

**IN THE HIGH COURT OF NEW ZEALAND
AUCKLAND REGISTRY**

CIV 2007-404-748

BETWEEN	INVERNESS MEDICAL INNOVATIONS, INC. First Plaintiff
AND	INVERNESS MEDICAL SWITZERLAND GMBH Second Plaintiff
AND	MDS DIAGNOSTICS LIMITED First Defendant
AND	SIVA PRAKASH APPANNA Second Defendant

Hearing: 18-21 and 25-29 May, 4-5, 8-12 and 24 June 2009

Further written submissions filed: To 3 July 2009

Appearances: C Elliott and S McLaughlin for the Plaintiffs
D Marriott and I Finch for the Defendants

Judgment: 24 June 2010

JUDGMENT OF WOODHOUSE J

*This judgment was delivered by me on 24 June 2010 at 10:00 a.m.
pursuant to r 11.5 of the High Court Rules 1985.*

Registrar/Deputy Registrar

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ANNEXURES 1 TO 41

A. Introduction

[1] This copyright case concerns artistic works. These are drawings of pregnancy testing devices, or parts of the devices. There are three devices, intended for easy use in the home or in medical clinics. Each device is designed to take a sample of a woman's urine and indicate, in a short time, whether the hormone human chorionic gonadotropin (hCG) is present. hCG is produced in pregnancy.

[2] At the heart of each device is a thin rectangular strip of nitrocellulose material. The devices also have one or more small pads of porous material which are connected to the nitrocellulose. The urine is applied to one end of the pads, or to a wick connected to the pads, and travels by capillary action through the pads to the nitrocellulose. A result is indicated at a pre-determined point on the nitrocellulose.

[3] I will refer to the pads and the nitrocellulose as "the strip". Drawings for construction and assembly of a strip, together with the wick, are in annexure 10. Photographs of three manufactured strips are in annexures 27 and 28. These photographs show a device which also has a wick.¹

[4] The three types of device are referred to generically as midstream, card and dipstick. The midstream is a handheld device. Photographs of three of the midstream devices are in annexures 29 to 33. The strip is contained in a rigid plastic case. The case is around 11 centimetres long, narrow and easy to hold. As shown in annexure 30, the wick protrudes from one end of the case. Results of a test are viewed through the apertures in the handle. The wick connects to a porous pad inside the case. A woman uses the midstream by applying her urine directly to the wick.

¹ There are three separate photographs in these annexures, and in annexures referred to in the following paragraphs. All of these annexures are best viewed from a landscape perspective, and references to right and left and top and bottom are from a landscape perspective in each annexure. The top and middle photographs are the plaintiffs' products. The bottom photograph in each case is the product of the first defendant.

[5] With the card, the strip is contained in a rigid plastic case which is generally rectangular, thin and roughly the size of a credit card. Photographs of the device are in annexure 34. Urine is collected in a container, then taken from the container with a pipette and applied through the hole shown at the left hand end of each device. Results are viewed through the other apertures in the middle of each device.

[6] The dipstick is, in essence, the strip with a flexible plastic coating enabling the strip to be held in the hand. Photographs are in annexure 35. The strip is held at what is the right hand end in the photographs. The arrows indicate the end that is dipped into a urine sample in a container.

B. The plaintiffs' predecessors in title

[7] The claims relate to drawings made by, or on behalf of, Unipath Limited (Unipath), a United Kingdom company, and Acon Laboratories, Inc. (Acon), a United States company. I will refer to the drawings as “the copyright works”, or “the works”, although there are issues whether copyright subsists in some of the drawings.

[8] The plaintiffs say that Unipath was the pioneer in developing the technology for this type of pregnancy testing and in designing strips and cases. Unipath was a subsidiary of Unilever UK Holdings Limited (Unilever). Unipath launched its first product of relevance in June 1988. It manufactured and sold midstream and card devices.

[9] Some assets of the Unilever group were purchased by the first plaintiff (IMI) pursuant to an agreement with Unilever made in December 2001. The plaintiffs say the assets transferred included ownership of copyright in drawings of strips and midstream and card cases.

[10] Acon was established in the United States in 1995. From around 1996 Acon manufactured and sold all three pregnancy testing devices, including the strips.

[11] By agreement dated 24 February 2006 IMI purchased Acon assets. The plaintiffs say the assets included ownership of copyright in drawings of strips, midstream and card cases, and dipsticks.

[12] The second plaintiff (IMS) is a subsidiary of IMI. The plaintiffs say IMS acquired other intellectual property from Unilever in 2002 and that, at the same time, IMS granted a licence to IMI to “exploit and enforce” all relevant interests in the copyright works. There are issues as to whether the plaintiffs acquired ownership of copyright in the copyright works, but there are no material issues in respect of the different roles played by IMI and IMS. Except where relevant, I will not draw a distinction between the plaintiffs and simply refer to them generally as Inverness.

C. The issues in outline

[13] The first defendant (MDS) sells midstream, card and dipstick devices in New Zealand. These are manufactured overseas and imported into New Zealand by MDS. Over the relevant period most of the parts of the products sold by MDS were manufactured by, or on behalf of, an American company called Phamatech, Inc. (Phamatech).

[14] Inverness alleges that the importation and sale of the MDS devices, and other actions of MDS and the second defendant, Dr Appanna, infringe the plaintiffs’ claimed copyright in the drawings. Infringement is said to have occurred from the date of the first importation by MDS, of card and dipstick devices, in about November 1999. It is alleged, in essence, that the MDS devices have been copied directly from the copyright works, being drawings contained in patents, or indirectly by copying from products said to have been made from the copyright drawings.

[15] Neither MDS nor Phamatech (or any other manufacturer of MDS products) had a copyright licence from Unipath, Acon or Inverness. Apart from that, most of the broad issues that can arise in a copyright case do arise in this case. They arise in respect of drawings of parts of the strips, the strips as a whole, the wick of the midstream, the midstream case, the card case, the dipstick and each device as a whole. Issues arise, as distinct areas of inquiry, in respect of the Unipath drawings

and products, the Acon drawings and products, and the MDS products. The inquiry is confined on the MDS side to its products because there were no drawings produced by the defendants for the design of the defendants' products.

[16] The broad factual inquiry, and the range of issues to be considered, is indicated, at least to an extent, by the table of contents. An outline of the principal issues is as follows:

1. Do the plaintiffs own the copyright works?
2. Did copyright arise in each copyright work when created? This requires an inquiry, in the usual way, into the extent of skill and labour applied by Unipath and Acon in creating their respective works. The inquiry is directed to copyright works for parts, and copyright works showing the relationship of various parts to each other – the arrangement of various features.
3. Has there been infringement of copyright by copying at least a substantial part of a copyright work (or works), either directly from a work, or indirectly from a Unipath or Acon product? The relevant provisions of the Copyright Act 1994 (the Act) are ss 16(1)(a), 29 and 30.

A range of subsidiary issues arise, including the following:

- Prior access: were the Unipath and Acon works, or products, available to MDS or Phamatech before the MDS products were manufactured?
- What is the degree of similarity between the copyright works and the MDS products?
- If there are similarities, can these be explained by factors indicating that there was no infringement by copying? For

example, do the similarities relate to commonplace things, or arise from constraints on design because of the underlying science or technology?

- Is there evidence other than relevant similarities which is indicative of copying?
- Where there are differences, what is their significance?
- If the inquiry to this point indicates that at least a substantial part of a copyright work has been copied in an MDS product, can MDS prove that the MDS product was in fact not copied from the Unipath or Acon works?

The remaining issues arise if there was relevant copying.

4. Is there primary infringement by issuing copies of the work to the public? See ss 16(1)(b), 29 and 31 and the definition of “issue to the public” in s 9 of the Act.
5. Is there primary infringement by authorising copying of the works or issuing of copies of the works to the public? See ss 16(1)(i) and 29 of the Act.
6. Is there secondary infringement, pursuant to s 35 of the Act, by importation of infringing copies, with knowledge of the infringement?
7. The second defendant, Dr Appanna, is a director of MDS. Is Dr Appanna liable for copyright infringement?
8. In terms of s 75 of the Act, were the Unipath and Acon works applied industrially and, if so, when? The principal issue here is whether the strips, once manufactured by Unipath and Acon, are two or three dimensional.

9. If there is infringement, are the plaintiffs entitled to damages, and if so, what is the quantum? The plaintiffs elected to seek damages, rather than an account of profits.
10. There are two separate claims by Inverness, essentially alleging breach of confidence by the defendants.
11. There are three counterclaims by MDS. The first alleges that Inverness issued the proceedings without proper justification or cause. The second alleges misleading and deceptive conduct by Inverness arising from correspondence in respect of the Inverness claims. The third alleges breach of an agreement made in 2002 between MDS and Acon.

D. Ownership : Unipath copyright works

[17] No material issue was raised by the defendants as to the original ownership of the copyright works created by or on behalf of Unipath. What was in issue is whether Inverness became the owner pursuant to the sale agreement dated 20 December 2001 between IMI and Unilever.

[18] The defendants contended that the agreement is unclear as to whether ownership of copyright was transferred to IMI and that other evidence suggests that it was not. I will note the relevant provisions before considering the defendants' submissions in more detail. In these provisions "Vendor" means Unilever and "Purchaser" means IMI.

[19] The preamble to the agreement records the intention to transfer to IMI ownership of, amongst other things, the "Shares", the "US Business Assets" and the "IP Assets". Clause 2 of the agreement makes provision for sale of the property just referred to, and some other items.

[20] Clause 2(F) provides, so far as material at this point:

On the terms set out in this Agreement, the Vendor shall sell, or procure the sale of, and the Purchaser shall purchase, or procure the purchase by the relevant Designated Purchaser of, the full legal and beneficial interest in the IP Assets as at and with effect from Completion ...

[21] “IP Assets” is defined as meaning “the Business IPR, the Domain Names and the IP Licences”.

[22] “Business IPR” is defined in part as follows:

... (ii) any or all of the Intellectual Property owned by a member of the Vendor’s Group which is used exclusively in the Transferring Business as at Completion; and (iii) any or all of the Intellectual Property owned by a member of the Vendor’s Group which has been used in the Transferring Business but has never been used in any other business carried on by members of the Vendor’s Group. The Business IPR includes, without limitation, those patents, patent applications, trade marks and trade mark applications listed in the Disclosure Letter.

[23] The relevant definitions of expressions used in the definition of the “Business IPR” are:

- (a) “Intellectual Property” means patents, trade marks, service marks, trade or business names, rights in designs, copyrights (including, without limitation, rights in computer software), rights in databases and topography rights (whether or not any of those is registered and including, without limitation, applications and rights to apply for registration of any such thing) and all rights or forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world.
- (b) “Vendor’s Group” means the vendor, Unilever N.V., Unilever PLC and their respective subsidiaries and subsidiary undertakings at the relevant time (but excluding the Companies).
- (c) “Transferring Business” means (i) the business as carried on at the date of this Agreement by the Companies (including through the occupation or use of the Bedford Property, the IP Assets and the Monoclonal Assets); (ii) the US Business; and (iii) the licensing ...
- (d) “Companies” means Unipath Limited, Unipath Management Limited, Unipath Diagnostics GmbH, Unipath Scandinavia A.B. and Unipath B.V, and “Company” shall be construed accordingly.

[24] These provisions, when construed in the light of the relevant background (the factual matrix relevant to interpretation) appear clearly to establish that full ownership of the Unipath copyright works was transferred by this agreement to IMI. However, Mr Marriott, for the defendants, submitted, in effect, that the plaintiffs

failed to prove certain facts necessary to remove uncertainty said to arise in respect of Unipath copyright works.

[25] Mr Marriott referred to sub-clause (iii) of the definition of “Business IPR”. This has the effective proviso or exclusion, commencing with the word “but” in respect of intellectual property that had been used in any other business carried on by a member of the Vendor’s Group. Except in respect of activities in the United States, which I will come to, Mr Marriott pointed to an absence of evidence to assist in determining whether the apparent exclusion in sub-clause (iii) applied to the Unipath copyright works.

[26] It appears that the primary point made for the defendants in this regard was that the page of the agreement “identifying or defining the ‘Vendor’s Group’” had not been produced in evidence. I do not consider that the omission of the page provides reasonable grounds for the submission. The page was missing from the copy provided to the Court, along with a number of other pages in an agreement totalling 211 pages with 16 further attachments. The main operative provisions were in 42 sections contained in the first 71 pages. Schedule 1 to the agreement was an interpretation section covering pages 72 to 93 of the agreement. The entire document up to page 87 – towards the end of the interpretation schedule – was produced (with some subsequent pages). The only provision I have referred to not included in the original bundle of documents is the definition of “Vendor’s Group”. Following the hearing I asked for copies of the missing pages, including the balance of the interpretation schedule. There was an objection from Mr Marriott. I have no difficulty in concluding that I am entitled to call for and consider missing pages which assist in interpreting pages I have already received in evidence and on which the defendants made submissions.²

[27] Apart from the missing pages, there is the question whether the apparent exclusion or proviso in sub-clause (iii) means that IMI did not acquire copyright in the Unipath copyright works. The weight of the evidence adduced by the plaintiffs

² I note that I received from the plaintiffs the entire document, including all of the schedules and a large number of attachments. I have not had regard to the additional pages, which are not relevant. I also note that they contain clearly confidential information.

was to the effect that the “Intellectual Property” represented by copyright in the Unipath copyright works was owned by Unilever, then a member of the Vendor’s Group, and was used exclusively in the business of Unipath; that is to say, used exclusively in the “Transferring Business”. There was also no evidence that the “Intellectual Property” represented by the copyright works, having been used in the “Transferring Business” had also been used in “other business carried on by members of the Vendor’s Group”. Having regard to the weight of the evidence adduced for the plaintiffs, this was then a matter for the defendants to explore in cross-examination, or to challenge with defence evidence, if they wished. There was no positive evidence adduced for the defendants in this regard. And no questions were put to any of the plaintiffs’ witnesses who would have been in a position to answer the question. In particular, there was evidence from Mr Veldhuis, the managing director of an Inverness subsidiary in Australia. Mr Veldhuis was employed by Unilever, and was on secondment to Unipath, between 1995 and 2001. He gave unchallenged evidence of his knowledge of the “various acquisitions recently made by” Inverness, and in particular in relation to the agreements with Unilever and Acon.

[28] I am satisfied that transfer of ownership of the Unipath copyright works was not effectively excluded by sub-clause (iii). More particularly, in relation to this point, I am positively satisfied that the Unipath copyright works are part of the “Intellectual Property” included in the “IP Assets” transferred pursuant to clause 2(F).

[29] Mr Marriott’s second point was made in relation to clause 2(E) of the Unilever agreement. Clause 2(E) states that Unilever shall sell to Inverness a range of “US Business Assets” (being a defined expression) but excluding a number of things. One of the things excluded by clause 2(E)(xiii) is “any rights in relation to Intellectual Property used in the US Business”. Mr Veldhuis gave evidence that Unipath products had been sold in the United States prior to the Unilever agreement. The defence submission from this was that “it appears that the IP in those products has not been assigned pursuant to this exclusion” in clause 2(E)(xiii).

[30] This submission is not supported by clause 2(E)(xiii). This provision is directed to “Intellectual Property used in the US Business”. Mr Veldhuis’ evidence does not raise uncertainty as to whether the intellectual property represented by copyright in the Unipath copyright works produced in the United Kingdom might come within the exclusion in clause 2(E)(xiii). If the defendants wished to pursue the applicability of clause 2(E)(xiii) more was required than the simple confirmation from Mr Veldhuis that Unipath products had been sold in the United States.

[31] In any event, clause 2(E)(xiii) merely excludes “Intellectual Property used in the US Business” from the assets included in the “US Business Sale” under clause 2(E). It did not exclude the sale of what the agreement elsewhere defines as “US IP Assets”. Clause 2(F) was discussed above in relation to the defendants’ first point. This is the main operative clause for sale of intellectual property. Clause 2(F) makes clear that “US IP Assets” are included in the “IP Assets” sold pursuant to clause 2(F). This may be seen, firstly, by reference to the definition of “IP Assets”, and the definitions of the other expressions, as earlier set out. The inclusion of “US IP Assets” in clause 2(F) is further made clear by a provision in clause 2(F) itself. The opening part of clause 2(F) is recorded at [20] above. The clause more fully provides:

On the terms set out in this Agreement, the Vendor shall sell ... and the Purchaser shall purchase ... the full legal and beneficial interest in the IP Assets as at and with effect from Completion free from all liens, charges, equities, encumbrances and other rights exercisable by third parties (other than (i) in the case of the US IP Assets only, encumbrances of the type within paragraph (i) of the definition of Permitted Encumbrances set out in Schedule 1 (interpretation), and (ii) ...

The qualification relating to encumbrances affecting US IP Assets would not be there if the US IP Assets were not being sold.

E. Ownership : Acon copyright works

[32] There is an issue whether the “acquisition agreement” between IMI and Acon and associated companies resulted in transfer of ownership of copyright in the Acon copyright works to Inverness. There is also a question of original ownership in

respect of one of the works. I will deal first with the question whether IMI acquired ownership of the copyright.

[33] The Acon acquisition agreement was entered into on 24 February 2006 between IMI as “Buyer”, Acon and associated companies as the “Seller Entities”, and a company defined as the “Parent” of the Seller Entities. The fact that there was a number of “Seller Entities”, and that the “Parent” was a party to the agreement, is not material to the issues raised by the defendants.

[34] The defendants’ argument that Inverness has not acquired ownership of copyright in the Acon works was founded on submissions as to the meaning of a number of clauses in the preamble. I will set these out with one further preamble clause not referred to by Mr Marriott. I have, for ease of reference, added clause numbers which do not appear in the original document:

[1] WHEREAS, certain of the Seller Entities currently develop and manufacture, among other things, lateral flow immunoassay products and directly related products at an existing facility in Hangzhou China and sell these products to certain other Seller Entities that market, distribute and sell these products in, among other geographic locations, the United States, Canada, Europe, Israel, Australia, Japan and New Zealand;

...

[2] WHEREAS, certain of the Seller Entities own or have the right to use certain intellectual property rights relating to lateral flow immunoassay products;

...

[3] WHEREAS, Buyer and certain Affiliates of Buyer have been engaged in legal proceedings with certain of the Seller Entities or their Affiliates or customers and the Buyer and each of the Seller Entities desire to settle such legal proceedings pursuant to the terms and conditions set forth in the Transaction Documents;

[4] WHEREAS, in the first phase of the transactions contemplated by this Agreement, and subject to the terms and conditions of this Agreement, (A) the Seller Entities desire to sell, transfer and assign to Buyer, and Buyer desires to purchase from the Seller Entities, the assets, properties, interests and business of developing, manufacturing, marketing and/or selling lateral flow immunoassay products and directly related products in the United States, Canada, Europe (excluding (i) Russia, (ii) the former Soviet Republics that are not part of the European Union as of the date of this Agreement, and (iii) Turkey), Israel, Australia, Japan and New Zealand, and (B) the Seller Entities desire to transfer and assign to Buyer and Buyer

desires to assume from the Seller Entities certain liabilities, in each case as solely to the extent provided in this Agreement;

[5] WHEREAS, subject to the terms and conditions of this Agreement, certain Seller Entities will license to the Buyer certain intellectual property rights (i) necessary for the conduct of the business described above in the geographic locations described above, and (ii) necessary to develop and manufacture the products described above in China on the earlier of the New Facility Closing or July 31, 2006 (as provided in the ACON License);

[6] WHEREAS, subject to the terms and conditions of this Agreement, certain Seller Entities (i) will agree to supply lateral flow immunoassay products and directly related products to Buyer for Buyer to market, distribute and sell such products in the geographic locations described above, (ii) will agree to supply, on arms-length terms, certain other products other than as provided in (i) above to Buyer for Buyer to market, distribute and sell such products, and (iii) will agree to provide Buyer with certain services to facilitate the transition to Buyer of the business described above in the geographic locations described above and the New Facility described herein;

[7] WHEREAS, in the second phase of the transactions contemplated by this Agreement, and subject to the terms and conditions of this Agreement, LBI desires to sell, transfer and assign to Buyer, and Buyer desires to purchase from LBI [one of the Seller Entities], the ownership of Rich Horizons International, Ltd., a British Virgin Islands company ("Rich Horizons") which owns ABON (as defined herein) and own and operate through ABON the New Facility (including the research, development, manufacture and testing equipment therein) and thereafter, certain Seller Entities will manage, direct and oversee the operation of that portion of the New Facility which is not Fully Functional (as defined herein) until such time as such portion is Fully Functional and control of such portion of the New Facility that has been transferred to Buyer;

[35] The clause not referred to by Mr Marriott is clause 7. Although these are preambles, not the operative clauses, they were the main focus of the defendants' submission and I will record my conclusions in that respect. To the extent that the preamble bears on the effect of the agreement, it supports the conclusion that ownership was transferred to Inverness.

[36] Mr Marriott submitted, firstly, that "the *first phase* of the acquisition agreement involves a licensing of intellectual property rights to IMI to enable it to sell Acon's lateral flow immunoassay assets in the listed territories only". I do not agree. The submission that there was licensing only in the first phase is founded on clause 5. The submission ignores clause 4. Clause 4 records the intention, in effect, to sell all interests owned by the Seller Entities in respect of immunoassay products. In the context, "immunoassay products" are pregnancy testing products. I consider

that the wide terms of clause 4 include transfer of ownership of copyright in the copyright works. Clause 5 does not qualify clause 4. Clause 5 records an additional part of the agreement.

[37] Mr Marriott further submitted that “the agreement clearly envisages a *second phase* involving an absolute assignment of copyright”. Based on that proposition, he submitted that the plaintiffs had failed to establish ownership because there was no evidence as to the completion of the second phase. This submission was made by reference to clauses 1 to 6 only. It was founded on the unstated but necessary premise that the preceding argument was correct; that is to say, that the licensing referred to in clause 5 was the only thing that was to happen in the first phase. The conclusion I have already reached removes the essential premise. The defence submission also made no reference to clause 7. Clause 7 expressly records the nature of the assets to be transferred in the second phase. These assets do not include ownership of copyright in the Acon copyright works or, more broadly, Acon intellectual property. Just as importantly, clause 7 does not qualify clause 4.

[38] Mr Marriott submitted that one clause in the operative provisions of the agreement supported the primary submissions I have already dealt with. This is clause 4.12(a)(ii) which defines “Assigned Acon Intellectual Property Assets” as “all Intellectual Property Assets owned by or purported to be owned by any or all of the Seller Entities and used exclusively in the First Territory Business”. This provision does not support the primary submissions for the defendant. This clause is contained in Section 4 of the agreement. Section 4 is headed “Representations and Warranties of the Seller Entities” and that is what section 4 is concerned with. The opening words of Section 4 make its ambit sufficiently clear:

As a material inducement to Buyer to enter into this Agreement and consummate the transactions contemplated hereby, the Seller Entities hereby jointly and severally make to the Buyer, the representations and warranties contained in this Section 4 ...

[39] The primary transaction “contemplated hereby” is contained in the principal operative clause in section 1 as follows:

SECTION 1. PURCHASE AND SALE OF FIRST TERRITORY ASSETS.

1.1 Sale of Assets.

(a) Subject to the provisions of this Agreement, at the First Closing (as defined herein) the Seller Entities shall sell, transfer and assign to Buyer, free and clear of any Liens (as defined herein) other than Permitted Liens (as defined herein), all right, title and interest (other than Intellectual Property Assets owned by a third party unless such Intellectual Property Assets are the subject of licenses or other agreements assigned hereunder) in and to all of the assets, properties, interests and business of researching, developing, manufacturing, marketing and/or selling lateral flow immunoassay products and all directly related products, including, those listed on Schedule 1.1(a) (together with all materials and components of such products to the extent directly related to the lateral flow immunoassay field) in the United States, Canada, Europe (excluding (i) Russia, (ii) the former Soviet Republics that are not part of the European Union as of the date of this Agreement, and (iii) Turkey), Israel, Australia, Japan and New Zealand (the “First Territory”) (such properties, interests and business, the “First Territory Business”, and such materials, components and products, the “First Territory Products”) of the Seller Entities (except for the Excluded Assets, as defined herein), of every kind and description, tangible and intangible, real, personal or mixed, wherever located, and whether existing as of the date of this Agreement or acquired prior to the First Closing, including, without limitation, as set forth below; provided, that Buyer acknowledges that Buyer is not acquiring any tangible manufacturing assets at the First Closing:

[40] This operative clause puts into effect what is recorded in preamble 4. The assets being transferred are expressed in very wide terms. In my judgment they plainly include ownership of copyright in the Acon copyright works, being works related to the matter expressly recorded in this clause – “lateral flow immunoassay³ products and all directly related products”. The very wide terms of this clause are subject to exclusions. These do not support the defendants’ submissions.

[41] I am satisfied that ownership of copyright in the Acon copyright works was transferred to IMI.

[42] There is the separate question relating to original ownership of one copyright work that the plaintiffs claim is owned by Acon. This is a work created by Ms Ying Yang. Ms Yang was commissioned to produce a drawing for the exterior of Acon’s midstream case. Ms Yang was not an employee of Acon (or any of the Acon associated companies; again, I will refer simply to Acon).

³ “Lateral flow” and “immunoassay” are processes used in the strips. They are explained in the next section of this judgment, section F.

[43] Chinese law applies. Mr Marriott submitted that, for Acon to be the owner, Ms Yang had to be “an employee of Acon and the engineering designs and product designs must have been created ‘mainly with the resources provided by the employer’”.

[44] The relevant provision of Chinese law is article 11 of the 1991 Copyright Law. The English translation is as follows:

Except where otherwise provided in this law, the copyright in the work shall belong to its author. The author of a work is the citizen who has created the work. Where a work is created according to the will and under the sponsorship and the responsibility of a legal entity or an entity without legal personality, such legal entity or entity without legal personality shall be deemed to be the author of the work. The citizen, legal entity, or entity without legal personality whose name is indicated on a work shall, in the absence of proof to the contrary, be deemed to be the author of the work.

[45] Article 11 was amended in 2001. It is not entirely clear whether the original provision or the amended provision applied, but the English translation of the amended provision shows that there was no material change.

[46] The evidence makes clear that the work produced by Ms Yang was “created according to the will and under the sponsorship and the responsibility” of Acon. I am satisfied that the copyright in this drawing was owned by Acon and was, therefore, included in the copyright works in respect of which ownership was transferred to IMI.

F. The underlying science and technology

[47] An outline of the science and technology that underlies the strips is relevant in a number of respects including the following: an understanding of the next section of the judgment, section G, which outlines the research and development undertaken by Unipath; whether the design of strips is in some way constrained by the underlying science and technology; and whether other pregnancy testing products in the market at relevant times, and with which comparisons might be made to determine questions of originality, used similar science or technology.

[48] The devices work by using two processes – an immunoassay and what was described as “lateral flow technology”.

[49] An immunoassay is one type of assay. A different type of assay, noted in the evidence, is an enzyme assay. The Oxford English dictionary defines an immunoassay as the use of antibodies for the detection of and measurement of bio-chemical substances. Antibodies are also referred to as reagents. The bio-chemical substance sought to be detected or measured, or both, is the analyte. The analyte in the pregnancy testing devices is the hCG molecules, produced during pregnancy (and which I will simply refer to as hCG).

[50] There are two types of immunoassay; a competitive assay and a sandwich assay. The devices in this case use a sandwich assay, so called because the analyte, if present, is sandwiched between two antibodies. I will call these antibodies A and B.

[51] The immunoassay and the associated lateral flow occur in and on the strips. In simplest terms, lateral flow involves the movement of urine from one end (the proximal end) of the strip to the other end (the distal end). The strip comprises substances which result in the urine flowing from one end to the other. Antibodies A and B are put on the strips at different points, with A closer to the proximal end than B. As a result, when urine flows along the strip it will meet antibody A before antibody B.

[52] Antibody A is put on the strip in a manner that results in its being mobilised when wetted and this occurs when the urine reaches antibody A. Labels are used in immunoassays to assist in indicating whether the analyte (hCG) is present. The devices in this case use coloured particles or markers. Antibody A, at the proximal end, is tagged with the label. When wetted by the urine the colour becomes visible to the naked eye. As the urine moves along the strip it takes the coloured antibody A with it. If hCG is present in the urine the coloured antibody A will bind to it. The compound consisting of the coloured antibody A and hCG then moves along the strip towards antibody B.

[53] Antibody B is put on the strip in such a way that it does not move when wetted by the urine. If hCG is present in the urine, the compound of the coloured antibody A and hCG will, in effect, be captured by antibody B and the hCG is sandwiched by the two antibodies at this point. The entire compound (hCG, antibodies A and B and the colourant or label) becomes fixed at that point (although some urine may continue to flow beyond the point at which antibody B is fixed, into a “sink”).

[54] The movement along the strip occurs chromatographically by capillary action. This process, as developed and applied to the strips, was described as “lateral flow technology” by Unipath.

[55] A more detailed description of the chemistry, and terminology, is contained in a judgment of the Federal Court of Australia on a patent infringement claim brought by IMS against MDS, Dr Appanna and an associated Australian company.⁴

G. Unipath copyright works and products

[56] Unipath was established by Unilever in 1984 to develop medical diagnostic devices related to women’s reproductive health. Its first pregnancy testing device was put into the market in 1985 under the brand name “Clearblue”. I will refer to this first product as “Clearblue original”. The first device directly relevant to this proceeding was launched in June 1988. I will refer to this as “Clearblue mark 1”. Clearblue original is relevant as indicative of the changes achieved with Clearblue mark 1, and the work that went into producing Clearblue mark 1. In simplest outline, Clearblue original took about 30 minutes for the test to be completed and required a series of tests to be taken over that time. Clearblue mark 1 was a one-step process producing a result in five minutes. There were other differences, but it is unnecessary to go into this.

⁴ *Inverness Medical Switzerland GmbH v MDS Diagnostics Pty Limited* [2010] FCA 108. The patents at issue in that case are briefly noted in this judgment as the May and Davis patents. In the Australian decision there were findings of infringement in respect of aspects of the May patent, findings of invalidity in respect of aspects of the May patent and the Davis patent, and Dr Appanna was held to be personally liable as a joint tortfeasor and for authorising infringement.

[57] The launch of Clearblue mark 1, a midstream device, in June 1988, followed that year by a card device, was the result of a decision made at Unipath in February 1986 to develop a new product which would, in essence, be quick and easy to use. This was what I will call stage 1 of four stages of development through to 2002. I will outline the four stages and record my conclusions on the subsistence of copyright.

Stage 1 : 1986-1988

[58] The principal evidence for the plaintiffs relating to the work undertaken between February 1986 and the launch of Clearblue mark 1 in June 1988 came from Mr Michael Prior. Mr Prior began working for Unilever in 1965. He transferred to Unipath when it was established in 1984. He started work in the field of immunochemistry in 1986. Mr Prior was directly and closely involved in all of the relevant work undertaken by Unipath both over the period from February 1986 to June 1988, with the launch of Clearblue mark 1, and in the further developments by Unipath through to 2002. I am satisfied from Mr Prior's evidence, and further evidence from another Unipath employee, Mr Balbir Raj, that the Unipath copyright works made to enable the production of Clearblue mark 1 in June 1988, and further copyright works created in subsequent years to enable production of new strips and cases, were the result of the input of a great amount of skill and work. This was a great amount of skill and work in respect of design, resulting in copyright works, as well as research into and development of the science and technology, and with design significantly influencing technical aspects as well as technical aspects influencing design.

[59] In relation to scientific innovation, Mr Prior said, after outlining the features sought to be achieved, and the range of ideas that were explored:⁵

Our major breakthrough came when we found that we could not only track antibodies bound to large coloured particles along a very thin two-dimensional membrane, but under the correct conditions, we could also dry these particles in the strip and get them to come back into suspension when a urine sample was wicked up the strip.

⁵ Mr Prior's brief of evidence, para 13(e).

[60] Following this, Mr Prior set out in considerable detail the steps taken by Unipath not only to refine their ideas but also how best to express them in drawings, proceeding from broadly conceptual drawings through to those required for production of the two products. This evidence also explained the way in which design, translated to copyright works, influenced aspects of science and technology, such as the positions on the strips where results might be indicated, as well as the influence of the science and technology on design.

[61] Mr Prior said:⁶

When the test strip was first patented in 1987, it was the first of its type in the world. This was the first test to use “lateral flow” technology involving immunochemical-based reactions and insoluble coloured markers. Instead of multiple step procedures involving accurate manipulation and timing, the Unipath test involved a single step with a result in 5 minutes and in doing so, revolutionised the rapid home and professional testing markets.

And:⁷

When Unipath launched its new Clearblue Onestep product, a true quantum leap was made in immunoassay design. On launch, Clearblue Onestep received rave reviews in both the popular and scientific press. As early as 1989, we were presented with a prestigious British Design Award by the Duke of Edinburgh and around this time our competitors began copying both the strip and casework design. Even today the design has not been superseded but only copied.

I accept this evidence, which was supported by other witnesses for the plaintiffs, and in particular Mr Raj.

[62] Mr Prior was cross-examined about other devices which may have been designed at around the same time, or even earlier. That evidence does not leave me with relevant doubt in respect of Mr Prior’s positive evidence because I accept his evidence in cross-examination. This was to the essential effect that relevant comparisons could not be made because of substantial differences, including the way in which other devices operated compared with those of Unipath. There was no defence witness with any expertise to challenge Mr Prior’s evidence. Some further evidence was produced through Dr Appanna, or other witnesses, in the form of

⁶ Mr Prior’s brief of evidence, para 63.

⁷ Mr Prior’s bundle of documents, para 48.

publicly available documents relating to products of other manufacturers. There was a substantial amount of evidence in this broad category, but it does not assist the defendants' case. I discuss this further at [231] and following.

[63] What leads from the evidence, which I have simply touched on, is my conclusion that there was a high degree of originality in the Unipath copyright works at issue in this case. I am here referring not only to the stage 1 copyright works leading to the launch of the midstream Clearblue mark 1 in June 1988, and Unipath's card device later that year, but also to further and substantial design modifications in stages 2 to 4. I am also of this opinion notwithstanding arguments for the defendants that a number of the drawings relied on are rudimentary or simple. I will come to the particular works relied on, which are annexed. At this point I record my finding, implicit in what I have already said, to the effect that in this case apparent simplicity in some drawings is not indicative of a modest amount of skill and labour in producing the drawings. Before coming to the works relied on I will continue the narrative in respect of Unipath's stage 2 development.

Stage 2 : 1988-1990

[64] Once Unipath was confident that the midstream and card devices launched in 1988 had become well established in the market, it proceeded with further development. This resulted in the design of a strip consisting of two parts – nitrocellulose, as before, together with what was generally described as a “conjugate pad”.

