Patents Act 1977 **Opinion Number** **02/24**

OPINION UNDER SECTION 74A

Patent	EP 2508122 B1
Proprietor	Bridea IP Limited
Exclusive Licensee	
Requester	Bridea IP Limited
Observer	Vernacare Limited and Robinson Healthcare Ltd
Date Opinion issued	03 April 2024

The Request

1. The Comptroller has been requested by Lewis Silkin LLP on behalf of their client Bridea IP Limited ("the requester") to issue an opinion as to whether EP 2508122 B1 ("the patent") is infringed by a product known as the Vernacare Instraspec Contour ("the contour"). The request was filed on 15th January 2024 (letter dated 12th January 2024) and was accompanied by a statement explaining the request.

Scope of the Opinion

2. The requester has provided evidence of why they consider that the contour falls within the scope of at least claims 1, 2, 4 - 10 and 12 - 15 of the patent. In view of the extensive analysis required, my opinion is restricted to the independent claims only, which are claims 1 and 15.

Observations and Observations in Reply

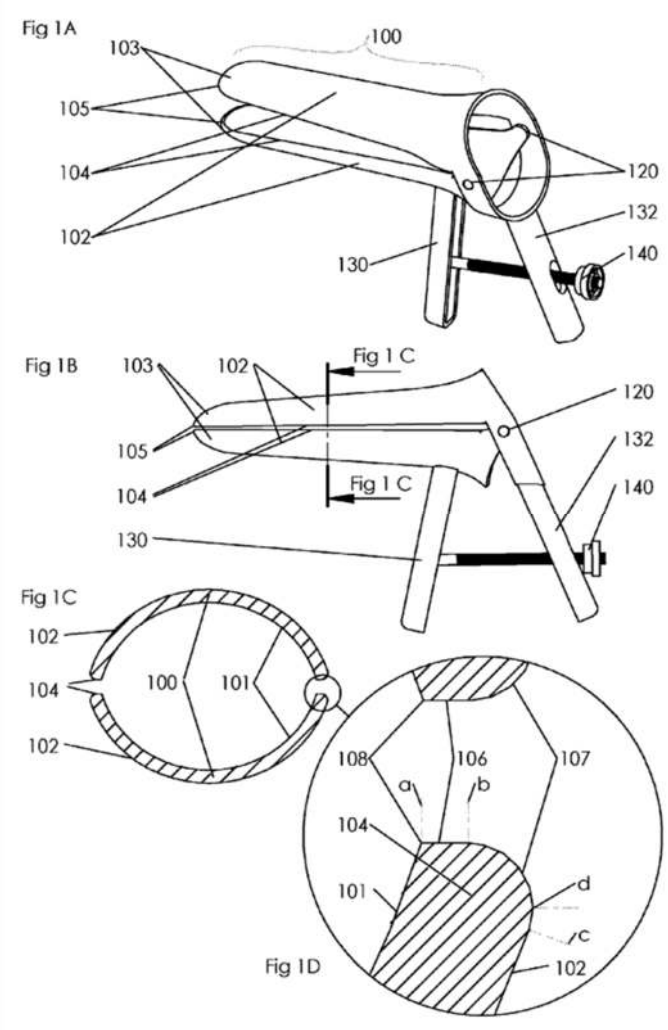
3. Observations were received on 14th February 2024 from WP Thompson Limited on behalf of Vernacare Limited and Robinson Healthcare Ltd ("the observer"), accompanied by a sample of the contour. The observer also supplied a sample of the Bridea Medical Orchid Spec Speculum ("the Bridea speculum"), a product of Bridea Medical, a related entity of the requester.

4. Observations in reply were received on 27th February 2024, also accompanied by a sample of the contour and the Bridea speculum.

The Patent

5. The patent is titled “Advanced surgical instrument such as a speculum” and relates to a speculum, which is a commonly used medical device for opening or distending an orifice or cavity of a patient’s body to permit examination of the interior and/or to enable a medical procedure to be carried out. The disclosure of the patent relates more specifically to a vaginal speculum for gynaecological use. The patent was filed on 6th April 2011 and a European patent designating GB was granted on 10th September 2014. The patent remains in force.

6. A prior art speculum is shown in figures 1A - 1D of the patent, which are reproduced below. The prior art speculum comprises two beak-shaped blades (100). The blades extend longitudinally and have cupped distal ends (103). A pivoting joint (120) at the proximal ends allows the blades to move away from each other to dilate a cavity into which the speculum is inserted.



