Neutral Citation Number: [2018] EWHC 345 (Pat)

Case No: HP-2016-000047

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST
PATENTS COURT

Royal Courts of Justice, Rolls Building
Fetter Lane, London, EC4A 1NL

Date: 23/02/2018

Before :

HIS HONOUR JUDGE HACON
(Sitting as a High Court Judge)

- -

Between :

(1) CANTEL MEDICAL (UK) LIMITED **(2) CANTEL (UK) LIMITED**	**Claimants**
- and -	
ARC MEDICAL DESIGN LIMITED	**Defendant**

- -
- -

Douglas Campbell QC and Geoffrey Pritchard (instructed by **DLA Piper UK LLP**) for the **Claimants**
Daniel Alexander QC and Henry Ward (instructed by **Carpmaels & Ransford LLP**) for the **Defendant**

Hearing dates: 16-19, 22-23, 25-26 January 2018

- -

Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

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HIS HONOUR JUDGE HACON

Judge Hacon :

Introduction

1. Colonoscopy is a procedure by which the colon is viewed using a camera and light positioned at the end of a flexible tube which has been inserted into the colon. It is a type of endoscopy which has been practised since the late 1960s. The apparatus used is a colonoscope. A principal application of the procedure is the detection of polyps: growths in the lining of the colon. A subset of polyps consists of a type known as adenomas; these are cancerous growths. The removal of adenomas can prevent the development of colorectal cancer and the potential spread elsewhere. Colonoscopy has become a primary tool in the detection and treatment of bowel cancer.

2. Colonoscopes are almost entirely supplied, in Europe anyway, by three giant Japanese manufacturers of optical equipment which I will refer to by their abbreviated names: Olympus, Pentax and Fujifilm.

3. Between 2008 and 2011 a product used with colonoscopes called the 'Endocuff,' was developed. The Endocuff was a plastic cuff, about 2 cm in length, fixed to the end of the colonoscope just behind the camera lens and light, with radially projecting elements. It assisted the colonoscopist in the detection of adenomas.

4. In October 2008 the Defendant ("Arc") was incorporated as a vehicle for the exploitation of the Endocuff, principally by Patrick Axon, identified as the designer. The design was finalised in December 2010. The product was launched on the market in the UK in August 2011.

5. In September 2012 Arc and Cantel Medical Corporation entered into a distribution agreement under which the latter marketed the Endocuff in the United States. Cantel Medical Corporation is the US parent of both Claimants. Since there is no need to distinguish the Cantel companies, I will refer to them collectively and individually as 'Cantel'.

6. In April 2014 an amended design of the Endocuff was finalised. The new product was named the 'Endocuff Vision' and was launched in the Netherlands in February 2015. Arc's case is that Mr Axon designed this too.

7. Images of the Endocuff Vision were presented to Cantel in August 2013 and early samples of the product were sent to Cantel for their consideration in August 2014.

8. In 2015 a majority of the shares in Arc were sold to Norgine BV, a Dutch pharmaceutical company. Cantel's distribution rights came to an end in June 2016. Since then Arc's products have been distributed in the US by a subsidiary of Olympus.

9. In anticipation of losing the distribution rights, Cantel developed their own colonoscope cuff. The design was created by a company in the Cantel group called Medivators, Inc ("Medivators"). There will generally be no need for me to distinguish Medivators from Cantel as a whole. Cantel's new design was finalised in

January 2016 and the product was launched later that year under the trade name 'AmplifEYE'. The AmplifEYE is now sold in many countries, including the UK.

10. Cantel brought these proceedings in September 2016 to clear the path for lawful marketing of the AmplifEYE, seeking revocation and/or declarations of non-infringement of Arc's rights. Arc has counterclaimed for infringement. The rights in question are:

    (1) European Patent (UK) No. 2 575 590 ("the Patent");

    (2) UK Patent No. 2 478 081 ("the UK Patent");

    (3) Registered Community design No. 001856121-0001 ("the Endocuff RCD");

    (4) Registered Community design No. 002523191-0001 ("the Vision RCD");

    (5) UK unregistered design right in the design of the Endocuff;

    (6) UK unregistered design right in the design of the Endocuff Vision.

11. Cantel have also sought declarations of non-infringement in relation to two alternative versions of the AmplifEYE, neither of which has yet been marketed, and which were referred to as AmplifEYEs 2 and 3.

12. The Patent and the UK Patent are for the same invention. The Patent is still the subject of opposition proceedings before the European Patent Office. The Patent was upheld in amended form but that decision is currently subject to appeal before the Technical Board of Appeal, so s.73(2) of the Patents Act 1977 does not yet bite.

13. Arc has implicitly conceded that both Patents are invalid in their current forms and has therefore advanced unconditional amendments. Alternative conditional amendments have also been sought. Cantel argue that none of the proposed amendments is allowable.

14. Douglas Campbell QC and Geoffrey Pritchard appeared for Cantel, Daniel Alexander QC and Henry Ward for Arc.

The Witnesses

The Experts

15. I had the benefit of evidence from Dr James East for Cantel and Professor Colin Rees for Arc. Dr East is a Consultant Gastroenterologist and Endoscopist, and Honorary Senior Clinical Lecturer who is based at the Translational Gastroenterology Unit, John Radcliffe Hospital, Oxford. Professor Rees is a Consultant Gastroenterologist at South Tyneside NHS Foundation Trust, where he is a Director of Research. Professor Rees is also Honorary Professor of Gastroenterology at Newcastle University. I found the evidence of both experts clear and helpful.

Witnesses of Fact

16. Cantel had several witnesses, of whom four were cross-examined. Their evidence was concerned with the development of the AmplifEYE by Cantel and much of it was directed to Arc's allegation that the project had involved copying the designs of the Endocuff and Endocuff Vision.

17. John Schreiner was until the end of September 2017 the Director of Research and Development at Medivators. I have no doubt that Mr Schreiner was doing his best to give a true account of what happened in the course of creating the AmplifEYE. But I think that on the question of whether and the extent to which the designs of the Endocuff and Endocuff Vision influenced that of the AmplifEYE, Mr Schreiner had by the time of the trial minimised that influence in his own mind, possibly out of loyalty to his former employer. My impression was that Mr Schreiner was not always comfortable reviewing the history of how the AmplifEYE came to look the way it does, which may reflect well on his honest instincts.

18. Anoopam Nath is Design Engineer and Manager of Technical Standardization, R&D, at Medivators. Mr Nath was the lead designer of the AmplifEYE under the overall direction of Mr Schreiner. I found that Mr Nath answered questions in cross-examination honestly and to the best of his ability, but like Mr Schreiner I think he had persuaded himself that the designs of the Endocuff and Endocuff Vision played much less of a role the AmplifEYE project than was the case. I will discuss below why I take that view.

19. Loyalty to his employer probably also influenced the evidence of Brent Geiger. Mr Geiger has been Senior Director Global Regulatory Compliance at Medivators since September 2015. He played a central role in obtaining regulatory approval for the AmplifEYE.

20. The fourth witness from Cantel who was cross-examined was Jørgen Hansen, currently President and Chief Executive Officer of Cantel, and at the time of the development of the AmplifEYE Chief Operating Officer. Mr Hansen gave his evidence clearly and I am sure accurately.

21. The remaining witnesses from Cantel were not cross-examined and the evidence given in their witness statements stood unchallenged. None of it played a significant role.

22. Aside from Ian Kirby, a partner in the firm acting for Arc who gave evidence regarding a procedural matter and was not cross-examined, Arc's only witness of fact was Patrick Axon, who stated how the Endocuff and Endocuff Vision came to be created. Mr Axon is a surgeon specialising in otology at Addenbrooke's Hospital, Cambridge (otology is a branch of medicine dealing with the physiology and diseases of the ear). I have no reason to doubt that Mr Axon gave honest answers to all questions put to him.

The Patents

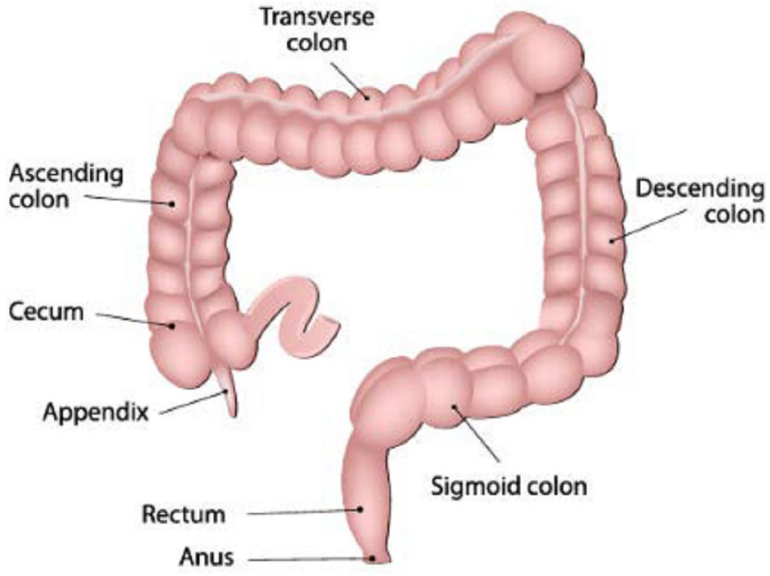
23. There was no difference of substance between the arguments relating to the Patent and those relating to the UK Patent. They had the same specification. I will refer largely to the Patent because its paragraphs are numbered.

Colonoscopy

24. The Patent states that a colonoscopy may take anywhere from 20 minutes to 2 hours. The evidence indicated that around 30 minutes is typical, but with some patients the procedure can be difficult and take longer.

25. There are two stages. First there is intubation, which involves introducing the colonoscope into the rectum and progressing it along the colon. When intubation reaches its end point, there follows the withdrawal of the colonoscope, sometimes referred to as extubation. It is during the gradual process of withdrawal that the search for adenomas takes place.

26. Ideally the physician would like the chance to see the whole of the mucosal lining of the colon. The first main difficulty is that it is not always possible to reach the far end of the colon, the caecum. Intubation may therefore be incomplete. This is a diagram of the colon:



27. As can be seen, despite the flexibility of the colonoscope, it may be difficult to manage the apparatus so that the tip reaches the caecum. The clinician must rely on his or her skill to push and manoeuvre the colonoscope from outside the patient. Colons vary and advancing the colonoscope beyond a bend may not prove easy.

28. The second relevant difficulty arises from the folded nature of the colonic lining. While it is generally easy to detect adenomas on the near side of a fold, i.e. the side facing the camera, those on the far side may be difficult to see.

29. I pause here to mention the terms ‘proximal’ and ‘distal’, much used in the evidence and in the Patent. In simple terms, proximal means nearer and distal means further way. The trouble is that this depends on context. It is conventional to describe the caecal end of the colon as proximal and the anal end as distal. Thus, claim 1 of the Patent refers to ‘proximal surfaces’ of colonic folds, meaning the surfaces facing towards the caecum. However, the terms are often also used from the perspective of the physician located at the anal end of the colon. Relative to the physician, the

proximal direction is towards the anus and distal towards the caecum. I will do my best to be clear about which sense of proximal and distal is meant.

Caecal Intubation Rate and Adenoma Detection Rate

30. Two standard clinical markers are used to assess the quality of a series of colonoscopies, for instance a sequence carried out by an individual clinician. The first is known as caecal intubation rate ("CIR"). It refers to how often intubation reached the caecum. The second is the Adenoma Detection Rate ("ADR"), namely the proportion of colonoscopies in which at least one adenoma is found. This is a surrogate marker in that the real measure of success is the proportion of patients who develop colorectal cancer following colonoscopy. But deriving such a measure takes years. ADR has been found to be inversely correlated with post-colonoscopy colorectal cancer rates so it is commonly used to gauge the quality of a clinician's colonoscopies.

The person skilled in the art

31. The parties agreed that the skilled team consisted of a clinician, being a gastroenterologist, and other members of a development team for devices to be used with colonoscopes. The other members were left vague because it didn't matter.

The common general knowledge

The importance attached to CIR

32. There was a dispute of minor importance about whether, as a matter of common general knowledge ("CGK"), CIR remained a preoccupation of the skilled person at the priority date (25 May 2010), as Dr East said, or whether CIR had become predictably high by the priority date, Professor Rees's view. I don't think these are inconsistent. There was probably less attention paid to CIR in May 2010 than there had been because clinicians' technique had become more proficient. But there was always room for improvement, so CIR was still relevant.

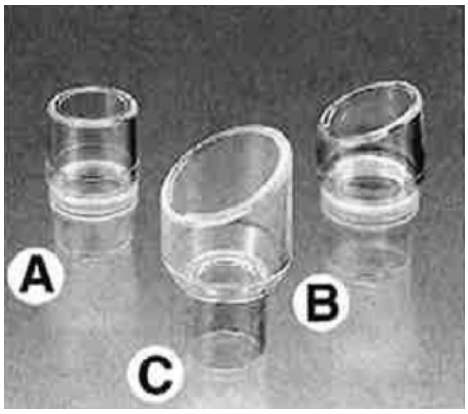
The desire for improved visualisation

33. There was a more significant debate about whether clinicians' – and therefore the skilled team's – desire for better visualisation of the mucosal lining had emerged shortly before May 2010 or some time earlier.