[65] The technical objective which resulted in the addition of this pad was to seek to increase the sensitivity of the test. To begin with, this was directed to a device intended to indicate ovulation, rather than pregnancy, because greater sensitivity was required for the detection of the hormone relevant for indicating ovulation. Mr Prior said:⁸

No matter what optimisation in reagent position and concentrations we performed, this sensitivity level could not be achieved with the single piece test strip design. Careful examination and experimentation led us to think

⁸ Mr Prior's brief of evidence, paras 61 and 62.

that not enough of the sample was coming into contact with the colour-labelled first antibody before this hormone-antibody complex was released from the location of the first antibody and moved up the strip. However, experiments where the particles were pre-mixed with the sample before being run up the strip, gave us more than the required sensitivity.

From this experimental work, it was decided that we needed to design a ‘mixing chamber’ into the strip that allowed the antibody labelled coloured particles to come into contact with a larger amount of urine sample before migrating up the strip. This ‘mixing chamber’ effect was achieved by adding a thin macroporous pad containing the coloured particles to the upstream portion of the test. A full description of this design is contained within the Davis patent.

[66] The first product with the additional pad – the “mixing chamber” – was an ovulation testing device launched in 1990. Midstream and card devices for pregnancy testing, with these modifications, were also put into the market in 1990. As indicated in Mr Prior’s evidence, the main features were the additional conjugate pad and the fact that this conjugate pad contained the tagged antibody A. The conjugate pad was saturated with the tagged antibody and then dried. With the midstream and card products, the time for the completion of the test was also enhanced, from five minutes to three.

Copyright works for stages 1 and 2 : 1986-1990

[67] Annexed to this judgment, as annexures 1 to 8 are the copyright works produced by the plaintiffs for the period up to 1990. The annexures are largely, but not entirely, chronological. There is one document (in annexure 4), not relied on as a copyright work in this case, but with some relevance, as I will explain. Most of the annexures have reproductions of two copyright works, with some of the individual works also containing more than one drawing in some cases. Where there are two works on a page, this is indicated by the words “top” and “bottom”.

[68] Annexures 1, 2 and 3 top are a series of drawings showing progressive refinements of design for the strip in stage 1. Annexure 1 top shows design at an early stage. The left hand drawing in annexure 1 top also illustrates, in a simple form, the lateral flow technology with urine being applied, as indicated in this drawing, at one end and moving first to the “free antibody” and then to the bound antibody. Design refinements shown in the following drawings include dimensions

of the strip overall, together with the relationship of the parts of it. Relationships include that of the “mobile band”, which I earlier described as the area containing antibody A, and the “immobile band”, which I earlier referred to as containing antibody B.

[69] The second drawing in this group, in annexure 1 bottom is, as recorded on it, a reproduction by Mr Prior, “from memory”, of “original sketches made by him during invention of lateral flow technology”. He estimated the date of production of this drawing at around May/June 1987. This drawing is the first to add a control zone, a further feature which found its way into the strips that were manufactured for the market in 1988.

[70] There are no final production drawings for the strips manufactured in 1988. There are production drawings for strips manufactured at subsequent stages. I do not consider that the absence of production drawings is relevant. I accept that there will have been a reasonably substantial number of drawings at various stages. As indicated by Mr Prior’s notation on his reproduction of the 1987 drawing, numbers of drawings can no longer be located. That does not create problems of proof if the evidence as a whole enables an inference to be drawn as to the existence of other drawings from which the physical product must have been made. I readily draw those inferences where necessary, and in respect of Acon works as well as those of Unipath.

[71] The plaintiffs emphasised a range of features in respect of the design of the strips said to give rise to copyright. These included the particular dimensions and the relationship of one feature to another, such as the position of antibody A, the position of antibody B being the point at which a result might be indicated, and the position of a control zone. The plaintiffs also gave emphasis to the use of lines for the test and control indicators.

[72] The positioning of the lines, as well as the overall dimensions of the strips, flowed through to the design of cases for the midstream and card devices. Annexure 3 bottom shows an early drawing for a device containing the strip. This records

basic dimensions, but it also shows what is effectively a cover with a single window for viewing the result of a test.

[73] Annexure 4 was not relied on as a copyright work, but it was put in evidence, with other drawings, or illustrations of prototypes, to indicate the extent of the design activities at Unipath.

[74] The drawings in annexure 4A, labelled Fig. 1 to Fig. 5, are numbers of drawings contained in a patent filed by Unilever with the Australian Patent Office on 2 December 1988. It has priority dates of 27 April and 30 October 1987 and an international filing date of 26 April 1988.⁹ This patent was referred to in the evidence as the “May patent” after the first-named inventor. There are three named inventors, one of whom is Mr Prior.

[75] It appeared, at least initially, that the defendants were questioning whether the plaintiffs are entitled to rely on drawings contained in a patent as copyright drawings. I am satisfied that publication of the drawings in the patent does not prevent the plaintiffs from relying on them as copyright drawings provided the requirements for subsistence of copyright are present.

[76] The May patent also contains drawings for midstream and card devices (as well as other possible embodiments). These are reproduced as annexures 5 top and 6 top. The bottom drawings in annexures 5 and 6 are drawings produced during stage 2, resulting in the addition of the conjugate pad and other changes. These drawings are contained in what was called the “Davis patent”, which I will discuss shortly, following a description of the drawings in the earlier May patent for the midstream and card, including the strips in them.

[77] I refer first to annexure 5 top, a drawing of a midstream device (Fig. 8) and a cross-section (Fig. 9). The portion labelled 503 is a cap. The remainder is the part held in the hand by the user. The wick is labelled “506”. When used, the cap is removed and the urine is applied to the wick. The apertures labelled “508” and

⁹ This is one of the patents dealt with in the Australian Federal Court proceeding by Inverness against MDS and others; see n 4 above.

“509” are holes in the plastic case through which the test and control lines can be seen.

[78] In the cross-section, Fig. 9, the thin, hatched section labelled 510 is the strip, consisting of nitrocellulose only. As will be seen it is contained entirely within the plastic casing and is connected to the wick (506) with an overlap. The number 511 points to another feature, which may not be readily apparent from the reproduction. This is a plastic backing to the nitrocellulose which, in the drawing, is in fact on top of the nitrocellulose. The “backing” is transparent. This means that results, from the coloured antibody, can be viewed through the apertures. The design relationship between the case and the lines for the test and control indicators will be apparent from these drawings.

[79] Annexure 6 top, in Fig. 10, has an enlarged cross-section view of the strip and the wick in the midstream. This shows more clearly the transparent backing to the nitrocellulose – item 511. The positions for test and control zones are labelled 517 and 518. The wick, as before, is 506. A portion of the test strip (opposite the backing strip 511 and adjacent to the wick 506) carries a glaze (510) on which is deposited a layer (520) of specific binding antibody. (The thickness of these two layers has been exaggerated for the purpose of illustration.) The arrows in Fig. 10 indicate the direction of flow of urine, commencing at the wick.

[80] Annexure 6 top has drawings for a case, in Fig. 11 and Fig. 12. The apertures in the middle of the case, (603) and (604), shown in both drawings, have the same functions as those just referred to in the midstream. Aperture 601 is the aperture through which the sample of urine is applied using a pipette or similar device. In this card, the urine is first received by a porous substance (605), serving a function broadly similar to the wick in the midstream.

[81] The further work undertaken by Unipath between 1998 and 1990, in stage 2, is illustrated in part by the drawings in the Davis patent which are in annexure 5 bottom (midstream) and annexure 6 bottom (card). Again, Mr Prior was one of the named inventors on this patent. The priority date in the patent, from the United Kingdom, is 17 February 1989. The application date in Australia is 16 February

1990. The drawings follow the same pattern as those in the May patent because these were drawings for a patent rather than for production, but I am satisfied that nothing turns on that adverse to the plaintiffs' case. The drawing of particular relevance, to illustrate embodiment in a drawing of the further work undertaken by Unipath in stage 2, is Fig. 3 in annexure 6 bottom. This is, in format, similar to Fig. 10 in the same annexure (annexure 6 top) taken from the earlier May patent. The prominent additional feature in the later drawing is labelled 113. This is the "conjugate pad" which now contained the tagged antibody A. The conjugate pad (113) is also illustrated in the Davis patent full cross-section of the midstream in annexure 5 bottom, Fig. 2.

[82] Annexures 7 and 8 are the final manufacturing drawings for the upper and lower halves of the case for a card. These indicate, amongst other things, the positioning of the strip in the case and the relationship of the relevant parts of the strip to the apertures in the case. As will be apparent from the drawings themselves, they contain fine measurements and refinements of the card cases, developed from the drawings in the May and Davis patents. The detail does not require further elaboration. The text in the lower right hand corner of each drawing (landscape view) states that the original drawings were made in August 1988. These particular drawings include modifications made in November 1989 and February 1990 with those modifications recorded as: "strip locations modified, four places"; "two lugs added both ends"; "two ribs added"; and "surface finish changed was charm '12'". The original drawings were, therefore, made shortly before the launch of Unipath's first card, at the end of stage 1, in 1988. The modifications were made around the time of the launch of the modified strip, at the end of stage 2. The drawings were made by a Mr Bekkers of a Dutch company called Technoplast. I am satisfied that copyright in the drawings was nevertheless owned by Unipath, or its parent, Unilever, the distinction between Unipath and Unilever not being material.

Stage 3 : 1994-2002 : "SOAPSUD"

[83] What I call stage 3 was a further development stage which commenced around 1994, with the project name "SOAPSUD". Mr Prior led the SOAPSUD

project. He produced in evidence a copy of his report on the project. This detailed report, excluding appendices, is 113 pages long. It sets out design developments as well as scientific research and development.

[84] Mr Prior explained that a number of market factors were taken into account in SOAPSUD. These included the fact that the market had become flooded with home and clinical tests largely copied from Unipath designs; the “off the shelf” availability of materials and machinery required to set up lateral flow technology; the prevalence of cheap far-Eastern imitation and manufacture; the acceptance of home pregnancy diagnosis; the growing speed and sensitivity of tests; and the transformation of home diagnostics from being under-the-counter products to being products akin to fashion accessories, and accordingly, the need for redesigning to take this into account.

[85] Mr Prior’s evidence of changes made to the design of the strip was as follows:¹⁰

Important changes were also made to the design of the strip. The one-minute run time (in and of itself a very significant improvement) and some of the savings in manufacturing costs came from the re-design of the test strip. Shortening the read time was achieved as a result of a series of specific changes:

- (a) The test and control lines were both moved 8mm upstream so that the mobile coloured marker reached them sooner. This also resulted in us gaining an extra 8mm of sink and as this was not required we found we could remove 10 mm from the total nitrocellulose length. This gave us a 20% cost reduction in one of our most expensive raw materials.
- (b) The test reagents were deposited onto the test strip in higher concentrations and improved formulations as the immunochemical reactions had to be faster to achieve the faster run time/sensitivity constraints.
- (c) A different macroporous particle-carrying pad was used in the test strip with the particles sprayed onto the surface of the pad as a discrete band rather than the pad being saturated with antibody solution as described in the Davis patent on page 5 at lines 31-33 that was used in the existing Clearblue Onestep device. This improved test strip construction gave the particle release dynamics required to achieve the one minute to result time constraint. Combination of this new reelable pad material along with a

¹⁰ Mr Prior’s brief of evidence, para 75.

continuous deposition process gave us significant savings in manufacturing costs.

- (d) We designed the test strip so that as you move from component to component up the strip, the pore size and flow rate decreases. The wick takes up and wants to release the urine to the next component so quickly that you often get some flooding right next to the pad/wick interface. Therefore, if the label was placed right next to this interface, the sample might flood over the top of it and leave it behind, thus ruining the test. Therefore, we designed the inclusion of an additional length of the macroporous pad which remained blank before the location of application of labelled reagent to the pad. This interface gap was not required in the second generation test, because the pad material chosen had a greater liquid handling capacity and could absorb the sample as fast as the wick could deliver it.

[86] The redesigned strip was put into the market in 1996. The copyright works relating directly to this redesigned strip are in annexures 9 to 13. These drawings are described in the following paragraphs.

[87] Annexures 9 and 10 come from Mr Prior's report for the SOAPSUD project. Annexure 9, entitled "RELAUNCH v SOAPSUD: Dimensions", compares the SOAPSUD strip with an earlier modification given the project name "Relaunch". The drawings illustrate, amongst other things, the significance in design of various dimensions as well as the changes in that respect between Relaunch and SOAPSUD. Both are strips for the Unipath midstream product (Clearblue).

[88] Annexure 10 has drawings for construction of the SOAPSUD strip (called a "chip" in these drawings). These drawings, amongst other things, illustrate the relationship of various features to each other in terms of the overall design; in effect, drawings for a collage.

[89] Annexures 11 and 12 are highly detailed drawings for manufacture of strips. Annexure 11 has an original date of 2 May 1995, with drawing modifications recorded from 26 April 1996 to September 2002. The title of the drawing is "Evolution/SOAPSUD OTC chipband" indicating that it was first used for SOAPSUD and then used in what I call stage 4, which had the project name Evolution, noted below. The central part of the drawing, being a long rectangle with 40 transverse lines, shows a lengthy strip of nitrocellulose from which 39 individual

pieces of nitrocellulose are cut for manufacture of individual strips. The black dots, which are “visible detection marks”, are at the distal end of the strip. A notation, related to an individual piece of nitrocellulose to be cut from this long piece, records: “typical strip width 8 ± 0.05 when cut on Mikron assembly machine”. This, and similar notations, records allowable manufacturing tolerances.

[90] Annexure 12 has an original date of 22 February 1996, with modification dates of 22 February 1998 and 12 January 2007. The legend includes the descriptions: “used on SOAPSUD (Clearblue)” and the title “Antibody lines: nitrocellulose band”. This records the positions of the two antibody lines, placed in production on the long piece of nitrocellulose before cutting into individual pieces. There are precise measurements, with acceptable tolerances, for the lines themselves and for their relative positions. There is an enlarged view which is a cross-section of two pieces of material combined at this stage of manufacture. These are the nitrocellulose and a polyester backing.

Stage 4 : 1999-2002 : “Evolution”

[91] The further development project, “Evolution”, commenced in 1999. It resulted in further modifications to the Unipath midstream (Clearblue). This was launched on 1 November 2002. Modifications to the strip do not have present relevance. One modification which is relevant, when compared with an MDS midstream, is that the wick was considerably wider than the wick in earlier versions. This is shown in a further Unipath copyright work, annexure 14. This drawing is dated March 2002. As indicated on the drawing, it was to be read in conjunction with another drawing (as is the case with other manufacturing drawings I have referred to).

[92] The final Unipath copyright work put in evidence by the plaintiffs is a stage 4 (Evolution) redesign of the case for the midstream. This is reproduced as annexure 15. It is dated 20 February 2002. The plaintiffs do not allege infringement in respect of this drawing. The alleged infringement of copyright works for a midstream case is in respect of Acon works. What this drawing serves to illustrate is that the significant skill and work that went into design of Unipath’s original product,

launched in 1988, continued with substantial redesign of products through to 2002 when IMI acquired copyright in all of these works. This drawing also assists in determining whether the MDS midstream case was copied from the Acon case, by way of contrast.

H. Acon copyright works and products

1995-1999

[93] Acon designed and manufactured all three devices; that is to say, a midstream, a case and a dipstick. Much of the design and manufacturing work was undertaken by an associated company operating in Hangzhou, China, and some work was contracted out by that company. These distinctions are not relevant and I will simply refer to Acon as including the associated companies.

[94] There is not much evidence relating to Acon's design work from its incorporation in 1995 until around 1998-1999. More particularly, there are no extant copyright works prior to 2000. The plaintiffs say there is good reason for the lack of copyright drawings prior to 2000. The evidence came mainly from Mr Qingning Xiang. Mr Xiang is the in-house patent counsel for the company in China which now manufactures the products acquired by the plaintiffs from Acon. Mr Xiang said:¹¹

I have tried very hard but have not been able to locate many documents in Aconlabs because many original documents have been lost due to three moves of the factory over the last few years as we have grown. Some of the documents may still be at ACON but as it is a separate company, it is difficult to know for sure. ...

He then described three moves between 1997 and 2006 and continued:

To find the original designers for these test strips is not easy because much of the useful information and evidence from Acon's Hangzhou site, to state when and who designed the test strips or the casings, has been lost. However, after much investigation and having spoken to at least 30 people, the names of which I provided in my Affidavit dated 25 August 2007 in paragraph 11 I have found some documents. I have spoken with Zhumin

¹¹ Mr Xiang's brief of evidence, paras 15 and 16.

Guan, Fei (Soar) Goa, Lijian Gou, Dengfen (Dennis) Xiong and Huikang (Jerry) Chen on the design of the test strip. All of these people are employees of either ACON or Abon. ... To the best of my knowledge and belief, Mr Guan went to the United States in late 1995 or 1996 and brought back from Arista Biologicals (“Arista”) information and know-how relating to the test strip.

[95] I am satisfied from the evidence that in the period from its inception in 1995 to 1999 Acon expended a considerable amount of time, effort and skill, as well as money, in developing and designing its own dipstick, card and midstream products. This may be seen from an outline of the evidence, with relevant findings of fact, for the earlier period.

[96] In late 1995 or 1996 the founder of Acon, Dr Jixun Lin, “learned the lateral flow technology”, as Mr Xiang put it, from an American company called Arista Biologicals, Inc (Arista). Another Acon employee, Zhumin Guan, also went to Arista in 1996 “to find out how to make the test strips and packaging”.¹² The defendants contended that the evidence established that Acon had simply copied the strips from Arista. I do not agree. I am satisfied that what Acon got from Arista was technology – how to make strips. What Acon then did was explained by Mr Xiang as follows:¹³

... I believe that when the multi-component strip technology was transferred from Arista the design and manufacturing teams at ACON produced different prototypes with different dimensions and materials to be used for the strip that they wanted the company to manufacture.

[97] Mr Xiang then referred to documents in the agreed bundle. These documents, however, are all dated 2001. Notwithstanding this, I accept the thrust of Mr Xiang’s evidence to the effect that reasonably significant amounts of work and skill were applied by Acon in designing its own strips and cases once the technology had been understood following the visits to Arista. Mr Xiang was not challenged in any material way on this aspect of his evidence. It is supported by other evidence and inferences I readily draw, as to what had gone before, from a design review commenced at Acon in 1999. This was a review of existing products. There is further evidence I will touch on.

¹² Mr Gao’s brief of evidence, para 3.

¹³ Mr Xiang’s brief of evidence, para 17.

[98] Mr Xiang said, based on his investigations and records of the company, that Acon sold the products in China, and other countries other than the United States, in the period 1996 to 1998. In cross-examination he said that all three products were sold. He was obviously referring to the three devices at issue in this case, the midstream, the case and the dipstick. Additionally, there was the following evidence from another witness, Mr Fei Gao:¹⁴

From 1996 onwards, ACON developed three products. These became known as the dipstick or strip product (FHC-101), the device or cassette product (FHC-102) and the midstream device (FHC-103). The test strip we developed was able to be used in two basic formats – the dipstick and the device [i.e. card] format. The first format was just a single strip which was stand-alone and the second format was a strip to be used in a casing. The strip was for home use, while the cassette was mainly for use in professional situations like in hospitals.

[99] Another Acon witness, Mr Jielin Dai, said that, in the course of his design work for Acon in 2001, he saw documents and drawings relating to design of a strip in about 1996 for use in a midstream device.¹⁵

[100] In 1997 and 1998 Acon gave what are known as 510(k) notifications to the United States Food and Drug Administration (FDA). This is notification required to be made of intent to market a medical device. There was notification given on 25 November 1997 for a product with the brand name “AimStick”, a device intended for professional use. On 23 February 1998 notification was given in respect of Acon’s dipstick. Also in 1998, although the precise date does not appear to be in evidence, Acon gave notification in respect of its midstream product. The earliest date in evidence relating to this 510(k) application is November 1998, being a response from Acon to review comments from the FDA. Mr Gao said that Acon’s midstream was Acon’s first product to appear in the United States market.

[101] On 1 December 1999 Acon made application in China to register a design. The rights associated with this were transferred to IMI. A copy of the application is in evidence. This consists principally of two photographs of a midstream device. These are not relied on by the plaintiffs as copyright works, but they are relevant to

¹⁴ Mr Gao’s second brief of evidence, para 4.

¹⁵ Mr Dai’s brief of evidence, para 14.

the plaintiffs' claims in respect of Acon copyright works for the case for Acon's midstream.

Acon design review from 1999

[102] In 1999 Acon commenced a design review of its products. It appears from the review that the process began on 29 November 1999. The design review, at least with some of the products, extended through to early 2002. In respect of the review, Mr Xiang said:¹⁶

This review document is set out in the standard form used at ACON. At page 3 it confirms that the *“proposed project is to take the existing ACON hCG products and strengthen their market appeal and lot-to-lot consistency by implementing”* certain changes *“according to the ACON product development design control document SOP01-001”*. This design control document is part of our ISO requirements.

The report also states that *“the entire ACON hCG product line will be modified. All of these hCG products use the same chemistry, but differ only in platform i.e., the strip is essentially the same whether assembled as a device, midstream or dipstick product”*.

[103] Mr Xiang gave further detailed evidence relating to the design processes at Acon in respect of this review, which went through three phases. There was further evidence from Mr Gao and Mr Dai. Mr Dai was responsible for, in particular, design of the inside of the case for the midstream. Mr Dai liaised with the designer contracted to Acon for the case exterior, Ms Ying Yang (noted earlier, at [42], in respect of the ownership issue).

The Acon copyright works

[104] The plaintiffs claim that a considerable number of drawings, or other forms of artistic work, produced over the review period from 1999 are copyright works and works in respect of which the defendants have infringed copyright. I do not intend to annex copies of all of them and it will not be necessary to refer to all of them. In

¹⁶ Mr Xiang's brief of evidence, paras 29 and 30.

respect of the copies that are annexed it is convenient to list them under headings relating to each product.

Midstream copyright works

[105] Summary descriptions of the midstream copyright works in the annexures are as follows. These all relate to an Acon midstream product variously described as the “CVS” or “Rexall” or “CVS Rexall”.

- a) Annexure 16: Exterior of the case. These are images from a computer. This is the design done by Ms Yang, using computer software.
- b) Annexure 17: The upper half of the case, inside and outside, and a cross-section.
- c) Annexure 18: The lower half of the case, inside and outside, and a cross-section.
- d) Annexure 19: The cap, top and bottom, and a cross-section.
- e) Annexure 20: Two drawings of the complete product. One has the cap removed and shows a wide wick which was introduced with this revision.
- f) Annexure 21: Drawings with dimensions and some specifications for the strip in the midstream (known by the product code FHC-103).

[106] The plaintiffs contended that there was infringement of 22 other copyright works for an Acon midstream product closely related to the CVS Rexall, known as Perrigo. Copies of those are not annexed. I am not satisfied that copyright in these drawings was infringed. This is because a product made from the drawings was not put into the market and there is no evidence that MDS, or its manufacturer Phamatech, had access to the product or to the drawings. The nature of the drawings

nevertheless supports the conclusion that there was substantial originality in the copyright works created by Acon for its pregnancy testing products. I am also satisfied that there is evidence of a coherent design path of Acon for its midstream product. This starts with the registered design, referred to above at [101], then the Perrigo, which was designed but not put into the market, and on to CVS Rexall, which was put into the market in 2002 as explained shortly.

[107] Some additional copyright works for the CVS Rexall midstream product have also been omitted. These are duplicates of drawings already referred to, but containing various handwritten workings and modifications indicative of further design skill and effort.

Card copyright works

[108] Descriptions of the works for the Acon card are as follows:

- a) Annexure 22: There is a descriptive box at the top of the page, under the heading which commences “hCG Urine test device ...”. The descriptions in the box may be related to the diagram of the strip at the bottom. The strip consists of four main parts: a sample pad, which receives the urine; a “label pad” containing the mobile antibody with a label, which in Acon’s case is red colloidal gold; the “immunoreaction area”, which is the nitrocellulose portion where the immunoassay occurs; and, at the distal end, an “absorbent pad”, also described as a sink. The sink is designed to absorb any excess urine. The label attached to the mobile antibodies produces a red colour, compared with the Unipath label producing a blue colour. The upper diagram is a representation of the exterior of a case, viewed from above.
- b) Annexure 23: These are drawings with dimensions and some specifications for the strip in the card (known by the product code FHC-102).

Dipstick copyright works

[109] Following is a summary description of Acon's copyright works for its dipstick.

- a) Annexure 24: The descriptive box at the top and the drawing of the strip at the bottom follow the format in annexure 22 for the card. The upper drawing, with the letters "hCG" at the right hand end (the distal end) and arrows at the left is a simplified drawing of the exterior of the strip looking at the face of the strip the user will look at.
- b) Annexure 25: These are drawings with dimensions and some specifications for the dipstick strip (known by the product code FHC-101).
- c) Annexure 26: These are drawings of the dipstick indicating how to read the device for a positive or negative result or an invalid test.

Completion of Acon's revised midstream drawings : Acon-MDS agreement

[110] A distribution agreement was entered into between Acon and MDS on or about 27 February 2002. In the event, MDS did not distribute any Acon products, but it is relevant that this agreement, and disclosures made by Acon pursuant to it, coincided with the completion of Acon's revised midstream drawings, both for the Perrigo and the slightly different CVS Rexall midstream products.

[111] Dr Appanna contacted Acon in 2001 to discuss the possibility of purchasing Acon's products as a back-up to, or alternative to, the products MDS was at that time getting from Phamatech. This led to the agreement made between MDS and Acon in February 2002.

[112] It is clear that the redesign of the Acon midstream devices was completed by the beginning of 2002, certainly in the case of the Perrigo design. The Perrigo design was approved for manufacture by the client, Perrigo, on 7 February 2002.

The plaintiffs, in their statement of claim, said that this product range “was not ultimately pursued” and this was confirmed by Mr Xiang. The plaintiffs argued, in closing, that in fact the product may have been put into the market, but I am satisfied that this was not so. However, in March 2002 Acon sent to MDS what were described as “registration files” for each of Acon’s products; that is to say, the midstream, the card and the dipstick. These are detailed files for each of the products. The timing of the provision of this information is relevant, as discussed later.

[113] The Acon CVS Rexall midstream product was put into the market. Although there was some debate about the date, I am satisfied that this occurred on or about 11 October 2002.

I. MDS and Dr Appanna

MDS history

[114] In 1995 Dr Appanna became a shareholder in a company called Medical & Dental Supplies (NZ) Limited (Medical & Dental). Medical & Dental was at that time selling surgical instruments. Dr Appanna got control of the company around the beginning of 1997. In about April 1998, Medical & Dental began distributing pregnancy test kits for “an Auckland based company” that had a contract with Pharmac. Pharmac is the New Zealand government agency responsible for, amongst other things, contracting for purchase of medical supplies for hospitals.

[115] Dr Appanna, in his evidence, referred to sales by Medical & Dental to doctors and medical centres on behalf of the other company during 1998, then said:¹⁷

We realised that there was considerable opportunity in this area, particularly if we could obtain a PHARMAC listing for the products we supplied. This was the key opportunity that MDS was incorporated to exploit. Initial enquiries revealed that the fees being charged to PHARMAC for the pregnancy test kits were exorbitant.

¹⁷ Dr Appanna’s brief of evidence, para 39.

A key point from this is that Medical & Dental, and then MDS, decided to compete on price. In the event, as will be noted, Medical & Dental was successful in securing Pharmac contracts, effectively on behalf of MDS. It may also be noted that what Dr Appanna was investigating for Medical & Dental in 1998 would involve competition with the company at that time represented by Medical & Dental and being a company with a Pharmac contract.

[116] Dr Appanna said that he made initial “enquiries of PHARMAC as to how a listing on the PHARMAC schedule could be obtained”. He then began looking for a supplier. This led to contact with Phamatech and then to a distributorship agreement with Phamatech made on 9 December 1998. The agreement was between Phamatech and Medical & Dental.

[117] Under the distributorship agreement, Phamatech appointed Medical & Dental “an exclusive authorised distributor of Phamatech’s pregnancy products in ... New Zealand and a non-exclusive authorised distributor in ... Australia”. The agreement made provision for sale of Phamatech’s card and dipstick devices, and one other Phamatech product which is not relevant. There was no reference to a midstream device. The agreement did provide for Medical & Dental to “have the first right of refusal to all Phamatech’s existing products and newly developed products” as they became available. The products sold to Medical & Dental were required to be shipped with Medical & Dental’s name “applied to outer kit boxes and imprinted on instruction sheet[s] at no additional charge”.

[118] Sometime between December 1998 and March 1999 Medical & Dental submitted a tender to Pharmac to supply the Phamatech dipstick and card pregnancy testing devices, known as QuickStick and QuickCard respectively. The tender was accepted on 30 June 1999, subject to approval by MedSafe, the New Zealand government agency responsible for approving a new “medicine”, which both of these devices were by definition. MedSafe approval was given on 14 October 1999.

[119] The letter of approval from MedSafe of 14 October 1999 is addressed to “Prakash Appanna, Managing Director, MDS Diagnostics a division of Medical & Dental Supplies (NZ) Limited”. MDS was incorporated on 4 November 1999. It

seems that Phamatech was willing to accept MDS as the other contracting party in place of Medical & Dental.

[120] Dr Appanna was the sole director of MDS on incorporation on 4 November 1999. Two further directors were appointed on 19 July 2000; Mr Randall Hills, the company's accountant, and Mr Michael Vallant, the company's solicitor.

[121] As noted earlier, the agreement with Phamatech appointed Medical & Dental a "non-exclusive authorised" distributor of Phamatech products in Australia. Dr Appanna decided to pursue opportunities in Australia, and to do so through a company. Because of Australian regulations, it was necessary to incorporate an associated company in Australia. MDS Diagnostic Pty Ltd (MDS Australia) was incorporated on 1 December 1999.¹⁸

MDS products

[122] In November 1999 MDS began importing and distributing card and dipstick devices acquired from Phamatech. These were sold under the MDS name and using the Phamatech brand names QuickCard and QuickStick. MDS has continued to import and distribute cards and dipsticks. Relevant features of these products will be considered later.

[123] MDS has distributed a number of versions of a midstream device. I will refer to these as version 1, version 2 and so on, but this does not necessarily correspond to the labels used by the parties, which were not consistent.

- a) Version 1 was first purchased by MDS from Phamatech on 28 October 2002. It had a white case.
- b) Dr Appanna said that version 2 was first purchased from Phamatech on 12 May 2004. This had a pink case, but the case was otherwise the same as the case for version 1.

¹⁸ This is the Australian company defendant, along with MDS and Dr Appanna, to the Inverness patent infringement proceedings earlier referred to – see [55] and n 4 above.

- c) Dr Appanna said that version 3 was first purchased from Phamatech on 15 June 2004. Inverness alleges that the case for version 3 infringes copyright in the Acon drawings for the Acon Rexall midstream, and that the strip infringes copyright in Unipath and Acon works for the strip. The case for the MDS midstream version 3 was the subject of much evidence and much debate. It is necessary to consider at least some of this evidence, and record my findings, because the findings of fact bear on several issues, including credibility.
- d) There is also an MDS midstream case which I will call version 4. This is a case with a changed profile in the opening of the case at the proximal end where the wick enters the case. The plaintiffs were unaware of this product until it was presented to their expert witness in the course of cross-examination. This also has a general bearing on questions of credibility or reliability of defence evidence. The discussion of it is deferred.¹⁹

History of the Phamatech products : design trail : reliability and credibility

[124] The evidence relating to the MDS midstream version 3 illustrates a prominent feature in respect of all of the MDS products purchased from Phamatech. There is a complete absence of evidence of design history. In addition, although Phamatech was apparently established in the United States in 1991, there is almost no evidence of relevance relating to the products it sold in the period up to around 1997. The documents that were produced, through a witness from Phamatech, were so limited, and seemingly random, that it led me to draw inferences adverse to the defence.

[125] Evidence in respect of Phamatech's activities was given directly by Mr Bruce Glasser, Phamatech's in-house counsel since 1999, and by Dr Appanna. Dr Appanna was not in a position to give any direct evidence on these matters; all he

¹⁹ See paras [216]-[217] below.

could do was refer to documents and hearsay. Mr Glasser's evidence was particularly unsatisfactory, and I will come back to that.

[126] The only documentary evidence for the earlier years of Phamatech related to apparent sales of Phamatech's dipstick in Vietnam. Dr Appanna and Mr Glasser referred to these documents, but neither of them was in a position to explain anything in relation to what these documents disclosed other than what might be gleaned from the documents themselves.

[127] One document is an application by Phamatech to the Vietnam Ministry of Health, dated 30 March 1993, for approval of, amongst other things, "One-step QuickStick for personal over-the-counter use". There are two invoices for sales of Phamatech's dipstick to two different Vietnamese companies.²⁰ There is also a copy of what appear to be advertisements from a Vietnamese newspaper dated 27 April 1993, including an advertisement for a product which is described as "hCG test Quickstick". There is a poor quality reproduction of a picture included in the small advertisement, but very little can be discerned from it.

[128] There is no material challenge by Inverness to the proposition that Phamatech may have manufactured and sold dipstick products in 1993. What is relevant is the design of those products and the source of the design. There was no defence witness who was able to give any direct and reliable evidence about design of Phamatech products, or able to produce admissible documents which provided evidence of any assistance in that regard. The Phamatech witness, Mr Glasser was of no assistance. The essential extent of his evidence is illustrated by the following on the dipstick:²¹

We manufactured the QuickStick from components sourced from third party suppliers. Unfortunately we have retained few records from that time so I cannot ascertain who the various components were sourced from at that time. I can confirm however that the QuickStick today is unchanged from the design it had then. That design was not copied from Inverness, Unipath, Acon or any other Inverness subsidiary.

[129] Mr Glasser did not become in-house attorney or counsel for Phamatech until 1999. It is plain from his evidence that he had no involvement at all in matters of

²⁰ Bundle of documents 8.5, 25 June 1993 and bundle of documents 8.6, 16 January 1994.

²¹ Mr Glasser's brief of evidence, para 8.

design. There is other evidence that the design of the QuickStick has changed over the years. I place no weight on Mr Glasser's evidence that the design of Phamatech's dipstick was unchanged since the early 1990s or as to the source of the design.

[130] The unreliable nature of evidence for the defendants in respect of the design of Phamatech's products is also illustrated by evidence from Dr Appanna relating to Phamatech's QuickStick. Dr Appanna said:²²

MDS first purchased the Quick stick product from Phamatech in November 1999 following Medsafe approval. This product was designed by Phamatech in the early 1990's. I cannot be sure when it was first sold by them but I know that it was sold in exactly the same form in Vietnam in 1993 because they have provided me with documents verifying that this was the case. We are endeavouring to get a representative of Phamatech to give evidence to confirm details as to the design and sales of their products. We definitely know that this product was created before 1996. From the 510K file submitted to the FDA in 1998 it can be seen that batches of the product had been manufactured and were being tested as early as February 1996.