7. The patent describes how a speculum blade formed by injection moulding, for example from plastic, usually has a ‘parting line’, which is a feature formed during manufacture along the line at which halves of the mould used for injection moulding meet. The angle between surfaces of the blade (101, 106, figure 1D) meeting at the parting line generally forms a sharp rather than a rounded edge (108). Such sharp

edges can cause discomfort and even injury to a patient during use of the speculum. The problem may be exacerbated by the presence of plastic flash, which is a very thin film or wall of plastic formed on a parting line, or by the parting line being unintentionally stepped if the mould halves are not perfectly aligned during manufacture of the speculum blade. The aim of the patent is to provide an improved speculum designed to reduce discomfort and injury to a patient during use.

8. Figures 3A - 3E (reproduced below) show an embodiment of a blade of the speculum of the invention. The blade (300) of the invention differs from the prior art blade represented in figure 1 in that it comprises an inwardly extended supporting surface (306) and an inwardly curved circumferential edge (314). The substantially flat supporting surface provides support to a patient's tissue protruding between the blades of the speculum. The parting line (308) is provided on one of, or between, an outer edge side (307) and an inner edge side (309) of the blade. Provision of the parting line closer to the inner edge side can reduce or avoid discomfort to the patient.

Fig 3 A

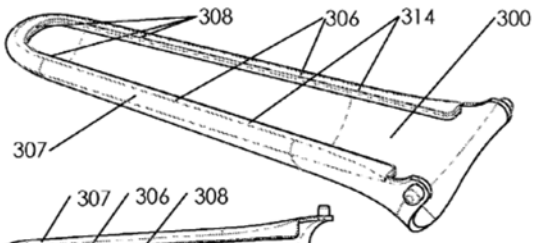


Fig 3 B

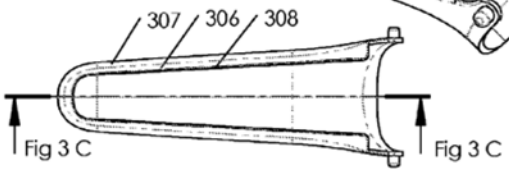


Fig 3 C

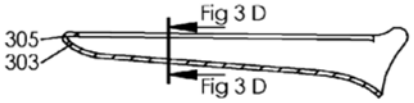


Fig 3 D

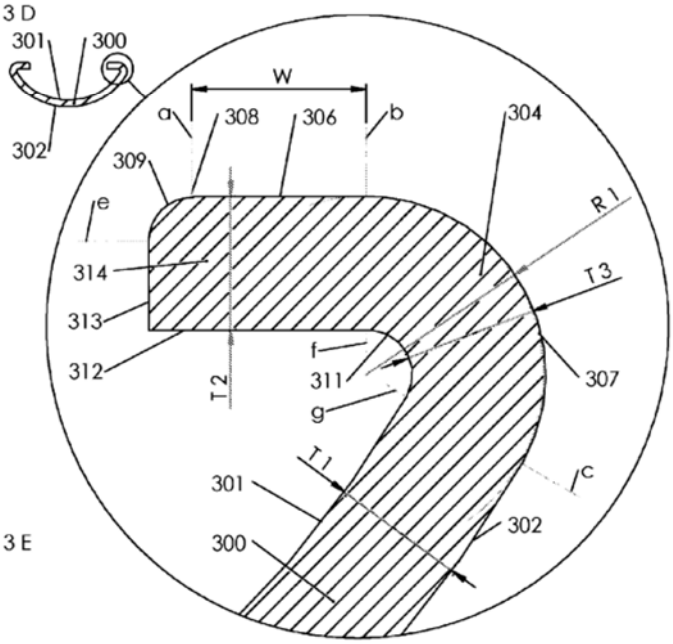
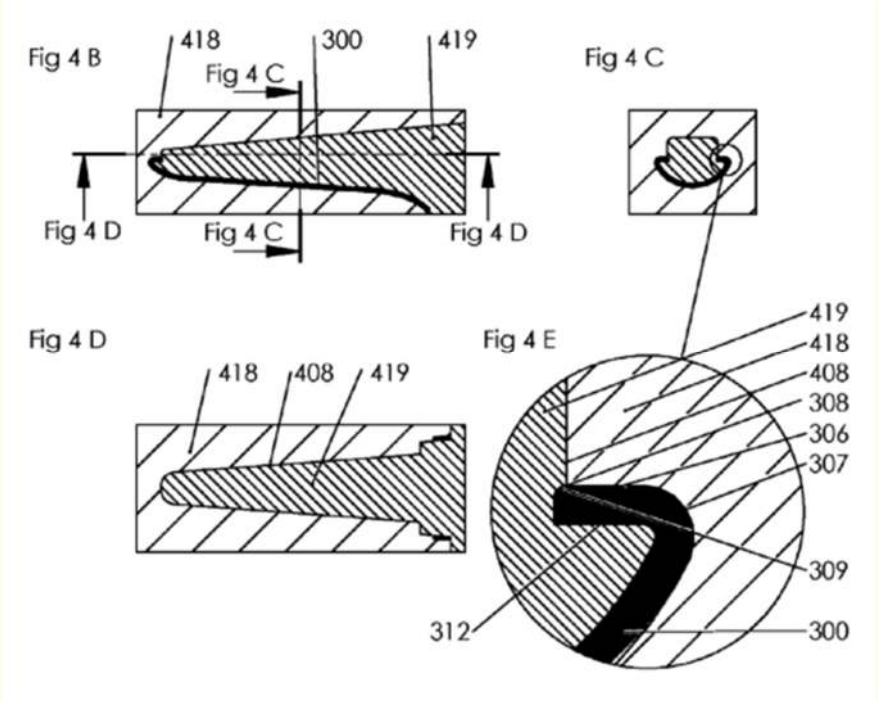