34. The idea that clinicians were unconcerned about visualisation until around 2010 does not make intuitive sense. The whole point of colonoscopy is to find polyps and among them adenomas and thus to improve ADR. Since the start of clinicians' concern about ADR, if not earlier, it must have been the case that there was an implicit wish to improve the visualisation of the mucosal wall afforded by colonoscopes. One of the leading figures in gastroenterology is Dr Douglas Rex. I was shown papers of which he was an author dated from 1997 and 2000 in which the need and means to improve the detection rate of adenomas was discussed. In my view, for more than a decade before the priority date and probably longer, the skilled team would have wished for the best visualisation of the wall of the colon, particularly of the proximal surfaces of the folds, that was feasible.

Prior art caps

35. It was common ground that in May 2010 there were already available devices which could be attached to the end of a colonoscope to improve its performance. Some clinicians favoured them, others not, and there was mixed evidence about their practical value. These are examples:



36. The caps allowed the distance from the camera lens and the polyp to be maintained such as to create a more focussed image. They were sometimes also used to encapsulate a polyp for removal.

37. In addition the caps could be used to flatten haustral folds – this is the technical name for folds in the wall of the colon, haustra being pouches. Professor Rees said that in May 2010 clinicians knew that anything which flattened the haustral folds would improve visualisation of polyps (day 3, 251). I take this to have been part of the CGK.

38. Professor Rees went on to say that in May 2010 people were still investigating the cap to see whether it could expose the proximal side of folds by flattening them and that there was research into the use of caps for polyp detection rate. He said that even today caps are not routinely used in the UK for detection (day 3, 257-260). I conclude from this that in May 2010 the value of caps, if any, in improving the visualisation of polyps, particularly those on the proximal surface, was not part of the CGK.

39. To enable advancement of the colonoscope towards the caecum, it may be desirable to straighten bends in the colon to some degree. The cap is gently hooked in the wall towards the far side of a bend and then the colonoscope is pulled back somewhat. If the cap is sufficiently lodged, the effect will be to straighten the colonoscope and with it straighten the colon. Further intubation is thereby facilitated. This technique was part of the CGK.

The Patent

40. The background section of the specification discusses disadvantages associated with colonoscopic procedures known in the prior art. Those most relevant to the arguments raised at trial were associated with the desire to gain the best possible view of adenomas. The specification explains at paragraph 5 the significant shortcomings of the prior art in relation to visualisation:

> "Firstly, the anatomy of the colon is such that the lining is thrown into folds. As the tip of the endoscope passes along the lumen of the colon, these folds hamper the endoscope's ability to visualise the entire surface of the mucosa and in particular, detect pre-malignant and malignant lesions tucked away on the proximal face of these folds during extubation.
>
> Secondly, the position of the tip may be difficult to maintain from the moment at which a lesion or polyp is detected to the completion of any therapeutic procedure. As the colonoscope is withdrawn the tip does not travel back at a constant speed but rather with jerks and slippages particularly when traversing a bend or length of colon where the bowel has been concertinaed over the endoscope shaft during intubation. The tip of the device may, at any moment, slip backwards thereby causing the clinician to lose position. If tip position is lost, the clinician is required to relocate the lesion or polyp for the therapeutic procedure to be continued."

41. Professor Rees described these as two of the most important difficulties with colonoscopies. The second, the tendency of the colonoscope to jerk past a section of the colon during withdrawal, was referred to in the evidence as 'rapid slide-by'. As will be seen, it matters that the two problems are presented in the specification as distinct from one another.

42. At paragraphs 11, 12 and 16 the specification states that the invention claimed reduces the problems of visualisation of the proximal sides of the folds in the colon and rapid slide-by, among other advantages.

Claim 1 of the unconditional application to amend

43. Claim 1 in the unconditional application to amend the Patent (which I will call 'amended claim 1') is as follows, excluding reference numerals:

> "1. A cover for a colonoscope shaft, the cover comprising an elongate tubular member and being arranged for application over a distal tip of the colonoscope shaft with the cover extending along at least a part of the length of a distal end of the shaft, the tubular member comprising an inner surface at least a part of which grips the shaft and holds the cover in place and an outer surface comprising a plurality of spaced projecting elements, characterized in that the spaced projecting elements are hinged and attached to an outer surface of the elongate tubular member, each projecting element having a tip and a base, the projecting elements being moveable about their hinged bases by an angle of between 0^o, wherein the tips of the projecting elements point towards a proximal end of the colonoscope, to an angle of $170\text{-}180^o$ wherein that the tips of the projecting elements point towards the distal end of the colonoscope or any angle between 0 to $170\text{-}180^o$, wherein the projecting elements are positioned in one or more rings running circumferentially around the cover, and wherein projecting elements in a distal ring are adapted to flare outwards on withdrawal from the colon to keep the instrument tip in the central part of the colon as the instrument moves backwards, and to evert colonic folds enabling their proximal surfaces to be viewed."

44. One embodiment of such a cover, very like the Endocuff, is shown in figure 11B:

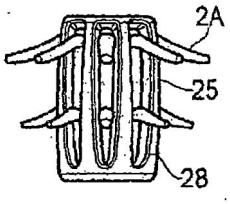


FIG. 11B

Applications to amend the UK Patent

45. Claim 1 of the unconditional application to amend the UK Patent is in similar, though not identical form to amended claim 1 of the Patent. It raises no additional issues.

46. There is a further and conditional application to amend the UK Patent. Claim 1 of the conditional application, which I will call 'UK conditionally amended claim 1' is as follows, with the amendments over claim 1 of the UK unconditional application marked:

> "1. A cover for a colonoscope shaft, the cover comprising an elongate tubular member and being arranged for application over the colonoscope shaft with the cover extending along at least a part of the length of a distal end of the shaft, the tubular member comprising an inner surface at least a part of which grips the shaft and holds the cover in place and an outer surface comprising ~~a plurality of~~ 8 evenly spaced projecting elements having a tip and a base that are moveable between a resting position to a position wherein the tip of the projecting element is substantially parallel to a longitudinal axis of the colonoscope and to a position that is at an angle approximately perpendicular to the longitudinal axis of the colonoscope shaft so that the projecting elements are fanned out to contact with and provide support for and to dilate a lumen wall of a colon into which the colonoscope has been inserted, wherein the projecting elements are constructed of a biocompatible material so that they are flexible and resiliently deformable and are positioned in ~~one or more~~ a single ring~~s~~ running circumferentially around the cover at the distal end of the elongate tubular member, ~~and~~ wherein the projecting elements ~~in a distal ring~~ are adapted to flare outwards on withdrawal from the colon to keep the instrument tip in the central part of the colon as the instrument moves backwards, and to evert colonic folds enabling their proximal surfaces to be viewed, and wherein the projecting elements are in the form of tapered bristles."

Construction

47. There were three points on the construction of amended claim 1.

Adapted to

48. The latter part of the claim states:

> "… projecting elements in a distal ring are adapted to flare outwards on withdrawal from the colon to keep the instrument tip in the central part of the

> colon as the instrument moves backwards, and to evert colonic folds enabling their proximal surfaces to be viewed."

(Here, the proximal surfaces of the colonic folds are those which at rest face towards the caecum and away from the lens of the colonoscope.)

49. Mr Campbell submitted that 'adapted to' meant 'suitable for'. He said that the latter part of the claim requires that the distal ring of projecting elements are (a) suitable for flaring outwards when the colonoscope is withdrawn so as to keep the tip of the colonoscope in the central part of the colon and (b) suitable for everting colonic folds so as to enable their proximal surfaces (distal surfaces from the clinician's perspective) to be viewed.

50. Pausing there, as I said earlier, the Patent states that the invention reduces both the problem of the colonoscope camera viewing the proximal side of folds and also the problem of rapid slide-by. But the final part of claim 1 requires only that the projecting elements are suitable to evert colonic folds enabling their proximal surfaces to be viewed. There is no requirement for any impact on rapid slide-by.

51. Returning to 'adapted', in *F H Brundle v Perry* [2014] EWHC 475 (IPEC) I considered the meaning of a claim which required that the product be 'adapted in use' to fulfil a stated function. I said this:

> "[45] … I accept that as a matter of ordinary English usage, 'adapted' carries a connotation of adaption or modification in design to achieve the purpose stated in the feature. However in my view, like feature (i) these are to be construed such that they contain no subjective element. To my mind it is irrelevant where the designer started and what adaptations were made in the design process.
>
> [46] Because these features must be assessed objectively, it seems to me that 'adapted to' and 'adapted in use to' mean the same thing as 'suitable for'. I am reinforced in this view by the judgment of Birss J in *Schenck* [*Schenck Rotec GmbH v Universal Balancing Ltd* [2012] EWHC 1920 (Pat)] in which he found 'constructed to receive' had the same meaning as 'suitable for receiving'. As in the present case the relevant claim was a product claim for a mechanical device: for fastening balancing weights to rotors.
>
> [47] I do not say that in the context of other claims it will never be possible to discern a difference between 'suitable for' on the one hand and 'adapted to' or 'adapted in use to', or 'constructed to' for that matter, on the other. But I think in this claim the first three mean the same thing."

52. Mr Alexander submitted that the claim in suit provided an instance in which there was a distinction between 'adapted to' and 'suitable for'. He disclaimed any element of subjective intention being introduced into the claim. He asserted that the cover would have projecting elements adapted to evert colonic folds, enabling their proximal surfaces to be viewed, if features have been included in the cover so as to enable that function to be performed.

53. I find the distinction so nuanced that it evades capture, at least by me. To my mind, the amended claim requires that the projecting elements of the cover be suitable for the two functions, (a) and (b), as I have referred to them above.

54. A similar point arose in the context of the application for the Patent as filed. Here the relevant words were 'designed to'. The application states (at p.22):

> "In use, the distal row of the projecting elements are designed to flare outwards on withdrawal."

55. For similar reasons I take the view that this requires the distal row of projecting elements to be suitable for flaring outwards on withdrawal.

Eversion

56. There is no definition of 'evert' in the Patent. Mr Campbell referred me to an OED definition:

> "turn (a structure or organ) outwards or inside out."

57. This gives some idea, but 'eversion' of folds during a colonoscopy, though not it seems an established term of art, must be understood in that context. The term is barely used in the Patent. Therefore the explanations given by the experts were particularly helpful.

58. Professor Rees defined the term this way (second witness statement, paragraph 6):

> " '*Everting*', in the context of colonic mucosal folds, describes what happens when an object makes contact with the surface of the fold, and then gently moves the fold in the distal direction (i.e. towards the anus) so that the proximal side of the fold is turned into the field of vision."

59. He added that eversion involves a degree of flattening of the fold being everted. But he distinguished eversion from flattening alone, particularly that which would be caused by stretching the colon and thereby flattening a sequence of adjacent folds. I have already given an instance of where the latter would happen: during intubation the tip of the endoscope is hooked or lodged into the mucosal wall and then the endoscope is pulled, straightening both endoscope and colon. A consequence of the technique is that a sequence of folds of the colon flatten out because that part of the colon has been stretched. For convenience, I will refer to this means of flattening colonic folds as 'stretch flattening'.

60. Dr East said the same thing. He distinguished eversion, where the tip of an individual fold is bent backwards and thereby flattened to some degree, from stretch flattening (day 2, 134-136).

Tapered bristles

61. A point arose on the construction of UK conditionally amended claim 1, namely the meaning of 'tapered bristle'. Page 18 of the UK Patent states that Figure 8A shows a projecting element 2 in the form of a bristle:

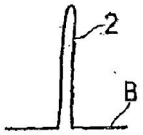


FIG. 8A

62. 'Tapered' is a word of ordinary English that presents no apparent difficulty and neither expert indicated otherwise.

The prior art

63. There were three items of prior art: two Japanese patents and one United States patent application. Olympus was the proprietor of all three and apparently responsible for all three claimed inventions. The inventor in one of the Japanese patents and in the US application was the same person, Hiroki Moriyama. It was not clear whether the name has been rendered into English with the family name first or second. The parties used 'Hiroki' as the abbreviated name for the Japanese patent and 'Moriyama' for the US application.

64. In chronological order of filing date, the prior art was:

    (1) JP-A-2003-033319A ("Hiroki");

    (2) JP-A-2003-339631A ("Hitoshi");

    (3) US-A-2004/0077926 ("Moriyama").