[131] The Vietnam documents were discussed above and establish nothing of relevance. The Phamatech witness was Mr Glasser, and I discuss his evidence further in the following paragraphs. Between 1997 and April 1998 Phamatech made five 510(k) applications to the FDA in the United States. These were put in evidence. These were two applications for dipsticks, two applications for cards and an application for midstream. The information contained in these does not assist on the question of the design origins for the Phamatech products.

Evidence on first production of MDS midstream version 3 : the evidence of Mr Glasser generally

[132] The defendants sought vigorously to demonstrate that the MDS midstream version 3 was manufactured before Acon's Rexall midstream device was put into the market in or about October 2002. In recording the defendants' approach in this way I am not indicating that there was an onus on the defendants to prove the point. The defendants nevertheless sought positively to persuade me that the MDS midstream version 3 was first manufactured at the beginning of 2002, if not earlier. For reasons

²² Dr Appanna's brief of evidence, para 64.1.

that I will explain, I do not accept this evidence. My positive finding, based on all of the evidence, is that the Acon Rexall midstream product was in the market before the MDS midstream version 3 was first manufactured, as well as being in the market approximately 20 months before the first purchase of this product by Phamatech for importation into and sale in New Zealand. In addition to the specific issue of prior access, this evidence bears on other issues and questions of credibility or reliability of defence witnesses.

[133] Proof that version 3 was first manufactured in 2002 was said by the defendants to come from invoices from a company called Trengo. These invoices were produced during the evidence-in-chief of Mr Glasser. Mr Glasser was the only Phamatech witness. His written brief of evidence made no reference to the invoices from Trengo. The documents had not earlier been discovered. It may be that copies of the invoices had not been in the possession or control of the defendants. This was the essence of Mr Glasser's evidence. Nevertheless, questions relating to Trengo, said to be the manufacturer of the case for version 3, were the subject of extensive inquiries by the plaintiffs, including protracted and contentious interlocutory applications. Answers by Dr Appanna to interrogatories in respect of Trengo also raise a serious credibility issue. This is discussed below.

[134] Mr Glasser produced six Trengo invoices. The earliest is dated 17 May 1999 and the most recent 28 October 2002. Mr Glasser said that the documents had only recently been found although there had been several earlier requests to Phamatech for them. Mr Glasser said that Trengo manufactured the cases of the midstream for Phamatech. He did not explain why so few invoices were found and why the most recent one was some seven years old.

[135] One invoice dated 6 March 2002 refers, amongst other things, to "midstream II by set (upper + lower white & purple cap) – PO # 17597". The other invoice, dated 28 October 2002 refers, amongst other things, to "midstream II cap purple". Mr Glasser was unable to provide any information in respect of these invoices other than by reference to what was recorded on them. Mr Glasser said that he did not

“know of any other product aside from the product that is described as a midstream that has a purple cap”.²³

[136] The cap of the MDS version 3 is purple. The rest of the case is white. This is the principal evidence ultimately relied on by the defendants to at least raise sufficient doubt as to whether the Acon Rexall was in the market before the MDS version 3 was first manufactured. The evidence from and in relation to the invoices is, at best from the defendants’ perspective, unpersuasive.

[137] Mr Glasser’s knowledge of Phamatech’s midstream devices, and its products generally, was limited and his evidence vague. All of the invoices referred to midstream items, and in some cases with a product number, but Mr Glasser was not able, as he said, “to specifically identify which midstream device [the invoice] pertains to”. He was asked if there was a Phamatech midstream with a blue cap. He said “the midstream device may also have a blue cap”.²⁴ He said that he thought that the Phamatech version 3 of the midstream, which had been shown to him, was “just a different colour of the same product”. There was the following in cross-examination:²⁵

So on my reckoning we have a total of 6 different products or iterations of midstream products referred to in these invoices... they are described in the invoices using different colours but I don't think that the difference in colour is a difference in the device I just think it is the way Trengo is able to describe certain of its products.

There were further acknowledgements from Mr Glasser essentially to the same effect. At another point he said:²⁶

Like I explained before I think that version 3 is just a different colour of the same product.

[138] In his evidence in chief, in an interpolation as he was reading his evidence, there was the following:²⁷

²³ Notes of evidence p 237, lines 10-13.

²⁴ Notes of evidence p 237, line 5.

²⁵ Notes of evidence p 237, lines 28-31.

²⁶ Notes of evidence p 241, lines 23-24.

²⁷ Notes of evidence p 230, lines 33-37.

And have any other versions of the casing to your knowledge been purchased from Trengo or which other... I believe that most if not all of the casings which Phamatech has sold have been purchased from Trengo. I also believe that the different versions that you are talking about may pertain only to the different colours. In other words I don't know if a version pertains to a new design if you will.

[139] As earlier noted, one of the plaintiffs' vigorous lines of inquiry before trial, by various interlocutory applications and private inquiries, was whether MDS had directly commissioned Trengo to design or manufacture the case of version 3. I do not consider it necessary to make any detailed findings in that regard. But against this background, and in the light of Mr Glasser's evidence that Trengo was the current case manufacturer for Phamatech, the failure to produce any up-to-date and informative invoices from Trengo to Phamatech leads me to the conclusion, which is supported by other evidence, that there is evidence adverse to the defendants which has not been disclosed. And there is also no adequate explanation as to why Phamatech would have been supplying MDS with the older versions 1 and 2 until June 2004, if version 3 had in fact been available in early 2002.

[140] Mr Veldhuis, the managing director of one of the Inverness Australian subsidiaries, gave evidence of an historical search of Phamatech's website listing products for sale on 30 January 2003. Phamatech's midstream products did not include the MDS version 3.

[141] Mr Glasser's evidence, as a whole, was unsatisfactory. I expressed that view in the course of the trial when dealing with an objection by the plaintiffs to production of some documentary evidence from a company called Syntron. My observations about Mr Glasser's evidence were as follows:²⁸

I also take into account the nature of the evidence adduced by the defendants from Mr Glasser, the in-house attorney for another American company called Phamatech. The evidence is that Phamatech supplies the midstream and other devices to the defendant. On the face of the documents now in contention there may be some sort of link between what Phamatech supplies to the defendant and what is shown in the Syntron document. The evidence from Phamatech, also provided by video-link, was evasive. In saying that I am not saying that Mr Glasser necessarily lacked credibility or that he was unreliable in his evidence. The problem with his evidence is that he was

²⁸ *Inverness Medical Innovations, Inc. v MDS Diagnostics Limited And Anor* HC Auckland CIV-2007-404-748, 10 June 2009, at [7].

able to answer very few, if any, questions relevant to the matters in issue in this proceeding. It appeared as if Phamatech executives had decided that Mr Glasser should give evidence because he would not be able to answer relevant questions because he had no personal knowledge of the contentious matters.

[142] My observation in the final sentence is demonstrated by the following part of an answer from Mr Glasser in cross-examination:²⁹

... the casings that we purchase from Trencos relate to the midstream device. It is not in my purview to say whether or not it is only purple devices, that's why I said with the earlier invoices that's why I could not tell you what those are.

[143] There was also the following in cross-examination:³⁰

The reason I am asking you these questions Mr Glasser is that you say in your evidence that certain products haven't changed over the years, paragraph 13 for example... this was information that had been provided to me for this brief of evidence.

Provided by who... various individuals at Phamatech.

Who drafted this document... I believe counsel for MDS had drafted it based upon input he was given and then asked me to review it.

Dr Appanna's answers to interrogatories on midstream design

[144] Interrogatories were put to MDS by the plaintiffs seeking answers to questions relating to the design and manufacture of the MDS midstream products. There was one set of interrogatories in a notice dated 11 May 2007. Dr Appanna answered the notice, by affirmation dated 28 May 2007. The first question and Dr Appanna's answer were as follows:

By whom were each of the Quickcard and Quickstream products designed?

MDS imports the Quickcard and Quickstream products from Phamatech Inc., a company based in San Diego, California. The officers, employees or agents of MDS have no knowledge of who designed the Quickcard and Quickstream products.

²⁹ Notes of evidence p 238, lines 13-15.

³⁰ Notes of evidence p 242, lines 22-27.

[145] This is not an accurate answer and I am satisfied Dr Appanna knew it was not accurate. This is established by e-mail communications between Phamatech, Trengo and Dr Appanna personally, and cross-examination of Dr Appanna on the e-mails. These were e-mails in March 2007, just two months before the interrogatory answer was provided. The e-mails came to light in the course of the trial. Because of the nature of my conclusion I will set out the relevant text of the e-mails commencing on or before 8 March 2007 and concluding with an e-mail from Dr Appanna to MDS's solicitors on 24 March 2007. First names are used and I have added some detail to explain who the people are. The e-mails arise from MDS inquiries to Phamatech and then Trengo in preparing for trial of this case.

- a) On or before 8 March 2007: from Jodee of Phamatech to Ted of Trengo:

Ted,

The e-mail that you sent a while back will not work in the patent case.

I need a copy of your earliest manufacturing records or something along this [sic] lines. THIS IS URGENT.

Jodee

- b) 8 March 2007: reply from Claire of Trengo to Jodee at Phamatech:

Subject: Re: Patent Info

Dear Jodee,

We have been contacting with our oversea [sic] office. Since the first production was around 1995 and we did not manufacture for Phamatech for [a] long period [of] time, it would take a while to find those files. As soon as we receive it, we will forward to you. We appreciate your understanding!

Best regards,
Claire

- c) The two preceding e-mails were sent on 20 March 2007 by Jodee of Phamatech to Dr Appanna, with a copy to Tuan Pham, the president of Phamatech. Dr Appanna responded to Phamatech and Trengo some time between 20 March and 24 March 2007 as follows:

Hi Jodee & Claire/Ted

I would really appreciate a simple letter from Trend [sic] Products signed and emailed as a pdf simply stating that Trend [sic] Products were manufacturing the casings used by Phamatech for the QuickCard and QuickStream prior to the 7th September 2001.

If Trend [sic] were the original creators of the drawings, it would be helpful to say you were. If Trend [sic] were not the original creators then it would be helpful to say that Trend [sic] are manufacturing them under licence. (Emphasis added.)

Please can I have this document as soon as possible as it needs to be filed with the court next week.

Many thanks
Prakash Appanna

- d) Claire of Trengo responded on 24 March 2007 by e-mail to Dr Appanna and Jodee of Phamatech with a copy to Tuan Pham of Phamatech as follows:

Hello Jodee / Prakash,

Sorry we did not find the Midstream drawings as per your request. (I only have the Midstream mold [sic] picture now.) We are the original creator of the parts, and we are willing to cooperate with you. Please have your lawyer prepare a draft statement that could help your case, and Mr. Hou will sign it for you. Thank you!! (Emphasis added.)

Best regards,
Claire

- e) The final e-mail is from Dr Appanna to his solicitor, Mr Rodney Hooker (and also to Mr Hooker's partner Mr Vallant, an MDS director) sending all of the preceding e-mails with the following message:

Hi Rod

Can you please draft something for me to send to them?

Thanks
Prakash

[146] Dr Appanna's answer to the interrogatory, in light of the e-mails, was put to him in cross-examination as follows:³¹

See the difficulty I am having Dr Appanna with your answers is the emails that you had with Trengo which predate this affidavit they clearly show that you had communicated with them on 24 March 2007, a couple of months before this... correct.

And without wishing to put too fine a point on it you knew Trengo had made the product. That statement that you have no knowledge is simply not true... Mr Elliott the question was not who had made the product, the question is who had designed the products.

You don't think the person who makes it designs it... I'm not sure you want me to answer that. We have gone through so many people who have designed things and had them made by other people that there is a differentiation between design and made.

[147] It is plain from the e-mail from Trengo of 24 March 2007 that Trengo was saying to Dr Appanna, and to Jodee of Phamatech, that Trengo had designed the casing. This is plain from the passages underlined in that e-mail standing alone. If there is any ambiguity in what Claire of Trengo said (and I do not consider that there is) the ambiguity is removed by the context provided from the earlier e-mails, and in particular the emphasised passage in Dr Appanna's own e-mail immediately before. Dr Appanna's answers in cross-examination are not at all persuasive.

[148] These e-mails also disclose further inaccuracies in evidence, or at the very least another reason not to rely on defence evidence. The thrust of the evidence of Mr Glasser, in 2009, was that Trengo continued to manufacture the cases for Phamatech. However, the first e-mail from Trengo, recorded at [145]b) above, states that in March 2007 that Trengo had not manufactured for Phamatech for a long period of time.

[149] Dr Appanna answered further interrogatories by an affirmation dated 23 October 2008. Questions 20 and 24, and the answers, are as follows:

Has the first or second defendant had contact, direct or indirect, with the entity Trengo Company?

Answer: The defendants object to answering this interrogatory on the grounds that it is fishing and oppressive and is irrelevant to any issue

³¹ Notes of evidence p 381, lines 24-34.

pleaded in the second amended statement of claim. The first and second defendants further say that the question which is posed in this interrogatory seeks an answer which, if answered in accordance with the question as posed, could give rise to a claim to legal professional privilege.

...

Has the Trengo Company, through its Chinese or any other facility, made or assembled the casing (or any part of it) for the QuickStream Mark III product referred to in paragraph 17 above?

Answer: The defendants object to answering this interrogatory on the grounds that it is fishing and oppressive and is irrelevant to any issue pleaded in the second amended statement of claim.

These answers are evasive.

[150] I drew, and continue to draw, from the interrogatory answers, and Dr Appanna's evidence on them, an adverse impression as to the quality of Dr Appanna's evidence generally. In saying this I have had full regard to the need for real caution before reaching an adverse finding on credibility and, separately, the need for real caution in assessing the implications for a case as a whole of misleading evidence on a particular topic. On the latter point, the misleading evidence I have just dealt with obviously could not, by itself, demonstrate infringement of copyright. But it is part of the evidence as a whole which needs to be weighed. The evidence on this topic related to a central issue. And the impact of this inaccurate evidence on the assessment of the defence evidence as a whole needs to be weighed with other evidence for the defendants which I consider was unreliable, and in some cases indicative of more serious failings. I will refer to one other matter in this section. Other aspects bearing on credibility or reliability are dealt with later.

Altered midstream exhibit

[151] The midstreams sold by MDS were contained in a sealed, plastic pouch (in turn contained in a rectangular box). A number of the MDS pouches were produced in evidence, by both parties. All but one of them had details printed on the exterior of the pouch. For example, and picking one at random, exhibit 29, has the following printed on it: "HCG – lot # E 81500 – Exp. 2010-05 – Made in USA".

[152] There is one pouch which does not have any detail printed on its exterior. It does have the date “1999” written in felt-tip on a sticker stuck on the surface of the pouch. There are two matters relating to this which do not reflect favourably on the defendants’ conduct of the case.

[153] The first concerns the removal of the coding and date. The coding and date would provide clear evidence as to when the product was manufactured. The second matter relates to the initial failure to discover the pouch with the midstream in it and Dr Appanna’s explanation as to why that happened. The pouch was not discovered in the first list of documents. It was discovered in a subsequent list when new solicitors were instructed by the defendants (who, in the course of this proceeding, instructed three firms of solicitors). There was the following in cross-examination of Dr Appanna, referring to this pouch (with letters substituted for some names):³²

And someone has kindly written 1999 on there. Who scratched off those details... I can't tell you who scratched it off but I recall being very very upset when I saw those details rubbed off. I had given this particular pouch to Ms D who was one of our solicitors initially and at some point when I reviewed it with her because I told her that this was the only sample we had with that expiry date noted on it, and when I came back to look at it it had been rubbed off. Now, these pouches are printed as you know and with multiple handling over time it is very easy for that to rub off and the writing of 1999 is not my writing and I would understand that to have been Ms D’s writing.

...

... is the date 1999 the expiry date or the manufacturing date... it would have been the expiry date. As Phamatech’s products have a 2 year, 24 month, validity, you would be able to deduce a manufacturing date of 24 months earlier. I am sure with modern technology there would be some scientist out there who would be able to look at the inkjet printing on there and be able to re-establish the date on there but I don't think anyone has done that.

...

Was that sent to you by Phamatech... yes it was.

And when was that sent to you... I can't tell you that because I don't know the date when it was sent but based on the information being carried on the packaging my understanding was that this was likely to have been in amongst the first set of samples that they would have sent to us in 1998 or 1999.

³² Notes of evidence p 363, lines 27-34; p 363, line 37 to p 364, line 5; p 364, line 21-25; and p 364, line 31 to p 365, line 5.

...

If you had that sample as far back as 98 why wasn't it discovered with your first lot of discovered documents... that's a question you may have to pose to the solicitors who were given the product.

It was only when Simpson Grierson got involved that we saw that product for the first time.... I can tell you without a doubt this product was handed to Ms D in probably our first or second meeting.

HIS HONOUR: Who is Ms D... Ms D was Mr H's [solicitor for defendants] associate.

MR ELLIOTT: You signed the affidavit of documents which said that all relevant documents had been discovered. Surely if you'd given it to Ms D you would have thought she's missed out an important document, a pouch with writing or lack of writing on it... that is correct I did sign the list of documents, the confirmation of the list of relevant documents, but as you are aware the process works such that you give your representatives all the material, they determine what is relevant.

[154] It will be apparent from my judgment to this point that the dates on which products were produced by the plaintiffs, and by Phamatech on behalf of MDS, are important. And the question of dates was particularly prominent with midstream devices. This pouch, as I have noted, was for a midstream device. It is unnecessary to make any finding as to the actual date of production, or expiry, of this pouch and its contents. It would probably not be possible to make any clear finding. What this evidence does do, in my judgment, is to lend weight to my adverse conclusion about the quality of the defence evidence as a whole. The direct evidence of Dr Appanna suggests that a staff solicitor at his and MDS's solicitor's office, had, at the least, allowed important and printed information to be rubbed off and had casually handwritten a date. I find that hard to believe and the general explanation is not plausible. Responsibility was, in my opinion, glibly shifted to a staff solicitor who was then not called to verify the assertions. And if the exhibit had the importance that Dr Appanna plainly suggests it did have, his failure to discover it in the first list of documents is difficult to excuse. And again he shifts responsibility to others who were not called to give evidence.

J. Subsistence of copyright : originality

[155] A concise statement of the inquiry under this heading was made by the Supreme Court in *Henkel KGaA v Holdfast New Zealand Limited* as follows:³³

[37] Once the plaintiff has identified the work for which it is claiming copyright, it is next necessary for the plaintiff to establish that the work is an original work. The concept of originality is not defined in the Act and common law principles apply. The Act does, however, prescribe when a work is not original. That will be so if it is, or to the extent that it is, a copy or infringement of another work. The Act thus gives some guide to the common law concept of originality, which must be carefully distinguished from novelty. There need be nothing novel in a work to qualify it for copyright protection. To be original for copyright purposes the work must originate from its author and must be the product of more than minimal skill and labour.

[38] The threshold for originality is a low one and it can be material for other purposes how original the work is; that is, how much skill and labour has gone into its creation. In general terms, the greater the originality, the wider will be the scope of the protection which copyright affords and vice versa. ... (Footnotes omitted.)

Does copyright subsist : originality : Unipath

[156] On this topic Mr Marriott made two points for the defendants. The first submission was directed to what he described as the “preliminary sketches” and to the drawings in the May and Davis patent specifications (annexures 1 to 6). Mr Marriott submitted, in essence, that these were “concept” drawings only – illustrative of the underlying idea or concept rather than artistic works expressing the idea – or at best very simple works, requiring “minimal effort” and therefore entitled to minimal protection.

[157] I do not agree that any of these drawings is merely a record of the underlying idea, or concept or invention. They are, in my judgment, expressions of the underlying ideas. I deal more fully with this topic below. I also do not agree with the submission that “minimal effort will have been expended in the creation of those drawings”, as Mr Marriott put it. The background narrative about the work at Unipath records the extent of the time, effort and skill that went into the creation of

³³ *Henkel KGaA v Holdfast New Zealand Limited* [2006] NZSC 102, [2007] 1 NZLR 577.

these early works. The questions are not to be determined simply by determining the time, effort and skill in putting lines on a piece of paper. That might be the proper approach if copyright was claimed for a doodle made on a paper napkin at a restaurant by someone with no artistic or other relevant skill. What was required for Mr Prior to produce, for example annexure 1 (WB 003 – bottom), cannot be divorced from the time, effort and skill that went not only into the scientific research but also the design which is reflected in the annexure. The underlying concept can be defined, but there is often no clear dividing line between skill and effort associated with the technical development of the concept, and skill and effort represented by the expression of the idea in a drawing; in my judgment that is certainly so in this case. Put another way, the evidence in this case satisfies me that there was an ongoing inter-relationship between development of concepts and expression of the concept, with one aspect influencing the other. And this continued over the years at Unipath with the on-going refinements represented by the later copyright works.

[158] The second point for the defendants concerned the two drawings for the case for Unipath's card: annexures 7 and 8. As earlier recorded, Unipath produced its first card, Clearview 1, in 1988 and its second card, Clearview 2, in 1990. Referring to the 1989 and 1990 dates on the drawings, Mr Marriott submitted:

7.8 ... Therefore they can only refer to the Clearview 2 released in 1990 as opposed to the Clearview 1 released in 1988. No evidence has been led as to how the casing design of the Clearview 2 differs from that of the Clearview 1, whether any aspects of that design were derived from any alternate source, nor as to the extent of level of originality of the later product. No assessment can therefore be made as to the extent of effort required to produce the drawings relied upon, and hence whether that effort has been appropriated or not.

[159] I do not consider there is anything in this point which could result in a conclusion that the two drawings are not copyright works and drawings resulting from substantial effort and skill. The reference to the two Clearview versions does not appear to bear on the primary question of subsistence of copyright. If there were no changes between Clearview 1 and Clearview 2, in respect of the drawings for the case, copyright would still have subsisted (although this would bear on other matters such as the first date of industrial application). The drawings themselves indicate that they evolved from drawings made in August 1988. There is evidence, from

notations on the drawings, of some changes made and I readily infer that some reasonable effort and skill was applied in respect of those.

[160] The defence submissions did not challenge subsistence of copyright, or question the extent of originality, in other important Unipath copyright works. These include, in particular, the drawings in annexures 9 to 12. Having regard to the evidence, and my conclusions recorded in section G above, I am satisfied that these works were the result of significant effort and skill; they are highly original. Before these drawings were created, but following the early drawings by Mr Prior and his colleagues, the drawings in the May and Davis patents were created (annexures 4A to 6). These were touched on in Mr Marriott's first submission, but the attention was on Mr Prior's drawings. The drawings in the May and Davis patents are significant design refinements indicative of the continuing application of effort and skill by Unipath.

Does copyright subsist : originality : Acon

[161] Mr Marriott made two submissions on the question of originality in the Acon copyright works. The first was that the drawings for the strips are not original because "the design of the test strip was copied from a third party Arista Biologicals". I have already recorded my conclusion that the copyright works of Acon have sufficient originality to give rise to copyright, but it is appropriate to respond more fully to Mr Marriott's closing submissions.

[162] Reference was made to the evidence of Mr Xiang and Mr Gao. This evidence is outlined at [94]-[103] above. The evidence, and further evidence in cross-examination referred to by Mr Marriott, does not support the defendants' submission that Acon's strips and, more particularly, Acon's copyright works, are copies of Arista strips or works. Mr Xiang's evidence was that it was "lateral flow technology" that was "learned" from Arista. Mr Xiang said that with knowledge of the technology Acon teams then set about designing their own strips. Mr Gao also said that an Acon employee, Mr Guan, went to Arista "to find out how to *make* the test strips and packaging" (emphasis added). This statement has a degree of ambiguity but, in light of Mr Xiang's evidence, there is not enough to suggest that

the Arista design was simply copied. The cross-examination of Mr Gao, to which Mr Marriott referred, does not materially alter that conclusion, particularly when assessed in relation to other evidence as to the extent of Acon's own design work.

[163] Reference was earlier made to Acon's reviews in the period 1999 to 2002. The copyright works put in evidence by Acon date from this period. Mr Marriott submitted that this did not assist the plaintiffs on the question of Acon originality because of Acon evidence that the design of the test strips had not changed in any significant way since the first production in 1995/1996. If there were no material changes between the copyright works created for the products made in 1995/1996 and the copyright works created between 1999 and 2002, this would not bear on originality. But I am also satisfied there is substantial originality in the works created in the review over the period to 2002. There are a few statements by Mr Gao which, taken in isolation, might tentatively support the submission that there was no change, or no significant change, in the design of the strips first produced in about 1996. But reading his evidence in light of all the other evidence, and allowing for the particular context in which Mr Gao was answering questions, I am satisfied, as recorded, that the works in question have sufficient originality for copyright to have arisen when they were created.

[164] There was an alternative, and somewhat faint, submission for the defendants that the extent of originality must be very low because "none of the plaintiffs' witnesses saw fit to highlight any changes to dimensions that were made". "Accordingly", it was submitted, "nothing short of almost exact reproduction will amount to infringement". There was then reference to *Henkel* at [38]. The submission is founded on the premise that the design of the original strips was simply copied from Arista, and I have already rejected that point.

[165] My overall conclusion on the Acon copyright works for strips is that there was a good deal of originality in them. Indeed, Mr Marriott, in his closing submissions, relied on an opinion of the plaintiffs' expert witness, Mr Bladen, that the Acon test strip was a work that was "original in its own right" when compared with Unipath strips. Mr Marriott submitted that this conclusion "must be highly persuasive". This point was made for the defendants in support of a submission that,

if the differences in the design (drawings) for Acon strips were sufficient to establish originality, and in particular compared with Unipath strips, then the same must apply to Phamatech strips, unless the Phamatech strips were copied from Acon. I will come back to the relationship between Unipath and Acon works (see [316]-[317]). But on the point now under consideration – whether Acon’s underlying drawings are original – the defendants cannot have it both ways.

K. Infringement by copying

Principles

[166] Principles bearing on the question of infringement by copying were stated by the Supreme Court in *Henkel* at [43]-[44] as follows:

Proof of copying

[43] The ultimate issue in a breach of copyright case concerns derivation, not similarity,³⁴ albeit the degree of similarity between the copyright work and the allegedly infringing work has evidentiary significance. Proof of copying will seldom be direct; in most cases the Court will rely on inference. The closer the similarity between the two works the stronger the inference is likely to be that the one was copied from the other. If the alleged infringer has had access to, and therefore an opportunity to copy, the copyright work, and the similarity between the works supports an inference of copying, it may well be appropriate for the Court to conclude, on the balance of probabilities, that there was indeed copying. This, of course, is subject always to the evaluation of any evidence there may be that no copying actually took place.³⁵

Substantial part

[44] It is not necessary for the plaintiff to show that the defendant copied the whole of the copyright work or that the copying was exact. It is enough if the plaintiff demonstrates that the defendant copied a substantial part of the copyright work.³⁶ This can sometimes be a difficult matter of evaluation and is usually the most difficult question which arises in copyright cases. What amounts to a substantial part in an artistic work case depends more on qualitative visual impression rather than on quantitative analysis.³⁷ As it has helpfully been put, what must have been copied is the essence of the

³⁴ See Kevin Garnett, Gillian Davies and Gwilym Harbottle (eds) *Copinger and Skone James on Copyright* (15th ed, Sweet & Maxwell Limited, 2005) volume 1 at [7-57].

³⁵ See *ibid*, at [7-17].

³⁶ Section 29(2)(a) of the Copyright Act 1994 and see *Copinger*, at [7-23] and following.

³⁷ *Ladbroke (Football) Ltd v William Hill (Football) Ltd* [1964] 1 WLR 273 (HL) at 279 per Lord Reid.

copyright work.³⁸ This is a subject upon which, in borderline cases, minds can reasonably differ, and it is appropriate for appellate Courts to give to the trial judge's assessment the degree of latitude that conventionally applies to appellate review of a discretion.

[167] As recorded in the footnotes, the Supreme Court referred, with approval, to several paragraphs in *Copinger*, including paragraph 7-57. The authority for a number of statements in 7-57 of *Copinger* is *Designers Guild Ltd v Russell Williams (Textiles) Ltd*,³⁹ and in particular the speech of Lord Millett at 2425; 708-709. The preceding paragraph 7-56 in *Copinger* is based largely on Lord Millett's speech. Having regard to the wide range of arguments advanced on both sides in this case, and some significant differences between the plaintiffs and the defendants as to the relevance or weight of evidence advanced on questions of infringement, it will be instructive to cite the relevant part of Lord Millett's speech in full. He said:

... I think that the Court of Appeal erred in principle in the approach which they adopted. In particular, I think that they misunderstood the function of a visual comparison of the two works in a case concerned with artistic copyright and the stage at which such a comparison should be undertaken.

It must be borne in mind that this is an action for infringement of copyright. It is not an action for passing off. The gist of an action for passing off is deceptive resemblance. The defendant is charged with deceiving the public into taking his goods as and for the goods of the plaintiff. A visual comparison of the competing articles is often all that is required. If the overall impression is that 'they just do not look sufficiently similar' then the action will fail.

An action for infringement of artistic copyright, however, is very different. It is not concerned with the appearance of the defendant's work but with its derivation. The copyright owner does not complain that the defendant's work resembles his. His complaint is that the defendant has copied all or a substantial part of the copyright work. The reproduction may be exact or it may introduce deliberate variations—involving altered copying or colourable imitation as it is sometimes called. Even where the copying is exact the defendant may incorporate the copied features into a larger work much and perhaps most of which is original or derived from other sources. But while the copied features must be a substantial part of the copyright work, they need not form a substantial part of the defendant's work (see *Warwick Film Productions Ltd v Eisinger* [1967] 3 All ER 367, [1969] Ch 508). Thus the overall appearance of the defendant's work may be very different from the copyright work. But it does not follow that the defendant's work does not infringe the plaintiff's copyright.

The first step in an action for infringement of artistic copyright is to identify those features of the defendant's design which the plaintiff alleges have been

³⁸ *Bleiman v News Media (Auckland) Ltd* [1994] 2 NZLR 673 (CA) at 678 per Gault J.

³⁹ [2000] 1 WLR 2416; [2001] 1 All ER 700 (HL).

copied from the copyright work. The court undertakes a visual comparison of the two designs, noting the similarities and the differences. The purpose of the examination is not to see whether the overall appearance of the two designs is similar, but to judge whether the particular similarities relied on are sufficiently close, numerous or extensive to be more likely to be the result of copying than of coincidence. It is at this stage that similarities may be disregarded because they are commonplace, unoriginal, or consist of general ideas. If the plaintiff demonstrates sufficient similarity, not in the works as a whole but in the features which he alleges have been copied, and establishes that the defendant had prior access to the copyright work, the burden passes to the defendant to satisfy the judge that, despite the similarities, they did not result from copying.

Even at this stage, therefore, the inquiry is directed to the similarities rather than the differences. This is not to say that the differences are unimportant. They may indicate an independent source and so rebut any inference of copying. But differences in the overall appearance of the two works due to the presence of features of the defendant's work about which no complaint is made are not material. In the present case the disposition of the flowers and (except in one instance) the colourways of the defendants' design are very different from those of the plaintiffs' design. They were not taken from the copyright work, and the plaintiffs make no complaint in respect of them. They make a significant difference to the overall appearance of the design. But this is not material where the complaint is of infringement of copyright and not passing off.

Once the judge has found that the defendants' design incorporates features taken from the copyright work, the question is whether what has been taken constitutes all or a substantial part of the copyright work. This is a matter of impression, for whether the part taken is substantial must be determined by its quality rather than its quantity. It depends upon its importance to the copyright work. It does not depend upon its importance to the defendants' work, as I have already pointed out. The pirated part is considered on its own (see *Ladbroke (Football) Ltd v William Hill (Football) UK Ltd* [1964] 1 All ER 465 at 481, [1964] 1 WLR 273 at 293 per Lord Pearce) and its importance to the copyright work assessed. There is no need to look at the infringing work for this purpose.

[168] As indicated in the preceding section of this judgment, an issue on which a lot of energy was expended in this case was whether it was possible that Phamatech could have had access to Unipath or Acon copyright works, or at least Unipath or Acon products, to enable direct or indirect copying. I have already recorded my conclusion that the relevant Unipath or Acon products, and in some cases drawings, were available for copying. A further and inevitable issue, and one at the heart of the case, is whether there is proof of copying. In that respect a substantial amount of the defence evidence was directed to differences between the MDS products, and the Unipath or Acon products or drawings. The passages I have cited from *Henkel* and *Designers Guild* note the relevance of differences, but emphasise the importance of

similarity in respect of a substantial part. The means of proving both of the matters I have referred to – prior access and, ultimately, copying – are discussed in *Copinger* at paragraph 7-17. This is another paragraph referred to with approval in *Henkel*. The first part of the *Copinger* paragraph is as follows:

It is for the claimant to prove copying, this being a question of fact,⁴⁰ the standard being the ordinary civil standard.⁴¹ In most cases copying can only be deduced by inference from all the surrounding circumstances because normally there will be no evidence from anyone “being present and looking over the [defendant’s] shoulder” at the time he designed or made his work.⁴² The case will therefore normally start with establishing substantial similarity combined with the possibility of access.⁴³ Where there is substantial similarity, this is *prima facie* evidence of copying⁴⁴ and also of access.⁴⁵ Once a *prima facie* is established in this way, a shift in the evidential burden takes place which the party charged may refute by evidence of independent creation⁴⁶ or by giving some alternative explanation for the similarities.⁴⁷ The task of the judge is then to decide, on the evidence as a whole, whether or not there has been copying.⁴⁸ This can be summarised by saying that proof of sufficient similarity, coupled with proof of the possibility of access, raises a *prima facie* case or inference of copying for the defendant to answer.⁴⁹ This shifting of the burden of proof is merely one of plain, rational thought.⁵⁰

[169] One other passage in *Copinger*, of particular relevance to this case, comes from paragraph 7-58:

⁴⁰ *Ibcos Computers Ltd v Barclays Finance Ltd* [1994] FSR 275 at 296.

⁴¹ *Biotrading & Financing OY v Biohit Ltd* [1998] FSR 109 at 121.

⁴² *Sifam Electrical Instrument Co Ltd v Sangamo Weston Ltd* [1973] RPC 899.

⁴³ In *LB (Plastics) Ltd v Swish Products Ltd* [1979] RPC 551 at 619, Lord Wilberforce speaks of “proof” of access but it is suggested that this goes too far. Proof of the possibility of access is surely enough.

⁴⁴ *King Features Syndicate v O & M Kleeman Ltd* [1941] AC 417 at 436.

⁴⁵ *Francis Day & Hunter Ltd v Bron* [1963] Ch 587 at 612. Of course, if it is very unlikely that a defendant could have had access to the claimant’s work, this will weaken the inferential case.

⁴⁶ *LB (Plastics) Ltd v Swish Products Ltd* [1979] RPC 551; *King Features Syndicate Inc v O & M Kleeman* [1941] AC 417. If the defendant calls no evidence, a court is therefore entitled to find copying proved: *Mathieson v Universal Stock Exchange* [1901-04] Mac CC 80; *Cadieux v Beauchemin* [1901-04] Mac CC 4 (Sup Ct of Can).