Fig 3 E

9. Figures 4B - 4E (reproduced below) represent the injection moulding tooling used to manufacture the blade, which comprises a cavity block (418) and a core block (419). The mould blocks are shown in the closed position adopted during injection moulding. The position at which the parting line (308) forms can be seen.



10. The patent has fifteen claims, including two independent claims (1 and 15).

Claim 1 reads as follows:

> *Surgical instrument such as a speculum comprising elongated cup-shaped pivotably mounted blades manufactured from a mouldable material, such as plastic or metal, wherein at least one blade has an inwardly curved circumferential edge provided with a moulding induced parting line, which circumferential edge has a supporting surface including an outer edge side and an inner edge side, characterised in that the parting line is provided on one of, or between the outer and inner edge sides of the supporting surface.*

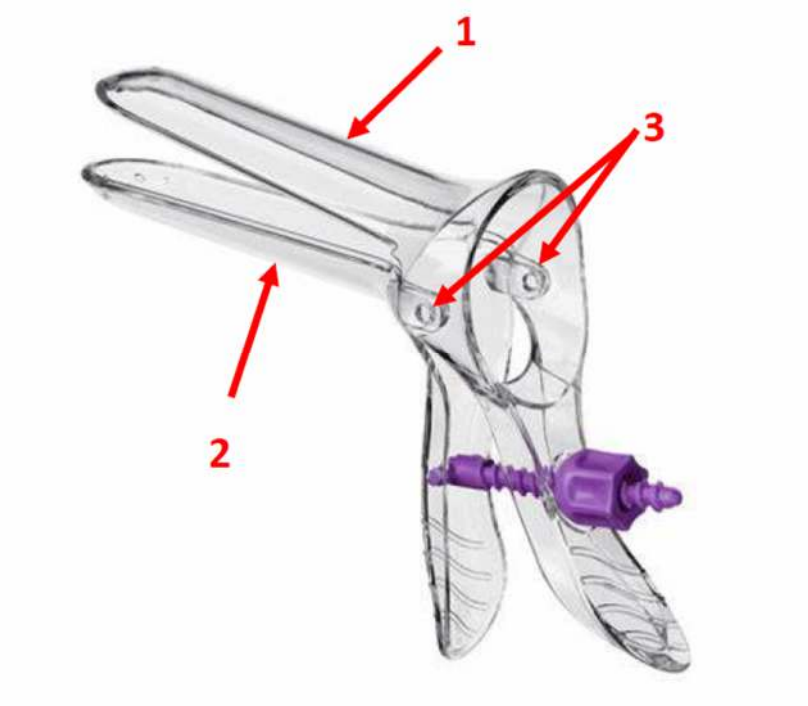
Claim 15 reads as follows:

> *A method of manufacturing an elongated cup-shaped blade for a surgical instrument such as a speculum, comprising positioning mould halves in a blade moulding process resulting in parting lines induced on the blade, which blade has an inwardly curved circumferential edge having a supporting surface including an outer edge side and an inner edge side, characterised in that the moulding process is such that the resulting parting line is provided on one of, or between the outer and inner edge sides of the supporting surface.*

The Vernacare Instraspec Contour

11. A photograph of the contour, provided by the requester, is reproduced below. The

contour comprises features of specula known in the art, such as beak-shaped blades (1, 2) extending longitudinally and a pivoting joint (3) to facilitate moving the blades apart.



The Law - Infringement

12. Section 60(1) of the Patents Act 1977 reads:

> *Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say -*
>
> > *(a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;*
> >
> > *(b) where the invention is a process, he uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent;*
> >
> > *(c) where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.*

13. The requester states in their letter that the contour *"is manufactured and sold in the UK"* and in the accompanying document that it *"is being at least sold, marketed, housed, and used within the UK"*. These assertions do not appear to be disputed by

the observer. The requester provides a link to a Vernacare web page, which includes an embedded video in which it is stated that the contour has a unique design that was developed and tested in the UK.

Claim Construction

14. As a first step I must correctly construe the claims. This means interpreting them in light of the description and drawings as instructed by Section 125(1). In doing so I must interpret the claims in context through the eyes of the person skilled in the art. Ultimately the question is what the person skilled in the art would have understood the patentee to be using the language of the claims to mean. This approach has been confirmed in the recent decisions of the High Court in *Mylan v Yeda*[1] and the Court of Appeal in *Actavis v ICOS*[2].

15. Claims 1 and 15 include many identical features, and it appears that an elongated cup-shaped blade of the instrument of claim 1 is manufactured by the method of claim 15. I consider that focussing on construing claim 1 only is sufficient.

16. The original request did not include any comments relating to claim construction. The observer points to certain sections of the claims which they consider to be unclear, which I will begin by considering.

17. The observer asserts that the meaning of the term 'cup-shaped' is unclear. Although the term might be taken in isolation to refer to an object having a similar shape to a drinking vessel and therefore capable of holding a liquid, it is clear to me that use of this term in the patent was not intended to be restrictive to this degree. The claim actually states that the blades are 'elongated' and 'cup-shaped'. I also note that the patent refers to the blades of both the prior art speculum and that of the invention as having 'cupped ends' at their respective distal ends. In light of the teaching of the patent, I consider it to be clear that an elongated cup-shaped blade refers to a blade having ends that are curved and possess depth in the manner of a cup, with the blade transitioning into an elongated section also possessing depth.

18. The observer further considers that *"although a blade may be considered to be elongate it is unclear as to how much of the item illustrated in the requestor's claim chart is a blade and the extent of the blade"*. I do not consider that the absence of a precise definition of the starting point of the blade at the end proximate the pivot causes any difficulty in understanding the meaning of the claim. Similarly, I do not agree with the observer's assertion that the extent of the circumferential edge is unclear due to the extent of the blade being unclear.

19. In order to construe the claims clearly, the terms 'inwardly curved circumferential edge', 'supporting surface', 'outer edge side' and 'inner edge side' require consideration.

20. I consider that figures 3D and 3E are most useful for understanding the term 'inwardly curved circumferential edge', which is labelled as feature 314 in figure 3E.

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[1] Generics UK Ltd (t/a Mylan) v Yeda Research and Development Co. Ltd & Anor [2017] EWHC 2629 (Pat)

[2] Actavis Group & Ors v ICOS Corp & Eli Lilly & Co. [2017] EWCA Civ 1671

The description also uses the term ‘inwardly extended edge’ for this feature, which it describes as having a thickness dimension T2. To my mind, the ‘inwardly curved circumferential edge’ therefore comprises the full thickness of the section of the blade that is horizontally represented in figures 3D and 3E.

21. The ‘supporting surface’ is labelled as feature 306. It is also referred to as the ‘inwardly extended supporting surface’ and the ‘inwardly extended surface’ and, although not claimed as such, is described in the embodiment of figure 3 as being substantially flat. It seems clear to me that the ‘supporting surface’ is the upper surface of the inwardly curved circumferential edge.