Novelty

The law

65. Cantel's case on novelty rested significantly on implied disclosures in the prior art. I considered implied disclosure in *Edwards Lifesciences LLC v Boston Scientific Scimed, Inc* [2017] EWHC 405 (Pat):

> "[139] … It is not essential that an item of prior art should expressly disclose all the features of an invention for that prior art to deprive the invention of novelty. It may be that one or more integers are disclosed by inference. But this must be an *inevitable* inference drawn by the skilled person reading the prior art. In *Smithkline Beecham Plc's (Paroxetine Methanesulfonate) Patent* [2005] UKHL 59; [2006] RPC 10, Lord Hoffmann, with whom the rest of the House of Lords agreed, considered the observations of Lord Westbury L.C. in *Hill v Evans* (1862) 31 L.J. Ch (NS) 457 at 463 and those of the Court of Appeal in *General Tire and Rubber Co v Firestone Tyre and Rubber Co Ltd [1972] R.P.C. 457*, at 485-486. On the facts of *Smithkline Beecham* Lord Hoffmann was concerned with the knowledge of the author of the prior art, but also emphasised that if the prior art allows even for the possibility that its performance would not result in the claimed invention, it will not deprive that invention of novelty:

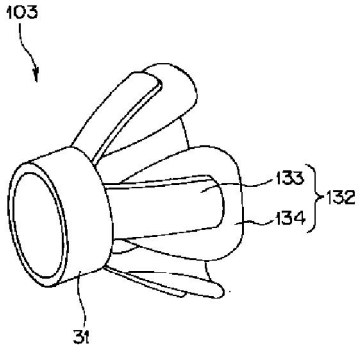
> "[22] If I may summarise the effect of these two well-known statements, the matter relied upon as prior art must disclose subject-matter which, if performed, would necessarily result in an infringement of the patent. That may be because the prior art discloses the same invention. In that case there will be no question that performance of the earlier invention would infringe and usually it will be apparent to someone who is aware of both the prior art and the patent that it will do so. But patent infringement does not require that one should be aware that one is infringing: "whether or not a person is working [an] … invention is an objective fact independent of what he knows or thinks about what he is doing": *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd [1996] R.P.C. 76*, 90. It follows that, whether or not it would be apparent to anyone at the time, whenever subject-matter described in the prior disclosure is capable of being performed and is such that, if performed, it must result in the patent being infringed, the disclosure condition is satisfied. The flag has been planted, even though the author or maker of the prior art was not aware that he was doing so.
>
> [23] Thus, in *Merrell Dow*, the ingestion of terfenadine by hay-fever sufferers, which was the subject of prior disclosure, necessarily entailed the making of the patented acid metabolite in their livers. It was therefore an anticipation of the acid metabolite, even though no one was aware that it was being made or even that it existed. But the infringement must be not merely a possible or even likely consequence of performing the invention disclosed by the prior disclosure. It must be necessarily entailed. If there is more than one possible consequence, one cannot say that performing the disclosed invention will infringe. The flag has not been planted on the patented invention, although a person performing the invention disclosed by the prior art may carry it there by accident or (if he is aware of the patented invention) by design."

66. The short point is that prior art contains an implied disclosure only if the information derived from the prior art by the skilled person would have inevitably included the implied element.

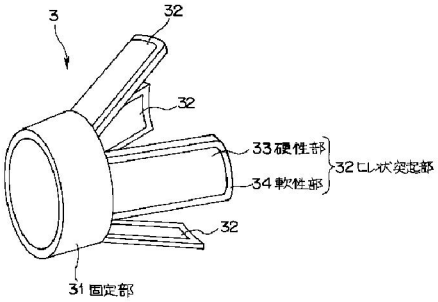
Hitoshi

67. The invention was entitled "Endoscope insertion assistance tool". The tool is releasably attached to the endoscope. It has fin-shaped projections. Figures 2 and 11 illustrate embodiments – the fin-shaped projections are numbered 32 and 132:

【図１１】



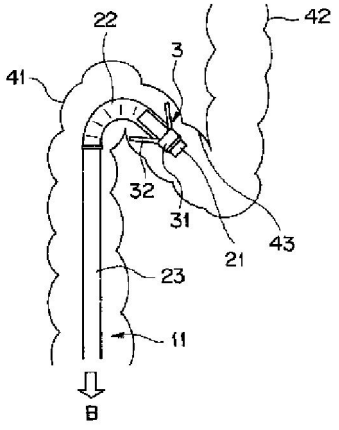
【図２】



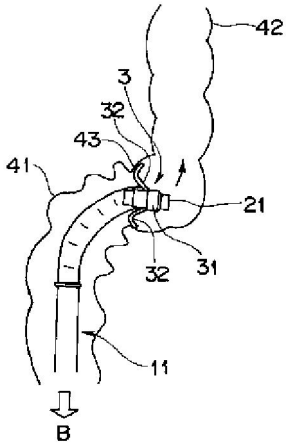
68. Paragraphs 8 to 10 of the specification explain the object of the invention, principally to improve the ease of inserting the colonoscope. There is no discussion of withdrawal of the colonoscope.

69. One use of the tool is to enable the clinician to straighten the colon during intubation, a process I have mentioned above. Paragraphs 26 and 33 to 42 describe how this works using the Hitoshi tool. It is illustrated in Figures 6-8:

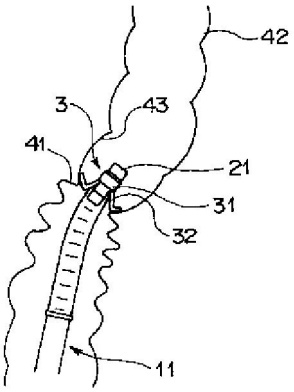
【図６】



【図７】



【図８】



70. The straightening process as disclosed in Hitoshi was summarised by Dr East:

> "[97] … Figure 6 shows the endoscope being inserted into the colon. Figure 7 shows the physician withdrawing the endoscope (in the direction of the arrow B), causing the projecting fins of the cover to engage with the colon wall, causing the walls behind the tip of the scope to concertina, and the colon itself to straighten. Figure 8 shows the result of the physician continuing to pull the endoscope back from the position in Figure 7, further concertinaing the wall behind the scope tip and straightening both the colon and the colon wall ahead.
>
> [98] The purpose of the projecting fins is to provide traction against the colon wall. The force exerted by the projecting fins on the colon wall through the physician pulling the scope backwards, causes both the walls of the colon to be drawn back (see Figure 7) and straightens the colon ahead of the scope (see Figure 8). This enables the physician to recommence intubation."

71. Arc argued that Hitoshi did not disclose the final part of claim 1 of the Patent:

> "… and wherein projecting elements in a distal ring are adapted to flare outwards on withdrawal from the colon to keep the instrument tip in the central part of the colon as the instrument moves backwards, and to evert colonic folds enabling their proximal surfaces to be viewed."

72. The issues were whether the projecting fins disclosed by Hitoshi were:

(a) adapted to flare outwards on withdrawal of the instrument from the colon to keep the instrument tip in the central part of the colon as the instrument moves backwards; and

(b) adapted to evert colonic folds enabling their proximal surfaces to be viewed.

73. Cross-examination and argument were directed to whether the projecting fins of Hitoshi were

(1) located sufficiently at the distal end of the endoscope (from the clinician's perspective) to satisfy (b); and

(2) of a length, shape and flexibility to satisfy both (a) and (b).

<u>Cantel's argument</u>

74. Cantel argued that the way the tool in Hitoshi behaved, particularly as shown in Figures 6-8, meant that when the clinician withdrew the colonoscope and began detailed examination of the colonic wall, as would always happen, inevitably the colon beyond the end of the endoscope (from the clinician's perspective) would straighten, the folds would flatten and their proximal surfaces (proximal in the sense of facing away from the camera lens) would be revealed to the view of the lens. In other words, during withdrawal the Hitoshi tool would inevitably behave in such a way that it must be a product with all the features of amended claim 1. This was true even though Hitoshi said nothing about withdrawal or visualisation.

75. If there were any doubt about this, the argument continued, one need only compare Figures 6-8 of Hitoshi with Figure 12C of the Patent. Figure 12C showed eversion of folds and visualisation during withdrawal using a cover within amended claim 1. It was in all material respects the same as what was shown in Figures 6-8 of Hitoshi:

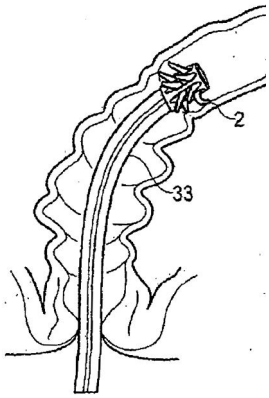


FIG. 12C

Discussion

76. I do not accept the argument. First, the flattening disclosed in Hitoshi is stretch flattening. Eversion, the bending backwards of individual folds, is not the same thing. Even if one were to assume that a colonoscopy carried out at the priority date using a Hitoshi tool would (a) result in stretch flattening during withdrawal, and (b) thereby enable the proximal surfaces of folds to be viewed within the meaning of amended claim 1, there would still be no eversion. More exactly, it cannot be inferred that eversion would inevitably occur.

77. Secondly, there was a practical difficulty with the argument. Professor Rees said in his first witness statement (at [188]) that during intubation the colon is deflated to assist the process of intubation and during withdrawal it is inflated to permit easier viewing. He maintained this evidence in cross-examination (day 3, 319):

> "The clear difference is between intubation and extubation. In intubation, you advance, deflate, advance, deflate. You suck, suck, suck because the more air you put in, the more you stretch the colon and the harder it is to get round and the more it loops. In extubation, it is very important that you inflate to stretch the lining of the colon."

78. Professor Rees had been challenged on this because in his view, the narrow diameter of the colon during intubation, when compared with extubation, meant that projecting elements which would grip the walls of the colon during intubation may not even reach the walls during extubation. He said that when the colonoscope was being withdrawn, the projecting elements:

> "… would have needed to be nearer the distal end of the scope in order to be able to manoeuvre the colonic folds in a way which the folds could be visualised, they would also have needed to be longer, softer, more flexible (since the eversion of the folds would be taking place when the colon was

> expanded rather than deflated and their function would no longer be to tightly grip) and narrower (so as not to block the potential view of the proximal surfaces of the folds)." (para. 188)

79. Dr East, when comparing Hitoshi with the Patent, said nothing about inflation or deflation. And they were not put to him in cross-examination. Mr Campbell submitted that accordingly the whole matter of intubation and withdrawal of the colon had not been established on the evidence.

80. I disagree. Dr East elsewhere acknowledged the practices of deflation and inflation. In his first witness statement he contemplated the possibility that the physician carrying out the colonoscopy might inflate the colon (presumably during withdrawal) such that fins in Hitoshi would not all be in contact with the colon wall (at para. 137). This was exactly Professor Rees' point.

81. In cross-examination Dr East was taken to a chapter from *Colonoscopy Principles and Practice*, published in 2003, which he said was one of the standard texts on colonoscopy. He added (day 2, 110) that by 2010 not much had changed, particularly in relation to insertion. I note that on the page he was referred to the authors set out steps to be followed when conducting intubation, specifically from the sigmoid to the descending colon, including this:

> "3. Deflate the colon (without losing the view) to shorten it and make it as pliable as possible."

82. In re-examination Dr East was taken again to the same page of *Colonoscopy Principles and Practice*. He said (Day 2, 215-216) that it set out a classical description of the series manoeuvres that one can apply to try and straighten a colonoscope (and thereby the colon, during intubation). He added that this would include "deflating the colon a little".

83. Earlier, in cross-examination, Dr East had maintained that the level of grip of the projecting fins in Hitoshi would serve to evert colonic folds on withdrawal as claimed in the Patent. In fact he said that he found it difficult to conceive that they would not (day 2, 183-184). However, he might have said this having ignored deflation and inflation, or possibly he was making some other unstated assumption.

84. I have no doubt that Professor Rees's evidence on this point was accurate. The practice of deflating the colon during intubation and inflating it during withdrawal was usual in May 2010 and in consequence projecting elements that are of a length, shape and flexibility to serve the function of gripping the colon wall during intubation are not likely to be suitable for everting folds during withdrawal.

85. I find that the skilled team reading Hitoshi would have taken the technique represented in Figures 6-8 to be a process carried out in a deflated colon, whereas visualisation during withdrawal, as contemplated in the Patent and shown in Figure 12C, will be carried out in an inflated colon.

86. I accept what Professor Rees said in paragraph 198 of his first witness statement:

> "The projections which were suitable for gripping the colon wall for the purposes of concertinaing the deflated colon during the intubation phase would not be suitable for improving visualisation of the colon walls during the withdrawal phase."

87. Putting this another way (going back to Professor Rees's paragraph 188 quoted above) the skilled team would have understood the projecting fins of Hitoshi to be of a length, shape, flexibility and a position relative to the end of the endoscope cuff such that they were suitable for gripping the colon wall during intubation. It is far from inevitable that such projecting elements would satisfy the requirements of amended claim 1 of the Patent.

88. The third difficulty with Cantel's argument is that it is not legitimate to compare Figures 6-8 of Hitoshi with Figure 12C of the Patent and conclude that they are delivering the same information just because they look similar. Figures in a patent are as much part of the patent's disclosure as any other. But they are generally diagrammatic, as in Hitoshi and the Patent. They are to be interpreted by reference to their respective written descriptions.

89. Figures 6-8 of Hitoshi would be understood to show projecting fins which must be of a length, shape, flexibility and position to grip the colon wall during intubation so that the colon may be straightened, as shown in those figures. They would not be interpreted as if they were photographs displaying projecting elements of the precise length, shape and position required.

90. The skilled team looking at Figure 12C in the Patent would similarly understand that the projecting elements are not illustrated with precision. The team would have in mind the idea that the elements must be of length, shape, flexibility and position suitable for everting the colonic folds during withdrawal, so as to improve visualisation of the proximal surfaces.

91. The information that the skilled person would derive from Figures 6-8 of Hitoshi is not the same as that which would be derived from Figure 12C of the Patent.