⁴⁷ *Billhöffer Maschinenfabrik GmbH v Dixon & Co Ltd* [1990] FSR 105 at 107.

⁴⁸ *LB (Plastics) Ltd v Swish Products Ltd* [1979] RPC 551, at 619, 621 (HL).

⁴⁹ *Francis Day & Hunter Ltd v Bron* [1963] Ch 587, at 612, 614; *Designers Guild Ltd v Russell Williams (Textiles) Ltd* [2001] 1 WLR 2416, per Lord Millett at [39].

⁵⁰ *Ibcos Computers Ltd v Barclays Finance Ltd* [1994] FSR 275 at 297; cited with approval in *Creative Technology Ltd v Aztech Systems Pte Ltd* [1997] FSR 491 at 501 (CA of Singapore).

... Again, in the case of a drawing of a utilitarian article, it is not correct to attempt to separate the skills of the creator of the copyright work into those which were purely “artistic” and those which were directed to giving the article its operational efficiency, perhaps at the direction of an engineer, and thus argue that if no use has been made of the former skills there will have been no infringement.⁵¹

[170] At [43] of *Henkel* the Supreme Court said that “the closer the similarity between the two works the stronger the inference is likely to be that the one was copied from the other”. This does not mean that proof of copying is dependent upon proof of close similarity. At least prima facie proof of copying may come from evidence of relevant similarities that, by themselves, are insufficient to indicate conclusively that one was copied from the other but which, when coupled with other evidence from which the Court is entitled to draw an inference of copying, is sufficient to indicate copying, subject to proof to the contrary by the defendant.

[171] This points to another aspect of the inquiry into the broad question whether there has been copying. For the purposes of analysis, the inquiry can be described as a series of steps one following logically after the other. However, the evidence does not always fit neatly into only one pigeon hole. Even where some pieces of evidence can be identified as relating entirely to a particular stage of the inquiry, the weight of that evidence, in favour of the defendant or the plaintiff, may bear on the assessment of the weight of other evidence. That is not to say that the Court can blithely take evidence relevant solely to one point and use it as a device to seek to answer another issue, but the strength of the case for one party or the other at one point may often properly be brought into account to assist in determining the weight of evidence on another point. This applies in this case against the defendants.

[172] As I have earlier recorded, one prominent feature of this case is the complete absence of evidence from the defendants of anything remotely approaching an independent design trail for the MDS products. There is no claimed copyright work put in evidence in respect of any of the products. There is no adequate explanation

⁵¹ *British Leyland Motor Corp Ltd v Armstrong Patents Co Ltd* [1986] AC 577 (HL) at 621, although cases of this kind will now usually only be relevant in the case of design right. It has been said that where the claimant’s design has been indirectly copied but only to the extent of features that are purely functional, there is no infringement: see *George Ward (Moxley) Ltd v Richard Sankey Ltd* [1988] FSR 66, per Whitford J, citing the dissenting judgment of Lord Griffiths in *British Leyland*. It is suggested that this is clearly wrong.

for this absence of such evidence, notwithstanding that there was evidence from a Phamatech witness. The negative inference against the defendant from this feature is compounded by the almost total absence of any other relevant documents from which it might be inferred that Phamatech had applied relevant skill and effort, directed to independent design of its strips and cases, sufficient to indicate an absence of copying. This difficulty for the defendants is compounded by other aspects of defence evidence, including questions of credibility and reliability, some of which I have already discussed.

Copying : the main witnesses and their approaches

[173] The plaintiffs called three principal witnesses on the general question of copying. One was Mr Prior. In addition to the evidence from Mr Prior that I have already outlined, Mr Prior provided detailed descriptions of what the plaintiffs claim are a number of original features in the copyright works for the strips. Mr Prior identified nine significant features and I accept the thrust of that evidence. There was further evidence from Mr Prior, which I do not intend to summarise, identifying features which he considered had particular importance in the design of the strips in particular, and I accept this evidence. It was persuasive in itself, not materially modified by cross-examination, and not subject to contrary evidence of weight from another witness.

[174] The second witness was Mr Raj. Mr Raj was employed by Unipath in various capacities from 1984 to 2007, including a period as technical manager. Mr Raj was involved in the development of the Unipath pregnancy testing products from the beginning. Mr Raj provided detailed evidence of what he said were close similarities between the Unipath and Acon copyright works, as represented in the Unipath and Acon products, and the defendants' products. Mr Raj's preparation for this evidence included comparison of a wide range of features, extensive physical examination, extensive comparison by measurements and some scientific analysis. Much of this work was explained in photographs put in evidence. Although a large part of the direct comparisons were product to product, rather than Unipath or Acon copyright work to product, I am satisfied that this nevertheless resulted in a

sufficiently effective comparison between the relevant copyright work and the corresponding MDS product.

[175] For reasons that I will come to, I do not consider it necessary to set out the detail of Mr Raj's evidence. Standing alone – that is to say, without contrary evidence for the defendants – Mr Raj's evidence by itself provided strong evidence of similarities indicative of copying in the MDS products. When I refer to Mr Raj's evidence I am, of course, including reference to his evidence in the course of very thorough cross-examination by Mr Marriott.

[176] The third principal witness for the plaintiffs on the question of copying was an expert, Mr Roy Bladen. The defendants also adduced evidence from an expert, Mr Brian Hanlon. Mr Bladen's and Mr Hanlon's areas of expertise were different. And there were differences in their approach and in the broad nature of their evidence. I accept the plaintiffs' submission that these differences have an important bearing on the weight to be attached to the evidence. My general conclusion is that these differences justify greater weight being attached to opinions expressed by Mr Bladen than to those expressed by Mr Hanlon. It was also apparent that the scope of the instructions to each expert, and the resultant range of their inquiries, differed in ways which diminished the extent of the assistance Mr Hanlon could provide.

[177] In pointing to these differences, and in recording my conclusion that I have in general terms attached greater weight to Mr Bladen's evidence compared with Mr Hanlon's, I am not intending to criticise Mr Hanlon, or to suggest that he lacks expertise in his particular field.

[178] Mr Bladen, having obtained some certificates in aspects of engineering between 1971 and 1973 at the London Institute and ITB London, has worked as a product designer since 1975. Between 1975 and 1982 he was employed in New Zealand as a design engineer at Tullen Industries Limited and in developing new consumer products for Wilkinson Sword Limited and Fiskars Limited. He described his work from 1972 as follows:⁵²

⁵² Mr Bladen's brief of evidence, paras 4-6.

Since 1982 I have worked as a product design consultant and since 1983 I have had my own business specialising in technical plastic injection moulded products for the consumer, agricultural and electronic industries. I have extensive knowledge in injection moulding and polymer materials processing.

I have designed a wide range of products including mobility carts, hand driers, electrical fencing housing units, travel games, shower and spa baths, animal ear tags, swimming pool pumps and filter units, fruit pallets and crates, screw thread unions for pressure pipe connections, irrigation fittings, plumbing fittings, hand tools, scissors, room heater, swimming pool cleaners, car mounted cycle racks, electrical switch gear, point of sale displays and food packaging.

My clients have included Fisher & Paykel, Englefield Industries, Englefield Medical, Oben US, Gallagher Electronics Limited, Zee Tags Limited, Reese Plastics Limited, Best Bars Limited, Spa Quip Limited, Saddlery Warehouse Limited and Penrice Supreme Limited.

[179] Mr Hanlon's background has focused more on engineering and production of products, as opposed to design. Mr Hanlon described himself as a plastics engineer. He has a certificate of engineering in plastics from 1969-1972 and further qualifications obtained in the United Kingdom. He said that the United Kingdom qualification "makes [him] one of the best qualified plastics engineers in New Zealand". Since 1978 he has been continuously involved in the development of education and training in the New Zealand plastics industry. Although the central focus of his employment has been as a plastics engineer, Mr Hanlon did say his "work can involve the study and development of design and manufacturing solutions for many different sectors serviced by [his] clients". He noted that he has, in recent years, run one day industry courses on behalf of Plastics New Zealand "covering the design and specification of plastics materials". He has been a judge of design awards in the plastics industry.

[180] Possibly as a consequence of the nature of the instructions received, the inquiries made by Mr Bladen to form his opinions were wider than those of Mr Hanlon. There were also important differences in their respective understandings of the nature of the inquiry into the question of copying. Mr Bladen understood his primary task was to determine whether there were similarities between the plaintiffs' drawings and products and, where there were similarities, to assess the significance of those similarities in his opinion as a designer. Mr Hanlon acknowledged similarities, but gave considerable emphasis to numbers of differences, many of

which were small differences of dimension or product fabrication detail. Mr Hanlon's opinion that copying had not occurred was based, in considerable part, on an assessment of the number of differences compared with the number of similarities. This is contrary to the nature of the primary inquiry. This was compounded by the yardstick Mr Hanlon used to determine whether there were similarities. He was looking for complete "replication". This is contrary to principle.

[181] Both aspects of Mr Hanlon's approach are captured in the following evidence in cross-examination:⁵³

Mr Hanlon you said when looking at the Clearview product as opposed to the Quik-check product... yes.

That you couldn't see totally clear replication from one product to the other... yes that is correct.

Is that your test for testing similarities and differences... excuse me I will just find the reference you are referring to.

You said that a few minutes ago you may not find it anywhere... when comparing these devices what I set out to do was in the first instance identify any similarities I could in the devices, externally and internally. And then I went through and identified or tried to list all the differences that I saw in the devices. And I used that list of similarities and differences to help me draw some conclusions about replication. In some situations the list of differences was so significantly much greater and had – and the differences were of more significance that it made the decision about whether there had been replication or not quite straight forward and that is demonstrated about my analysis of the midstream devices. In the case of the cards I did a similar exercise as documented in my brief and the prospect of replication was not so clear as I have noted there. There was a similar list of similarities and differences and the content of those similarities and differences were not so significant that it swayed me one way or the other.

So when you made the comment about totally clear replication from one product to the other that was just a passing comment, it wasn't the approach you had adopted... no the approach I adopted was the one I just reviewed.

Well what did you mean then when you said its not totally replicated one from the other... you are referring to my earlier comments.

Yes... when I was reviewing the - I think it seems to me it's obvious I mean the – what I was doing was comparing the devices for – to see if I could identify replication.

⁵³ Notes of evidence p 261, line 26 to p 262, line 19.

And to see whether there had been totally clear replication or not... yes yeah to see whether it was – whether I felt it was obvious that one item had been replicated from the other.

Pretty high test isn't it... high test.

Yes. Pretty exacting... you need to look at the detail yeah.

So that's the way you approached your task... yes it is.

[182] This may be contrasted with a prominent feature of Mr Bladen's evidence when dealing with specific MDS products. He referred to his assessment as being whether as MDS product had taken the "core essence" of the copyright work in question. This, in my judgment, represented an assessment consistent with principle when determining whether a substantial part of a copyright work has been reproduced in the defendants' product, even if that substantial part is a small part of the defendants' product. It is also the area in which the Court is likely to be most assisted by expert evidence. Experts can assist generally in pointing to similarities and differences. But a critical inquiry will often be, as it is in this case, whether a substantial part of the plaintiffs' works have been copied by the defendants. The opinion of a suitably qualified expert in this regard may be of importance. This was explained by Hoffman J in *Billhöfer Maschinenfabrik GmbH v T H Dixon & Co Ltd*.⁵⁴

... the question of whether the actual dimensions and relationships visually depicted on the drawings are sufficiently important to be a substantial part must in my judgment depend upon their significance to the kind of person to whom the drawing is addressed.

[183] On occasion Mr Bladen made references to what the consumer sees. Mr Marriott submitted that this indicated the application of the wrong test; a test that would be appropriate in an action for passing off, but not in copyright. In my judgment, Mr Bladen's references to what the consumer sees, put into the overall context of his evidence, did not represent the application of the wrong test. My assessment of this evidence is that it was a different way of talking about the significance to Mr Bladen as a designer of a particular feature which could be seen by a consumer. It was the designer's – the expert's – perspective, not the consumer's perspective.

⁵⁴ [1990] FSR 105 (Ch) at 121-121.

[184] One passage of cross-examination⁵⁵ will assist in illustrating this, as well as illustrating other features of Mr Bladen's evidence which I consider addressed the real issues when considering copying. The subject matter was a comparison between the Acon (Rexall) and MDS version 3 midstream cases. Photographs are in annexure 29 to 33.

... So in terms of that portion of the device, the grip, apart from the concept of having a grip at the end of the device nothing is the same is it... your Honour we can debate these differences all day long and I can get - Mr Marriott can get me to say yes and no to those differences. He is missing the point completely that the design essence is reproduced. So yes the design of the grip is different. Does it affect what the consumer sees, what the consumer buys, no.

But if a designer was told to put a grip on the end of the product you would accept each of these designers has gone about fulfilling that brief in a completely different way... your Honour I've not seen the design brief for the MDS part. I have seen interpretation that the Rexall designer had. So I don't know what that brief was but they have gone about it in a slightly different way. Significant to the end design, no. That is in my view as a designer.

Look at it from another perspective, is there anything at all similar about the way they have gone about creating a grip on the end of the product... proportionally they are similar, they are in the same position, but the execution is different.

Do you agree that the same applies to the windows, the execution is different... based on the original Rexall CAD images that I have seen the original design intention of the Rexall product is virtually the same. The final product is different.

But just comparing the window in the Rexall with the window in the QuickStream do you accept that the execution in each of those 2 cases of the window is different... the design intention is identical the execution is different.

Does the same apply to the cap of each product... the caps are possibly the most dominant part of the design though the core essence of what this product is about is dominated by that cap. The executions in both products are of a different size. The design intention appears to be the same.

And the execution in terms of shape is different as well, the caps.. there is less difference but there is some difference. The Rexall cap is slightly slimmer.

And the way in which they attach to the product, one is a friction fit and the other is a click fit... yes your Honour, this is where we start to see what I see as significantly different in the MDS product, the way the cap interfaces with the body.

⁵⁵ Notes of evidence p 214, line 26 to p 215, line 36.

When we look at the bodies with the caps removed do you accept that the proportions of the different sections of the bodies are quite different in each case... as a designer I wouldn't accept they are quite different, they are different, but they are repeating the same design concept.

So are you again saying it is only the execution of that design concept that is different... can you - I don't quite understand that question.

You drew a distinction before between a design concept and the execution of that concept, are you saying it is only the execution that is different but the concept is the same... I think in this case I am taking the concept to be the core quality of the design but the quality is repeated in both. The interpretation is slightly different.

If we look at the proximal end or the wick end of the product you would accept that the proportion of that first end – perhaps we could call it the shoulder end, to the rest of the product is significantly different in each case. The shoulder portion of the Rexall is quite small compared to the rest of the body as opposed to what you see in the QuickStream, isn't it... I think your Honour if you place the products, the Rexall product on top of the MDS product you can see how the end is very similar. The length as Mr Marriott has pointed out, is longer on the MDS part. I have to say again the core intention is the same. The end of this product is not round, it's not triangular, it's the same as the Rexall part.

[185] Mr Bladen's evidence on other products, or parts of them, was to the same general effect.

The idea and the expression of the idea

[186] It is said that copyright protects expression, not ideas. The principle is outlined in *Copinger* at paragraph 7-13 as follows:

Idea versus expression. In dealing with the question of copying, there should be borne in mind the well established principle that there is no copyright in mere ideas, concepts, schemes, systems or methods.⁵⁶ Rather, the object of copyright is to prevent the copying of the particular form of expression in which these things are conveyed. If the expression is not copied, copyright is not infringed.⁵⁷ Thus, to be liable, the defendant must have made a substantial use of the form of expression; he is not liable if he has taken from the work the essential idea, however original, and expressed the idea in his own form, or used the idea for his own purposes. Protection of this kind can only be obtained, if at all, under patent law or the law relating to confidential information. This principle finds expression in many of the

⁵⁶ There are many statements in the cases to this effect. For modern examples, see *LB Plastics Ltd v Swish Products Ltd* [1979] RPC 551 (HL) at 619; *Johnstone Safety Ltd v Peter Cook (Int) Plc* [1990] FSR 161 (CA) (functional concepts); *Harman Pictures NV v Osborne* [1967] 1 WLR 723 at 728. For older examples, see *Hollinrake v Truswell* [1894] 3 Ch 420; *McCrum v Eisner* (1917) 87 LJ Ch 99.

⁵⁷ *Hollinrake v Truswell* [1894] 3 Ch 420 at 424, 427.

cases, to the effect, for example, that it is no infringement of the copyright in a literary or dramatic work to take its basic idea or plot⁵⁸ or of an artistic work to take the general idea.⁵⁹

[187] This general principle was given some emphasis in this case, particularly having regard to the nature of the science and technology involved in the development and in the operation of the products. I will generally refer to the various scientific and technological aspects as “the concept”. The defendants submitted that much of what was being complained about in the defendants’ products involved illegitimate use of copyright to seek to protect the concept, or that the design of products was constrained by the nature of the underlying concept. The distinction is important, but the dividing line between concept and expression is often not easy to find. As stated in *Copinger*, immediately following the passage recorded above:

As with all such general statements of principle, however, it must be treated with caution and not taken too far. It is not a correct statement of English law that because a copyright work contains the expression of an idea it may be copied; nor that if there is only one way of expressing an idea, then that way cannot be the subject of copyright⁶⁰; nor that where the expression of an idea is inseparable from its function, it forms part of the idea and is not entitled to copyright protection.⁶¹ The correct position is that although copyright cannot prevent the copying of a general idea, where the idea has been worked out in detail in the form of writing, drawings, etc. it will be an infringement if the labour which went into the expression of the idea is appropriated. In such a case, it is not the idea which has been copied but its detailed expression.⁶² Thus the law of copyright is concerned not with originality of ideas but with the original expression of thought (in the case of a literary work, for example, the expression in writing).⁶³ The originality which is required, and thus the protection conferred, relates to the expression of thought.⁶⁴ In each case, it will be a matter of degree whether the line

⁵⁸ *Wilmer v Hutchinson & Co Ltd* [1936-45] Mac CC 13. There are many similar examples in the field of dramatic works. See *Copinger* at [7-52].

⁵⁹ *Kenrick & Co v Lawrence & Co* (1890) 25 QBD 99 (drawing of hand filling in voting slip, made to help illiterate voters, not infringed by use of the same concept); *Gleeson v H R Denne Ltd* [1975] RPC 471 (idea for design of ecclesiastical collar). See further, *Copinger* at [7-58].

⁶⁰ See the criticisms of *Total Information Processing Systems Ltd v Daman Ltd* [1992] FSR 171 and *John Richardson Computers Ltd v Flanders* [1993] FSR 497 in *Ibcos Computers Ltd v Barclays Finance Ltd* [1994] FSR 275.

⁶¹ Such statements are often made in relation to computer programs, drawing on United States authorities. See, for example, *Autodesk Inc v Dyason* [1992] RPC 575 at 583 (High Ct of Aus) citing *Lotus Development Corp v Paperback Software International* (1990) 18 IPR 1 at 25 (U Dis Ct).

⁶² *LB (Plastics) Ltd v Swish Products Ltd* [1979] RPC 551 (HL) at 619, 633; *William Hill (Football) Ltd v Ladbroke (Football) Ltd* [1980] RPC 539 at 546; *Leco Instruments (UK) Ltd v Land Pyrometers Ltd* [1982] RPC 140 (an idea put into permanent form may be the subject of copyright).

⁶³ *Ibcos Computers Ltd v Barclays Finance Ltd* [1994] FSR 275.

⁶⁴ *University of London Press Ltd v University Tutorial Press Ltd* [1916] 2 Ch 601 at 608, cited with approval in *Ladbroke (Football) Ltd v William Hill (Football) Ltd* [1964] 1 WLR 273 at 277.

which divides the copying of an idea from copying of its expression has been overstepped.⁶⁵ For the same reason, care should be taken when it is said that there is no copyright in news. The original expression of a news story is certainly capable of being the subject matter of copyright and of being infringed by the appropriation of that expression.⁶⁶

[188] As to the dividing line in this case, both counsel referred to a statement by Mr Raj as to the broad principle involved in the devices:⁶⁷

As I say all tests have this tagged antibody in a macroporous body that becomes mobile on wetting and travels to the test and control line.

Mr Marriott referred to this as a statement “of some assistance”. Mr Elliott accepted that this was a way of describing the underlying idea or concept.

[189] In my judgment, there are two underlying “concepts”. One is what Unipath called lateral flow technology. The essence of this is contained in a passage from Mr Prior’s evidence recorded at [59] above. The second concept, or the second essential element of the overall concept, is the need to indicate the result of a test. It may also be desirable to indicate whether the test has worked; that is, whether there is a positive or a negative result or a failure in the testing.

[190] In Mr Raj’s statement, quoted above, he referred to “the test and control line”. However, the use of lines to indicate a result, and that the process has operated properly, are not underlying concepts, but matters of design. This was responsibly acknowledged by Mr Marriott in his closing submissions when he said, in effect, that the reference in Mr Raj’s statement might more properly have been to test and control “zones”. The concept in this regard, may be stated more broadly again. What is needed, for a test, is some way of indicating whether a result is positive. That is a concept, of a very well known kind, and one which places

⁶⁵ *Ibcos Computers Ltd v Barclays Finance Ltd* [1994] FSR 275. So, in *Bowater Windows Ltd v Aspen Windows Ltd* [1999] FSR 780, a particular technique for selling double glazing had been given expression in the form of documents used by salesmen used in the course of their “pitch”. Only the form in which the technique had been expressed in the documents could be protected, not the technique itself. In that case the sales technique was common in the industry and the defendant had not copied the detailed expression of the technique from the claimant’s documents. There was therefore no infringement even though the claimant’s documents had been the inspiration for the defendant’s. (Although there had been some copying of expression from the claimant’s documents, there had been no sufficient skill and labour expended on these parts to make the amount copied a substantial part.)

⁶⁶ The matter is considered further at *Copinger* [7-40].

⁶⁷ Notes of evidence p 91, lines 2-5.

constraints on design. The concept is providing an indication that a test is positive and, perhaps, also indicating if it is negative. How this is indicated is a matter of expression. Unipath chose to use a line running across the strip as the means by which a positive test is indicated. Having some means of indicating that a test has operated properly, whether producing a negative or positive result, is also a well known concept, achieved by having some form of control. But again, how that is conveyed is a matter of expression. And again, Unipath used a control line. There is a range of other considerations in respect of the underlying concept and the expression, but it is unnecessary to traverse them all.

[191] For the plaintiffs Mr Elliott submitted, following reference to Mr Raj's evidence, that another way of defining the concept is:

A lateral flow one-step test device in which a tagged antibody is dried onto a porous carrier and then subsequently wetted by a liquid to re-mobilise it and move it along to one or more untagged immobilised antibodies on the carrier to produce one or more visible indicators to the user.

[192] I consider that that is a good definition of the underlying concept in this case. As discussed below, this concept is capable of being expressed in a variety of significantly different ways.

Similarities

[193] I am satisfied that, when the MDS products are compared with the plaintiffs' copyright works, directly with the works or indirectly through the plaintiffs' products, there are similarities of a nature sufficient to indicate that they are more likely to be the result of copying than coincidence. For reasons already set out, the related conclusion is that the copying was by MDS or Phamatech from the Unipath or Acon works or products, rather than the other way round. In this section I will note some of the prominent similarities leading to the present conclusion, before considering other issues bearing on the ultimate issue as to whether the similarities in fact arise by infringement from copying, or from some other factor or factors, such as constraints on designs from the underlying science and technology.

[194] The discussion in this section is not intended to be a survey of all of the evidence and submissions on similarities and differences. This included comprehensive and competent submissions from Mr Marriott, founded on wide-ranging and competent cross-examination of witnesses for the plaintiffs, as well as a substantial amount of evidence on differences from Mr Hanlon, in particular, as well as from Dr Appanna. I acknowledge that there are numbers of differences and, if one looks at certain details, sometimes many differences. But for reasons I have sought to explain, in the end I do not consider that these are sufficient to dissuade me from a conclusion of apparent copying, subject to consideration of other possible explanations for the similarities. My conclusion, after surveying these matters, is as I have already recorded. The purpose here is to note some of the prominent similarities that lead to the conclusion. It is convenient to do this under sub-headings related to the three products, while bearing in mind that the need is to determine, in the end, whether copyright works have been copied.

[195] To explain my conclusions, copies of some of the photographs put in evidence are annexed to this judgment. These are photographs taken by Mr Raj and on which he, and other witnesses, were extensively cross-examined and in respect of which Mr Bladen and Mr Hanlon also gave evidence. As will be apparent, descriptions and dimensions have been superimposed on some photographs. Some of the photographs show three products, or parts of a product, some show two. The fixed sequence, in the case of three products or parts, is for the Unipath product to be on top, the Acon product next and the MDS product at the bottom.

Midstream

[196] Annexure 27 shows the strips and wicks in the three midstream devices. The top image shows the Unipath strip and wick resulting from Project SOAPSUD. The relationship between the product (strip plus wick) and the copyright work can be seen by comparing this image with the copyright work in annexure 10. The middle photograph is the strip and wick from the Acon Rexall midstream released in October 2002. I am satisfied that this strip is derived from the Acon copyright works. The bottom image shows the strip and wick from MDS's midstream version

3 (called QuickStream). One prominent feature in the MDS strip which appears to be copied from the Unipath strip is what the plaintiffs referred to as the “multi-component test strip”. This includes the sink, which is at the distal end of the strip (the right hand end in the photographs). With the Unipath strip, the sink is simply part of the nitrocellulose part of the whole strip. The MDS strip has an added component operating as a sink. The added sink component is also present in the Acon strip which, like the Unipath strip, predated the MDS strip. Another prominent aspect of the “multi-component” nature of the strip is the conjugate pad. As will be apparent from the images, the Unipath strip has a single “conjugate pad”, but the MDS strip has a smaller conjugate pad and then two further pads described as sample pad 1 and sample pad 2. This feature is also found in the Acon strip, although Acon added one sample pad, not two. It is relevant to record at this point, although dealing principally with similarities, that I am satisfied from the evidence that the additional pad or pads are not of significance in respect of the central issue of copyright infringement. The same applies to the addition in the MDS strip of an additional absorbent pad to operate as a sink.

[197] A further prominent feature of the Unipath strip is the use of lines for the test and control indicators, with these lines running across the narrow part of the nitrocellulose strip. Annexure 28 shows Unipath, Acon and MDS strips following a test, and therefore with the test and control lines made prominent from the coloured labels attached to what I have called antibody A. As was noted in the course of the evidence, for the Unipath strip the plaintiffs inadvertently included a photograph of a strip in a more recent midstream product (resulting from the “Evolution” project). This uses a + indicator at the test zone. The relevant product for comparison was that arising from the SOAPSUD project and the relevant copyright work is annexure 10. These show Unipath’s use of lines at that time, and preceding the first production of the MDS midstream version 3. (The rectangular object at the far left of each image in annexure 28 is the wick, to be discussed shortly. This is very faint in the top photograph.) Of importance in the discussion to this point is not simply the individual items I have identified, but the way in which they were arranged as a collage. This arrangement of features also appears to have been copied.

[198] A further indication of copying comes from the dimensions. Following is a table comparing relevant dimensions of the Unipath, MDS and Acon midstream strips (which are set out in that sequence in the table). This table is taken, with some modifications, from a table presented by the plaintiffs in closing submissions. I am satisfied that it is accurate. Some of the measurements make adjustments for the overlapping of component parts, but I am satisfied that the allowances are justified in light of the evidence. The dates recorded for the MDS midstream products versions 1, 2 and 3 are the dates of first production by Phamatech, as opposed to first importation by MDS (with uncertainty in respect of version 1).

	Unipath (Clearblue)				MDS (QuickStream)				Acon
	Stage 2	Stage 3	Stage 4		MDS Version 1	MDS Version 2	MDS Version 3		Rexall
Year:	1990	1996	2002		1998?	2002	2003/04		2002
COMPONENTS									
Wick type	narrow	narrow	wide		narrow	narrow	wide		wide
No. of pads	1	1	1		2	3	3		2
Total length of pad/pads (mm)	12	25	25		30	25	25		22
Tagged antibody application method	dip & dry	spray	spray		dip & dry	dip & dry	dip & dry		spray
Total length of nitrocellulose plus sink (mm)	50	40	40		40	45	40		40
Pad materials	Poly-ethylene	Glass Fibre	Glass Fibre		Glass Fibre?	Glass Fibre?	Glass Fibre		Glass Fibre
Test line position (from conjugate pad interface) mm	15.5	6.5	6.5		7.5	13	5		5
Control line position (from conjugate pad interface) mm	25	15	22.5		14.5	20	15		13
Type of sink	nc	nc	nc		paper	paper	paper		paper
Strip width (mm)	8	8	8		8	8	8		7
Overall strip length (mm)	63	63	63		67	67	63		60
PERFORMANCE									
Claimed read time (mins)	3	1	1		1 to 5?	1 to 5?	1 to 5		1 to 3
Sensitivity at read time (mIU/ml hCG)	50	50	25		25?	25?	25?		25

[199] There are a number of similarities between, in particular, the Unipath stage 3 and stage 4 products, the Acon Rexall 2002 product, and the MDS version 3 first produced in 2003 or 2004. In my judgment, these are indicative of copying. There are two particularly prominent features. The first is the dimensions that have been

highlighted for the Unipath stage 3 (SOAPSUD) 1996 strip and the MDS version 3 2003/2004 strip. All but one of the dimensions is identical. The only difference is the position of the test line measured from the conjugate pad, a difference of 1.5 mm (i.e. 6.5 mm for Unipath compared with 5 mm for MDS). The second feature is the difference between dimensions of the three MDS versions. Dimensions indicate a direct link between the Unipath 1996 midstream and the MDS version 3, but there is no coherent link between the MDS products themselves.

[200] This chart highlights other indicia of copying. One is the wick. Unipath changed to a wide wick in 2002. Acon's Rexall, introduced in 2002, also had a wide wick. The earlier Unipath and MDS wicks were narrow. The use of any wick in itself suggests copying; at least the use of a more or less rectangular wick that protrudes from the case. This is because there are design alternatives to a protruding, rectangular wick, as indicated by other products (as will be discussed below). The reasonable probability of copying, however, is given emphasis by the sudden change in the MDS wick from a narrow wick to a wide wick, and with this occurring after Unipath and Acon produced products with a wide wick. In Acon's case, the introduction of the MDS wide wick in version 3 also occurred after MDS entered into the distribution agreement with Acon and obtained Acon's registration files for the Acon midstream, dipstick and card.

The midstream cases

[201] Annexures 29 to 33 are copies of photographs of the cases of the three midstream products.

[202] A brief description of the annexures is as follows.

- a) Annexure 29 shows the entire case, with the cap on.
- b) Annexure 30 shows the three devices with the caps off.

- c) Annexure 31 shows the interior of the lower and upper halves of each case with the strips contained in the lower half and the wicks extending out on the left hand side of each image.
- d) Annexure 32 shows the interior of the lower and upper halves of each case with the strips removed and with dimensions superimposed.
- e) Annexure 33 has similar images, in this case with notations relating to the internal detailed mouldings intended to hold the strip.

[203] The plaintiffs pleaded that the MDS midstream case version 3 infringed copyright in the Acon copyright works for the case, as well as associated works for the strip illustrating the arrangement of the entire product. Prominent features of the Acon copyright works which I consider appear to have been copied in the MDS midstream case are, in barest summary: the case as a whole is elongated with a prominent waist; there is a prominent cap; each has a rounded end; there is a protruding wick; it is a wide wick; the strip has to be aligned with a result window or windows; the result windows are contained in a single indentation in the case; and internal mouldings are similar.

The cards

[204] In respect of the cards, the plaintiffs alleged that MDS has infringed copyright in Unipath's copyright works for the strip and the case, and that MDS has infringed Acon's copyright in Acon's works for the strip.

[205] So far as the strips are concerned, the features which I have just concluded are sufficiently and relevantly similar to be indicative of copying with the midstream strips, are essentially the same for the card strips. Aspects of this are indicated in the table below.

[206] In relation to the case, the Unipath copyright works closest in time are annexures 7 and 8. The coherent design trail goes back to the drawings in the May and Davis patents and earlier drawings.

[207] Photographs of the cases are in annexure 34. The letters T and C on each case have been superimposed to indicate the position of the test and control lines and the fact that lines are used as the indicators with all of the strips. What I consider to be an obviously prominent feature of the Unipath copyright works represented in the Unipath case, and which appears to have been copied in the MDS case, is that both are white (although the colour does not show) and rectangular. The Unipath case is longer and slightly wider. However, the essence of the design – the essence of the Unipath copyright work – is substantially the same. This latter aspect becomes more apparent when the interior of each case is compared by reference to relevant dimensions of the strips.

[208] A table of dimensions relating to the strips in all three cards, following a similar format to the table for the midstream, is as follows.

	Unipath (Clearview)		Acon (Quik- Check)		MDS (QuickCard)
Year	1990		1997		1997
COMPONENTS					
Wick type	na		na		na
No. of pads	1		2		3
Total length of pad/pads (mm)	20		22		31
Tagged antibody application method	dip & dry		spray		dip & dry
Total length of nitrocellulose plus sink (mm)	50		40		33
Pad materials	Polyethylene		Glass Fibre		Glass Fibre
Test line position (from conjugate pad interface) mm	15		6.5		7.5
Control line position (from conjugate pad interface) mm	23		12.5		12.5
Type of sink	NC		paper		paper
Strip width (mm)	7		4		7
Overall strip length (mm)	63		60		63

[209] The striking feature, when considering whether the case has been copied, is that although there are differences in dimensions of individual parts of the strip, the width and the overall length of the Unipath and MDS strips are identical. And that – length and width – is what has to be contained in an appropriate way within the case, and in such a way so as to ensure that the positions of the test and control lines (with these also copied in the MDS strip) align with the aperture. The slightly reduced length and width of the MDS card case may have been to save cost, or to seek to make the case look different, or possibly both. In the absence of adequate evidence as to why this was done, the inferences adverse to the defendants remain.

[210] Each case has the aperture, in the same position, to expose the test and control line. As may be visible from the photographs in annexure 34, this aperture in the Unipath card has a dividing bar, which separates the area for the test line from the area for the control line. There is no dividing bar in the MDS card. That is an obvious difference, but not a relevant difference in my judgment. Both cards have the further aperture, at the left hand end in each photograph, being the aperture through which the urine sample is applied. The obvious differences in the shapes of the aperture do not, in my judgment, bear on the conclusion that there has been copying because the aperture as such is an important element of the substantial part copied.

The dipsticks

[211] The plaintiffs alleged that the MDS dipstick infringes copyright in Acon's copyright works for its dipstick (with the code reference FHC-101). The Acon copyright works are in annexures 24 to 26. Photographs of the Acon and MDS products are in annexure 35. Photographs of the strips for the two dipsticks are annexures 36 to 38.