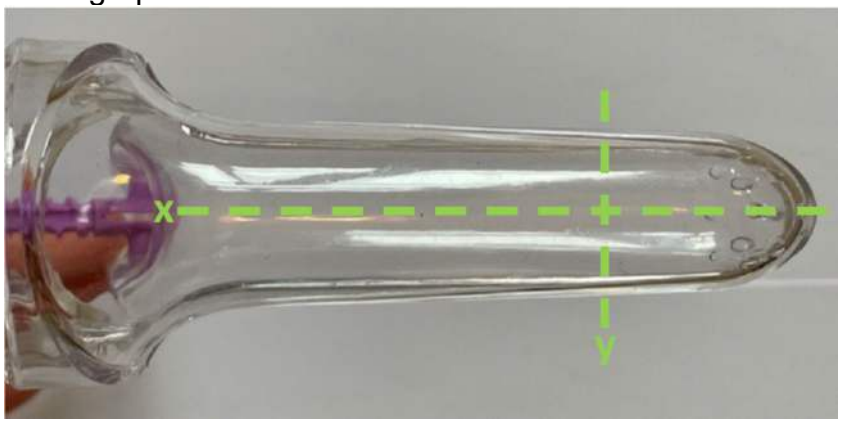
22. I initially found the terminology ‘outer edge side’ and ‘inner edge side’ to be somewhat confusing. The ‘outer edge side’ and the ‘inner edge side’ are labelled as 307 and 309 respectively in figure 3E, and are also interchangeably referred to in the description as the ‘outer radius’ or ‘outer edge’ and as the ‘inner radius surface’ or ‘inner radius’. I understand from their statement that *“the inner edge side and supporting surface are planes and terminate where they intersect to form a corner”* that the observer construes the term ‘inner edge side’ (and presumably also ‘outer edge side’) as referring to a plane. It is my view, however, that the terms ‘outer edge side’ and ‘inner edge side’ should be construed as referring to linear features extending into the plane of figure 3E at the positions labelled 307 and 309.

23. For completeness, I consider the term ‘parting line’ to refer to an identifiable physical manifestation on the blade formed at the line of intersection between the cavity block, core block and injection moulded blade.

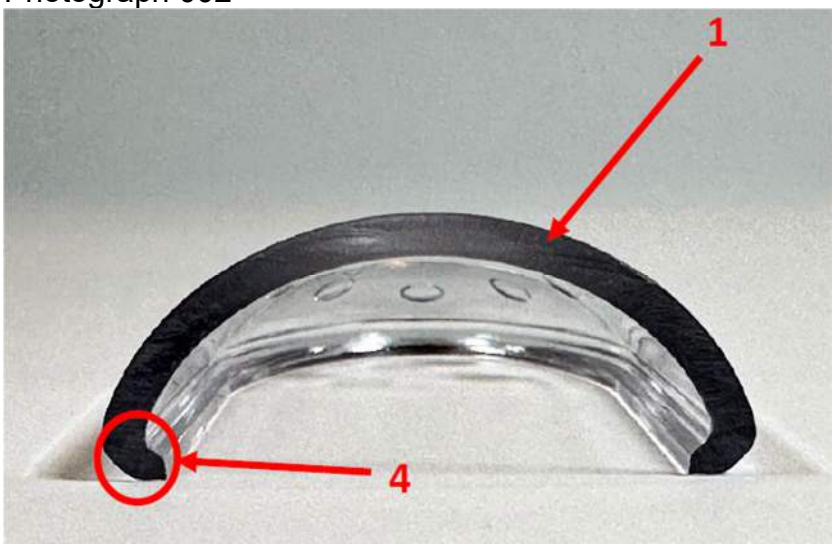
Discussion

24. The requester provided further photographs of the contour, some of which are reproduced below. Photograph 006 shows a top view of the contour having x and y axes superimposed, photograph 002 shows a section taken along the y axis, photograph 003 a section taken along the x axis, and photograph 004 an enlarged detail of photograph 003.