92. For those three reasons I find that amended claim 1 is not anticipated by Hitoshi.

Hiroki and Moriyama

93. In closing Mr Campbell accepted that if Cantel did not succeed in its argument that amended claim 1 lacked novelty over Hitoshi, it could not succeed by relying on either Hiroki or Moriyama.

Inventive step

The law

94. The only point of law that arose on inventive step concerned secondary evidence. There was no plea of commercial success by Arc. Mr Campbell submitted that there was nonetheless an attempt by Arc to ramp up its argument on inventive step by smuggling in evidence of how well the Endocuff and Endocuff Vision had done in the marketplace.

95. Mr Alexander said that the point he wished to make was the one often relied on: if the claimed invention was obvious, why was it not done before? He submitted that the relevance of such an argument did not depend on proving commercial success.

96. Mr Alexander referred to *Schlumberger Holdings Ltd v Electromagnetic Geoservices AS* [2010] EWCA Civ 819; [2010] RPC 33, particularly the passage in which Jacob LJ quotes with approval the list of questions set out by Laddie J in *Haberman v Jackel International Ltd* [1999] FSR 683, at 699-701. Leaving out the annotations, they were:

> (a) What was the problem the patented development addressed?
>
> (b) How long had that problem existed?
>
> (c) How significant was the problem seen to be in the trade?
>
> (d) How widely known was the problem and how many were likely to be seeking a solution?
>
> (e) What prior art would have been likely to be known to all or most of those who would have been expected to be involved in finding a solution?
>
> (f) What other solutions were put forward in the period leading up to the publication of the patentee's development?
>
> (g) To what extent were there factors which would have held back the exploitation of the solution even if it was technically obvious?
>
> (h) How well has the patentee's development been received commercially?
>
> (i) To what extent can it be shown that the whole or much of the commercial success is due to the technical merits of the development, i.e. because it solves the problem.

97. To these, Jacob LJ in *Schlumberger* (at [81] to [83]) added two further questions:

> (j) What was the reaction of experts at the time of the invention, both before and after?
>
> (k) Has another party thought the development sufficiently important to apply itself to patent the development?

98. In *Haberman* Laddie J was considering whether an argument of commercial success carried any force and questions (h) and (i) seem to have had that solely in mind. But courts will entertain arguments based on the remainder of those questions even where there has been no plea of commercial success.

99. The relevance of questions (b) to (g) rests on the problem having been seen by those in the industry at the priority date as warranting at least some time and money being spent on trying to solve it. In the real world this generally means that those in the

industry would have appreciated at the priority date that the solution was of commercial value. If no commercial value was attached to the solution up to the priority date, the fact that the problem was not solved earlier says little about whether it was obvious – either way, it was not worth bothering about.

100. Strictly, therefore, question (a) and another question – was the problem seen by those in the industry to warrant at least some time and money being spent in trying to solve it? – come first as preliminary questions. If there are appropriate answers to those, (b) to (g) follow on. (Laddie J intended question (c) to incorporate the further preliminary question I have set out above. Perhaps pedantically, I would separate them out and leave (c) to be about the extent to which those in the industry were prepared to devote their efforts on solving the problem at the priority date, by itself relevant.)

101. An invention could of course be made without realising there was a problem at all, never mind recognising the commercial value in solving it. But in such instances the answer to (a) would be 'none that the industry was aware of', and questions (b) to (g) would have no bearing on the assessment of inventive step.

102. There can sometimes be a broad-brush assumption that the parties would not be spending time and money litigating the patent in suit if the claimed invention were not of commercial value and that the commercial potential must have been apparent in the industry at the priority date. The preliminary questions are then presumed answered and possibly also (c). Such a presumption, if adopted, is plainly rebuttable.

103. In the present case there was no evidence directly addressing the commercial appreciation of those in the industry at the priority date regarding the technical development claimed in the Patent. There was an answer given in passing by Mr Hansen, now CEO of Cantel, in which he said that when Cantel distributed the Endocuff, they did so at a loss. But the fact of this litigation suggests that the parties today believe that Arc's claimed invention has commercial value. Also, I have found that for at least a decade before the priority date the skilled team would have wished for the best feasible visualisation of the wall of the colon, particularly of the proximal surfaces of the folds. The evidence as a whole gives me no reason to doubt that at the priority date those in the industry would have believed that a device which improved visualisation in such a way would be of potential commercial value. The two preliminary questions are answered. The others (apart from (h) and (i)) are relevant to the assessment of inventive step in this case.

104. Despite relying on *Schlumberger*, Mr Alexander did not go through the questions one by one. He ran some of them together under the general inquiry: why was Arc's invention not made before? He was entitled to do that even though there was no plea of commercial success.

105. It may not be often that a plea of commercial success will provide a more persuasive argument in favour of an alleged inventive step than could be afforded by addressing all or some of questions (a) to (g), (j) and (k) above without reference to commercial success. Secondary evidence (and primary evidence on inventive step, for that matter) works, if at all, by inference. An inference drawn from commercial success enjoyed some time after the priority date will be more remote than most.

The two arguments on inventive step

106. Cantel put their overall argument on inventive step in two ways. The first was that even a skilled team with no thought of improving ADR or better visualisation would have contemplated obvious variations of the prior art, thinking only about improved intubation. In doing so the skilled team would have arrived at a product within the scope of amended claim 1.

107. The second argument was based on the skilled team having in mind at the priority date the desirability improving the visualisation of colonic folds during withdrawal. Starting with the prior art, it would have been obvious to modify any of the three devices to make at a product within amended claim 1.

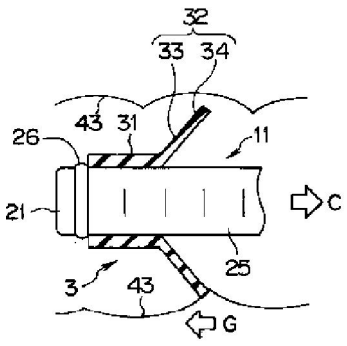
Hitoshi – amended claim 1

108. Cantel's first argument depends on the idea the skilled person would have believed that the projecting fins of Hitoshi were variable in position, length, flexibility and shape. Then, only with improved intubation in mind, among the obvious variants was a combination which would create a product within amended claim 1.

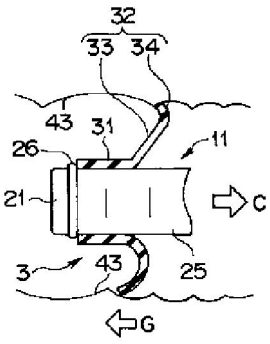
109. The variables are related. For instance, if the fins were sufficiently near the tip of the endoscope to evert folds within the viewing field of the camera, they may be too wide (see Figures 2 and 11) and thus obscure the folds. Or they may be sufficiently narrow but too far back. Or in either case they may be too short to evert the folds or alternatively be of the wrong flexibility, and so on.

110. Dr East provided no real support for this argument. He referred to Figures 19 and 20 which, he said, best show why Hitoshi discloses the eversion of colonic folds enabling their proximal surfaces to be viewed:

【図１９】



【図２０】



111. This assertion is open to the objections I have discussed in relation to the argument on novelty. Otherwise, the evidence did not support the conclusion that the skilled person would have found it obvious to select the right combination of properties for the projecting fins of Hitoshi and thereby, by chance, make the fins suitable for everting colonic folds during withdrawal so as to improve visualisation of the proximal surfaces. In fact, this was unlikely since *ex hypothesi* the skilled team would concentrate on the fins being suitable for anchoring the endoscope to the wall of a probably deflated colon during intubation.

112. Cantel's second argument requires the skilled team to have (a) considered Hitoshi as a suitable starting point for a device to improve visualisation during withdrawal and (b) thought it obvious to make the necessary combination of changes to achieve that result.

113. The experts differed. In his witness statement Dr East asserted that the skilled team reading Hitoshi at the priority date, having a desire for better ADR, would be motivated to explore adapting it to improve visualisation (para. 144). Mr Alexander suggested in closing that in the course of cross-examination (day 2, 189-193) Dr East became rather tentative about this. That may be right, and anyway, to my mind Dr East's evidence on this point had the flavour of hindsight.

114. I am supported in this view by the secondary evidence. Those in the industry most likely to think of the invention at the priority date were the three main suppliers of colonoscopes: Olympus, Fujifilm and Pentax. They presumably have large and well-funded research departments. One of them, Olympus, was responsible for all three items of prior art although, I was told, none led to a product on the market. Arc's case was that since none of these three giants thought of the invention, neither would have the skilled team.

115. Mr Campbell presented a number of reasons why this secondary evidence should be discounted, taking Olympus as the prime example. First, there was no way of knowing what Olympus's commercial motivations may have been and how these may have affected what they did with Hitoshi's work. Secondly, Olympus is a distributor of the Endocuff Vision, so Arc could have invited it to give evidence and its failure to do so was telling. Thirdly, when Hitoshi's work was done there was less interest in ADR. Fourthly, the prior art was not common general knowledge and no products embodying that work had been marketed, so the skilled team would not have been aware of it.

116. I find none of these arguments compelling. The logic of the first is that absent knowledge of the commercial policy of other players in the relevant industry, secondary evidence of this kind is valueless. That seems to me to be contrary to the law as stated by the Court of Appeal in *Schlumberger*. It is true that Olympus might have had commercial motivations that steered the company away from exploiting Hitoshi to make an aid to visualisation during withdrawal. But anything that improved ADR when using its colonoscopes would certainly have been of interest to Olympus and its commercial policy would have been idiosyncratic indeed to ignore an obvious route to better ADR. As I have said, all secondary evidence works by inference. In my view, where such evidence exists, the job of the court is to give it appropriate weight, if any, depending on the strength of the inference.

117. With regard to the second argument, an inference having been established, the evidential burden rested on Cantel to rebut it. Besides, I would not wish to suggest that any party is *obliged* to explore comprehensively the commercial motivations of other parties in the relevant industry. As has been said in a different context, life is too short.

118. As to the third argument, it was common ground that at least by the priority date there was a lively interest in ADR. Even so, Olympus appears not to have seen its research

work on improving intubation as a worthwhile basis for improving visualisation of adenomas on withdrawal. Nor did Pentax or Fujifilm.

119. Finally, it is of no matter that none of the prior art was common general knowledge. The state of knowledge of the skilled person is not relevant here. Secondary evidence of this type is about what real people in the industry did or failed to do and what, if anything, may be inferred from that. Olympus undoubtedly had access to the prior art. It is virtually certain that the research departments of Pentax and Fujifilm did too.

120. In my view the secondary evidence in the present case is persuasive. It is likely that if the product claimed in amended claim 1 had been obvious to the skilled team at the priority date, it would have been likewise obvious to the relevant research teams at Olympus, Pentax or Fujifilm. There can be no certainty, but I think that Olympus, or alternatively Pentax or Fujifilm, would then have developed a product along the lines of the Endocuff or Endocuff Vision. On a clear balance of probabilities, the secondary evidence supports Arc's case that there was an inventive step.

121. This is also consistent with what happened at the start of the Endocuff project. The history of a claimed invention can be another matter to be added to the non-exhaustive list of factors which a court may take into account by way of secondary evidence. Mr Axon explained in cross-examination (day 5, 592-5) that a prototype called 'Bog Brush 1', a name which would reassure any patient, was used on Mr Axon's forgiving father. Bog Brush 1 had been created to improve caecal intubation rates, not ADR. It was happenstance that Mr Axon noticed that a cuff of this design improved visualisation of the colonic folds during withdrawal. Though I give it less weight, what Mr Axon did not expect would probably not have been expected by the skilled team either.

122. I find that amended claim 1 does not lack inventive step over Hitoshi.

Hiroki – amended claim 1

123. Hiroki and Moriyama both disclose cuffs to be put on to the end of an endoscope. The title of the invention in Hiroki, like that in Hitoshi, is 'Endoscope insertion assistance tool'. It is solely concerned with intubation and is further from the claimed invention than Hitoshi because the projections disclosed are further from the tip of the endoscope. Amended claim 1 is not obvious over Hiroki.

Moriyama – amended claim 1

124. The title of Moriyama is 'Endoscope Hood'. The hood is similar to the caps known in the prior art. One embodiment has tongue portions which protrude rearward of the main part of the cuff and are used to ease the removal of the hood from the endoscope. The tongue portions have the further function of assisting with intubation. The distal end of the hood (from the clinician's perspective) projects beyond the tip of the endoscope to assist in the maintenance of a predetermined distance between the lens of the endoscope and the wall of the bowel. Moriyama is concerned with visualisation to that extent.

125. Cantel relied on Figure 5 of Moriyama:

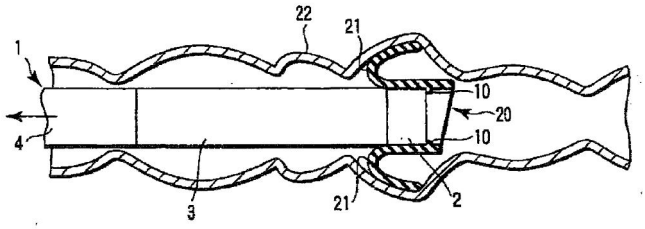


FIG. 5

126. The suggestion was that the tongue portions, marked 21 and here shown to fold towards the tip of the endoscope, could be made longer and of a position, flexibility and shape to evert folds during withdrawal and thus enable the viewing of the proximal surfaces. Dr East conceded that this would be challenging (day 2, 199).

