. The importer is liable for infringement proceedings. Therefore, we can bring proceedings against TAB for import of the infringing products.

Validity

DA is granted and can be enforced immediately. Check DA is inforce and renewal fees are up to date, the last renewal fee was due at the end of June 2024. ✓

Currently, DA is not valid because claims 1-5 are not novel or inventive.

We need to amend DA to incorporate that the capsule halves do not touch, as described in the amendment section above.

We should amend the patent to restore validity before we bring proceedings against TAB because the allow ability of amendments when there are no proceedings which may question validity pending is much better.

Actions

Request the amendment to DA asap in writing, providing reasons and citing the suspected infringement.

Once amended, send a copy of DA to TAB to put them on notice and remove any innocent infringer defence. Doing this before amending may make TAB aware and invite them to oppose our amendments, so better to amend first.

In answer to your question, yes it is possible to enforce DA against TAB in the UK, for import of infringing medicament and, depending on the nature of the agreements with the subsidiary manufacturing site, possible also for manufacture. However, it is important that we amend DA to restore validity first.

Bring infringement proceedings against the subsidiary manufacturing facility for the manufacture of infringing medicaments.

Bring infringement proceedings against TAB for import of infringing medicaments.

Remedies available are damages, account of profits, delivery up, destruction, declaration of infringement and injunction. Given that TAB's KC has become popular over the last year and has caused CAP to lose several contract bids, it seems that requesting damages is the most appropriate course. We may also request an injunction to prevent TAB and the subsidiary carrying on their activities in the UK.

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Interim injunction?

- Serious case to be tried – yes because there is infringement.
- Balance of convenience? Yes, this can be readily assessed through the loss of valuable contract bids. ✓
- Would damages received at eventual trial be sufficient to repair the harm done? The product provided over 75% of CAP's profit last year. Loss of this profit would be detrimental to the business and may cause CAP to go bankrupt before they can reach trial. ✓
- Thus there are grounds for an interim injunction to stop TAB's activities and we will request this.

TAB are US company – check if client has any US patents under which we can take action against TAB in the US. Reach out to a US attorney for advice on this point.

MARKS AWARDED: 4.5

adv 4.5

Page sub-total