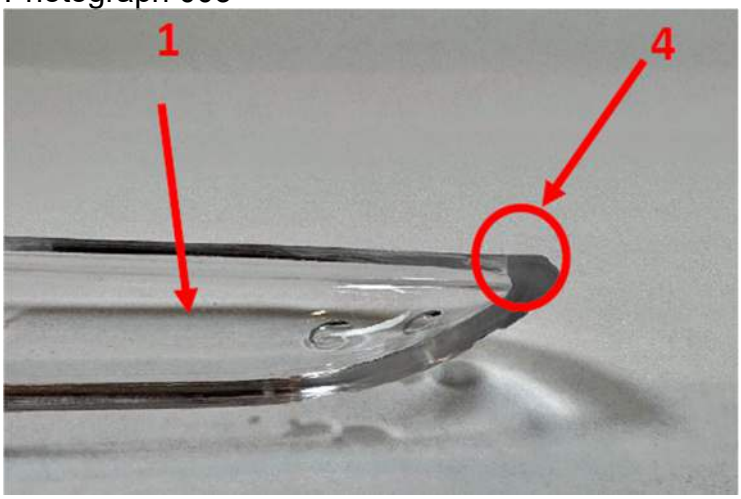
Photograph 006



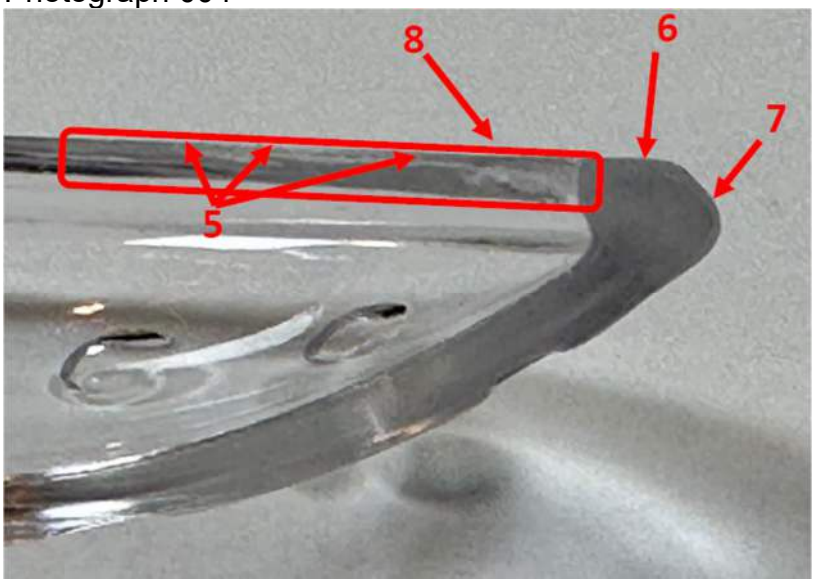
Photograph 002



Photograph 003



Photograph 004



25. Considering claim 1, it is evident to me that the contour is a surgical instrument, such

as a speculum, comprising elongated cup-shaped pivotably mounted blades manufactured from a mouldable material, such as plastic or metal.

26. The observer has not commented on the presence or absence of the features of claim 1 which they consider to be unclear, including the inwardly curved circumferential edge of at least one of the blades. The requester indicates that this is formed by feature 4 of photographs 002 and 003. I am in agreement with the requester.

27. The observer agrees that the contour blades comprise a supporting surface including an outer edge side and an inner edge side, although, as previously discussed, their definition of which features form the outer and inner edge sides differs from my understanding. The requester asserts that features 6, 7 and 8 of photograph 004 form respectively the supporting surface, the outer edge side and the inner edge side. I agree that arrow 7 points to an end of the section through the outer edge side and that arrows 6 and 8 respectively point to positions on the supporting surface and the inner edge side. To my mind, these features are therefore clearly present on the contour.

28. The observer states categorically that there is no parting line present on the contour. The requester considers that *"parting lines are an unavoidable byproduct of injection moulding induced where the mould splits into its respective halves"*, which I understand to be correct. The requester further states that *"[t]he dispute comes down to where the parting line is on the Contour"*. Implicit within this statement is the assumption that the contour is manufactured by injection moulding. I can find no indication in the observer's submissions of the method used to manufacture the contour.

29. The requester pointed out that the contour was the subject of patent application publication no. GB2578723, which is not apparently denied by the observer. Therefore, as it would seem that GB2578723 does relate to the contour, its contents may provide an indication of the manufacturing method used. It is stated in GB2578723 that the blades of the speculum disclosed therein are 'moulded plastic components'. It seems, therefore, extremely likely to me that the contour is formed by a compression moulding or injection compression moulding process. It is my understanding that both these processes would result in the presence of a parting line on the moulded product. To my mind, the pertinent questions are, therefore, is there any evidence of a parting line on the contour and where is it located?