127. With regard to Cantel's first argument (no thought of everting colonic folds by the skilled team), there was provided no ground for supposing that the skilled team would wish to adapt Moriyama in this way with only the functions of easily removing the hood and assisting with intubation in mind. As to the second, even if the skilled team thought about using Moriyama as a starting point for finding a way to evert colonic folds so as to visualise their proximal surfaces, I take the view that, for the same reasons as apply to Hitoshi, it was not obvious to select the necessary modifications to the tongues such as to make a product within amended claim 1.

Conclusion on amended claim 1 and inventive step

128. Amended claim 1 does not lack inventive step over any of the prior art.

Conditional amendment to claim 1 of the UK Patent

129. Since I have found that amended claim 1 is not obvious, neither is UK conditionally amended claim 1. I will, however, consider briefly the further amendments.

130. In relation to the argument that UK conditionally amended claim 1 lacks inventive step over Hitoshi, in closing Arc relied on the following additional features of that claim:

(i) 8 evenly spaced projecting elements, as opposed to a plurality of them;

(ii) the 8 elements should be in the form of tapered bristles.

131. The argument goes forward on the basis that it was obvious to modify the teaching of one or all of the items of prior art to make a product within amended claim 1. On the hypothesis that the projecting elements have all the necessary qualities, Arc provided no reason why there would be invention in making them tapered bristles. Dr East thought that there would be no invention in doing so.

132. Nor do I think that the evidence supported the argument that having 8 such bristles, as opposed to a plurality of them, was inventive. Hitoshi's examples showed 4 wide fins, but on the present hypothesis the skilled team believed it to be obvious to replace these with long and narrow elements. Albeit in the context of the case on designs, it

was common ground between the experts that there was freedom to select any number of projecting elements between about 4 and 12.

133. Similar arguments were advanced by Arc in relation to the inventive step of UK conditionally amended claim 1 over Hiroki and Moriyama and for the same reason I do not accept them.

134. In my view, UK conditionally amended claim 1 is not separately inventive over claim 1 of the unconditional application to amend the UK Patent.

Other claims

135. In closing Arc did not advance an argument of separate inventiveness of any of the other claims over claim 1 of the two unconditional applications to amend.

Added matter

The law

136. The law on added matter was reviewed by Floyd LJ (with whom Longmore and Lewison LJJ agreed) in *AP Racing Ltd v Alcon Components Ltd* [2014] EWCA Civ 40; [2014] RPC 27:

> "[9] In the end the question is the simple one posed by Jacob J. (as he then was) in *Richardson-Vick Inc's Patent* [1995] R.P.C. 568 at p.576 (approved by him as Jacob L.J. in *Vector Corp v Glatt Air Techniques Ltd* [2007] EWCA Civ 805, [2008] R.P.C. 10 at [4]):
>
> > 'I think the test of added matter is whether a skilled man would, upon looking at the amended specification, learn anything about the invention which he could not learn from the unamended specification.'"

137. Intermediate generalisations were explained by Kitchin LJ (with whom Laws and Etherton LJJ agreed) in *Nokia Corporation v IPCom GmbH & Co KG* [2012] EWCA Civ 567; [2013] RPC 5.

138. In the present case Arc raised a general and primary defence to Cantel's allegations of added matter. It was that Cantel had confused the scope of a claim with disclosure. I discussed this in *Edwards Lifesciences* at [227] to [232], relying in particular on what Floyd LJ said in *AP Racing*. For the reasons given in *Edwards Lifesciences*, I will also here assume that a claim covering an embodiment would imply to the skilled addressee that the invention as disclosed in the Patent includes such an embodiment.

Objections raised to amended claim 1

139. Cantel drew attention to the final part of the claim:

> "… wherein the projecting elements in a distal ring are adapted to flare outwards on withdrawal from the colon to keep the instrument tip in the central part of the colon as the instrument moves backwards, and to evert colonic folds enabling their proximal surfaces to be viewed."

140. Cantel raised three arguments on this part of the claim. Similar objections were raised by the Comptroller of the UK Intellectual Property Office in a letter dated 5 October 2017:

(1) If 'adapted' means more than 'suitable for', the claim adds matter.

(2) The application as filed is silent as to how the projecting elements are adapted to flare outwards in use.

(3) The limitation in the claim that the projecting elements "in a distal ring" are adapted to flare outwards adds matter.

141. Cantel also referred to an earlier part of amended claim 1 (which appears also in claim 1 as granted). I quote it below with the addition of the letters (a) and (b) to assist in the explanation of Cantel's argument:

> "…the projecting elements being moveable about their hinged bases by (a) an angle of between 0^o, wherein the tips of the projecting elements point towards a proximal end of the colonoscope, to an angle of 170-180^o wherein that the tips of the projecting elements point towards the distal end of the colonoscope or (b) any angle between 0 to 170-180^o, …"

142. Cantel's further argument, not one raised by the Comptroller, was:

(4) The alleged support for this part of the claim is at page 11 of the application as filed, penultimate paragraph. However the disclosure in the application was limited to a preferred embodiment having further limitations. That context has been abandoned in amended claim 1 and therefore constitutes an intermediate generalisation.

Discussion

143. I have found that 'adapted to' means 'suitable for' in amended claim 1. The first objection falls away.

144. With regard to the second, the application as filed includes the following at page 22:

> "In use, the distal row of the projecting elements are designed to flare outwards on withdrawal. They keep the instrument tip in the central part of the bowel lumen as the instrument moves backwards, gently holding the mucosa to prevent the tip from flipping backwards, they maintain position during therapy and improve all-round visualisation. During extubating they evert the folds enabling their proximal surface to be viewed."

145. As I have indicated, this passage would be understood to mean that the distal row of projecting elements are suitable for flaring outwards on withdrawal. The skilled addressee would gain the same understanding from amended claim 1.

146. The third objection appears to be based on a construction of amended claim 1 which would require the distal ring of projecting elements to be adapted to flare outwards simultaneously – the simultaneous requirement being new. I do not think that this is correct. Both amended claim 1 and the application as filed would be interpreted by

the skilled addressee to mean that the projecting elements must all be adapted to flare outwards, but not necessarily at the same time.

147. As to the fourth objection, Arc submitted that the error in Cantel's argument on intermediate generalisation lay in Cantel's assertion that the support for the relevant part of claim 1 as granted, and amended claim 1, was to be found on page 11 of the application as filed. Arc pointed out that there was support on page 10 and that this part of the disclosure was not contained within a preferred embodiment. I agree.

148. On page 10 the application states that the projecting elements are moveable between at least three, and in some embodiments four positions. This is a general disclosure, not confined to any particular embodiment. In the second position, which occurs when the endoscope is pushed into the lumen (intubation), the projecting elements will be substantially parallel to the longitudinal axis of the endoscope. This is the angle of 0^o referred to in the claim. In the fourth, which occurs during withdrawal, the tips point towards the distal end of the endoscope. This is the angle of $170\text{-}180^o$ wherein the tips of the projecting elements point towards a distal end of the colonoscope found in the claim. Since the projecting elements are moveable between those positions, the angle may be any between 0 and $170\text{-}180^o$. This part of the claim provides no further information to the reader than was available from the application as filed.

Objections raised to UK conditionally amended claim 1

149. Cantel raised allegations of added matter against UK conditionally amended claim 1. They were that the application as filed disclosed neither:

(1) tapered bristles, nor

(2) 8 evenly spaced elements positioned in a single ring at the distal end of the elongate tubular member.

150. The application as filed does not refer to tapered bristles, although what is meant by a bristle is illustrated in Figure 8A. Mr Alexander relied on Figures 11A-E and said that these show tapered bristles. That may be so, but they are shown in the context of all the other features of the covers illustrated in Figure 11. Arc's argument was that having seen tapered bristles shown in Figure 11, the reader of the application would necessarily understand that such bristles could be used for embodiments other than those illustrated in Figure 11. I don't see why. Amended claim 1 discloses tapered bristles in the context of a wider range of embodiments. This is an intermediate generalisation that adds information.

151. Turning to the second allegation, there is a disclosure on page 13 of the application as filed that the projecting elements may be in a single ring. Cantel argued that there was no disclosure of the ring with 8 elements at the distal end of the elongate tubular member. Mr Alexander again referred to Figure 11 which, he said, showed what was meant by 8 elements at the distal end of the elongate tubular member. But Figure 11 shows two rings. Embodiments having the combination of 8 elements in a single row at the distal end of the elongate member are disclosed in the claim but not in the application as filed.

Conclusion on added matter

152. Amended claim 1 does not disclose added subject-matter. UK conditionally amended claim 1 does.

Lack of clarity

Amended claim 1

153. Cantel alleged that the words 'adapted to' led to a lack of clarity. I have dealt with that above.

154. Cantel also adopted an objection raised by the Comptroller in the IPO's letter of 5 October 2017 which applies only to the proposed unconditional amendment to claim 1 of the UK Patent: it is not clear how the requirement that the projecting elements are to 'flare outwards', introduced by the proposed amendment, differs from the earlier requirement in the claim that the projecting elements are, in a certain position, 'fanned out'. In my view, the skilled person reading the specification as a whole would understand that projecting elements flared out means the same thing as projecting elements fanned out. For neatness, within claim 1 it would be better to stick to one term or the other, but I see no formal lack of clarity.

UK conditionally amended claim 1

155. No objections were raised other than those made in relation to added matter.

Lack of support

Amended claim 1

156. The only new objection raised under this head was that the passage in the specification on which Arc relied to support the key final part of amended claim 1, the third complete paragraph on page 22 of the PCT Application as reproduced in paragraph 91 of the EP specification, is a description given in the context of Figures 12A to D. Cantel argued that introducing general limitations based on that passage constituted an intermediate generalisation.

157. I disagree. In my view the reader of paragraph 91 would understand it to refer generally to the invention claimed. References earlier and afterwards to Figure 12 are intended to assist the reader in understanding what is being said, but would not be taken to indicate that Figure 12 represents the only embodiments possible.

UK conditionally amended claim 1

158. No objections were raised other than those made in relation to added matter.

Infringement

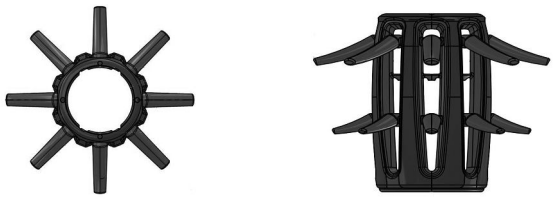
159. In their closing submissions Cantel did not submit that any version of the AmplifEYE fell outside the claims of the Patent and the UK Patent as unconditionally proposed to be amended.

Conclusion on the Patent case

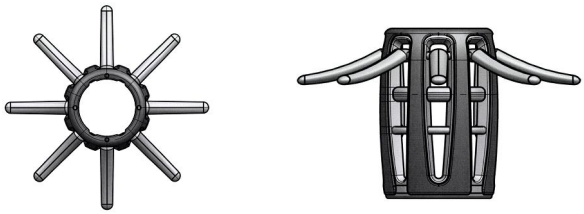
160. Arc has permission to amend the Patent and the UK Patent in the forms of the unconditional applications to amend. In those forms both Patents are valid and infringed.

Registered Community Designs

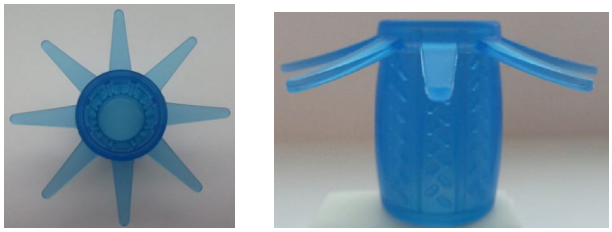
161. On 27 April 2011 Arc applied for and was subsequently granted the Endocuff RCD. Two of the images registered are shown below:



162. On 28 August 2014 Arc applied for and was subsequently granted the Vision RCD. These are two of the images:



163. Arc alleges that both are infringed by sales of Cantel's AmplifEYE, which looks like this:



164. In their Particulars of Claim Cantel seek a declaration of non-infringement in relation to all versions of the AmplifEYE.

The Regulation

165. So far as is relevant, Council Regulation No. 6/2002 ("the Design Regulation") provides as follows:

> Recital 14:
>
> *The assessment as to whether a design has individual character should be based on whether the overall impression produced on an informed user viewing the design clearly differs from that produced on him by the existing design corpus, taking into consideration the nature of the product to which the*

design is applied or in which it is incorporated, and in particular the industrial sector to which it belongs and the degree of freedom of the designer in developing the design.

Article 3(1)(a):

… "design" means the appearance of the whole or a part of a product resulting from the features of, in particular, the lines, contours, colours, shape, texture and/or materials of the product itself or its ornamentation.