[212] The similarities I have earlier identified for the strips in the midstream and card devices apply in general terms to the Acon and MDS strips for the dipsticks. The photographs in annexures 37 and 38 show the two strips separated into their component parts. In my judgment these show relevant and sufficient similarity in a fairly compelling way (subject, as always, to any explanation from the defendants consistent with non-infringement).

[213] In broad outline, the following features in Acon's copyright works appear to have been copied in the MDS dipstick: the multi-component test strip; an additional proximal length for the strip; a long sink; a separate conjugate pad containing a purple coloured antibody (called a "gold sol label"); an additional length to the conjugate pad in the Acon drawing which was translated, but taking the substance, as an additional separate sample pad in the MDS dipstick; the nitrocellulose membrane with lines used for indicating the test and control results and in both cases being pink lines. The Acon strip has covers over the strip consisting of paper, enabling the strip to be held and dipped into the sample. This appears to have been copied in the MDS dipstick. With the Acon strip there is a line at the proximal end (the left end of the photograph) indicating how far the dipstick should be inserted into the urine sample, with arrows further indicating the same point. That design is similar, in a relevant way, on the MDS dipstick.

[214] Other similarities, including dimensions, are indicated in the following table. The highlighted dimensions are identical or within 1 mm of each other. The final measurement in the table is the overall length of the strip, with a difference of 7 mm. The reason for this was explained by Dr Appanna, but that explanation gives rise to other issues, as discussed later.

FEATURES	Acon FHC 101		MDS QuickStick
Year:	1996		?
COMPONENTS			
Wick type	na		na
No. of sample pads	1		2
Total length of pad/pads (mm)	12		12
Tagged antibody application method onto separate conjugate pad	Spray		dip & dry
Length from dip line to test line (mm)	21.5		23.5
Length of nitrocellulose strip containing test and control lines (mm)	20		21
Distance of test line and control line from start of nitrocellulose (mm)	8 and 13		8 and 13.5
Total length of nitrocellulose strip containing test and control lines plus sink (mm)	53		59
Pad materials	Polyester		Glass Fibre
Test line position on nitrocellulose from start (mm)	6.5		6
Control line position (from conjugate pad interface) mm	11.5		12
Type of sink	paper		paper
Strip width (mm)	4		6
Overall strip length (mm)	81		88

Other indications of copying

[215] Mistakes in a defendant's product may be evidence of copying.⁶⁸ There was what appeared to be a significant design mistake in the MDS midstream version 3, and one which was not satisfactorily answered by the defendants. The wick end of both the Acon and MDS version 3 midstream case has an aperture which holds the wick. The Acon wick is flat on the bottom side and curved on the top and the Acon aperture in the case is correspondingly flat on the bottom and curved on the top. In the MDS case, at the aperture, the bottom half is similarly flat and the top half curved. But the wick used in the MDS midstream version 3 is flat on both sides. Mr

⁶⁸ See *Billhöfer Maschinenfabrik GmbH v T H Dixon & Co Ltd* [1990] FSR 105 at 123; *Ibcos Computers Ltd v Barclays Finance Ltd* (1994) IPR 25 at 44.

Bladen regarded this as a marked design error. Weighing that evidence, and the defence evidence, primarily from Mr Hanlon, and considering this feature in the light of the complete absence of any reliable evidence about the design of the MDS case, my finding is that this is a design error indicative of copying.

[216] This conclusion is reinforced by the sudden appearance, well into the four week hearing, of another MDS midstream case, labelled version 4. The upper and lower halves of the aperture of the version 4 case are flat. Version 4 was first seen by the plaintiffs in the course of the trial when a sample was presented to Mr Bladen for the purposes of cross-examination on a completely different point. Mr Bladen immediately noticed the difference.

[217] There was an absence of reliable evidence as to when, why and how this version came into existence, who made it, and who was responsible for the change. It is instructive that it was apparent that neither Mr Marriott nor Mr Hanlon was aware of the change until Mr Bladen referred to it. Dr Appanna gave evidence to the effect that he was completely unaware of the change until the trial. If that is the case, the only other rational explanation for the change would seem to be that the manufacturer of the product not only made material changes to it without notifying MDS but also for reasons which are unexplained by any defence witness. My conclusion is that Dr Appanna's evidence to the effect that he had no knowledge how this came about is difficult to credit. This is because the apparent design error in the MDS version 3 had been highlighted by the plaintiffs before the trial. In the absence of any other evidence, my conclusion is that whoever manufactures the case must have been advised by Dr Appanna, for himself and MDS as the defendants in the proceeding, and that this is what prompted the sudden appearance of a redesigned case part way through the trial. As well as giving emphasis to the design flaw in version 3, this is another aspect of defence evidence in respect of which I draw an inference adverse to the integrity of the defence case as a whole.

[218] Another indication of copying is that, although there is a coherency of design development in the Unipath and Acon products, that is not the case with MDS products where there is evidence of changes over time. This point was touched on earlier in respect of the three versions of the MDS midstream. Examination of the

products, including separate examinations of strips and cases, does not indicate either a pattern of coherent design development over a period of time, or changes readily explicable from assumed design considerations. This point is given further emphasis by the fact that Phamatech, over the relevant period, had yet another midstream version markedly different from the three versions imported by MDS (and different from version 4 which appeared during the trial).

[219] In contrast there is a clear coherency of design development in the Unipath and Acon products and as illustrated in the present context by the Acon midstream case. This commenced with what was referred to in evidence as the “grandmother” – the product which obtained the Chinese design registration in 1999. Mr Bladen provided careful and detailed evidence in support of the proposition that there was a coherent design progression for the Acon midstream from the grandmother through what was called the “mother” or Perrigo case, to the “son” – the Acon Rexall – first sold in October 2002. Mr Bladen also gave evidence as to the lack of any coherency between the MDS products. I accept that evidence.

[220] The current MDS dipstick is 7 mm longer than the Acon dipstick. The defendants submitted that this is a difference pointing to an absence of infringement because it was indicative of originality. The plaintiffs contended that the increased length was simply another example of a cosmetic change intended to disguise copying. I am satisfied from the evidence that the increased length has no material bearing on the operation of the strip. In the absence of relevant defence evidence, there also appeared to be no reason for the change other than as a cosmetic change to seek to disguise copying.

[221] The only evidence bearing on the dipstick length came from Dr Appanna. Dr Appanna said that the reason for the greater length of the MDS strip was to enable it to be used by dipping it into urine contained in what Dr Appanna described as “a standard diagnostic medlab urine collection tube”. Dr Appanna produced one of these tubes. It is like a small test tube, except that it has a screw on cap. It has a diameter of approximately 15 mm and an internal length which is approximately the same as the length of the MDS dipstick. Dr Appanna said that this is “the only

container that is supplied by the laboratory for testing of urine”. There was the following in his evidence in chief:⁶⁹

And in terms of the size difference what was the significance of that difference to MDS... when we initially looked at pregnancy test kits as an item we were looking to sell at that particular time the pregnancy test kits that were available to be sold and subsidised on the pharmaceutical schedule, in other words the Pharmac subsidised pregnancy test devices were of a stick nature and the tubes were of the same nature and I think I might have mentioned in one of my briefs the fact that prior to establishing our relationship with Phamatech and successfully winning the Pharmac tender we were distributing a product from another distributor which was also a test strip device and was called Preg-Check, and that was a device that was similar in dimensions I guess to the Acon type test strip, and our knowledge of what was being utilised in the market and the problems that people were facing with it allowed us to select the wider longer Phamatech test strip as the option that we were offering to supply on the Pharmac tender.

[222] This evidence came by way of interpolation as Dr Appanna was reading his prepared brief of evidence. There was no reference to this explanation in the brief of evidence, prepared before trial and served on the plaintiffs. As to the manner in which urine is collected in laboratories, there is no evidence challenging what Dr Appanna said. His evidence, in this respect, would provide a reasonable explanation as to why Dr Appanna may have selected a dipstick longer than other dipsticks. But as with most of the defence evidence bearing on questions of design, this evidence does not provide any explanation as to why the dipstick manufactured by Phamatech was longer than other dipsticks.

[223] Additionally, in relation to the credibility of the defence case as a whole, Dr Appanna’s explanation is not capable of being reconciled with what is disclosed in Phamatech’s own 510(k) 1997 notification to the FDA for its dipstick, or with the instructions accompanying the MDS dipstick marketed in New Zealand. The Phamatech 510(k) notification has pictures of a dipstick inserted into an open dish containing urine, not into a urine collection tube. Importantly, the MDS instruction sheet is the same. What is more, the MDS “QuickStick” is supplied in a packet which is relatively large compared with the size of a dipstick. The reason for this, as explained in the instruction sheet, is that the packet contains, in addition to either one

⁶⁹ Notes of evidence p 330, line 27 to p 331, line 3.

or two dipsticks, “one Urine collection Cup”. It is, as the word suggests, a cup – a small open dish – not a tube.

[224] The instruction sheet explains the way in which the strips should be used in words and with a picture: the strip is to be held at one end and dipped into urine contained in the open dish or cup. The exterior packaging has a similar illustration of the stick being dipped into the open dish. The instruction sheets and the packaging are all especially produced for MDS with wording plainly as instructed by MDS. The instruction sheet commences with the words “MDS QuickStick™”. The exterior packaging has the same branding together with MDS addresses in New Zealand and Australia on the side of the packaging that contains the illustration. It may be, as I have indicated, that urine is sometimes – perhaps often – collected at a laboratory in a tube. However, in light of the evidence I have traversed and the way in which this explanation was introduced, I consider that this is another instance of evidence for the defendants from which I draw inferences adverse to the defendants’ case.

[225] Further inferences adverse to the defendants may be drawn from some changes that were made in the defendants’ products. A prominent example is that the MDS strips in the MDS midstream version 3 and the MDS card have three pads, compared with two in the Acon strips and one in the Unipath strips. I accept the plaintiffs’ evidence in respect of the additional pads to the essential effect that they have no material effect on the operation of the test and, having regard to the material used, are a relatively easy modification. There may be some benefits in having one additional pad, as occurred with Acon. The introduction of two additional pads in the case of the MDS strips, having regard to the weight of the evidence, is indicative of simple changes to suggest an absence of copying.

[226] A different indicator of copying comes from the May patent. The May patent discloses five different methods of putting Unipath’s claimed invention into practice, each of these said to satisfy the best method requirement. Unipath converted only two of those embodiments into commercial products. It is the same two, rather than some of the other possibilities, which were manufactured by Phamatech and imported and sold by MDS.

[227] The MDS strips are markedly similar in respect of substantial parts of the plaintiffs' copyright works, but the evidence establishes that the defendants' products are not as efficient. This suggests copying, because what has found its way into the defendants' products are substantial features readily copied. An example relates to changes introduced following Unipath's SOAPSUD project. Unipath's original method of applying the antibody (reagent) to the strip was with a technique described as "dip and dry". The same technique was used for the MDS strips. One of the changes by Unipath, as a result of the SOAPSUD project, was a new technique of spraying the antibody onto the strip. This change was not one readily apparent from examination. After the launch of the SOAPSUD strip, dimensions and other features of the MDS strip changed to become in almost all relevant respects identical to those of the Unipath SOAPSUD strip. However, the MDS strips continued to have the antibody applied using the dip and dry method. In other words, things capable of being readily copied, because they were visible, were copied without recognising the relevance of the changes in the Unipath strip relating to matters which were not readily apparent.

Design constraints?

[228] In my judgment the similarities which I have identified as indicative of copying, are not common place or unoriginal features. They therefore cannot be discounted for reasons of that nature. There is a further question whether the relevant features of the copyright works apparently copied have arisen in the MDS products because they are dictated by constraints of a technical or scientific nature; constraints arising from the underlying science and, in particular, aspects of an immunoassay and lateral flow. The earlier discussion of the principles relating to the idea compared with the expression, and the application of those notions in this case, is relevant.

[229] Assuming my distinction between the underlying concept and the expression of it is broadly correct, and allowing for the grey area between the two, I am satisfied that the features that I have identified as indicative of copying do not arise from constraints on design arising from the underlying science or other technical aspects.

The conclusion is reinforced, with some emphasis, when regard is had to other products which utilise the underlying ideas, but express them in quite different ways. There was a substantial body of evidence adduced by the plaintiffs supporting this conclusion.

[230] Mr Prior and Mr Raj, because of their scientific knowledge and experience in development of the strips, were both able to give direct evidence on matters relevant to the question whether the science constrains design to the extent that it would explain the relevant similarities between MDS strips and the plaintiffs' strips. Both witnesses were fully and competently cross-examined on these matters by Mr Marriott. My overall conclusion from this evidence is that the science does not impose constraints sufficient to explain the similarities I have identified. There was no witness called for the defendants who had any relevant qualifications or experience to give any contrary evidence. Dr Appanna did give some evidence touching on these matters, but he did not claim to have any relevant expertise. Indeed, when addressing other issues, such as the question as to whether he may have personal liability, Dr Appanna, in broad terms, sought to distance himself from relevant knowledge.

[231] The defendants adduced a large body of documentary evidence relating to pregnancy testing products of third parties on the market and publicly available documents in relation to some of those documents. Publicly available documents include patents of other manufacturers, such as Beckton, Dickinson and Co. (1998), Abbott Laboratories (1998) and Carter Wallace (Charlton patent, 1988). 510(k) notifications by other manufacturers were produced, and in particular those of a company called Syntron Bioresearch, which filed 510(k) applications in 1991 and subsequent years for card, dipstick and midstream devices. There is also a Syntron United States patent, filed on 5 November 1992, for "a method and apparatus for performing assays in a single step" which contains drawings of a card case and strip broadly similar to the ones at issue in this case. There were a number of other publicly available documents produced by the defendants and relied on in support of the broad proposition that apparent similarities between MDS products and plaintiffs' copyright works arise from constraints on design.

[232] I am not persuaded by this evidence that the similarities in the MDS products arise from design constraints. In essence, the defendants' argument asks the Court to draw an inference, favourable to the defendants, simply from the existence of these other documents. Numbers of these documents certainly appear to disclose similarities comparable to those I have identified. However, I am not satisfied that I can draw any reliable conclusion from these documents which would support the defendants' case. The existence of these documents, all of which, on the face of them, were created well after Unipath's pioneering work, does not indicate that there were design constraints. The existence of these documents also does not indicate that features of the strips or cases which I have identified as relevant could be described as "common place", in the sense that that expression is used in copyright cases. They may be prevalent because there has been a great deal of copying from Unipath. Much of the defendants' case in this context essentially invited speculation. This evidence does not assist the defendants, either in respect of design constraints or in the broader context I have just touched on.

[233] Some of the documents produced by the defendants in fact point to an absence of relevant design constraints. For example, the Syntron patent⁷⁰ describes a range of ways in which positive or negative results, and successful operation irrespective of the result, might be indicated. There is reference to another patent which describes the use of plus (+) and minus (−) signs to indicate, respectively, the presence or absence of the analyte of interest in the sample. In Syntron's own patent description of the preferred embodiments it is said:

A positive result is indicated when color changes forming substantially similar shapes ... appear in both display ports ... in contrast ... a negative result is indicated when a colour change forming a distinguishable shape (e.g. a horizontal bar ...) appears only through [one display port]. Finally, an inconclusive result is shown ... where color changes appear in both ports having substantially dissimilar shapes (i.e., horizontal bar ... and smudge ...).

⁷⁰ Bundle of documents 13.7 p 209-212.

[234] Evidence of products available in the market demonstrates an absence of relevant design constraints. The “Predictor” is the brand name for a midstream pregnancy test device manufactured by a company based in Ireland, Chefaro UK Ltd. Annexure 39 is an illustration of this product. As will be seen from the top image, the device consists of two main parts. The right hand part slides into and out of the left hand body. A device in two main parts is in itself a significant difference and indicative of an absence of relevant design constraints. The right hand part is a wand or stick for obtaining the sample. The wand has an area to which the urine is applied, serving the same function as a wick in the plaintiffs’ midstream products, but this is rod shaped, pink and made of foam material and attached to the separate, extractable wand. Unlike the plaintiffs’ midstreams, the wick equivalent is not connected to the strip. In the Predictor, the strip is contained in the left hand body. Flooding from too much urine cannot occur because of the separation in this way of the “wick” from the strip. Urine is conveyed to the strip by putting the wand with the wetted “wick”, back into the left hand cartridge. As Mr Elliott said in submissions: “what these designers have done is effectively put the test strip in the cap.” The cartridge has three distinct windows which are round, and with the central window of greater diameter than the left and right hand windows. If colour moves across all the windows, that indicates that the test is working. Results are indicated with spots. The windows are unglazed. The test strip is also quite different. The result indicators – the spots – form on paper, not nitrocellulose. The strip has a unique waist, more or less in the middle of its length. The strip is not supported with plastic backing, as is the case with the plaintiffs’ and MDS’s strips.

[235] Annexure 40 has drawings produced by the plaintiffs based on design features of the Predictor. These illustrate graphically numbers of the points made in the preceding paragraph.

[236] Mr Hanlon was cross-examined on the Predictor. He had not earlier considered this device, or numbers of other devices which had been referred to in the statement of claim and in the plaintiffs’ briefs of evidence filed before the trial. He was taken through various aspects of the Predictor and acknowledged his understanding of those aspects, both in terms of design and function. Before this evidence Mr Hanlon had referred to what he understood to be design constraints.

Once Mr Hanlon had confirmed his understanding of the Predictor there was the following:⁷¹

So would that suggest to you that perhaps the constraints that you understood were not constraints at all... it's clearly a different approach, different solution utilising the same technology. I guess the thoughts that occur to me that while it is quite different it may not necessarily suggest it's a good product or even an acceptable product. It may be that it's a product that was a bit innovative but in fact for reasons that I wouldn't know about perhaps hasn't been successful in the market place it may not work very well. But I do agree with you on the face of it it is a different solution to the teachings of the patent.

And a very different solution embodying the concept which we agreed the concept which determines the design parameters in this particular case... yes – I just repeat what I said, yes it does embody a different design solution but a product is more than just the design of it, it's the cost of manufacture of it, it's the actual functionality of it, it's a whole bunch of other things and coming up with a different design is not necessarily a complete solution. It might be a different design but in practice it may not prove to be able to be commercialised or commercially useful.

Well if there is evidence before the Court that that product is in fact a commercial product would that sway some of your concerns.. yes certainly.

[237] Mr Hanlon's evidence on this also illustrates a general point earlier made in respect of his approach: he took into account a range of considerations not relevant to the essential inquiries in a copyright infringement case.

[238] Another product is the "Testpack". It may be described, in general terms, as a card device. Drawings of it are in annexure 41. The exterior of the case is in the right hand drawing (from a landscape view). The interior, with a strip, is shown to the left. The following, at least, indicate an absence of relevant design constraints. The case is square. Urine is applied in the round aperture shown at the bottom left of the drawing of the exterior. The strip runs diagonally across the essentially square case. At the top right hand corner there is a small aperture. A colour appearing in that aperture indicates completion of the test. There are two central windows, a small round one and a larger more oval window. A positive result is indicated by a cross appearing in the oval window. A negative result is indicated by a horizontal bar — that is to say the sign for negative. These appear in the oval window. The control indicator is the smaller central window, where a tick appears.

⁷¹ Notes of evidence p 279, lines 4-20.

[239] As with the Predictor, Mr Hanlon had not looked at the Testpack in preparation of his evidence. It was put to him in cross-examination and, having been taken through its design and operation, he confirmed his understanding of the product. Mr Hanlon then agreed that “the designer [had] gone for a very different looking device and deliberately so”. After then being taken to aspects of the design of the strip there was the following:⁷²

And as you can appreciate from having read the drawings that sample will move up diagonally to the top right hand corner. Once again I think you would agree with me that this is a fundamentally different design... yes it is. It certainly seems to me that it would require quite different technology for placing the reagent on the nitrocellulose strip in order to obtain the positive and negative sign, the tick sign etc that are there compared to the sort of products that I reviewed in my evidence.

I have included the full answer, following Mr Hanlon’s agreement, because it is again indicative of a focus on matters not relevant to the question whether there has been copying of copyright work. The reference to the means by which the reagent is applied to the nitrocellulose is a manufacturing consideration and certainly within Mr Hanlon’s broad field of expertise. But it is not indicative of a design constraint in respect of the underlying concepts. How the reagent might be applied to the strip is not part of the underlying concept.

[240] Another product has the brand name “Neonatal”. It is a midstream device. It is about the same length as the case of the plaintiffs’ and MDS midstreams, but there the visual similarities end. The case is rounded at the distal end and wider at that end than the proximal end. It might be described as carrot shaped. There is no cap. There is a wick contained within the single case. The wick is retractable, rather like a retractable pen. To use the device a slide on one side of it is pulled back and the wick appears. The test does not begin until the wick is retracted back into the body using the slide device. There is a simple but effective mechanism to operate the exposure and retraction of the wick. It has obviously been produced as a consequence of careful design with, I infer, a range of design drawings which would presumably attract copyright. Mr Hanlon, who again had not earlier examined this product, agreed that it was a “completely different solution to exactly the same idea”.

⁷² Notes of evidence p 281 lines 8-13.

[241] Another product called “Pregnosis Clear” uses the same technology but again with markedly different design. The design differences, indicative of substantial independent effort and skill and inferred copyright works, are perhaps exemplified by the fact that this product can work either as a midstream or a dipstick. There is a single clear plastic moulding which contains the strip. There is no wick. The clear moulding means that no window is required. It has a markedly different shape from the plaintiffs’ midstream and dipstick copyright works and products, and the MDS midstream and dipstick products.

[242] Mr Bladen also illustrated, using his own design skills, a hypothetical essentially midstream product designed by him for purposes of illustration, referred to as “Project Teaspoon”. Mr Bladen’s drawings are markedly different from those of the plaintiffs which are in issue and, as such, indicative of the input of considerable design skill and a reasonable amount of effort. There is a wide range of design differences which I will not describe, save to mention the design possibility of a tubular strip with results indicated by rings running round a tube with clear polished areas to view the result. Mr Hanlon, understanding that the design was hypothetical in that it had not been tested in fact, acknowledged the marked difference. There was the following:⁷³

It embodies the idea which we agreed underlied all of these works but expresses it in a completely different way... yes it does seem to do that.

The onus on the defendants

[243] Having regard to the matters dealt with to this point, I am satisfied that the plaintiffs met the onus of establishing a prima facie case of copying. The remaining broad issue in respect of copying is whether the defendants met the onus now shifted to them of establishing that the similarities did not in fact result from copying.

[244] A number of possible explanations other than copying have already been discussed and the findings do not assist the defendants. It remained open for the defendants to demonstrate, on the balance of probabilities, that the relevant

⁷³ Notes of evidence p 296, lines 30-31.

similarities in respect of substantial parts arose from independent and original design work.

[245] I have already discussed the absence of evidence of independent design. Coupled with that is the largely unhelpful evidence from Mr Glasser, of Phamatech, and some marked reservations I have as to the reliability of some other evidence for the defendants. There was some evidence to the effect that Phamatech may have had a licence to produce the products it did produce and with the implication that the licensor was the owner of copyright works which were the source of the products. This evidence did not assist the defendants. It was decidedly vague. Even if there was reliable evidence of a licence granted to Phamatech, that by itself would not demonstrate an absence of infringement by copying. This gets back to the areas of speculation I earlier referred to. There would need to be a reliable foundation for a conclusion that the licensor had not infringed the plaintiffs' copyright. There was no such evidence. The claimed licensing document was not even produced, notwithstanding the fact that Phamatech's in-house attorney, Mr Glasser, gave evidence.

[246] For the reasons summarised here and fully covered in earlier sections, I am satisfied that the defendants did not meet the onus shifted to them at this point.

L. Primary infringement : copying and issue of copies to the public

[247] The plaintiffs alleged primary infringement by the defendants of three types:

- a) Copying the whole or a substantial part of the copyright work: Copyright Act 1994 ss 16(1)(a), 29 and 30.
- b) Issuing copies of the work to the public: ss 16(1)(b) and 31 .
- c) Authorising another person (1) to copy the work and (2) to issue copies to the public: ss 16(1)(i) and 29.

[248] The material parts of ss 16 and 29-31 are as follows:

16 Acts restricted by copyright

(1) The owner of the copyright in a work has the exclusive right to do, in accordance with sections 30 to 34 of this Act, the following acts in New Zealand:

- (a) To copy the work:
- (b) To issue copies of the work to the public, whether by sale or otherwise:
- ...
- (i) To authorise another person to do any of the acts referred to in any of paragraphs (a) to (h) of this subsection.

29 Infringement of copyright

(1) Copyright in a work is infringed by a person who, other than pursuant to a copyright licence, does any restricted act.

(2) References in this Act to the doing of a restricted act are to the doing of that act—

- (a) In relation to the work as a whole or any substantial part of it; and
- (b) Either directly or indirectly;—

and it is immaterial whether any intervening acts themselves infringe copyright.

...

30 Infringement by copying

The copying of a work is a restricted act in relation to every description of copyright work.

31 Infringement by issue of copies to public

The issue of copies of a work to the public is a restricted act in relation to every description of copyright work.

[249] A “restricted act” is defined in s 2 as meaning “any of the acts described in section 16”.

Copying in New Zealand or authorising copying

[250] In respect of copying, the evidence does not establish that either of the defendants, in New Zealand, copied any of the works. Nor do I consider that liability for infringement could arise by one of the defendants authorising Phamatech, or another overseas entity, to copy the work overseas. Infringement arising by doing the restricted act of authorising the making of a copy is, having regard to the provisions of s 16(1), directed to authorising another person to make a copy in New Zealand.

[251] If I am wrong in my conclusion that a territorial restriction applies to what is authorised as well as to the primary acts in s 16(1)(a) to (h), then my conclusion would be that both defendants authorised Phamatech to make copies of the relevant copyright works. The reasons are contained in the discussions below of the meaning of the expression “to authorise” and in respect of the personal liability of Dr Appanna.

Issuing to the public

[252] I am satisfied that MDS infringed by issuing copies to the public contrary to ss 16(1)(b) and 31. The expression “issuing to the public” is defined in s 9. The material provisions are:

9 Meaning of “issue to the public”

(1) References in this Act to the issue of copies of a work to the public mean the act of putting into circulation copies not previously put into circulation; and do not include the acts of—

- (a) Subsequent distribution or sale of those copies; or
- (b) Subject to subsections (2) and (3) of this section, subsequent hiring or loan of those copies; or
- (c) Subsequent importation of those copies into New Zealand; or
- (d) Distribution of imported copies that are not infringing copies within the meaning of section 12 subsequent to their importation into New Zealand.

(2) ...

[253] There is no definition of “putting into circulation”. Nor was I referred to any authority on the meaning of this expression. The definition of “issue to the public” is itself somewhat circular. The following opinion is expressed in *Copinger*:⁷⁴

As to what acts amount to issuing to the public, or putting a copy into circulation, the latter expression is not further defined [in the UK Copyright, Designs and Patents Act 1988] but suggests a release of a copy onto the market such that it may be passed on to other members of the public.

[254] The definition referred to in *Copinger* is in s 18 of the UK Act. On the present point – the meaning of “putting into circulation” – there are no material differences between s 9 of the New Zealand Act and s 18 of the UK Act. I agree with the opinion expressed in *Copinger*.

[255] Including the *Copinger* opinion, there are three closely related, and in many respects interchangeable, notions: issuing to the public, putting into circulation copies not previously in circulation, and the first release of a copy onto the market. Certainly the two statutory provisions bear on each other. Issuing to the public requires putting into circulation and putting into circulation does not occur unless the public is involved.

[256] In this case there are only two stages to be considered: the transactions between Phamatech and MDS and the point at which MDS sold products in New Zealand. In my judgment it is clear on the facts of this case that the issue to the public occurred when MDS first released the products into the market in New Zealand. Before that they were not in circulation. Before that there was no transaction with the public. The transactions between MDS and Phamatech did not involve the public. The issue can probably be resolved at that point from the primary expression, but the conclusion is reinforced by the definition in s 9 and supported by the opinion in *Copinger*.

[257] It may be, in some cases, that the point at which a party acquires a product from the manufacturer does amount to an issue to the public. But the facts in this case are removed from such a possibility. This is exemplified by the fact that MDS ordered in bulk, completed packaging in New Zealand, released each of the products

⁷⁴ At [7-80], p 427.

in packets under the name of MDS, and recorded the products on the packets as “MDS QuickStick™”, “MDS QuickCard™” and “MDS QuickStream™”. Nothing was put into circulation until it left MDS’s premises after the goods had been packaged.

[258] This conclusion is not altered by the possibility that Phamatech, independently of its dealings with MDS, itself put other copies into circulation in countries other than New Zealand. In any event, there is insufficient evidence to lead me to the conclusion that products the same as those put into circulation in New Zealand by MDS had earlier been put into circulation, or issued to the public, by Phamatech in other countries.

[259] There are the provisos to the definition in s 9(1). However, because of the conclusion reached, and the reasons for it, the provisos have no application on the facts of this case. In particular, although MDS imported copies into New Zealand, the copies imported by MDS had not earlier been issued to the public in any country.

M. Secondary infringement by importation

[260] The plaintiffs allege that both defendants are liable for infringement by importation, a category of secondary infringement under s 35 of the Act. Although I have concluded there is liability for primary infringement by issuing to the public, it is appropriate to decide whether there is liability under s 35.

[261] The material provisions of s 35 are:

35 Infringement by importation

- (1) A person infringes copyright in a work if—
 - (a) that person imports into New Zealand an object that is an infringing copy of the work and,—
 - (i) in the case of a work that is a sound recording, film, or computer program to which subsection (6) applies, that person knows or ought reasonably to know that the object is an infringing copy; or

- (ii) in the case of other works, that person knows or has reason to believe that the object is an infringing copy; and
- (b) the object was imported into New Zealand without a copyright licence; and
- (c) the object was imported into New Zealand other than for that person's private and domestic use.

[262] The fact of importation by MDS was clear and is not in issue. Also, the defendants did not raise any issue under s 12(3) as to the meaning of “infringing copy”, in cases of importation. The primary question of fact is whether Dr Appanna had knowledge as prescribed in s 35(1)(a)(ii). That is to say, did Dr Appanna know, or have reason to believe, that the products imported by MDS were infringing copies. The inquiry at this point is directed to Dr Appanna’s knowledge not in respect of the plaintiffs’ allegation that he has personal liability, but in respect of the liability of MDS. Knowledge of MDS could only be knowledge imputed to it based on knowledge of Dr Appanna or another director or employee of MDS. The plaintiffs did not argue that knowledge could be imputed from any person other than Dr Appanna.

[263] There are two stages to the factual inquiry; the state of Dr Appanna’s knowledge before express notice of alleged infringement was given by the plaintiffs in 2006, and following that notice.

[264] I am not satisfied that, before the plaintiffs first gave notice of their claims, Dr Appanna actually knew that the products imported by MDS were infringing copies. The question is whether Dr Appanna had “reason to believe” that the products were infringing copies.

[265] As to the meaning of the expression both counsel cited a statement of Morritt J in *L A Gear Inc v Hi-tec Sports plc*.⁷⁵ That statement was applied by Smellie J in *Husqvarna Forrest & Garden Ltd v Bridon NZ Ltd*.⁷⁶ The principles are concisely stated in *Copinger* at paragraph 8-10 as follows:

⁷⁵ [1992] FSR 121 at 129.

⁷⁶ [1997] 3 NZLR 215 at 226. It has been followed in several subsequent cases and most recently and relevantly in *Electroquip Ltd v Craigco Ltd* HC Auckland CIV-2006-404-006719, 29 April 2010. See in particular at [36].

The words “has reason to believe” should be construed in accordance with their ordinary meaning. In particular:

- (a) “Reason to believe” involves a concept of knowledge of facts from which a reasonable man would arrive at the relevant belief. The test is thus an objective one;
- (b) Facts from which a reasonable man might *suspect* the relevant conclusion are not enough;
- (c) The section promotes the allowance of a period of time to enable the reasonable man to evaluate the facts to convert them into a reasonable belief.⁷⁷

The reasonable man will be taken to be a reasonable man in the position of the defendant and with his knowledge and experience.⁷⁸ If a defendant has knowledge of relevant facts giving grounds for belief that is all that is necessary; it is no defence that the defendant did not in fact believe the copies to be infringing⁷⁹ or for a defendant to say that although he knew the facts he nevertheless believed that as a matter of law no infringement would be committed, even if this was on the basis of legal advice.⁸⁰

[266] Two further points may be noted. The first is that what is required to establish “reason to believe” is less than “wilful blindness”. The second point is that there is a difference between the expression “reason to believe” in s 35(1)(a)(ii) and the expression “ought reasonably to know” in the preceding sub-paragraph (i). The latter expression sets a higher standard for the importer.

[267] There are a number of facts which satisfy me, on the balance of probabilities, that by 2002 Dr Appanna had reason to believe that the Phamatech products infringed copyright of Unipath or Acon.

[268] Dr Appanna began to acquire knowledge of the pregnancy testing market in about 1998. This was when his earlier company, Medical & Dental, began selling pregnancy test kits on behalf of another New Zealand company. As earlier outlined, Dr Appanna then began looking for a supplier of pregnancy testing products in order to put in a tender to Pharmac in New Zealand. Dr Appanna’s evidence is that there

⁷⁷ *L A Gear and Linpac Mouldings Ltd v Eagleton Direct Export Ltd* [1994] FSR 545 (CA).

⁷⁸ *ZYX Music GmbH v King* [1995] FSR 566 at 578 (knowledge of reasonable record distributor in defendant’s position); *Raben Footwear Pty Ltd v Polygram Records Inc* (1997) 37 IPR 417 (regard to be had to “the knowledge, capacity and circumstances of the particular defendant”).

⁷⁹ *Nouveau Fabrics Ltd v Voyage Decoration Ltd* [2004] EWHC 895 (ChD).

⁸⁰ *ZYX Music GmbH v King* [1997] 2 All ER 129 (CA) applying *Cillitoe v McGraw-Hill Book Co* [1983] FSR 545 (decided under the 1956 Act). See also *International Business Machines Corp v Computer Imports Ltd* [1989] 2 NZLR 395 at 418.

was a thorough investigation of the market and the evidence establishes that the thorough investigation was made by him. Indeed, the defendants made the following submission:

During the course of investigating suitable suppliers in the late 1990s (and subsequently) it is clear that Dr Appanna had been exposed to a large range of pregnancy test devices produced by numerous manufacturers which are functionally and visually similar to the designs in which Inverness claims copyright (to varying degrees).

[269] This submission, which I find to be a correct statement of fact, was made in support of a further submission that, because there were a number of products on the market similar to those of Unipath and Acon, it was reasonable for Dr Appanna to conclude that the Phamatech products did not infringe Unipath or Acon copyright. There is more evidence than this and my findings on it are against the defence. Even if this was the only evidence on the subject, my conclusion would remain contrary to the thrust of the defendants' submission. However, the important point in the present context is the express acknowledgement, abundantly supported by Dr Appanna's own evidence, that he had extensive knowledge of the products on the market from 1998.