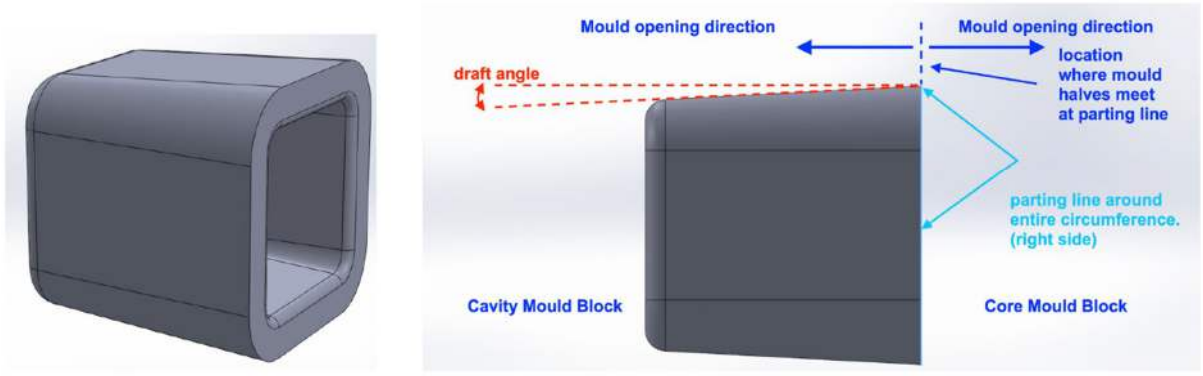
30. The requester asserts that the parting line *"is shown as line 5 on inner edge side 8"* in photograph 004. This would seem to be the same feature referred to by the observer as the interior corner of the jaw, which they note is *"sharp and therefore a feature discernible to touch".* They assert, however, that *"inspection fails to find any discernible manifestation of a parting line on [the corner] or near it"*. On inspection of the provided samples of the contour, it is my view, however, that a raised feature can be felt on the interior corner.

31. The observer further asserts that *"even if there was a parting line on the touch perceptible feature of the corner, which is not admitted, the interior corner of the supporting surface - the only 'sharp' bit on the device peripheral edge - is not "on the inner edge side" of the supporting surface"*. As previously discussed, I do not agree

with the observer's definition of the location of the inner edge side. It is my view that the position of the raised feature discernible by touch on the contour does coincide with the position of the inner edge side of the supporting surface.

32. The requester presented further arguments regarding the position of the parting line on the contour, based on the concept of 'draft angle', which I understand to be the angle between a shared plane of the mould cavity (or mould core) and the product being moulded and the mould opening direction. The draft angle must be zero or take a positive value to allow de-moulding, as represented in the simple example of a tapered hollow cube, provided by the requester and reproduced below.

A design for a hollow cube:



33. Considering figure 4B of the patent, the de-moulding direction is along a horizontal axis in the plane of the paper, with the mould block moving to the left and the mould core moving to the right. It seems to me that the parting line of the blade of the Bridea speculum could not be located other than on or between the inner edge side and the outer edge side, as stated in the claims. A position outside of either of these two limits would result in a negative draft angle, thus preventing de-moulding. Assuming the use of a similar moulding process, it seems to me that this must also be the true for the contour. In the absence of a discernible raised or sharp feature on the contour other than the corner, the requester asserts that *"the parting line must be coincident with this 'corner' because of the draft angles of the design"*. I tend to agree with this assertion.

34. In view of the common features between independent claims 1 and 15, I do not consider that a separate discussion of claim 15 is required here.

Summary

35. Taking into account the evidence placed before me, I consider it to be extremely likely that the contour is manufactured by a compression moulding or injection compression moulding process and, therefore, must comprise a parting line. Based on this assumption, it is my view that the contour or manufacturing method thereof falls within the scope of claims 1 and 15 of the patent.

Opinion

36. It is my opinion that the disposal or offer of disposal in the UK, importation into the UK or manufacture in the UK of the Vernacare Instraspec Contour would amount to an infringement of claims 1 and 15 of EP 2508122 B1.

Karen Payne
Examiner

NOTE

This opinion is not based on the outcome of fully litigated proceedings. Rather, it is based on whatever material the persons requesting the opinion and filing observations have chosen to put before the Office.