Article 4(1):

A design shall be protected by a Community design to the extent that it is new and has individual character

Article 5:

1. A design shall be considered to be new if no identical design has been made available to the public:

…

> *(b) in the case of a registered Community design, before the date of filing of the application for registration of the design for which protection is claimed, or, if priority is claimed, the date of priority.*

2. Designs shall be deemed to be identical if their features differ only in immaterial details.

Article 6:

1. A design shall be considered to have individual character if the overall impression it produces on the informed user differs from the overall impression produced on such a user by any design which has been made available to the public:

…

> *b) in the case of a registered Community design, before the date of filing the application for registration or, if a priority is claimed, the date of priority.*

2. In assessing individual character, the degree of freedom of the designer in developing the design shall be taken into consideration.

Article 7:

1. For the purpose of applying Articles 5 and 6, a design shall be deemed to have been made available to the public if it has been published following registration or otherwise, or exhibited, used in trade or otherwise disclosed, before the date referred to in Articles 5(1)(a) and 6(1)(a) or in Articles 5(1)(b) and 6(1)(b), as the case may be, except where these events could not

reasonably have become known in the normal course of business to the circles specialised in the sector concerned, operating within the Community.

Article 8

1. A Community design shall not subsist in features of appearance of a product which are solely dictated by its technical function.

Article 10:

1. The scope of the protection conferred by a Community design shall include any design which does not produce on the informed user a different overall impression.

2. In assessing the scope of protection, the degree of freedom of the designer in developing his design shall be taken into consideration.

The case law

Solely dictated by technical function – art.8(1)

166. It has been held by what was then the OHIM Board of Appeal that art.8(1) of the Design Regulation deprives a feature of protection solely where the need to achieve the product's technical function was the only relevant factor when the feature in question was selected to be part of the overall design. If aesthetic consideration played any part, art.8(1) does not bite. This is to be assessed objectively from the standpoint of a reasonable observer. See *Lindner Recyclingtech GmbH v Franssons Verkstäder AB* (R 690/2007-3) [2010] ECDR 1, at [28] to [36].

167. *Lindner* was followed by Arnold J in *Dyson Ltd v Vax Ltd* [2010] EWHC 1923 (Pat); [2010] FSR 39, at [31] and apparently also approved by the Court of Appeal in *Samsung Electronics (UK) Ltd v Apple Inc* [2012] EWCA Civ 1339; [2013] FSR 9, at [31].

168. Since art.8(1), where it applies, deprives a feature of design protection, I think that such features are to be ignored in the assessment of overall impression under art.10(1). This is to be contrasted with the approach to the related question of designer freedom under art.10(2). As discussed below, assessment of the latter is not binary, but more flexible, with greater or lesser weight being attached to similarities or differences in appearance, as may be appropriate.

Scope of protection – art.10

Comparison with the design corpus

169. A registered Community design ("RCD") which is markedly different from any member of the design corpus will confer protection of a scope greater than would be conferred by a RCD only incrementally different from a member of the design corpus, see *Procter & Gamble Co v Reckitt Benckiser (UK) Ltd* [2007] EWCA Civ 936; [2008] FSR 8, at [35(ii)].

170. Designs which are strikingly new in every way will be unusual. More often some features will be commonly found in the design corpus, others not. In such a case the correct approach is to give little or no weight to common features. In *Grupo Promer Mon Graphic SA v OHIM* (Case T-9/07) EU:T:2010:96; [2010] ECDR 7, the General Court said at [72]:

> "… in so far as similarities between the designs at issue relate to common features…, those similarities will have only minor importance in the overall impression produced by those designs on the informed user."

Designer freedom

171. The designer in question is the designer of the RCD, whether considering freedom of design under art.6, see *Proctor v Gamble Co v Reckitt Benckiser (UK) Ltd* [2006] EWHC 3154 (Ch); [2007] FSR 13 at [42], or under art.10, see *Dyson Ltd v Vax Ltd* [2011] EWCA Civ 1206; [2012] FSR 4, at [18].

172. The General Court discussed designer freedom in *H&M Hennes & Mauritz BV & Co. KG v OHIM* (Case T-525/13) EU:T:2015:617; [2015] E.C.D.R. 20 and placed it in the context of the whole assessment of overall impression:

> "[28] As regards the degree of freedom of the designer of a design, it is apparent from the case law that that is determined, inter alia, by the constraints of the features imposed by the technical function of the product or an element thereof, or by statutory requirements applicable to the product. Those constraints result in a standardisation of certain features, which will thus be common to the designs applied to the product concerned (judgment of 9 September 2011 in *Kwang Yang Motor Co Ltd v Office for Harmonisation in the Internal Market (Trade Marks and Designs) (OHIM) - Honda Giken Kogyo (Internal combustion engine)* (T-10/08), judgment of 9 September 2011, not yet reported, at [32], and judgment in *Wristwatch* case EU:T:2013:214 at [112]).
>
> [29] Therefore, the greater the designer's freedom in developing a design, the less likely it is that minor differences between the designs at issue will be sufficient to produce different overall impressions on an informed user. Conversely, the more the designer's freedom in developing a design is restricted, the more likely it is that minor differences between the designs at issue will be sufficient to produce different overall impressions on an informed user. Consequently, if the designer enjoys a high degree of freedom in developing a design, that reinforces the conclusion that designs that do not have significant differences produce the same overall impression on an informed user (judgments in *Internal combustion engine* at [33], and *Wristwatch* case EU:T:2013:214 at [113]).
>
> [30] In the present case, the Board of Appeal correctly found that, in the context of fashion items like handbags, the designer's degree of freedom was high. Moreover, the applicant does not contest that assessment. However, it submits, in essence, that the Board of Appeal erred inasmuch as the 'freedom of the designer' test should have been an integral part of the analysis of the individual character of the contested design and that the Board of Appeal

> inverted the steps involved in that analysis. Accordingly, the applicant maintains that the Board of Appeal's approach of, first, comparing the two designs at issue in order to conclude that they did not produce the same overall impression on the informed user and, secondly, examining the argument relating to the freedom of the designer, is incorrect. Furthermore, it takes the view that the differences between the designs at issue are not significant enough to produce a different overall impression on the informed user.
>
> [31] First, it must be stated that a 'two-step test', such as advocated by the applicant, is not required by either the applicable legislation or the case law.
>
> [32] The text of art.6 of Regulation 6/2002, concerning the assessment of individual character, lays down, in para.1 thereof, the criterion of the overall impression produced by the designs at issue and states, in para.2, that the degree of freedom of the designer must be taken into consideration for those purposes (see para.20 above). It is apparent from those provisions, and in particular from art.6(1)(b) of Regulation 6/2002, that the assessment of the individual character of a Community design is the result, in essence, of a four-stage examination. That examination consists in deciding upon, first, the sector to which the products in which the design is intended to be incorporated or to which it is intended to be applied belong; secondly, the informed user of those products in accordance with their purpose and, with reference to that informed user, the degree of awareness of the prior art and the level of attention in the comparison, direct if possible, of the designs; thirdly, the designer's degree of freedom in developing his design; and, fourthly, the outcome of the comparison of the designs at issue, taking into account the sector in question, the designer's degree of freedom and the overall impressions produced on the informed user by the contested design and by any earlier design which has been made available to the public (see, to that effect, judgment of 7 November 2013 in *Budziewska v Office for Harmonisation in the Internal Market (Trade Marks and Designs) (OHIM) - Puma (Bounding feline)* (T-666/11) EU:T:2013:584 at [21] and the case law cited).
>
> [33] As is apparent from the case law and from the case law cited in [29] above and referred to by the applicant itself, the factor relating to the designer's degree of freedom may 'reinforce' (or, *a contrario*, moderate) the conclusion as regards the overall impression produced by each design at issue. It is not apparent either from the alleged pattern which the applicant identifies in the case law or even from the extract from the judgment of the *Bundesgerichtshof* (Federal Court of Justice, Germany) reproduced in para.29 of the application that the assessment of the designer's degree of freedom constitutes a preliminary and abstract step in the comparison of the overall impression produced by each design at issue."

173. As explained, similarities between the designs of corresponding parts of two products which are attributable to design constraints will be given little significance in the comparison of the overall impressions they produce. Though where the entirety of each design is subject to design constraints, minor differences between them can be sufficient to produce different overall impressions.

174. However, where there are at least some elements in respect of which the designer had a high level of design freedom, attention is likely to be focussed on those parts with their greater potential for variability. Similarities cannot be explained away by design restraints and will tend towards the view that the overall impressions do not differ, whereas differences will lead towards the opposite conclusion.

175. Freedom of the designer should form part of the assessment of overall impression according to the four-stage examination set out in *H&M Hennes*.

176. The General Court has stated in *Sachi Premium-Outdoor Furniture Lda v OHIM* (T-357/12) EU:T:2014:55 that a restriction on the designer's freedom due to design trends is not relevant:

> "[23] … according to the case-law cited in paragraph 19 above, the designer's degree of freedom may be limited by the constraints of the features imposed by the technical function of the product or by statutory requirements applicable to the product. However, a general design trend cannot be regarded as a factor that restricts the designer's freedom (Joined Cases T-83/11 and T-84/11 *Antrax It* v *OHIM – THC (Radiators for heating)* [2012] ECR, paragraph 95)."

Whether the informed user discriminates between elements of the design

177. A comparison between designs must be between the whole of each design. Aside from the influence of the design corpus and matters of designer freedom, a question arises whether the informed user may be taken to attach more significance to some elements of an RCD than others. Intuitively that will be the case since one point of assessing overall impression through the eyes of an informed user is likely to be that an informed user might appreciate that some elements of the design of a product matter more. Therefore similarities or differences in relation to those elements carry more weight.

178. This seems to be what the General Court had in mind in *Sachi Premium-Outdoor Furniture Lda v OHIM* (T-357/12) EU:T:2014:55. A design for armchairs and loungers was alleged to be invalid over an earlier design for the same products. The Board of Appeal had found that the only relevant difference between the two designs in issue was that the later design included three cushions:

> "[37] In the contested decision, the Board of Appeal took account of the fact that the cushions were not a fixed element, but elements that were easily separated from the main product, and that they were often sold and purchased separately, at a relatively low cost compared to that of the structure of an armchair. It inferred therefrom that those factors decreased the importance that could be attributed to the cushions in assessing the overall impression and that the informed user would attribute far more importance to the overall impression produced by the structures of the armchairs. The Board of Appeal added that the informed user might perceive the cushions as a mere optional accessory and that they could hardly be considered to be 'a significant part of the design'.

> [38] The Board of Appeal was right in taking the view that, because they are not fixed, the informed user will perceive the cushions as less important and be more sensitive to the overall structure of armchairs. It found that the overall impression produced by the designs at issue was dominated by the structure of the armchairs itself and not by the cushions, which could be regarded as secondary elements. Contrary to what the applicant claims, it is not irrelevant to assessing the individual character of the contested design that the cushions are removable elements."

179. Some design elements are thus more equal than others. An informed user may discriminate between elements of an RCD when comparing each with the corresponding element of an accused design. Greater or lesser significance may be attached to similarities or differences, as the case may be, depending on the practical significance of the relevant part of the product or on other reasons affecting the degree to which their appearance would matter to the informed user. What could be taken as an extreme example of this came in *Bell & Ross BV v OHIM* (T-80/10) EU:T:2013:214 (the so-called *Wristwatch* case referred to by the General Court in *H&M Hennes*). The design in issue was in fact of a watch which would be embedded in the dashboard of an aeroplane, leaving only the front face visible. The General Court said that those elements of the RCD that would not be visible in use, in particular the thickness of the case, would have little influence in the overall design produced on the informed user (at [133]-[135]).

180. There may be other reasons for discrimination aside from practical significance and visibility, see *European Union Design Law*, Stone, 2nd ed., at 12.137(j).

Summary of the approach to comparison of overall impressions

181. I here adapt the four-stages prescribed by the General Court in *H&M Hennes* for assessing the individual character of a Community design to the comparison of an RCD with an accused design, adding other matters relevant to the present case. The court must:

(1) Decide the sector to which the products in which the designs are intended to be incorporated or to which they are intended to be applied belong;

(2) Identify the informed user and having done so decide

(a) the degree of the informed user's awareness of the prior art and

(b) the level of attention paid by the informed user in the comparison, direct if possible, of the designs;

(3) Decide the designer's degree of freedom in developing his design;

(4) Assess the outcome of the comparison between the RCD and the contested design, taking into account

(a) the sector in question,

(b) the designer's degree of freedom, and

(c) the overall impressions produced by the designs on the informed user, who will have in mind any earlier design which has been made available to the public.

182. To this I would add:

(5) Features of the designs which are solely dictated by technical function are to be ignored in the comparison.

(6) The informed user may in some cases discriminate between elements of the respective designs, attaching different degrees of importance to similarities or differences. This can depend on the practical significance of the relevant part of the product, the extent to which it would be seen in use, or on other matters.

Discussion

The relevant sector

183. The relevant sector is colonoscopy.

The informed user

184. It was common ground that the informed user is a clinician who uses devices such as the Endocuff and AmplifEYE to perform colonoscopies.

The design corpus

185. The only items referred to in relation to the Endocuff RCD were the transparent endoscope caps. The single addition to the corpus for the Vision RCD was the Endocuff.

186. The degree of awareness of the corpus was not an issue. It was assumed that the informed clinician would have been well aware of the caps in April 2011 and in addition the Endocuff in August 2014.