[270] Although Dr Appanna said, with emphasis and examples, that he made wide ranging inquiries about products on the market, he expressly denied knowledge of some of the products in issue in this proceeding. For example, he said he had never seen Unipath's card product (Clearview) until he obtained, or was provided with, a sample for the purposes of this proceeding. I am unable to accept that evidence. Unipath's Clearview card product was in the New Zealand market in the early 1990s. As earlier recorded, Dr Appanna obtained copies of Phamatech's 510(k) applications. One of these expressly refers to Unipath's Clearview as a predicate device. And, in a tender round with Pharmac, the MDS card product was competing with Unipath's Clearview.

[271] I am also satisfied that Dr Appanna would have acquired detailed knowledge of pregnancy testing products available in the Australian market. There is a reasonable body of evidence justifying that inference. This includes the fact that Dr Appanna effectively controlled MDS Australia. This company was competing in

Australia against, amongst others, Unipath's pregnancy testing devices. In addition, there was evidence for the plaintiffs from Mr Mark Volling. Mr Volling is the general manager of subsidiaries of Inverness in Australia and a director of an Inverness subsidiary incorporated in New Zealand. Mr Volling said that he had four to five dealings with Dr Appanna in a period of approximately three years before these proceedings were issued. Mr Volling said:⁸¹

Based on my dealings with him, I have no doubt that Dr Appanna was aware of Inverness' fertility test devices in the Australian marketplace, as he would have continually assessed his competition for marketing and pricing purposes. He has also always been a very hands-on operator in my experience.

[272] There was cross-examination of Mr Volling directed principally to issues bearing on the extent of Dr Appanna's control of the MDS companies and, from that, whether he has personal liability. That aspect is encapsulated in the final sentence of Mr Volling's evidence. As to knowledge of products, I accept Mr Volling's opinion that Dr Appanna would have been aware of Inverness's fertility test devices in the Australian marketplace. The context of that evidence indicates clearly that he was referring principally to Inverness's Unipath products on the market in Australia.

[273] I am also satisfied that, at least by 2002, Dr Appanna had detailed knowledge of Acon products. The dealings between MDS and Acon in 2002 were summarised earlier. The evidence establishes that the direct contact with Acon was made by Dr Appanna personally and that, in the course of his dealings, he sought detailed information from Acon about its products. This included the Acon registration files. These documents were sent to Dr Appanna by Acon in March 2002. They were directed to Dr Appanna personally. There are three files relating to each of the Acon products. They contain a substantial amount of technical information. Importantly, in respect of Acon's midstream, dipstick and card, there are drawings of the products, including the strips.

[274] I consider the sequence of events in relation to the Acon midstream (Rexall) and the MDS midstream version 3 to be significant on the question of Dr Appanna's knowledge. The facts have earlier been set out in some detail. In essence: there are

⁸¹ Mr Volling's brief of evidence, para 34.

the points noted in the preceding paragraph; the market launch of Acon's Rexall product in October 2002; and the introduction of the MDS midstream version 3 in about June 2004. The MDS midstream version 3, even to a casual observer, appears to be very similar to the Acon Rexall. If, by 2002, Dr Appanna did not have reason to believe that copyright was being infringed by Phamatech, he certainly had reason to believe it by June 2004. However, in case there is any ambiguity from what I have just said, my finding is that Dr Appanna did have relevant knowledge by 2002. Further reasons follow.

[275] The facts relating to Dr Appanna's dealings with Acon and his knowledge of the Acon midstream are relevant not only to the question whether Dr Appanna had reason to believe that the MDS midstream products were infringing copies. They also bear on the same question in respect of the MDS dipstick and card products. If there was reason to believe that Phamatech was copying another manufacturer in producing the midstream, that would at the least raise similar issues for the other products MDS was getting from Phamatech. And MDS's direct dealings with Acon were not limited to the midstream; they applied to all three Acon products.

[276] I am satisfied, and again from a substantial body of evidence, that Dr Appanna is a person with considerable experience, competence and intelligence to enable him to make relevant appraisals of, and reach relevant conclusions in respect of, the competing products he had knowledge of. This was made clear from Dr Appanna's own evidence as to his experience as a medical general practitioner, his dealings over an extended period of time with pregnancy testing products, and his competence in investigating and understanding technical matters relating to these products. In fact a lot of the technical analysis supporting the defence to Inverness's claims came from Dr Appanna, directly or indirectly.

[277] The detailed technical information that Dr Appanna required before making decisions was also borne out by the evidence of Mr Steven Smith. Mr Smith now works as the senior manager of an Inverness subsidiary in San Diego, California. He was international sales manager for Acon from 2004, with his territory including New Zealand and Australia from 2005. Mr Smith had dealings with Dr Appanna from 2005. At that time Dr Appanna was investigating the possibility of a new

contract with Acon. The information sought by Dr Appanna from Acon, through Mr Smith, covered a wide range of highly technical matters relating to Acon's pregnancy testing devices. Dr Appanna also visited Acon's facility in San Diego, where he met Mr Smith.

[278] In March 2006 Inverness gave notice to MDS Australia alleging breach of the May and Davis patents. There is no evidence that before that Dr Appanna, or any other person on behalf of MDS or MDS Australia, made any relevant inquiries of Phamatech, or otherwise, on the question of infringement of Unipath, Acon or Inverness copyright. There is no evidence of such inquiries being made notwithstanding the substantial body of information acquired by Dr Appanna by 2002, and with that information added to in the following years. Related to this is the fact, as I find it, that it was Dr Appanna's objective to secure valuable Pharmac contracts by competing aggressively on price. This finding is based on Dr Appanna's own evidence. Although he did not talk about 'aggressive' price competition, that is the thrust of what he said. The two matters I have referred to in this paragraph – the absence of inquiries of Phamatech and the aggressive price competition – combine to add support to an inference adverse to Dr Appanna on the question of knowledge.

[279] The fact that there was no inquiry before the first cease and desist letter from Inverness in March 2006 is confirmed by Dr Appanna's evidence that, following that letter, assurances were sought from Phamatech that there was no infringement. Dr Appanna's evidence was not borne out by Mr Glasser. This does not, by itself, prove that Dr Appanna and MDS had relevant knowledge of infringement, but it is a further matter I take into account in reaching a conclusion adverse to the defendants on the question of knowledge.

[280] Mr Glasser's evidence was that no assurances were given by Phamatech to Dr Appanna personally or to MDS. Mr Glasser's evidence on this single point was in marked contrast to almost all of his other evidence. As earlier recorded, I found most of Mr Glasser's evidence to be vague, and he was simply unable to answer many relevant questions. On the question of the assurances, however, he was quite firm. As in-house counsel for Phamatech, this is a subject of which Mr Glasser

would be expected to have direct knowledge. In addition, Mr Glasser was present at a meeting in San Diego between Dr Appanna and the president of Phamatech, Dr Pham, which is one occasion on which Dr Appanna said he got the assurances which Mr Glasser said were not given.

[281] If I am wrong in my conclusion that Dr Appanna had requisite knowledge by 2002, there is the question whether he had such knowledge following the first cease and desist letter from Inverness in March 2006, or at some later date. Mr Marriott submitted that Inverness's particulars of alleged infringement as conveyed to the defendants in successive letters and then pleadings, expanded over time with the addition of more works allegedly infringed. I agree with the submission. If these letters and pleadings were the only evidence of knowledge or reason to believe, then any remedy given would need to make proper allowance for the different dates on which the defendants would be deemed to have acquired knowledge of infringement in respect of a particular copyright work. However, such letters and pleadings are not the only evidence of knowledge or reason to believe. Before March 2006 Dr Appanna and, through him, MDS did have the detailed knowledge about products in the market, and about Acon, and about the other matters I have already referred to. The premise on which I am now discussing matters is that such information fell short of what was required for Dr Appanna to at least have reason to believe that there was infringement. It was certainly enough to get close to that point however. In my judgment, on the present assumption, the further knowledge acquired from the first cease and desist letter was sufficient to give Dr Appanna knowledge of infringement of the particular works referred to and reason to believe that the remaining products MDS was getting from Phamatech were infringing copies.

N. Personal liability of Dr Appanna

[282] The plaintiffs claim that Dr Appanna is liable, with MDS, on two grounds. These are pleaded as follows (excluding lengthy particulars):

- 95 The second defendant authorised, directed, counselled and procured the acts of [MDS as earlier pleaded] ...

96 Further, and in the alternative ... the second defendant fronted and/or adopted and made his own the acts of [MDS as earlier pleaded].

[283] The pleading appeared to be founded on an unstated proposition of law. This is that, where a corporation has civil liability (in this case for what is effectively a statutory tort), questions whether a director of that corporation is also liable must be decided in accordance with special rules which govern the liability of directors in such cases, but which do not apply to people who are not directors. It was clear from the submissions for both parties that counsel were, in effect, proceeding on this basis. Neither counsel made any express reference to a special category of liability for directors, but both cited an Australian case, as the applicable authority, which does make express reference to this proposition.

[284] The case is *Microsoft Corp v Auschina Polaris Pty Ltd*.⁸² Lindgren J said, at 235:

Where copyright is infringed by a corporation, the question of the nature and extent of involvement on the part of a director necessary for him or her to be personally liable in respect of the infringement is not answered by principles dealing with joint tortfeasors, or by the notion of ‘authorisation’ as it is used in copyright statutes.

[285] In support of that proposition, Lindgren J referred to *WEA International Inc v Hanimex Corp Ltd*.⁸³ Gummow J said, at 203:

Where the infringer is a corporation questions frequently arise as to the degree of involvement on the part of directors necessary for them to be rendered personally liable. Those questions are not *immediately* answered by principles dealing with ‘authorisation’ or joint tortfeasance. Rather, recourse is to be had to the body of authority which explains the circumstances in which an officer of a corporation is personally liable for the torts of a corporation. (Emphasis added.)

[286] In my judgment a different approach is required in New Zealand. There are two reasons. The first is that, because this case is concerned with the application of provisions in a statute, the Copyright Act, the first inquiry on a question of liability should be whether provisions of the Act appear to apply. The second is that the proposition that the liability of directors is to be determined by reference to special

⁸² (1996) 36 IPR 225 (FCA).

⁸³ (1987) 17 FCR 274 (FCA).

legal principles which apply to directors of a corporation and, implicitly, which do not apply to others, is contrary to principle and to authority that is binding on me.

[287] The relevant provisions of the Act which prescribe liability for infringement are set out at [248] and [249] above. I have held that MDS infringed copyright by importing the MDS products and by issuing copies to the public. Whether Dr Appanna is also liable for those acts will require a determination whether he, together with or as well as the company, imported or issued to the public, or whether Dr Appanna has liability in tort for procuring or assisting MDS to import or issue to the public. But there is also the separate statutory wrong of infringement by authorising another to issue to the public (although not by authorising importation). In consequence, as a matter of seemingly straight forward statutory interpretation, Dr Appanna will be liable if he authorised MDS to issue copies to the public. This will be so whether or not others, whether directors or other employees of MDS or not, also authorised the issuing to the public of the copies by MDS.

[288] Approaching the question of Dr Appanna's liability as a matter of statutory interpretation, the first point is that, because the Act applies to corporations and MDS is a corporation, the act of issuing to the public by MDS can only have occurred as a consequence of authority being given by another corporation or by a human or humans. The Act does not exclude directors of corporations from those who may be liable for authorising another act of infringement by the corporation. And it is directors of corporations who are most likely to be the humans, where authority comes from a human, who do give the requisite authorisation.

[289] As a matter of statutory interpretation, it is then not apparent why the fact that a person is a director should put that person in a special category when determining whether or not that person has authorised the act of another. I would therefore conclude that the provisions of the Act should be applied to determine Dr Appanna's liability unless there are principles of law binding on me which require an approach contrary to the apparent statutory intent.

[290] In my judgment this approach is, in fact, consistent with basic principles that apply when a corporation has committed a civil wrong and there is a question whether a person who is a director of that corporation has also committed the same civil wrong, or a related civil wrong. The principles were recently considered by the Court of Appeal in *Body Corporate 202254 v Taylor*.⁸⁴ In respect of the fundamental principles, the Court of Appeal followed the reasoning of the House of Lords in *Williams v Natural Life Health Foods Ltd*⁸⁵ and *Standard Chartered Bank v Pakistan Shipping Corp (Nos 2 and 4)*.⁸⁶ It is unnecessary to consider the way in which the broad principles were applied in those cases because the civil wrongs alleged were different from the infringements under the Copyright Act with which I am concerned. *Williams* concerned negligent misstatement, *Standard Chartered* concerned the tort of deceit, and *Taylor* concerned negligence (and an action against a director under the Fair Trading Act 1986.) The basic principles, as well as their application in the case of different civil wrongs, are analysed with clarity by Neil Campbell and John Armour in *Demistifying the Civil Liability of Corporate Agents*⁸⁷ and by Professor Peter Watts in *Directors' Powers and Duties*.⁸⁸

[291] The question then is whether the evidence establishes that Dr Appanna authorised MDS to issue the copies (the MDS products) to the public. The word 'authorise' has often been defined as meaning to "sanction, approve and countenance".⁸⁹ The plaintiffs' first pleading against Dr Appanna (paragraph 95 of the statement of claim at [282] above) expressly alleges that he authorised the acts of MDS and also uses synonyms for authorisation or related concepts. I am not sure that the meaning of the word 'authorise' is made much clearer by finding synonyms for it.

⁸⁴ [2009] 2 NZLR 17 (CA).

⁸⁵ [1998] 1 WLR 830; [1998] 2 All ER 577.

⁸⁶ [2003] 1 AC 959; [2002] 1 All ER 173.

⁸⁷ [2003] CLJ 290.

⁸⁸ Lexis Nexis, Wellington, 2009, pp 355-369.

⁸⁹ See *Copinger* at [7-132].

[292] Having regard to findings already recorded in respect of the extent of Dr Appanna's activities and the role he played, I am satisfied that Dr Appanna infringed copyright by authorising MDS to issue the products to the public. I need to be satisfied on the balance of probabilities. In fact, I am in no doubt that the requisite authorisation had to come from Dr Appanna and that it did come from him. It should also be apparent from findings I have already made that this is not simply a conclusion that formal authority had to come from Dr Appanna along with authority from the other two directors. I am in no doubt that the decision of substance was that of Dr Appanna.

[293] Although this conclusion determines the question of personal liability, I will, in fairness to Dr Appanna, further consider the question of personal liability in the light of the submissions advanced on his behalf. It is also appropriate to consider personal liability for importing copies where there is no apparent statutory liability for authorising MDS to import the copies.

[294] Mr Marriott cited *Microsoft Corp v Auschina Polaris Pty Ltd* as "the applicable authority ... in terms of the general propositions", this being the authority also relied on for the plaintiffs. Mr Marriott then submitted, by reference to *Microsoft*:

It reinforces that in 'dealings cases' a director is not liable in respect of the tortious conduct of the company unless the director has personally assumed a duty to the other per *Trevor Ivory Ltd v Anderson* [1992] 2 NZLR 517.

[295] The decision of the Court of Appeal in *Trevor Ivory* has no relevance on the point made for the defendants. This is not a 'dealings case'. More specifically, *Trevor Ivory* was concerned with the question whether a company director could be liable for negligence in the course of dealings between the plaintiffs on the one hand and the company and its director on the other. The elements of an action for infringement of copyright are far removed from the elements of an action in

negligence.⁹⁰ There is a judgment of Allan J, on an interlocutory application in the present proceeding, which addresses these issues.⁹¹ Allan J said at [17]-[18]:

... There is a clear distinction between cases involving prior dealings between parties (where the *Trevor Ivory* principle may apply) and those where there are no such prior dealings: *Microsoft Corporation v Auschina Polaris Pty Ltd* ... I agree with the observation of Lindgren J there, to the effect that:

References to assumption of a duty are beside the point where there has been no relevant contact between the company and the aggrieved party.

Here, there can be no suggestion of prior contact between the parties. Of their very nature copyright infringement cases seldom involve such prior contact.

As will be apparent, I agree with Allan J's observations.

[296] On the question of joint tortfeasance, Lindgren J in *Microsoft* said that the appropriate test was whether the director "directed or procured the infringing act".⁹² That was in preference to an inquiry as to whether the director made "the tortious act his own". The plaintiffs' pleadings, in broad terms, rely on both tests and contend that both are met. Mr Marriott submitted:

The defendants do not express a view in respect of either test, opting instead for the balanced approach advocated in *Whitehorse Distillers Ltd v Gregson Associates Ltd*⁹³ that 'the facts of each case must be broadly considered in order to see whether, as a matter of policy requiring the balancing of the two principles of limited liability and answerability for tortious acts or conduct, they call for the directors to be held personally liable'.

[297] The statement from *Whitehorse Distillers* is in a longer passage in the judgment of Nourse J.⁹⁴ The obiter observations of Nourse J were disapproved by the Court of Appeal of England and Wales in *C Evans & Sons Ltd v Sprite Brand Ltd*.⁹⁵ With respect I do not agree with the opinion expressed by Nourse J and, in

⁹⁰ As to the different elements of different torts, including statutory torts, and their applicability to acts of directors where a company has primary liability, see N Campbell and J Armour, *Demistifying the Civil Liability of Corporate Agents*, [2003] CLJ 290 at 299-300; H Carty, *The Economic Torts in the 21st Century*, (2008) 124 LQR 641. More generally see Peter Watts, *Directors' Powers and Duties*, above n 87, at 355-369, and in particular at 360-362.

⁹¹ HC Auckland, CIV-2007-404-748, 1 November 2007.

⁹² See the discussion at 235-239.

⁹³ [1984] RPC 61.

⁹⁴ *Ibid*, at 91-92.

⁹⁵ [1985] 2 All ER 415 at 422-424.

essence, for the reasons stated by the Court of Appeal in *Evans*. The earlier judgment of Allan J in this proceeding lends some support to my conclusion, although Allan J was not required to give the matter any detailed consideration.

[298] If the question of personal liability is assessed by determining whether Dr Appanna directed or procured the infringing act, as favoured in *Microsoft* and not opposed by the defendants, then there is personal liability as I have already indicated. The evidence is abundant and clear. All of the critical decisions in this case relating to infringement of copyright were decisions made by Dr Appanna and, on the basis of the evidence before me, by Dr Appanna alone. There were the two other directors, the company solicitor and the company accountant. Various documents were produced indicating, as would be expected, that these directors had involvement in various matters. But the documents did not bear on the nature and extent of Dr Appanna's activities in a way which assisted Dr Appanna on the question of his personal liability. And there was no evidence from the other directors or from any other employee of the company.

[299] The points made by Mr Marriott for Dr Appanna on the facts were succinct and may be summarised as follows: the board of directors operated properly and effectively; the company had a proper management structure and staff; Dr Appanna only undertook dealings within his own areas of responsibility and expertise; correspondence was directed to him personally because he was the designated contact; finances, budgets and payments were handled by others; Dr Appanna did not 'handle' the ordering, importation or sale of any products personally; the company was incorporated specifically to limit liability; and the concluding point as follows:

There is no evidence that any third party was ever unaware that he was dealing with them solely in his capacity as a director. All of the documentation in which he is named or that he has signed makes this abundantly clear.

[300] These matters, individually or taken together, do not persuade me that Dr Appanna is not personally liable. Some of them, with respect, are not on point, and in particular the last two factors. Some of them, when considered in the full evidential context, support my conclusion. This includes the statement that Dr

Appanna “only undertook dealings on behalf of the company that were within his own areas of responsibility and expertise”. All of the primary decision making activities of MDS, from the selection of products through to the critical marketing activities in New Zealand, were plainly Dr Appanna’s areas of responsibility and within his special expertise. There is no evidence that the other directors of MDS had any requisite expertise. It is also clear that, although MDS had other employees, they were not employees who “directed or procured” the primary acts of importing and issuing. All relevant activities were controlled personally by Dr Appanna.

[301] The alternative test, relied on in some cases and accepted as an alternative approach by the defendants, is that the director made “the tortious act his own”. Assuming, without deciding, that that is the appropriate test, or an appropriate alternative test, I am satisfied that Dr Appanna personally and deliberately associated himself with the relevant acts of MDS. This is exemplified by two matters in particular. One is that, in MDS’s public promotions of the products, Dr Appanna, in effect, personally endorsed them. He associated himself personally with the products. The second point is that Dr Appanna was registered as the owner of trade marks for the MDS products. And it may be noted that he was registered as the owner notwithstanding the fact that the agreement with Phamatech acknowledged that Phamatech was the owner of the trade marks and the product names.

O. The defence under s 75 : works “applied industrially”

[302] Section 75 provides a defence to infringement in respect of artistic works which have been “applied industrially”. The relevant provisions of s 75 are:

75 Special exception from protection of artistic work that has been applied industrially

- (1) The making of—
 - (a) Any object in 3 dimensions; or
 - (b) Subject to subsection (3) of this section, a copy in 2 dimensions reasonably required for the making of the object—

does not infringe copyright in an artistic work if, when the object or copy is made, the artistic work has been applied industrially, in New Zealand or in any other country, by or with the licence of the copyright owner,—

- (c) In the case of a work of artistic craftsmanship, more than 25 years before the object or copy is made:

...

- (e) Subject to subsection (2) of this section, in the case of any other artistic work, more than 16 years before the object or copy is made.

- (2) ...

- (3) Subsection (1) of this section does not authorise the making of a copy in 2 dimensions of an artistic work that is in 2 dimensions, where the copy is made directly from that artistic work.

- (4) For the purposes of subsection (1) of this section, an artistic work is applied industrially if—

- (a) More than 50 copies in 3 dimensions are made of the work, for the purposes of sale or hire; or

...

[303] It is not in issue that Unipath and Acon, on different dates, made more than 50 copies of the relevant works. The principal issue is whether, when strips were manufactured, the result was a copy in three dimensions, as the defendants contended, or in two dimensions, as the plaintiffs contended. The practical point of the argument is that some products were first applied industrially by Unipath more than 16 years ago. For example, the case for Unipath's card was applied industrially in 1990. The plaintiffs did not contend for any later date. There could be no infringement in respect of the works from which the case was produced beyond some date in 2006. As to the cut-off date in any particular year, the defendants proposed 1 April, and that was accepted by the plaintiffs. For convenience, I will refer to the cut-off date as the "copyright expiry date".

[304] As with most issues, I heard a substantial amount of evidence on this. Some of it was evidence of facts of a technical nature, including evidence as to the chemistry and physics. But much of it involved opinion on a topic which in considerable measure is a matter of statutory interpretation. The opinions came, in particular, from Mr Prior, Mr Raj and Mr Bladen for the plaintiffs, and Dr Appanna and Mr Hanlon for the defendants.

[305] I am satisfied that the manufacture of strips, by Unipath and Acon, resulted in the making of copies in three dimensions. I was not referred to any authority as to the meaning of the expression. Mr Elliott did refer to the Designs Act 1953 and the Designs Regulations 1954, with particular reference to provisions indicating designs that are registerable and those that are excluded designs under the Regulations. Mr Elliott submitted that “the test strips would not be registerable as designs”. I understood him to be referring there to the manufactured strips. He continued:

They are thin, flat, primarily artistic works designed to appeal to the eye of the consumer. If they are unregistrable as designs they must by definition be protectable as two-dimensional printed artistic works protected as ‘artistic’ works under the law of copyright.

[306] I do not consider that that reference to the provisions of the Designs Act is of assistance. The submission, to an extent, begs the question. The registrability under the Designs Act is also beside the point.

[307] The broad thrust of the evidence for the plaintiffs to the effect that the manufactured strips are two dimensional emphasised the following: the strips (which do not include the wicks of the midstreams) are very thin, even with the additional pads; important parts of the strip which make the strips effective for pregnancy testing are invisible to the naked eye; the user is only concerned with results observable on what is effectively the two dimensional surface of the strip; and the chemical activities in the immunoassay occur at a molecular level.

[308] I do not consider this evidence to be of much assistance in determining what is meant by “two dimensions” and “three dimensions” as used in this Act. The meaning, in my judgment, is plain. The Act, in s 75, is directed to copyright works which, so far as this case is concerned, were created in what is undoubtedly two dimensions; that is the drawings. Before considering the nature of the strips, once manufactured, it is of assistance to consider the essential subject matter of s 75, and again so far as it relates to the facts of this case. Section 75 is concerned with drawings which may be used for the manufacture of products. As a matter of ordinary language, drawings are in two dimensions (and notwithstanding evidence I heard even on that topic). Section 75 draws a distinction between making a copy of a drawing by producing another drawing and making a copy of the drawing by

manufacturing the product. Manufacture is exactly what has occurred in this case. Determining whether the result is in three dimensions, on this approach, is answered simply by determining whether another drawing has been made or whether the object has been manufactured using the drawing.

[309] If the inquiry does need to extend to consideration of the physical product, the facts relating to the manufactured strips leads to the same conclusion. The microscopic, or even molecular, aspects of some important parts of the strips, the very thin nature of the nitrocellulose, and other features referred to by the plaintiffs' witnesses, are not pointers to two dimensionality. Nor is the fact that a user may only be interested in the result that may be viewed by looking at the surface of a part of the strip. The product can only work because it is in three dimensions. Urine physically moves through the strip. Antibodies and coloured particles move along the strip. Whatever the consumer may be interested in, the strip is an operating device.

[310] For these various reasons I accept the defendants' submission that all of the strips, once manufactured, were in three dimensions and, in consequence, applied industrially once 50 copies had been manufactured.

[311] This conclusion requires a further determination as to when the relevant Unipath and Acon products were applied industrially. The defendants analysed this point in submissions mainly by reference to Unipath works only. However, the defendants' accounting expert, Mr Lazelle, produced a table based on his instructions which included copyright expiry dates for Acon works as well as those of Unipath. The plaintiffs also produced a table recording their contentions for Acon as well as Unipath.

[312] There are differences in the dates in the tables. These arise in large measure because the defendants have, quite properly and with some care, sought to identify individual dates for each of the relevant Unipath and Acon products and, in the case of the midstreams and cards, further breaking this down into dates for the strips and separate dates for the cases. In some cases the different dates may have a bearing on

any remedy. But in my judgment, on the facts of this case related, in particular, to the nature of the products, the different dates are not material.

[313] The dates could be material in two respects. The first relates to the fact that, with the midstreams and cards, there are, or could be, different expiry dates for the cases and for the strips. The second aspect relates to strips only. I have concluded that there has been copying of both Unipath and Acon works for strips, but there are different expiry dates for Unipath and for Acon. That might, in theory, require a remedy tailored to different parts of the strip itself.

[314] The first point, involving different dates for a case and for the strip in the case, may be considered by principles determining whether there should be apportionment. On the facts of this case the issue arises only in respect of the Unipath card case, which was industrially applied, on the plaintiffs' contention, in 1990, and in 1988 on the defendants' contention. My finding is that the relevant works of Unipath were industrially applied in 1990. The result is that, if the case is considered in isolation, what I call the copyright expiry date for the case was 1 April 2006. This could have some bearing on the calculation of damages. However, for reasons discussed in section P, dealing with damages, I have concluded that it is not appropriate to apportion damages in respect of the case.

[315] The second area of potential complication is with different expiry dates for Unipath and Acon strips. The conclusion I reached on copying is that individual MDS strips copy substantial parts from both Acon and Unipath works, with these substantial parts in effect merged into an MDS strip. This feature of copying from Unipath and Acon is illustrated, in some of the relevant respects, by the table at [198]. The chart indicates, and I concluded, that all but two of the dimensions recorded in that chart were copied from Unipath's strip put into the market in 1996 (the SOAPSUD strip). Another feature copied from Unipath was the wide wick introduced in 2002. The test line position appears to have been copied from Acon. The same general point is illustrated by the table relating to the strips in the three cards, at [208] above.

[316] The dates on which the relevant Unipath and Acon strips were applied industrially are relatively easily established and are in large measure agreed. They are different dates. If the law requires these different dates to be taken into account in assessing damages and granting an injunction, both exercises would be likely to be complicated and an effective injunction difficult to construct. In my opinion, it is not necessary to go down this path. This is for two reasons. One is that, as with the case, apportionment is not appropriate. The second is contained in the principles relating to copyright infringement claims by a plaintiff whose works are in part derived from copyright works owned by a third party. The principle is stated in *Copinger*, at paragraph 3-263, as follows:

Works infringing other works

Today it is clear that copyright can subsist in a work which itself infringes copyright in an earlier work,⁹⁶ and the issue is whether the court will enforce such copyright. As to this, a work which itself is an infringement of an earlier work, but which otherwise satisfies the requirements for copyright to subsist in the work,⁹⁷ will normally be entitled to protection, subject to the right of the owner of the earlier copyright work to receive a share of any sum recovered.⁹⁸

[317] In my judgment, and supported by some evidence from Mr Prior, the design of the Acon strips is, in part, derived from the Unipath strips. However, as earlier discussed, I am also satisfied that Acon's works otherwise satisfy the requirements for copyright to subsist in them. Any obligation for Acon to account to Unipath does not arise in the unusual circumstances of this case; the interests of those two companies, in this respect, have now merged following the successive acquisitions by IMI.

⁹⁶ *Redwood Music Ltd v Chappell & Co Ltd* [1982] RPC 109 at 120 per Goff J, applying *Wood v Boosey* (1866) LR 2 QB 340; (1967) LR 3 QB 223 at 229 (arrangement of a score of an opera held to be subject of copyright, notwithstanding that its publication without the authority of the composer of the original opera would be an infringement).

⁹⁷ As to whether such a work qualifies as original, see *Copinger* [3-141]. In some of the older cases, relief was refused on the ground that the work was infringing: see *eg Cary v Faden* (1799) 5 Ves 23; *Sailendra Nath De v Chayanika Chire Mandir* (1950) 55 CalWN 713; *Gouindan v Gopalakrishna Kone* [1955] MadWN 369.

⁹⁸ *ZYX Music GmbH v King* [1995] FSR 566; [1995] 3 All ER 1 at 9h to 11b, per Lightman J.

[318] Based on this analysis I accept the plaintiffs' calculations for expiry dates, which are as follows (reproducing, with minor amendments, the table contained in the plaintiffs' closing submissions in reply).

PRODUCT	DATE MADE & SOLD	EXPIRY DATE
Dipstick		
<i>ACON dipstick test strip (FHC-101)</i>	1996	2012
<i>Modified design with anti-LH scavenger antibody added to test strip and blank half of conjugate pad</i>	2000	2016
Card		
<i>Unipath case</i>	1990	2006
<i>Unipath stage 2 test strip including conjugate pad</i>	1990	2006
<i>ACON test strip in Quik-Check (FHC-102)</i>	1996	2012
<i>Modified ACON test strip (FHC-101) design with anti-LH scavenger antibody added to test strip and blank half of conjugate pad</i>	2000	2016
Midstream		
<i>Acon Rexall case</i>	2002	2016
<i>ACON test strip in midstream (FHC-103)</i>	1996	2012
<i>Modified ACON test strip (FHC-103) design with anti-LH scavenger antibody added to test strip and blank half of conjugate pad</i>	2000	2016

P. Damages

[319] The plaintiffs elected to seek damages rather than an account of profits. There are different ways in which damages for infringement of copyright may be assessed. It is unnecessary to consider principles established by the cases as to which method should be selected. This is because, by the time of closing submissions, there was broad acceptance that damages could be assessed and should be assessed by applying a royalty to the infringing products sold by MDS. Both expert accounting witnesses, Mr John Hagen for the plaintiffs and Mr Murray

Lazelle for the defendants, provided evidence for calculation of damages based on a royalty. I am satisfied that this is an appropriate basis for assessment of damages.

[320] The principal issue that arises is the appropriate royalty rate. Mr Hagen made calculations based on rates of 10% and 15%. In cross-examination, Mr Hagen explained that he had used the 15% figure because Mr Veldhuis, of Inverness, had informed him that a 15% royalty rate had been adopted in settlement of another infringement claim. Mr Hagen accepted that this royalty rate might well be higher than that normally adopted in an arm's length commercial negotiation.⁹⁹

[321] Mr Veldhuis had earlier given evidence of the 15% rate as, in effect, a figure agreed between Inverness and another party, unnamed, in settlement of proceedings issued by Inverness. There was no other evidence for the plaintiffs in respect of an appropriate royalty rate. This was notwithstanding evidence that Inverness had sold its products in New Zealand through other companies and on a royalty basis.

[322] Mr Veldhuis' evidence does not provide a principled basis for assessing the rate. In saying that I am not intending to criticise Mr Veldhuis. He has simply given evidence of a particular rate arrived at in particular circumstances. The point is that the circumstances are not those applicable to the exercise I am concerned with. The rate must be one arrived at on the basis of a notional arm's length transaction between MDS and Inverness, Unipath or Acon, taking account of relevant market considerations and relevant considerations for each of MDS and Inverness.¹⁰⁰ Mr Veldhuis' evidence does have some relevance for this purpose, but not to the effect contended for the plaintiffs. Mr Veldhuis' 15%, obtained from a party being sued and as part of the consideration for settlement, is at the least strongly suggestive of a rate above the rate that would be arrived at following an arm's length, commercial negotiation in the market.

⁹⁹ Notes of evidence p 254, lines 21-27 and 33-35.

¹⁰⁰ *Aktiengesellschaft für Autogene Aluminium Schweissung v London Aluminium Co Ltd (No. 2)* (1923) 40 RPC 107 at 113-114; *Ludlow Music Inc v Williams (No. 2)* [2002] FSR 57.

[323] The defendants adduced some evidence indicative of commercial market rates for pharmaceutical products. This came from a World Health Organisation (WHO) report entitled “Remuneration guidelines for non-voluntary use of a patent on medical technologies”. The report was published in 2005. The opening statement, in the executive summary to the report, refers to the obligation on members of WHO to “implement intellectual property laws in a manner that promotes access to medicines for all”. It refers to royalty rates imposed by governments. However, for the purposes of discussing the primary topic of “non-voluntary” remuneration, there is reference to commercially negotiated royalty rates in the pharmaceutical industry. The executive summary says:

There is some conflicting evidence on cross-industry licensing averages, but there seems to be agreement in reports from the pharmaceutical industry and others that licensing fees for the pharmaceutical industry congregate at 4-5%.

There is an expanded discussion in one section of the report which supports this summary.

[324] I consider that the market indication of 4-5% for a royalty is the rate to be applied in this case. This is for the following reasons, which in large measure summarises what I have already referred to: both parties accept a royalty calculation as the appropriate means of assessing damages; the rates of 10% and 15% used by Mr Hagen are not appropriate because they are not based on evidence of rates reached at arm’s length; the plaintiffs have not adduced any other evidence of market rates; there is evidence from the WHO report which I am prepared to accept in the absence of other evidence of greater weight; and the plaintiffs did not, as such, challenge the accuracy of the WHO report, beyond arguing that the range of 10% to 15% should apply. The only point raised by the plaintiffs in respect of the report was to the essential effect that the average rate of 4-5% was in some way related to compulsory licensing. That submission is not borne out by a reading of the report.