The level of attention paid by the informed user in the comparison

187. A colonoscopy is not a trivial procedure. The equipment used will be considered with care and the level of attention paid by the informed clinician in comparing designs of items such as the Endocuff and the AmplifEYE will have been particularly high. He or she had the opportunity to compare the products side by side.

Solely dictated by technical function

188. It is convenient to take next whether any of the features of either RCD fall out of consideration because of art.8(1) of the Design Regulation.

189. Cantel argued that all of the features did because the appearance of each of them was dictated solely by one or other of the functions of a colonoscope cover.

190. I reject this. The evidence convincingly showed that, viewed objectively, aesthetic considerations would be seen to have played a part in the design of all the features of

both RCDs. Although the most important considerations when designing a cover for a colonoscope will be functional, it was clear that the designer will always also have in mind aesthetic considerations. Clinicians resist using a product that might cause concern to a patient about to receive it. The experts were agreed on this. Professor Rees said that "aesthetics are really, really important" (day 3, 381). Dr East said that what the products look like mattered in terms of their acceptability to both medics and patients (day 2, 211).

191. Since the design of the whole of the Endocuff and Endocuff Vision had to be aesthetically acceptable, I find that a reasonable observer would believe that none of the features shown in the RCDs was dictated solely by its technical function.

Designer freedom

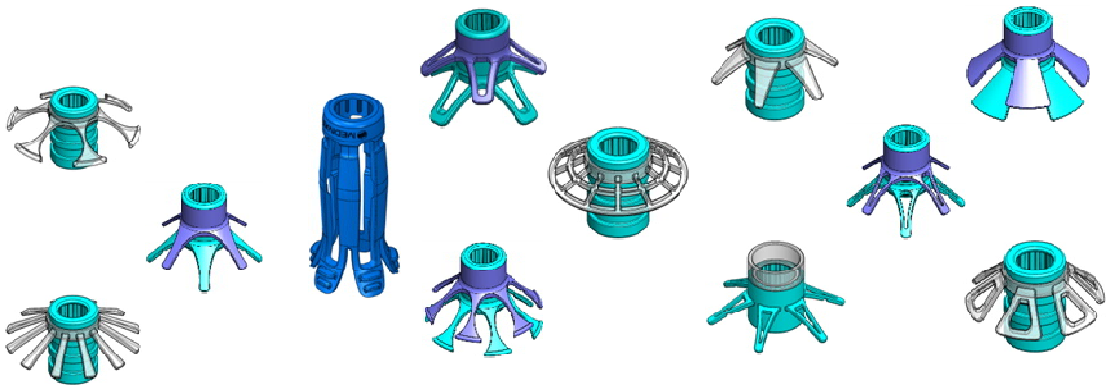
192. In his closing argument, Mr Campbell submitted that freedom of design was limited in respect of both RCDs in two ways. First, there were absolute constraints in that the cover must fit the endoscope and its projecting elements must touch the walls of the colon. Secondly, there were less rigid constraints in that the designer would be bound to arrive at a design with between 4 and 18 projecting elements and the shape must not hinder insertion.

193. As to the alleged absolute constraints, the need to fit the colonoscope would affect the shape and dimensions of the interior surface of the central portion, that part in contact with the colonoscope tip. Absolute (as opposed to relative) dimensions form no part of the RCDs. The interior surface must be broadly round in plan view, but could be smooth or ribbed (as appears to be the case) and the ribs may be of different shapes. I accept, however, that there was some design constraint regarding the interior surface of the central portion. I would add that there is also a degree of design constraint in relation to the exterior shape of the central portion. It must be of a shape that facilitates intubation and withdrawal – which suggests a barrel shape.

194. The projecting elements must touch the walls of an inflated colon, but that does not put an absolute limit on their length since they must be flexible.

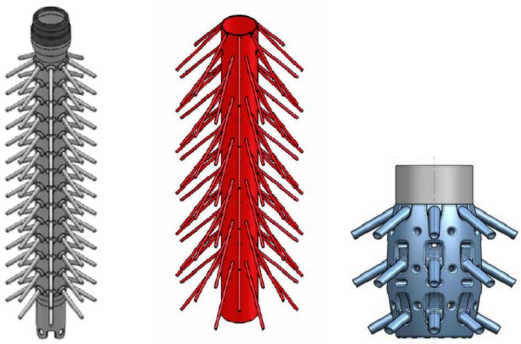
195. Mr Campbell's suggested less rigid constraints are barely constraints at all.

196. There was telling evidence in the form of the wide range of designs created by Cantel when coming up with a potential commercial rival to the Endocuff. This suggests a high degree of designer freedom:



197. As will be discussed below, Cantel were driven towards a product which it realised was similar to the Endocuff Vision not for functional reasons, but because of feedback received from the clinicians it consulted. Even assuming that a corresponding market preference would have influenced Mr Axon as designer of the Endocuff Vision RCD (it could not have affected him as designer of the Endocuff RCD), a constraint on freedom caused by a design trend is not relevant (see above).

198. Mr Axon likewise contemplated a variety of candidate designs when creating the Endocuff, including Bog Brush 1 on the right:



199. On this evidence, in relation to both RCDs the designer enjoyed a high degree of freedom in developing his design.

Whether any elements of the designs would be accorded particular significance

200. It emerged from the evidence, as appears from my discussion above in relation to the Patent, that the key design features of products such as the Endocuff, Endocuff Vision and AmplifEYE are the position, length and shape of the projecting elements. In my view the informed clinician would be alive to this and therefore those aspects of the designs would be accorded particular weight in the overall impression they produce.

Overall impression of the Endocuff RCD compared with the design corpus

201. The differences between the Endocuff RCD and the prior art caps are so self-evident that I need spend no time on them. The Endocuff RCD creates a different overall impression and is validly registered.

Overall impression of the AmplifEYE compared with the Endocuff RCD

202. The wide difference between the Endocuff RCD and the design corpus implies a broad scope of protection. Aside from the interior and exterior overall shape of the central barrel, there was a high degree of designer freedom. The informed user would attach most significance to the position, length and shape of the projecting elements.

203. Cantel relied on the following differences between the Vision RCD and the AmplifEYE:

(a) The shapes of the projections.

(b) The lack of slits in the barrel of the AmplifEYE.

(c) The raised internal surface pattern in the barrel of the AmplifEYE.

(d) The cog-like indentations of the inner surface of the barrel of the Vision RCD, absent from the AmplifEYE.

204. When compared to the Endocuff RCD, to these must be added the presence of two rows of projecting elements in the Endocuff RCD, one at the distal end of the barrel and the other near the middle, whereas in the AmplifEYE there is only the distal row.

205. In my view, notwithstanding the wide scope of the Endocuff RCD, the AmplifEYE would produce a different overall impression on the informed user. Significance would be attached to the projecting elements. Apart from anything else, the difference between one and two rows by itself causes the overall impression to be different. The AmplifEYE does not infringe the Endocuff RCD.

Overall impression of the Vision RCD compared with the Endocuff RCD

206. There are two significant differences between the two RCDs: the Vision RCD has only the distal row of projecting elements and the elements are longer in the Vision RCD.

207. The position, shape and length of the projecting elements would be accorded particular importance because of design freedom and the significance that the informed user would attach to those aspects of the design. In my view, the Vision RCD would produce on the informed user a different overall impression and is therefore validly registered.

Overall impression of the AmplifEYE compared with the Vision RCD

208. The design corpus now includes the Endocuff RCD. This would reinforce the degree of attention which the informed user would pay to the projecting elements. Cantel argued that the informed user would see the following differences between the shapes of the projecting elements:

(1) They are longer in the AmplifEYE.

(2) The elements in the AmplifEYE have rounded tips.

(3) In plan view, the projecting elements in the AmplifEYE are elongated triangles whereas those of the Vision RCD are more rectangular.

(4) In side view, the projecting elements of the AmplifEYE have a constant cross-section whereas those of the Vision RCD taper.

209. Cantel also relied on differences numbered (b) to (d) discussed above in relation to the Endocuff RCD. As I have said, I think these matter less.

210. In my view, the length of the projecting elements is a similarity, not a difference. The differences (2) to (4) exist, although they are minor and in the case of (4) very minor.

211. As against those, aside from the similarity in length of the projecting elements:

(1) The designs have the same number of projecting elements (eight).

(2) The projecting elements are evenly spaced around a single ring.

(3) The single ring is located near the distal end of the central barrel.

(4) The projecting elements are tapered with rounded ends.

(5) The projecting elements are at a similar angle to the central barrel in side view (in the case of the AmplifEYE, the resting angle).

212. Turning back to the designs as a whole, I think the view of Mr Schreiner had some relevance even though he is not an informed user. He was head of the R&D team at Cantel which designed the AmplifEYE and someone who was aware not only of other products on the market but also of the many alternative designs which Cantel considered before moving forward with the AmplifEYE design. He said of the Endocuff Vision and the AmplifEYE:

> "I would accept that they look similar and there are no two ways about that, …" (day 4, 408)

213. Mr Schreiner implied that there were design constraints that would explain the similarities. Yet later in cross-examination Mr Schreiner admitted that he and two or more one of his colleagues at Cantel were sufficiently worried about the similarities between the Endocuff Vision and a proposed Cantel design – the one which became the AmplifEYE and to which it is very similar – to argue against the adoption of this 'Endocuff clone' design by Cantel. Their misgivings were not for functional, but for market reasons. They were overruled. I discuss this further below.

214. Considering the designs as whole, given that the Endocuff is part of the design corpus, given the design freedom afforded to the designer illustrated by the alternative designs shown above and taking into account the significance that would be attached by the informed user to the position, length and shape of the projecting elements, in my judgment the AmplifEYE would not produce on the informed user a different overall impression to that produced by the Vision RCD.

215. The AmplifEYE infringes the Vision RCD.

AmplifEYEs 2 and 3

216. Very little was said about AmplifEYEs 2 and 3. I was shown images of them, which are not included in this judgment because of their confidential nature.

217. Alterations from the AmplifEYE include a change from 8 evenly spaced projecting elements and the elements individually have a different appearance. I have reached the view that AmplifEYEs 2 and 3 would both produce on the informed user an overall impression different to that produced by the Vision RCD. AmplifEYEs 2 and 3 would not infringe the Vision RCD.

UK Unregistered Design Right

218. Arc alleged infringement of its UK unregistered design rights in the designs of the Endocuff and the Endocuff Vision. The designs relied on were those first recorded in a design document dated 9 December 2010 for the Endocuff and one dated 7 April 2014 for the Endocuff Vision.

The Act

219. The relevant provisions of the Copyright, Designs and Patents Act 1988 ("the Act"), as amended, are these:

> "***213 Design right.***
>
> *(1) Design right is a property right which subsists in accordance with this Part in an original design.*
>
> *(2) In this Part "design" means the design of ~~any aspect of~~ the shape or configuration (whether internal or external) of the whole or part of an article.*
>
> *(3) Design right does not subsist in—*
>
> *(a) a method or principle of construction,*
>
> *(b) features of shape or configuration of an article which —*
>
> *(i) enable the article to be connected to, or placed in, around or against, another article so that either article may perform its function,*
>
> …
>
> ***226 Primary infringement of design right.***
>
> *(1) The owner of design right in a design has the exclusive right to reproduce the design for commercial purposes —*
>
> *(a) by making articles to that design, or*
>
> *(b) by making a design document recording the design for the purpose of enabling such articles to be made.*
>
> *(2) Reproduction of a design by making articles to the design means copying the design so as to produce articles exactly or substantially to that design, and references in this Part to making articles to a design shall be construed accordingly.*
>
> …
>
> ***227 Secondary infringement: importing or dealing with infringing article.***
>
> *(1) Design right is infringed by a person who, without the licence of the design right owner —*
>
> *(a) imports into the United Kingdom for commercial purposes, or*

> *(b) has in his possession for commercial purposes, or*
>
> *(c) sells, lets for hire, or offers or exposes for sale or hire, in the course of a business,*
>
> *an article which is, and which he knows or has reason to believe is, an infringing article.*
>
> …
>
> ***228 Meaning of "infringing article".***
>
> *(1) In this Part "infringing article", in relation to a design, shall be construed in accordance with this section.*
>
> *(2) An article is an infringing article if its making to that design was an infringement of design right in the design.*
>
> *(3) An article is also an infringing article if —*
>
> *(a) it has been or is proposed to be imported into the United Kingdom, and*
>
> *(b) its making to that design in the United Kingdom would have been an infringement of design right in the design or a breach of an exclusive licence agreement relating to the design.*
>
> … "

Points of law in dispute

220. In closing, Mr Campbell identified three points of law which he said were in issue, although I think in substance there were fewer.

221. The first concerned whether Arc was relying impermissibly on rights in abstractions of designs. I discussed this part of the law in *Action Storage Systems Ltd v G-Force Europe.Com Ltd* [2016] EWHC 3151 (IPEC); [2017] FSR 18, at [9]-[16] and [52]-[56]. I repeated a view given in *DKH Retail Ltd v H Young Operations Ltd* [2014] EWHC 4034 (IPEC); [2015] FSR 21, that the deletion of the words 'any aspect of' from section 213(2) of the Act (marked in the subsection as set out above) by s.1(1) of the Intellectual Property Act 2014 probably removed any right there may have been to claim unregistered design right in abstractions of a design, i.e. anything other than the precise design of an article which exists or has existed. I went on in *Action Storage* to say that the same result may in any event be achieved by the effect of s.213(3)(a). As I indicated, neither view is free from argument although Arnold J has agreed with the first in *Whitby Specialist Vehicles Ltd v Yorkshire Specialist Vehicles Ltd* [2014] EWHC 4242 (Pat); [2016] FSR 5, at [41] and the second is drawn from Mann J's judgment in *Rolawn Ltd v Turfmech Machinery Ltd* [2008] EWHC 989 (Pat); [2008] RPC27, at [79]-[80] and [93]-[94].

222. I don't think it matters here. Unregistered design right subsists in the design of an article, but the rights in the present case were identified by reference to the two design

documents in which the designs were recorded. There is nothing abstract about the designs in those documents. Moreover, Mr Alexander did not put his case on the basis of any abstraction from those recorded designs.

223. Next, Mr Campbell referred to was what has been called a claim to a 'dynamic design right'. Where a design right is claimed in article with moving parts may the owner claim rights to the design in any of its potential configurations? In *Neptune (Europe) Ltd v DeVol Kitchens Ltd* [2017] EWHC 2172; [2018] FSR 3, a case about kitchen units, Henry Carr J took the view that it would not be possible to consider the functionality of moving parts if their dynamic features were excluded from consideration, at [61]. Dynamic design rights, if there are any here, were not part of Arc's case.

224. The third point is the 'must fit' objection to design right raised by Cantel pursuant to s.213(3)(b)(i) of the Act. In this regard I think there was a live dispute on the law. Cantel alleged that the designs relied on by Arc consisted entirely of features which enabled the cuff to be connected to, or placed in, around, or against the colon so that the cuff could perform its function. Therefore design right did not subsist in the designs or any part of them. There was a secondary point: design right did not subsist in the design of the interior of the central barrel because it had to fit the end of a colonoscope.

225. It is convenient to deal with the secondary point right away. Arc did not place any reliance on this part of the design of the cuffs.

226. Turning back to the law on Cantel's primary point, I discussed the 'must fit' objection to design right in *Action Storage*. I referred to *Ocular Sciences Ltd v Aspect Vision Care Ltd* [1997] R.P.C. 289:

> "[67] Thus a feature of the design of an article which promotes stable interaction with another article may be excluded from design protection under s.213(3)(b)(i). That need not be the only function of that article, see the passage from *Ocular Sciences* quoted above and *Dyson Ltd v Qualtex (UK) Ltd* [2006] EWCA Civ 166; [2006] R.P.C. 31, at [40]-[44].
>
> [68] There will be a limit to the exclusion of design right protection under this provision. I take the view that the shapes of the relevant parts of the connecting articles must be such that there is a degree of precision in the interrelationship between one article and the other, i.e. the designs afford some precision in the fit. For example, it would be surprising if the handle of a coffee mug were refused design protection solely because it is shaped to enable a human hand to connect to it to pick up the mug. (I use the convenient term 'fit' but this does not imply that the articles must touch. Section 213(3)(b)(i) can apply to features of shape or configuration of an article which enable it to be placed around another article and so there may be a gap between them, see *Dyson* at [31]-[38])."

227. There is a final matter to be considered. It is the relationship between a finding that the defendant has copied and a finding that such copying has resulted in an article substantially to the design copied. I discussed this in *DKH Retail*:

> "[58] In *Virgin Atlantic Airways Ltd v Premium Aircraft Interiors Group Ltd* [2009] EWHC 26 (Pat); [2009] ECDR 11, Lewison J said this:
>
> …
>
> 33. Although, at least in theory, two separate criteria must be satisfied viz. copying and making articles exactly or substantially to the copied design, it is not easy to conceive of real facts (absent an incompetent copyist) in which a design is copied without the copy being made exactly or substantially to the copied design. In practice, if copying is established, it is highly likely that the infringing article will have been made exactly or substantially to the protected design. If copying is not established, then whether the article is the same or substantially the same as the protected design does not matter. However, similarity in design may allow an inference of copying to be drawn.
>
> [59] In this last paragraph Lewison J drew on what the House of Lords had said in *Designers Guild Ltd v Russell Williams (Textiles) Ltd* [2001] 1 All ER 700; [2001] FSR 11. Both judgments come close to endorsing "the rough practical test that what is worth copying is prima facie worth protection" without quite going that far. This comes from the judgment of Peterson J in *University of London Press Ltd v University Tutorial Press Ltd* [1916] 2 Ch 601, at 610, in the context of whether examination papers were original copyright works, though the majority in *Ladbroke (Football) Ltd v William Hill (Football) Ltd* [1964] 1 WLR 273 (HL) found force in Peterson J's maxim in the context of copyright infringement (Lord Reid at 279, Lord Hodson at 288 and Lord Pearce at 294.)"

The remaining issues

228. Pleaded allegations that the designs relied on lacked originality, both in the copyright sense and because they were commonplace, were not pursued in closing. Nor was the allegation under s.213(3)(a) of the Act (method or principle of construction), save insofar as it was relevant to the complaint that the designs relied on were abstract, already discussed above.

229. The remaining points in issue were:

(1) Whether Arc owned the design rights relied on.

(2) Whether subsistence of the design rights was excluded pursuant to s.213(3)(b)(i) ('must fit').

(3) Whether Cantel copied the designs of the Endocuff and/or the Endocuff Vision.

(4) If so, whether the AmplifEYE is an article substantially to either of those designs.

(5) Whether Cantel knew or had reason to believe that AmplifEYE cuffs imported into the United Kingdom were infringing articles, within the meaning of ss.227 and 228 of the Act.

Ownership

230. Cantel did not dispute that if Mr Axon created the design of the Endocuff and Endocuff Vision, by relevant assignment the design rights were owned by Arc. However, Cantel ran an argument that the products were in fact designed by Mr Axon's father, Anthony, who unlike Mr Axon was an experienced colonoscopist. Alternatively, parts of the designs came from other colonoscopists who were consulted by Mr Axon in the course of the design process, particularly Professor Brian Saunders of Imperial College, London.

231. The cross-examination of Mr Axon suggested that Cantel had assumed that he had had no experience at all of colonoscopy, but it turned out that he had, as a junior doctor at St James's Hospital in Leeds. There was also an apparent assumption that Mr Axon had had no design experience before the Endocuff, but again, as Mr Axon explained, he had. It was unambiguously put to Mr Axon that he did not design the Endocuff or Endocuff Vision. He said clearly, and to my mind convincingly, that he did. I accept his evidence.

232. I find that the unregistered design rights are owned by Arc.

Must fit

233. Mr Campbell argued that the designs relied on consisted of features which undoubtedly enabled the articles to be placed in or against the colon wall so that it may perform its function. Therefore the 'must fit' exception to the subsistence of design right applied.

234. I disagree. For the reasons I gave in *Action Storage*, in my view s.213(3)(b)(i) applies only where there is a sufficient degree of precision in the fit between the articles in question. That is not the case between an Endocuff or Endocuff Vision and the wall of a colon. The must fit exception does not apply.

Whether Cantel copied

235. It was not in the end in dispute that the R&D team at Cantel responsible for designing the AmplifEYE was familiar with both the Endocuff and Endocuff Vision during the design process. Nor was it in doubt that Cantel designed the AmplifEYE in the knowledge that it would lose the US distribution rights for the Endocuff in June 2016 and so that it could market a cuff of its own. There was even a move by Cantel to buy Arc so that they could acquire all rights to Arc's products.

236. Cantel nonetheless denied copying either the Endocuff or the Vision design. Mr Nath, who designed the AmplifEYE, said that any similarities in design were a coincidence (day 6, 796-8).

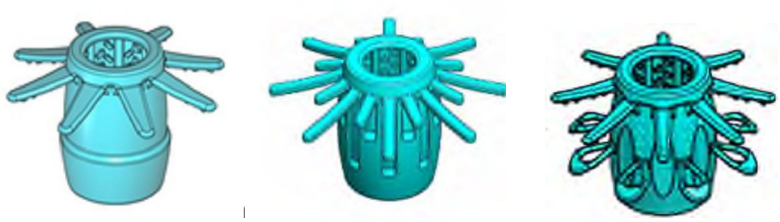
The evidence

237. There was a lot of evidence on this which I will not attempt to summarise. I will just note some of the main points.

238. Mr Schreiner, head of the R&D team which developed the AmplifEYE, had no prior experience in the design of a product to improve ADR. Nor did any of his team, including Mr Nath. Therefore the input from expert clinicians, referred to in the evidence as 'key opinion leaders', or 'KOLs', was crucial. Mr Schreiner said that they almost became key members of the design team (day 4, 464).

239. The KOLs clearly favoured the Endocuff over its competitors. A Medivators design review document dated 19 August 2015, done for the purpose of the project to develop an endoscope cover to increase ADR, noted at page 13 the very positive feedback from clinicians regarding the Endocuff.

240. By 23 September 2015 the design team had reduced the wide variety of candidate designs down to a shortlist of three:



241. Mr Schreiner said that he preferred the design shown in the middle. However, the KOLs indicated a clear preference for the design on the left. As Mr Schreiner acknowledged, the latter was the design much more like the Endocuff Vision than the others (day 4, 475-7).

242. Mr Schreiner admitted that he, John Gutauskas who was Head of Marketing, and others on the team were unhappy about developing and marketing a product that was so similar to the Endocuff Vision. In an email dated 23 September 2015 Mr Schreiner favoured ordering moulds of all three designs to keep their options open:

> "We really cannot come out with a Endocuff clone, nor do we want to. I think that it is reasonable for us to incur the cost of three molds and the parts …"

243. Mr Schreiner, Mr Gutauskas and others were apparently overruled. Mr Schreiner was not prepared to say by whom, save that it was a collective decision (day 4, 479-483). Cantel went with the 'Endocuff clone', by which Mr Schreiner had probably meant the Endocuff Vision clone.

244. Mr Geiger, responsible for regulatory compliance, said that generally when the new device was submitted for regulatory approval, the more similar it was to a device already approved generally the easier it was to obtain regulatory approval for the new product (day 6, 868).

245. Cantel submitted a 'Premarket Notification 510(k)' form to the US Food and Drug Administration on 25 March 2016 to gain regulatory approval for the AmplifEYE. It stated

> "AmplifEYE is directly based on and substantially equivalent to…Arc Endocuff…and Arc Endocuff Vision"

The form did not say that the AmplifEYE was based on any other product.

Conclusion on copying

246. I have no doubt that both the Endocuff and Endocuff Vision were copied in the course of creating the design for the AmplifEYE. It is surprising that Cantel maintained otherwise.

Whether the AmplifEYE is an article substantially to either of Arc's designs

247. Bearing in mind the observations of Lewison J in *Virgin Atlantic* quoted above and copying having been established, it would be difficult for Cantel to show that the AmplifEYE was not substantially to the design of the Endocuff and Endocuff Vision. I have discussed the features they share. In my view the AmplifEYE is substantially to the design of both.

248. I also take the view that the differences between the AmplifEYE and AmplifEYEs 2 and 3 are insufficient to prevent the latter from being substantially to the design of the Endocuff and Endocuff Vision, given the chain of copying and the similarities that exist.

Knowledge or reason to believe

249. Cantel's pleaded case was that it had only done acts which could qualify as secondary acts of infringement of Arc's design rights, so secondary infringement was all that could be in issue. Arc did not raise any evidence to dispute this, so I need consider only secondary infringement.

250. Mr Nath said in his third witness statement that no one in the Cantel design team was aware that design rights existed. He was not challenged and indeed it was part of Arc's case that Cantel did not know anything about design rights. It was put to Mr Schreiner in cross-examination that because Cantel was unaware of design rights, they took no steps to avoid copying. Mr Schreiner agreed (day 4, 414). There might in theory have been a case that Mr Schreiner and Mr Nath were in the US whereas the claimants were both UK companies, so there was no necessary equivalence of knowledge. Arc did not pursue such an argument, presumably for good reason.

251. Arc's only pleaded case on knowledge or reason to believe was based on common knowledge in the trade, which was not explored, and an inference drawn from a distributor agreement which was not referred to.

252. I find that Cantel have not had the requisite knowledge or reason to believe that the AmplifEYE products are infringing articles, but it does from the date of the judgment.

Conclusion on UK unregistered design rights

253. The Endocuff design right entered its licence of right period on 1 January 2017. Cantel have undertaken to take a licence so no injunction may be granted. Arc

remains entitled to an injunction to restrain Cantel from infringing its Vision design right. No order for damages or an account of profits will be made.

Overall Conclusion

254. Arc has permission to amend the UK designation of the Patent and the UK Patent in the form of the respective unconditional applications to amend. Both Patents are valid and infringed. Infringement has occurred by acts done in relation to the AmplifEYE and would occur by acts done in relation to AmplifEYEs 2 or 3.

255. The Endocuff RCD is valid but not infringed. The Vision RCD is valid and infringed by acts done in relation to the AmplifEYE but not AmplifEYEs 2 and 3.

256. UK unregistered design rights subsist in the designs of the Endocuff and Endocuff Vision and are owned by Arc. They will be infringed from the date of this judgment by acts done in relation to the AmplifEYE and would be infringed by acts done in relation to AmplifEYEs 2 and 3.