[325] Mr Lazelle made a calculation of damages based on a royalty of 4%. Assuming infringement by all of the MDS products, the total calculated by Mr Lazelle is \$259,998. There were separate calculations for the cases for the cards and the midstreams, and for the strips in the cards and the midstreams. The separate

calculations were made to allow for the possibility of a finding that the strip infringed and the case did not, and vice versa. That distinction is not relevant given my earlier findings.

[326] There was also a separate calculation for the case of the Unipath card, with royalty damages calculated up to 1 April 2004, but not beyond that date. This was on the basis that the Unipath card case was industrially applied in 1988 and there could therefore be no infringement by MDS from 1 April 2004.¹⁰¹ The plaintiffs contended that the Unipath card case was industrially applied in 1990. I have already held in favour of the plaintiffs on that point, but the issue remains because the copyright expiry date, which is then 1 April 2006, has passed. This comes back to the question whether damages should be apportioned.

[327] As earlier indicated, I do not consider that there should be an apportionment between the case for the MDS card and the strip, with the calculation of damages for the case going to April 2006 only. Sometimes apportionment may be necessary, or at least appropriate.¹⁰² But there is no rule that, where part only of the defendants' product infringes, there should always be some apportionment. The broad principle was stated by Windeyer J in the High Court of Australia in *Colbeam Palmer Ltd v Stock Affiliates Pty Ltd*:¹⁰³

The true rule, I consider, is that a person who wrongly uses another man's industrial property – patent, copyright, trade mark – is accountable for any profits which he makes which are attributable to his use of the property which was not his ...

If one man makes profits by the use or sale of something, and that whole thing came into existence by reason of his wrongful use of another man's property in a patent, design or copyright, the difficulty disappears and the case is then, generally speaking, simple. In such a case the infringer must account for all the profits which he thus made.

¹⁰¹ An issue of this sort does not arise in respect of the Acon card case. The plaintiffs' claim, in relation to a card case, is in respect of Unipath works only.

¹⁰² See *ABB Ltd v New Zealand Insulators Ltd* (2007) 11 TCLR 978 (HC) at [90] ff, and the cases there cited.

¹⁰³ (1998) 122 CLR 25 at 42. See also *Dart Industries Inc v Décor Corp Pty Ltd* (1993) 26 IPR 193 at 202-203 (HCA).

[328] Although Windeyer J was there considering an account of profits, in my opinion the principle is equally applicable to an assessment of damages and, as in this case, an assessment using a royalty calculation.

[329] Applying the broad principles to this case, I am satisfied that there should be no apportionment as contended for by the defendants. The practical effect of the apportionment would be to exclude a royalty for a period in relation to the case for the card. The case, in the present context, is not significant. The product, as a whole, simply could not have been sold without the strip.

[330] If there is no apportionment, Mr Lazelle's total of \$259,998 increases to \$305,938. I consider that that is the appropriate figure for damages calculated to 31 March 2009 if the royalty is fixed at 4%. However, there is a further issue whether it should be 4% or 5%.

[331] I consider that the percentage should be 5%. The defendants relied on the evidence that the figure is between 4-5%. In view of the fact that I have found the defendants to have infringed the plaintiffs' rights, it is not appropriate in my judgment to pick the lower figure. Further, the evidence from Mr Veldhuis as to the 15% rate agreed in settlement of the litigation at least lends some support to using the 5% rate. The result on this basis is to increase the figure from \$305,938 to \$382,422. This sum is broadly similar to the figure arrived at if Mr Hagen's calculations at 10% and 15% are adjusted to a 5% rate.

[332] I accordingly fix the damages calculated to 31 March 2009 at \$382,422.

[333] An adjustment needs to be made for royalties after 31 March 2009. The royalty rate of 5% should be applied, to all products without any apportionment, up to the date of this judgment. I do not have the information to make the calculation. I will therefore reserve leave to the parties to apply for further directions if agreement cannot be reached.

[334] The plaintiffs claimed additional damages said to result "from the flagrancy of the infringement and any commercial benefits accruing to" MDS by reason of the

infringement. I am not persuaded that a claim for additional damages has been made out.

Q. Injunction

[335] The plaintiffs seek an injunction restraining the defendants from continuing infringement. The plaintiffs are entitled to an injunction, the terms of which are recorded at the conclusion of this judgment.

R. Plaintiffs' further claims

[336] There were two further claims by both plaintiffs against both defendants. The first alleges breach of contract, in respect of contractual obligations of confidentiality. The second alleges misuse of confidential information arising in circumstances requiring the defendants to maintain confidentiality. It is unnecessary to explain the nature of these claims in any further detail. They were, in effect, not pursued by the plaintiffs. In closing submissions, the following submission was responsibly made by Mr Elliott (at para 320):

In terms of affirmative proof that either MDS or Dr Appanna breached the plaintiffs' confidences and passed on confidential information belonging to ACON to Phamatech or to other competitors or potential competitors, this cannot be pointed to.

[337] There are other important elements of the claim lacking proof. In consequence, these claims are dismissed.

S. MDS counterclaims

[338] MDS has three counterclaims. The first is that Inverness "instituted this proceeding and in particular the claims for infringement of copyright without proper justification or cause". The second is as follows: "The actions of the plaintiffs in sending letters to the defendants and their solicitors and patent attorneys and in bringing and prosecuting this proceeding amount to misleading and deceptive conduct". The letters referred to are the cease and desist letters and subsequent

correspondence. Because of the conclusions I have reached on the plaintiffs' claims, neither of these claims can succeed and they are dismissed.

[339] The third counterclaim is that IMI is in breach of the agreement entered into by MDS and Acon in 2002. It is alleged that IMI, in breach of the contract, failed or refused to supply documents required by MDS to comply with medical regulations in New Zealand and Australia for registration of pregnancy testing devices. It is alleged that the failure or refusal by IMI occurred "on various occasions in 2006". MDS pleaded that, as a result, MDS was "unable to obtain regulatory approval in New Zealand and Australia for pregnancy testing kits as supplied by the first plaintiff thereby causing to the first defendant loss". This claim cannot succeed.

[340] It was not established that the 2002 agreement between Acon and MDS is in some way binding on IMI. Nor was it established that IMI procured breach of the agreement by Acon. In my judgment it is also clear that the 2002 agreement had lapsed long before IMI entered into the Acon acquisition agreement, which was on 24 February 2006. There is no evidence that IMI would have been in a position to influence Acon in any material way much before that date, which is also long after the date on which the 2002 agreement lapsed.

[341] The relevant terms of the 2002 agreement were earlier noted. The intention of the parties was that MDS might become a distributor of Acon products in New Zealand. This never happened. That of itself does not mean that the agreement lapsed, but it is the essential background. I am satisfied from the evidence that the 2002 agreement was treated as being at an end, although possibly for different reasons, by Dr Appanna and by Acon. There is no evidence of any relevant contact, let alone dealings, between MDS and Acon from around March 2002, when Acon sent its registration files to MDS, until February 2005 when Dr Appanna contacted Mr Joel Heidecker, who had been Acon's international sales manager in 2002. Dr Appanna's initial inquiry was whether Acon was interested in acting as a manufacturer for MDS. There was no suggestion that there was an existing, binding contract. Discussions proceeded during 2005. On Acon's side these were conducted by Acon's new international sales manager, Mr Smith. These discussions proceeded on the clear basis that the parties were exploring the possibility of a new contract for

Acon to become a manufacturer for and supplier to MDS. This is the conclusion I reach based not only on Mr Smith's evidence but also on Dr Appanna's evidence.

[342] The matter is really put beyond doubt by an e-mail of 11 September 2005 from Dr Appanna to Mr Smith, responding to an e-mail from Mr Smith. (It also provides a single illustration of the extent of Dr Appanna's control of MDS activities and, to an extent, his technical knowledge.) Dr Appanna's e-mail is as follows:

Thanks Steven.

I have been searching through my files and found the original agreement we had with Acon, which I believe was never signed. I have attached this as a starting point for us to work from. We will need to replace the price list with the latest version and update the products to be included in the agreement.

I am quite keen to proceed immediately with the Prostate Test kit. What is the lead time from order to delivery?

By the way, any progress on the validation of the chlamydiae test on female urine?

Regards

Prakash

[343] Dr Appanna subsequently found a signed copy of the 2002 agreement, but that does not have any bearing on the present issue. Dr Appanna earlier referred to the 2002 agreement as an agreement that had been binding, whether or not there was a signed agreement. With Dr Appanna and Acon then having express knowledge that the 2002 agreement had been signed, each side continued negotiations on the basis, known to the other side, that they were not bound by any existing agreement; any contractual obligations would require a new agreement to be entered into.

[344] After Dr Appanna sent Mr Smith a copy of the signed agreement, Acon and MDS, through Dr Appanna, continued negotiations towards a new agreement. Dr Appanna's evidence for this period was on that basis – that a new agreement was required. But it went beyond this, to a point that cannot be reconciled with the counterclaim. Dr Appanna expressly contended that a contract was entered into between MDS and Acon in January 2006. Mr Smith's evidence supports Dr Appanna's evidence to the effect that both parties were proceeding on the basis that a

new agreement was needed. They diverged on the question whether an agreement was in fact made.

[345] In case there is some basis upon which the defendants could maintain a counterclaim based on the agreement said to have been entered into in January 2006, I record my conclusion that an agreement was not made in January 2006. It is clear that the parties did not intend to be bound in the absence of a written agreement signed by both parties. That did not happen.

[346] In the final submissions for MDS on this counterclaim the argument was directed back to the proposition that IMI has liability under the 2002 agreement. For the reasons I have outlined, I am satisfied that there was no agreement binding on Acon at any time when IMI was in a position to influence Acon. Because there was no binding agreement when IMI entered into the acquisition agreement with Acon, that cannot provide a route for liability for IMI. This further MDS counterclaim is also dismissed.

T. Result

[347] There is judgment for the plaintiffs.

[348] There is an order by way of injunction in favour of both plaintiffs prohibiting the defendants, and the defendants' employees, servants, agents and distributors, from reproducing, importing, distributing, selling, offering for sale and marketing the pregnancy testing devices currently sold by the defendants under the names MDS QuickStream, MDS QuickStick and MDS QuickCard, and any other pregnancy test products or parts of such products that are copied or substantially copied from the plaintiffs' copyright works.

[349] Without prejudice to the immediate effect of the preceding order of injunction the parties have leave to apply for further orders as to the duration of the injunction and any further definition of its scope.

[350] The defendants are to pay damages to the second plaintiff as follows:

- a) In a sum of \$382,422 for damages calculated to 31 March 2009.
- b) Further damages from 1 April 2009 to the date of this judgment to be calculated on a royalty basis on the same terms as the calculation leading to the award of \$382,344, with leave to apply if the parties cannot agree on the sum.
- c) The liability of the defendants is joint and several.

[351] The plaintiffs' further claims are dismissed.

[352] The defendants' counterclaims are dismissed.

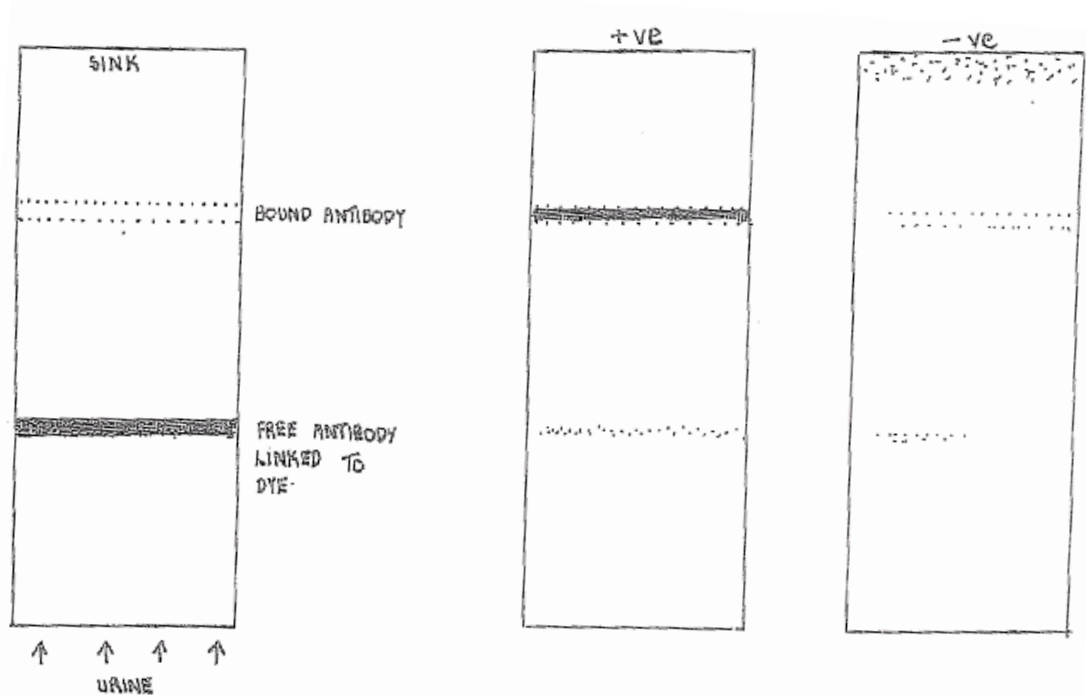
U. Costs

[353] The plaintiffs are entitled to costs. If the parties cannot agree on quantum the plaintiffs should file a memorandum in support of their claim within six weeks and the defendants should reply within a further three weeks.

Peter Woodhouse J

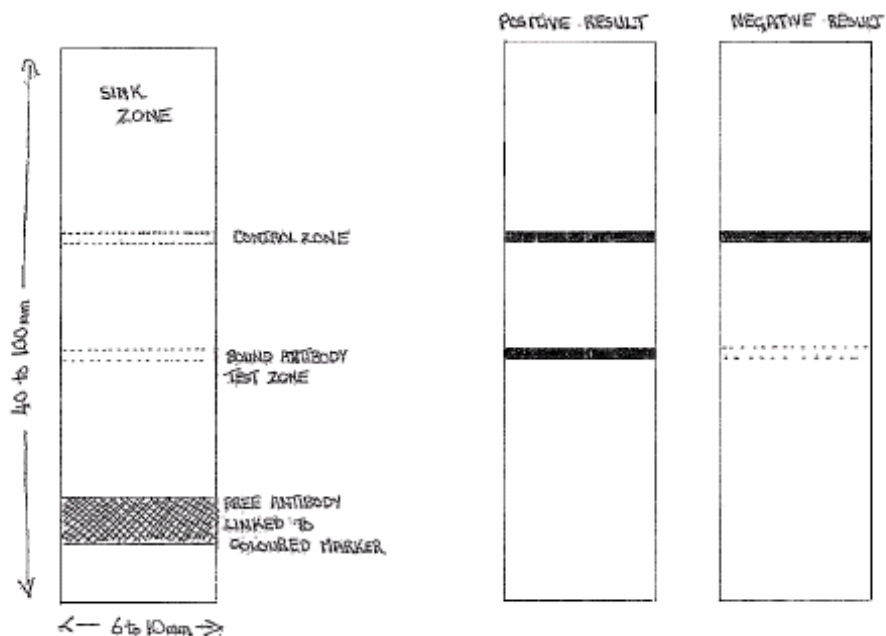
ANNEXURE 1

(WB 001 - top)



(WB 003 - bottom)

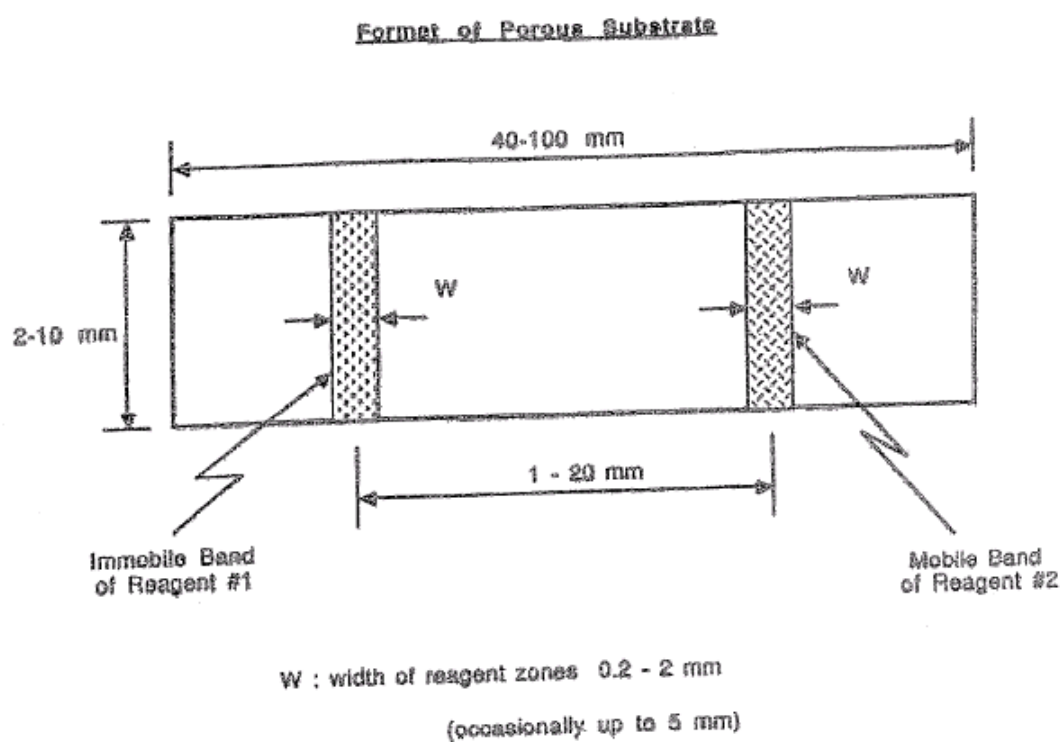
DESIGN FOR CELLULOSE NITRATE ASSAY STRIP WITH CONTROL ZONE CIRCA MAY/JUNE 1987



Drawn March 2002 by M.E. from memory of original sketches made by him during invention of lateral flow technology.

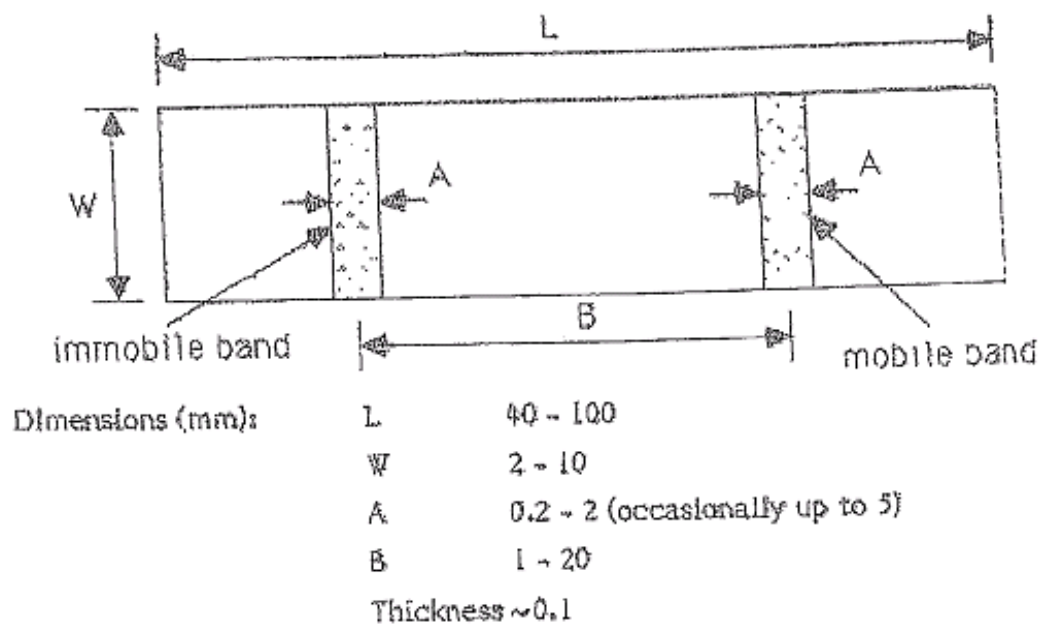
ANNEXURE 2

(WB 004 – top)



(WB 006 – bottom)

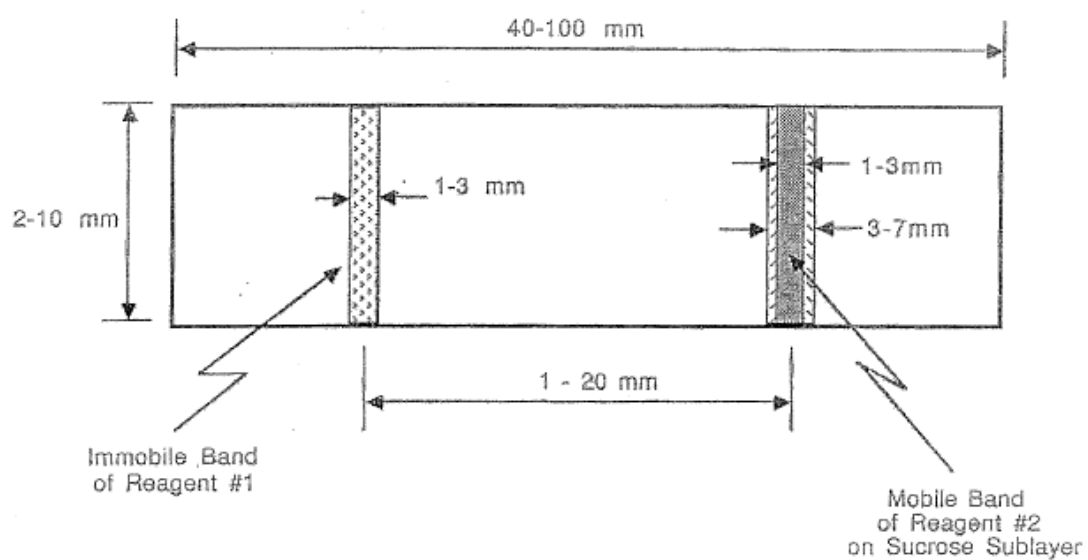
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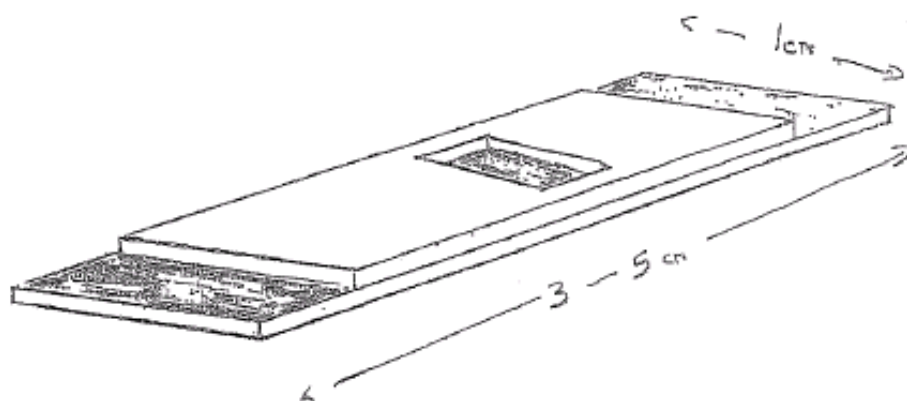
ANNEXURE 3

(WB 004A - top)

Updated Format of Cellulose Nitrate Assay Strip



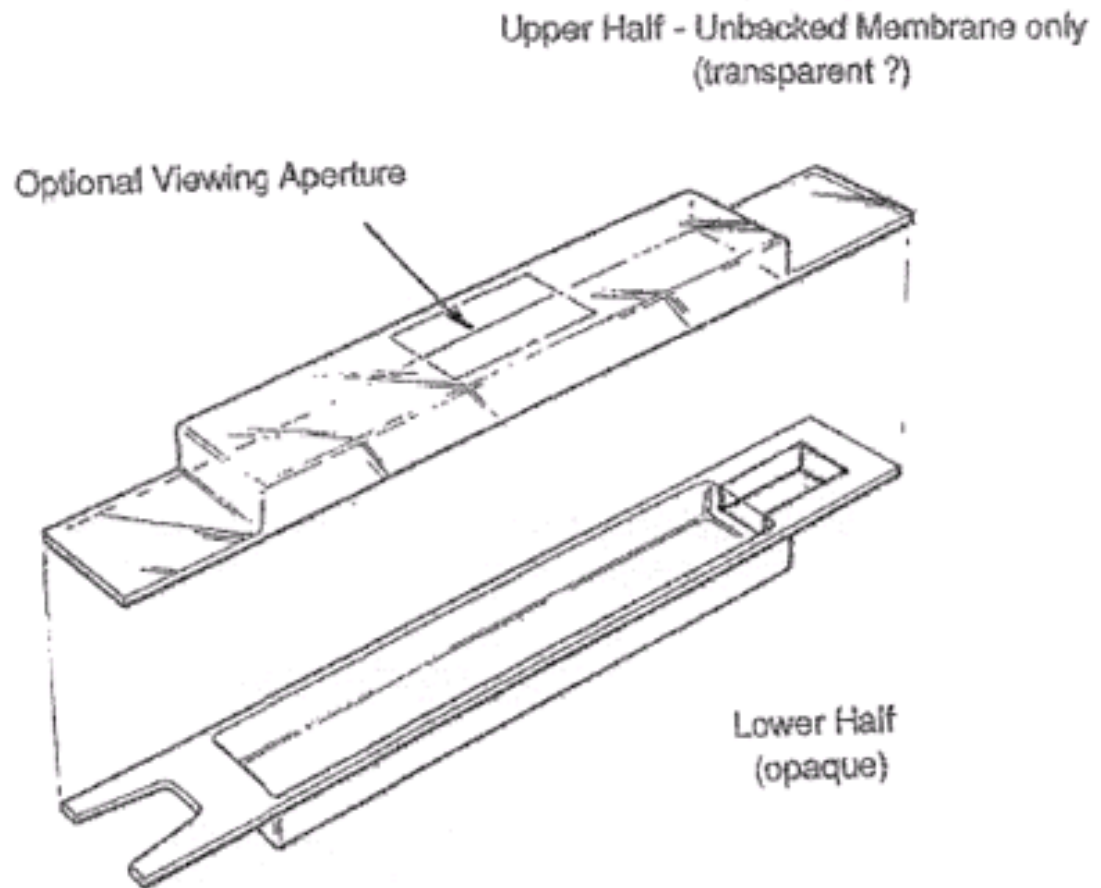
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ANNEXURE 4

(WB 007)

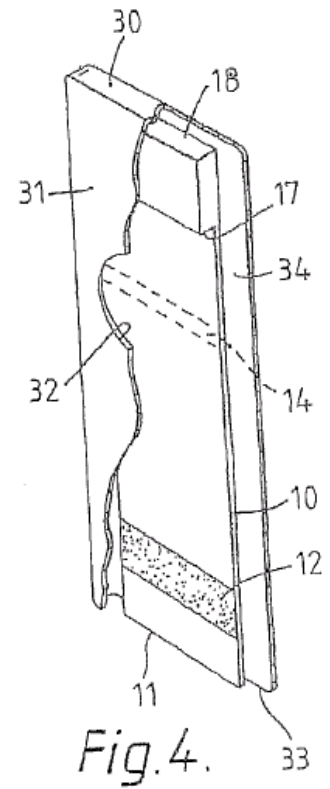
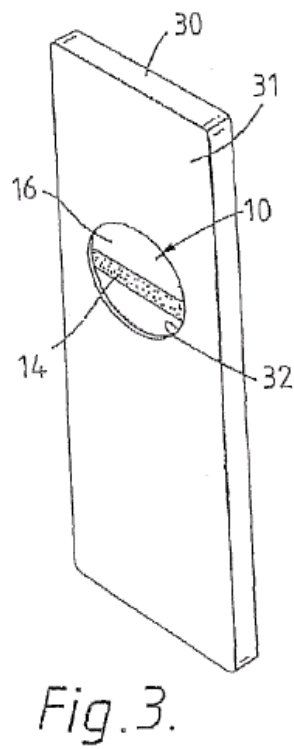
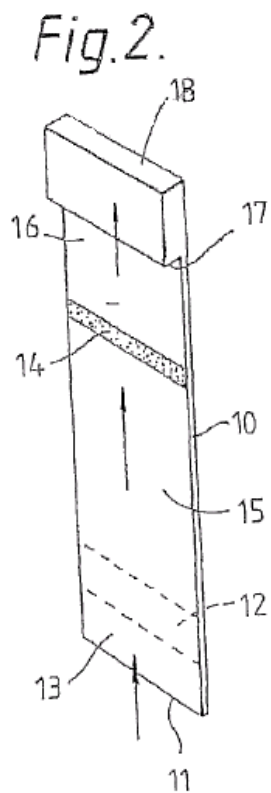
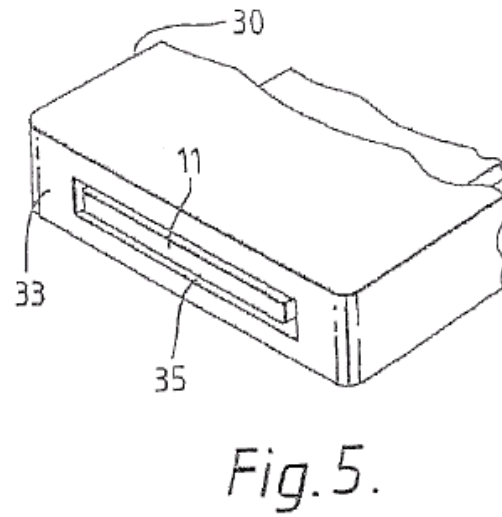
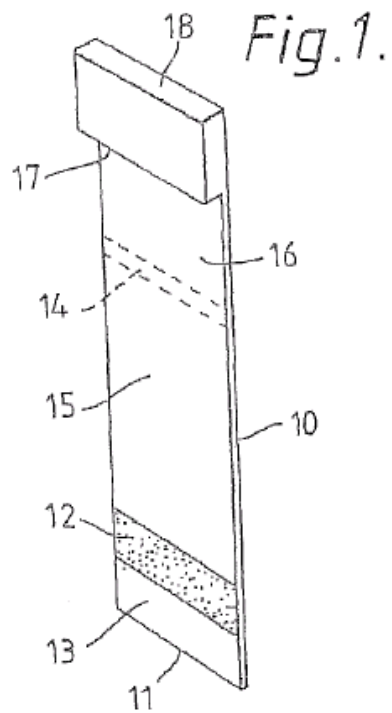
PROJECT POTATO



ESSENTIAL FEATURES OF "TOP HAT" FORMAT

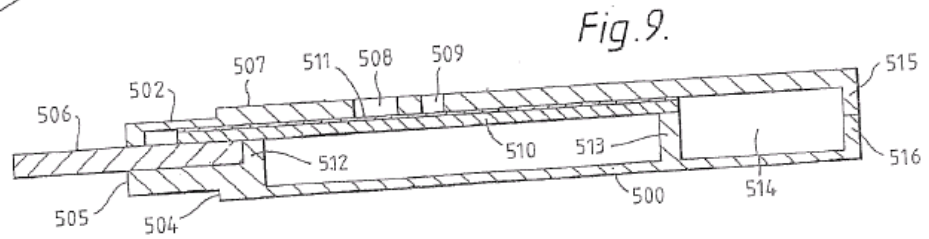
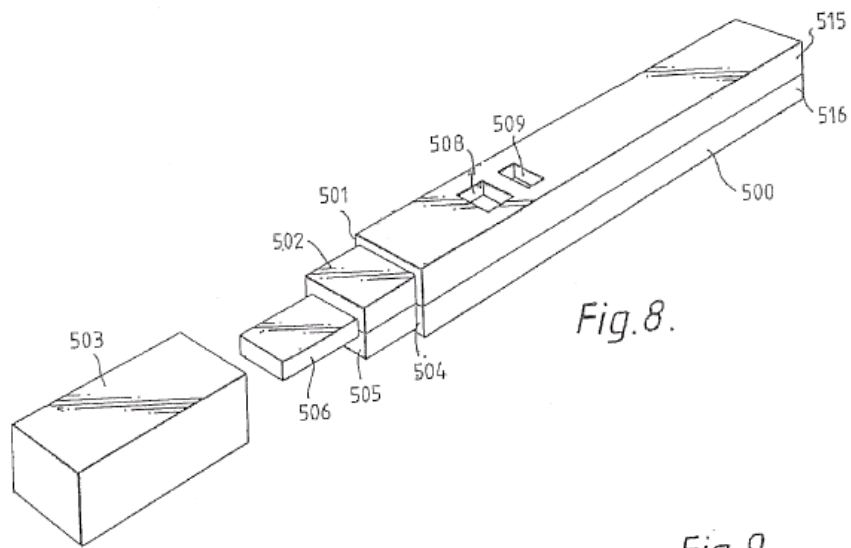
ANNEXURE 4A

(WB 008)

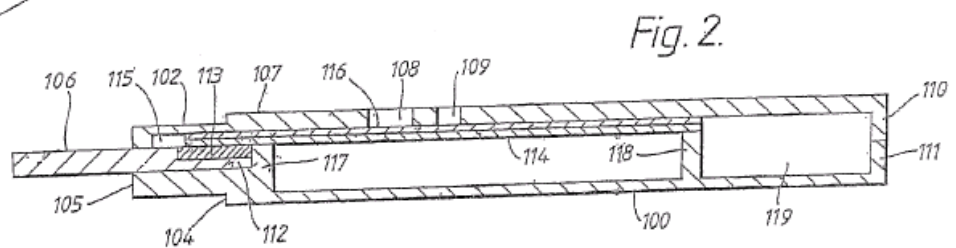
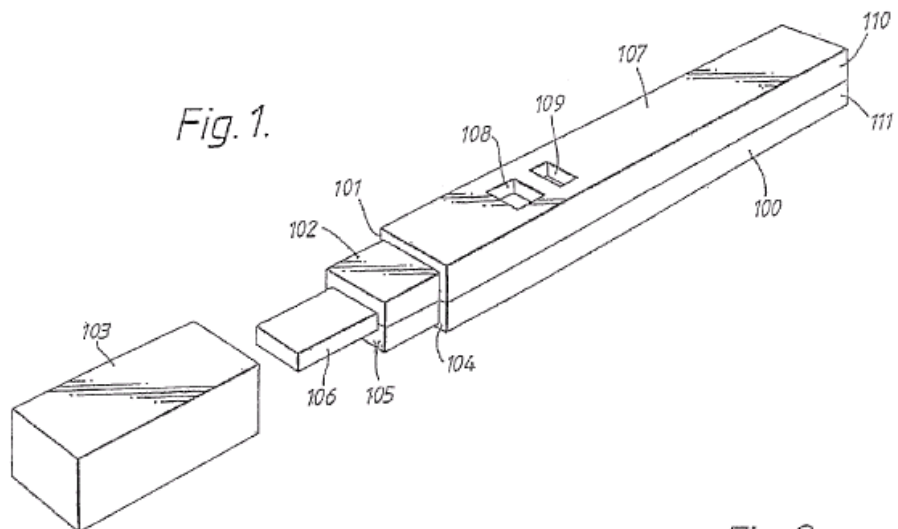


ANNEXURE 5

(WB 017 - top)

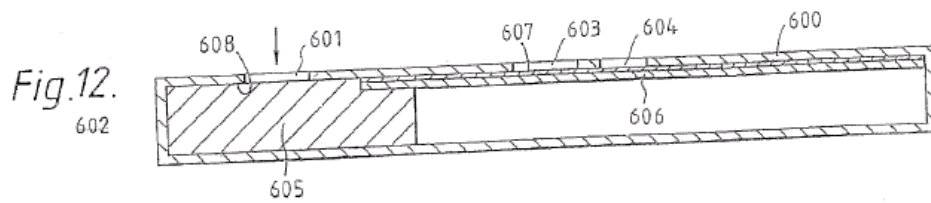
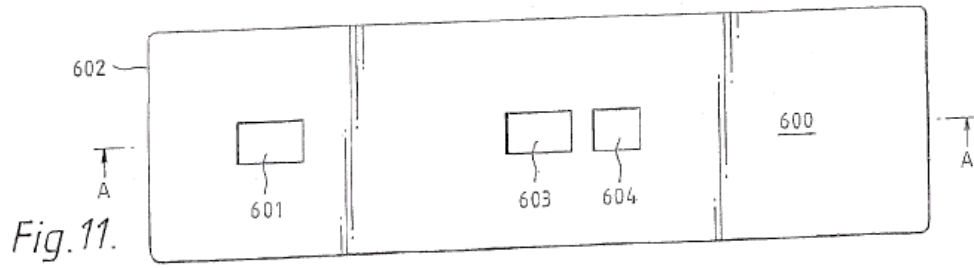
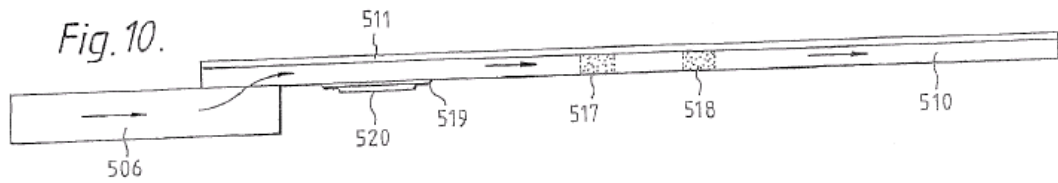


(WB 018 – bottom)

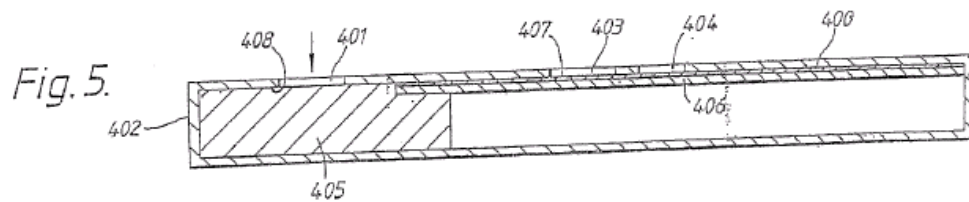
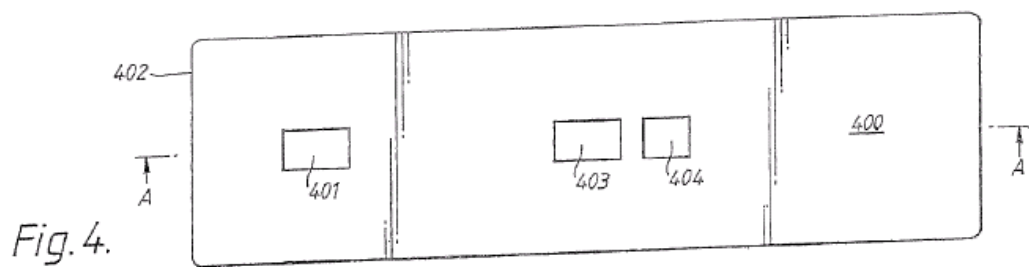
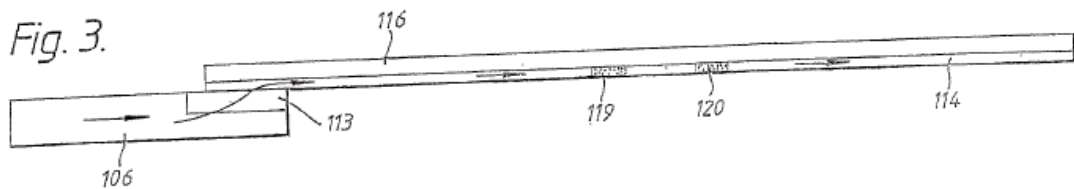


ANNEXURE 6

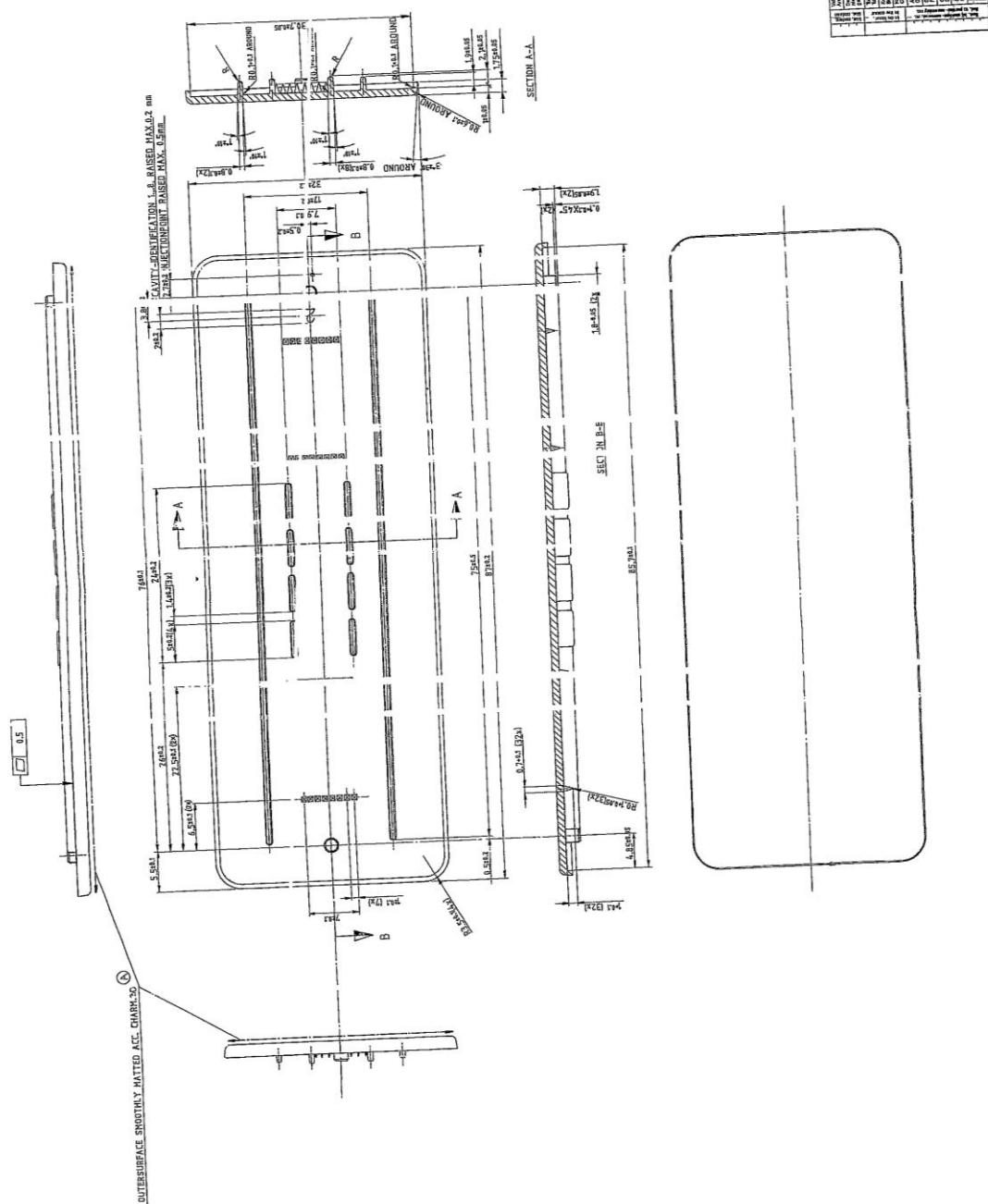
(WB 009 - top)



(WB 019 - bottom)

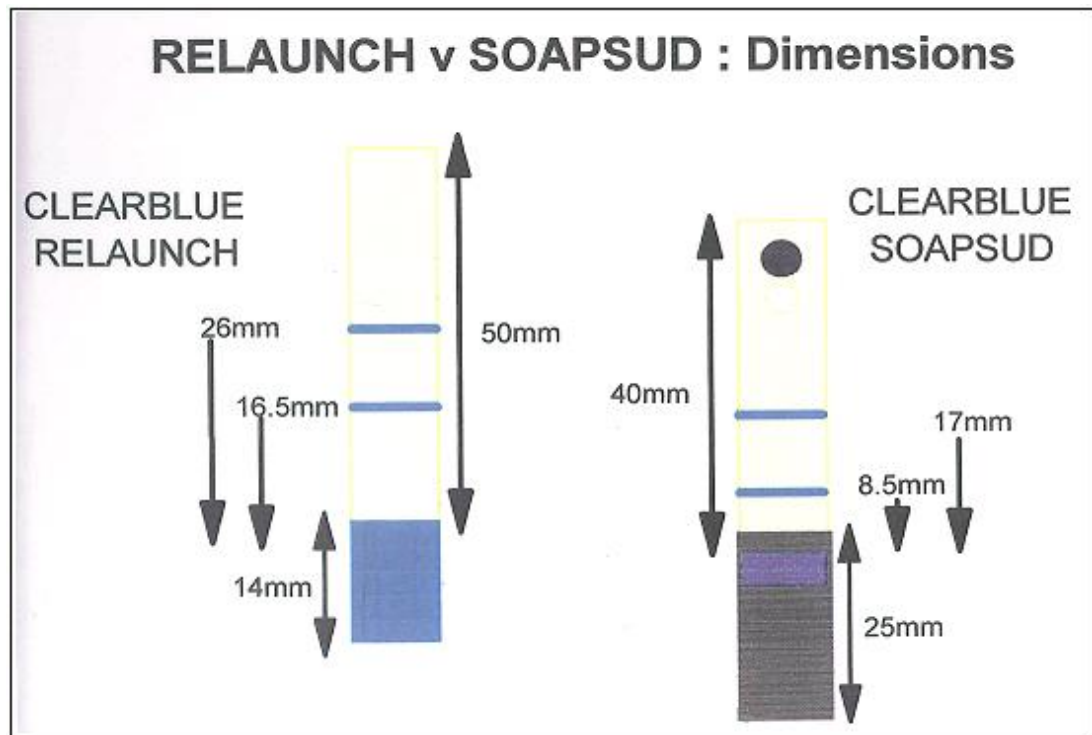


(WB 011)



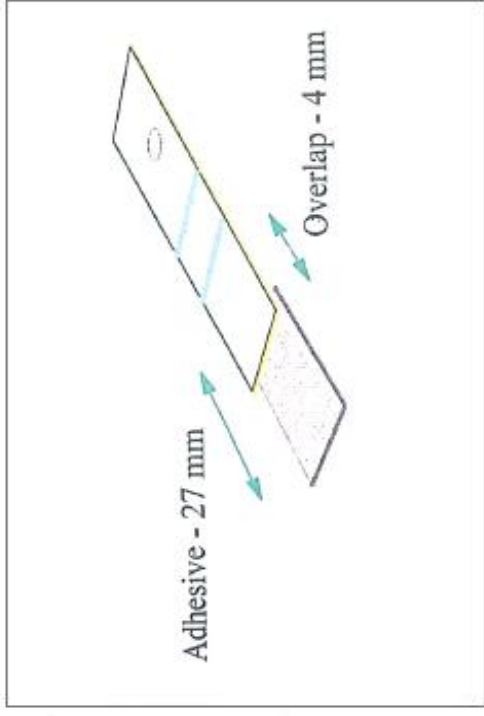
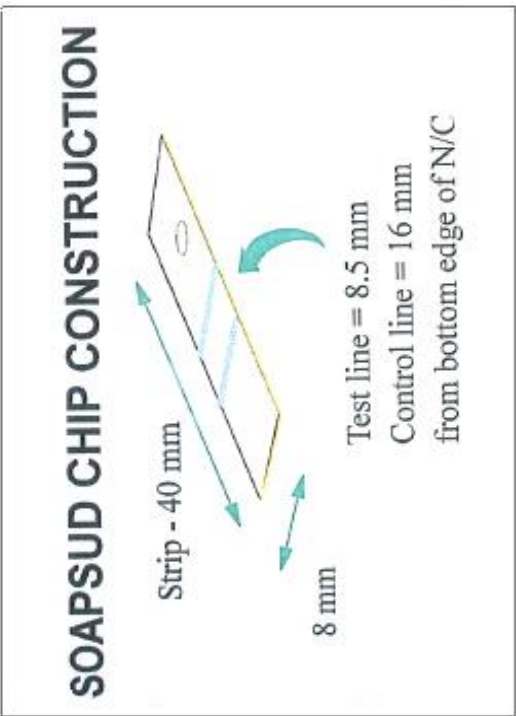
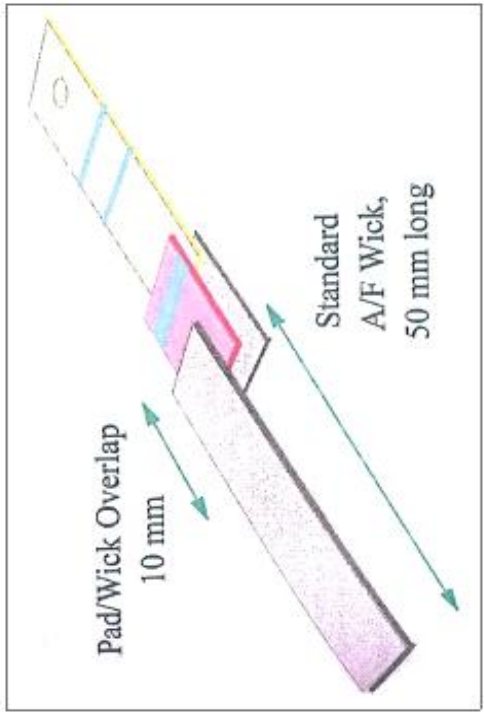
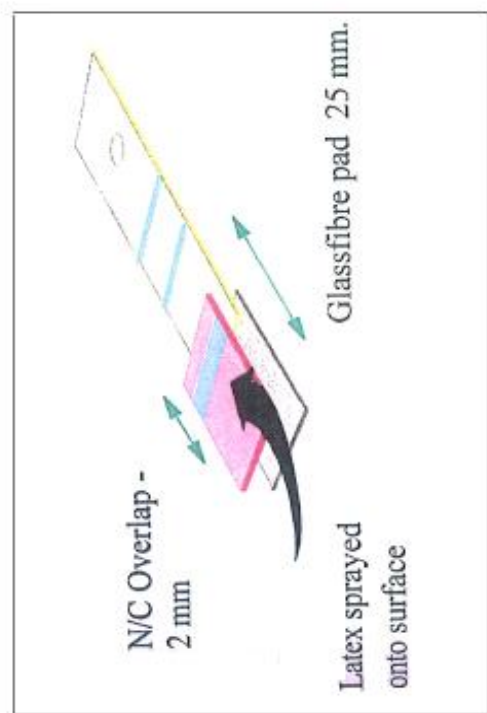
ANNEXURE 9

(WB 020)

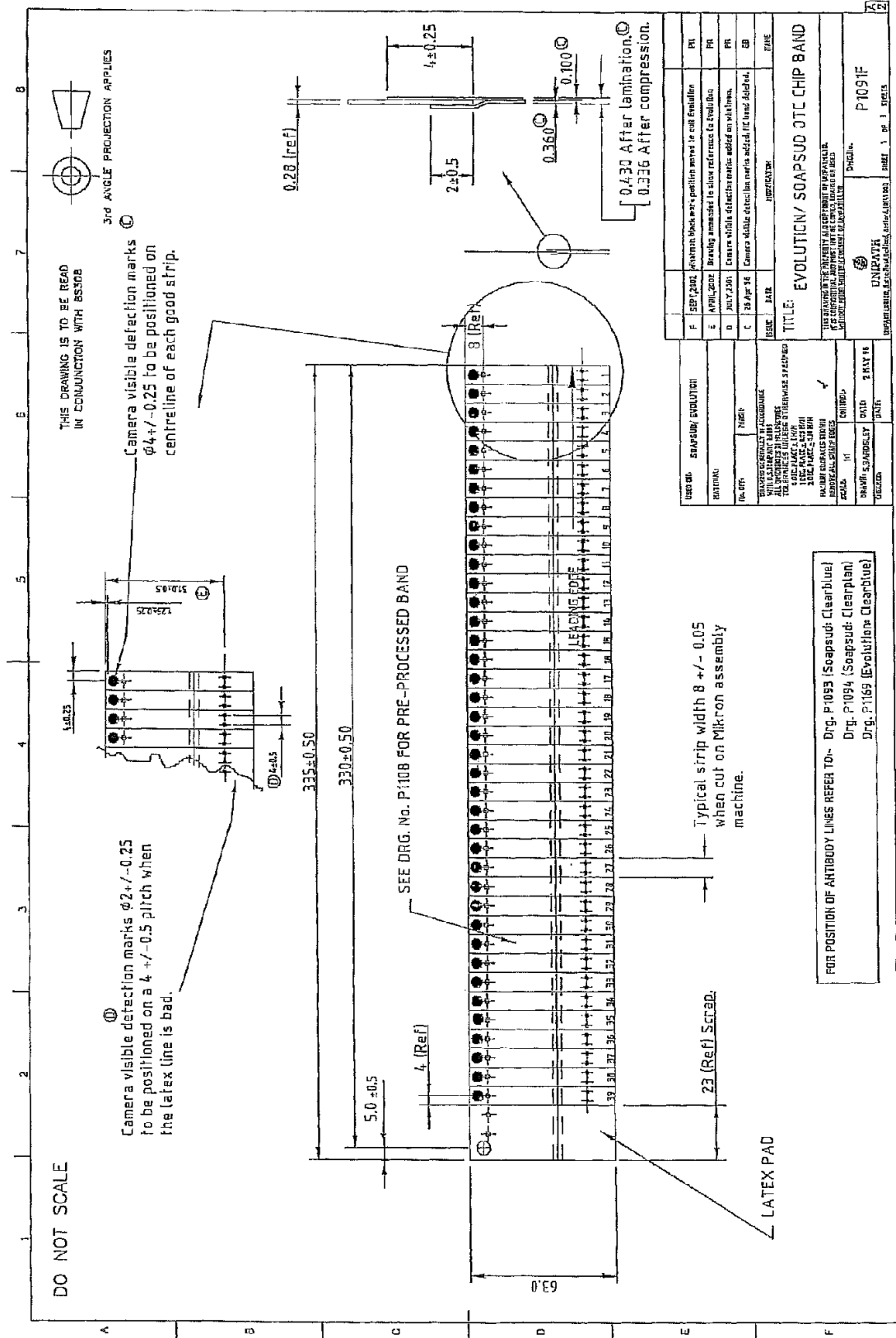


ANNEXURE 10

(WB 021)

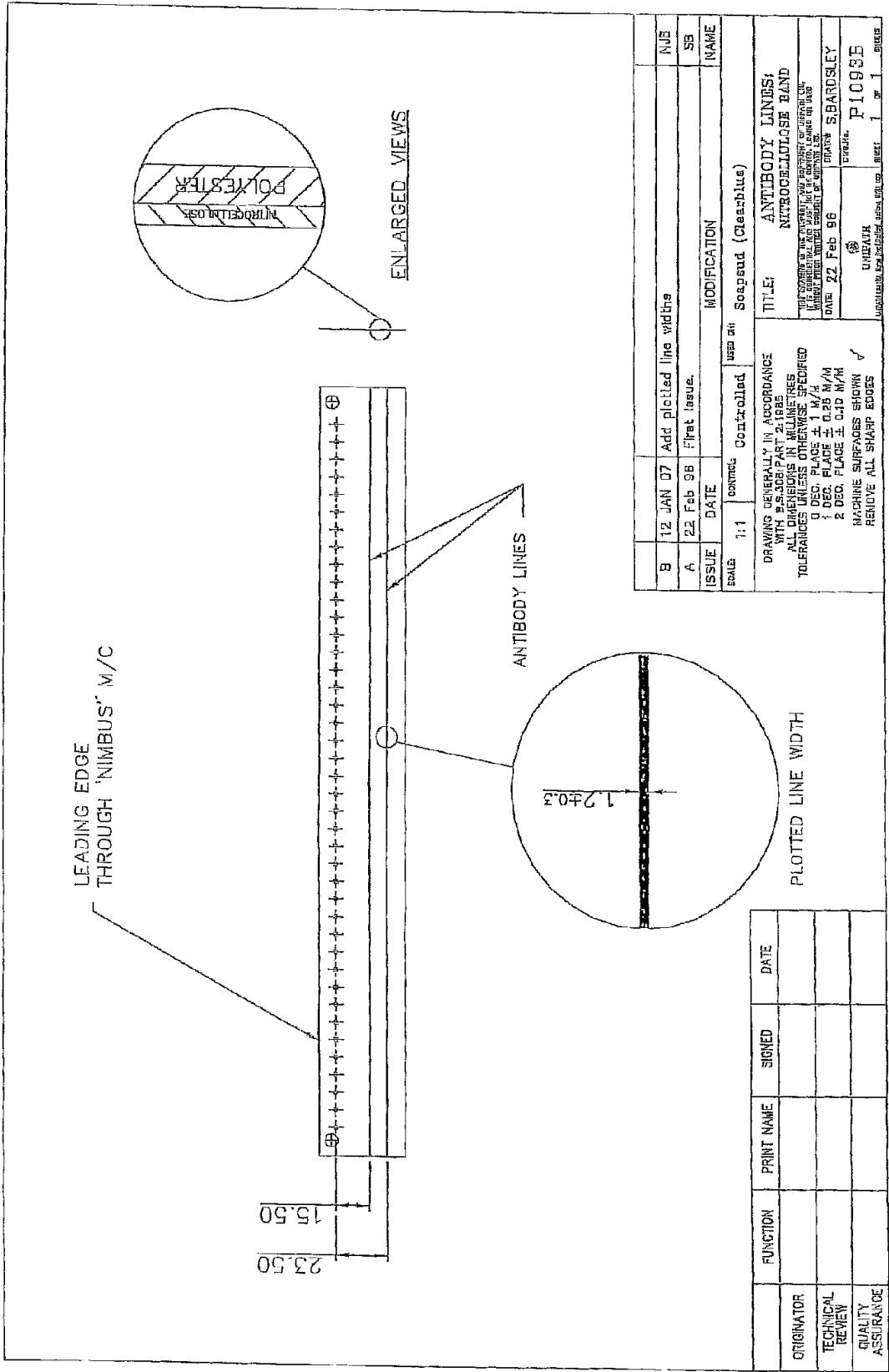


(WB 022)

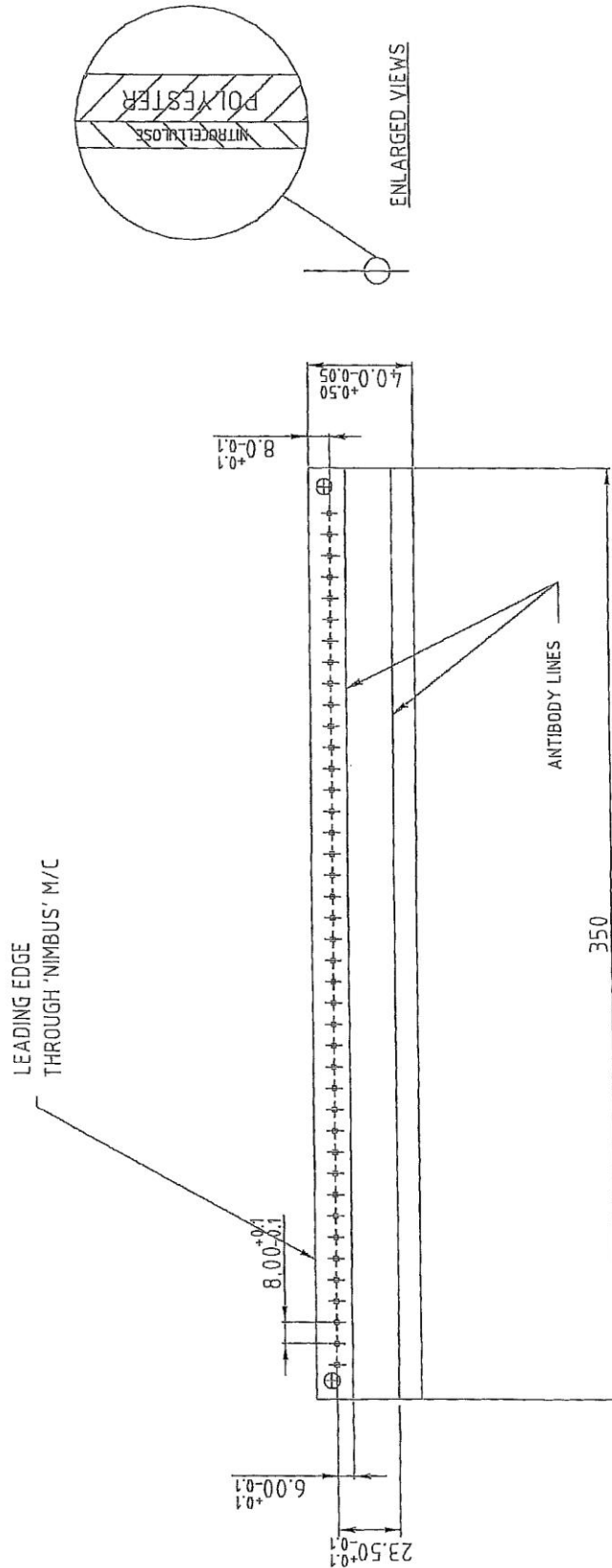


ANNEXURE 12

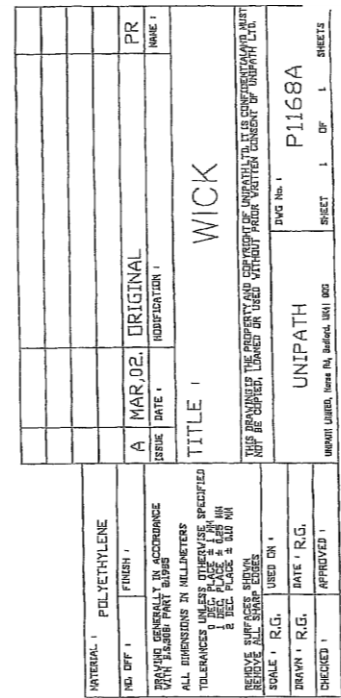
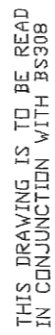
(WB 023)



(WB 030)

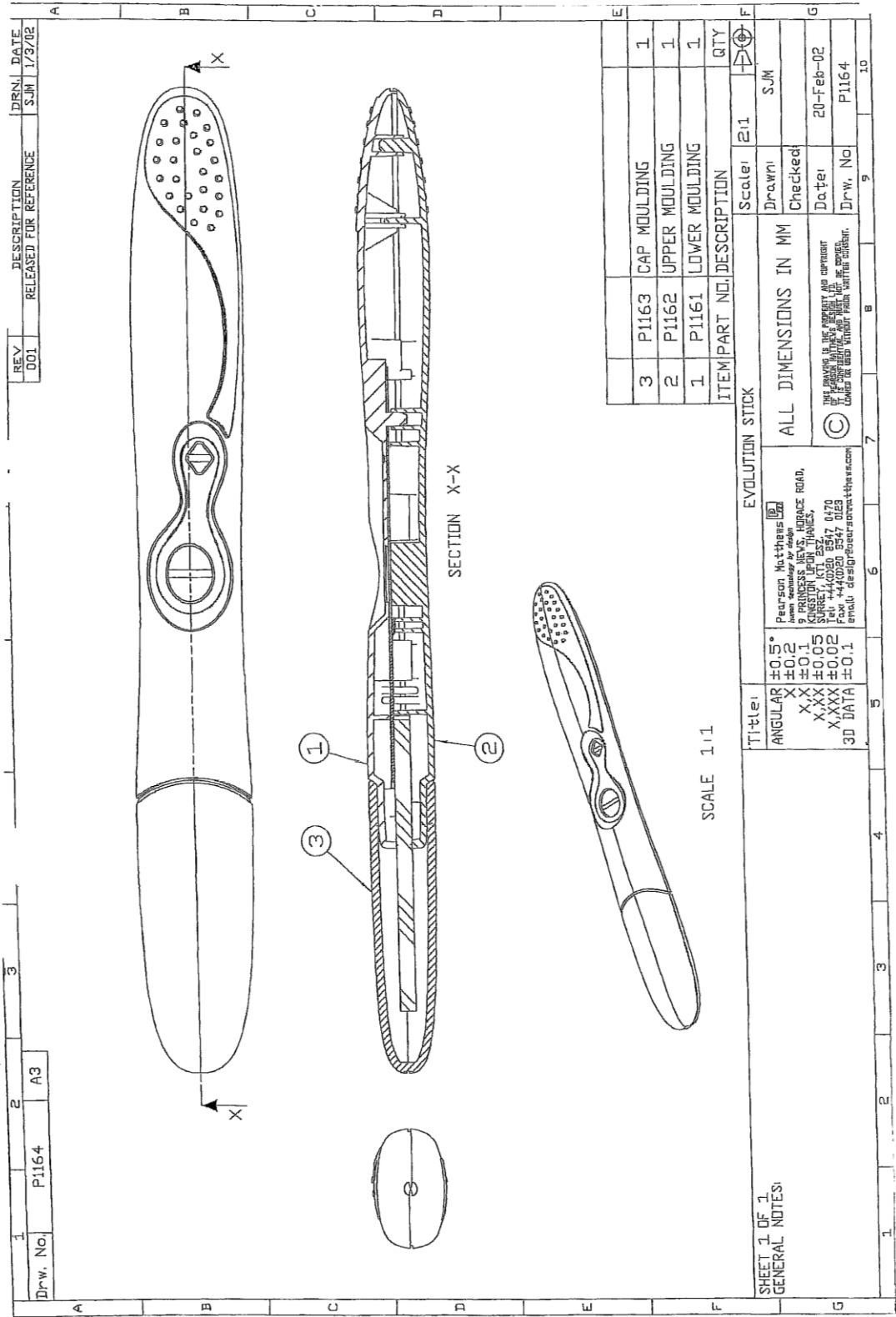
[illegible]

(WB 025)

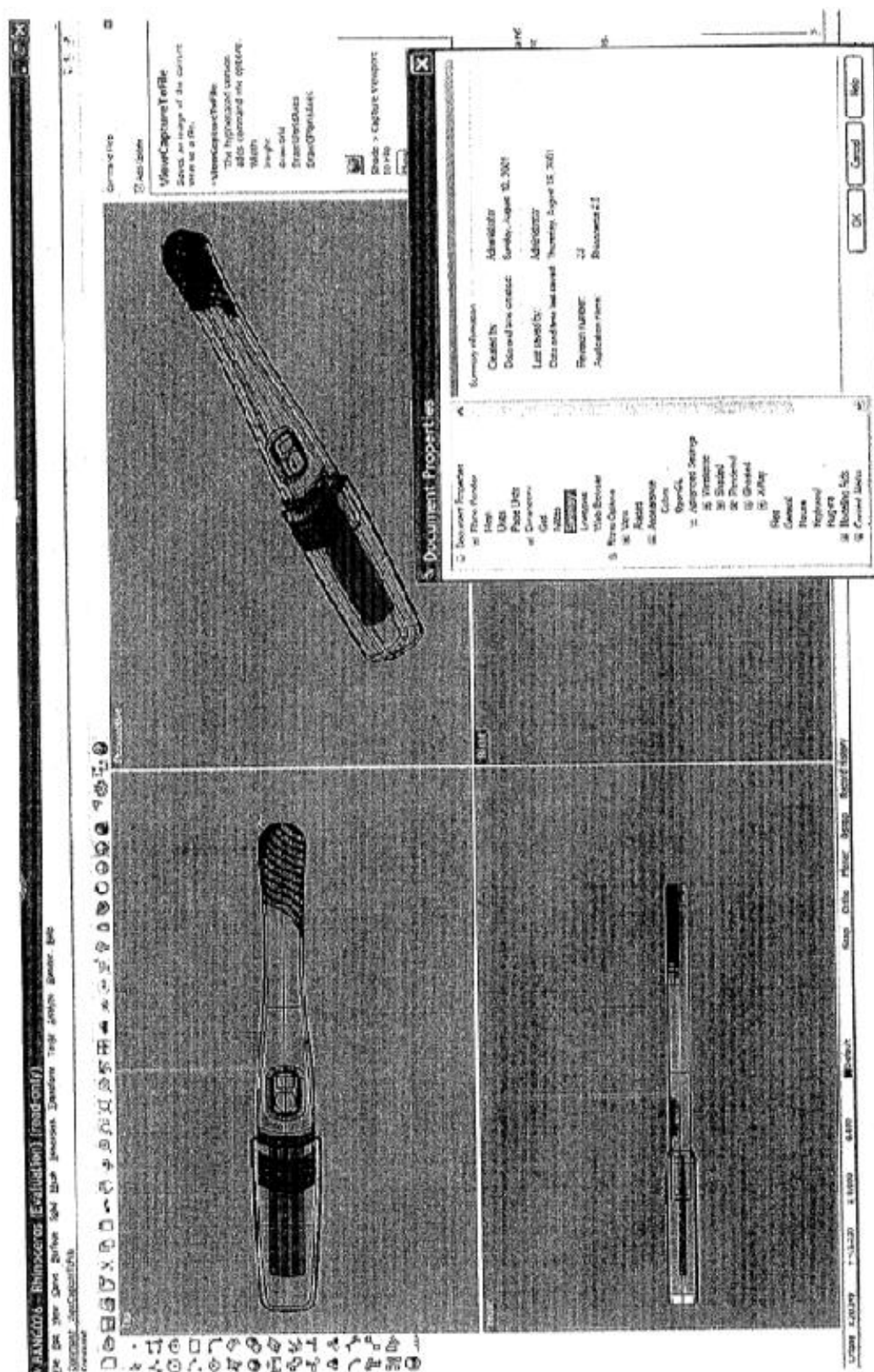


ANNEXURE 15

(WB 031)

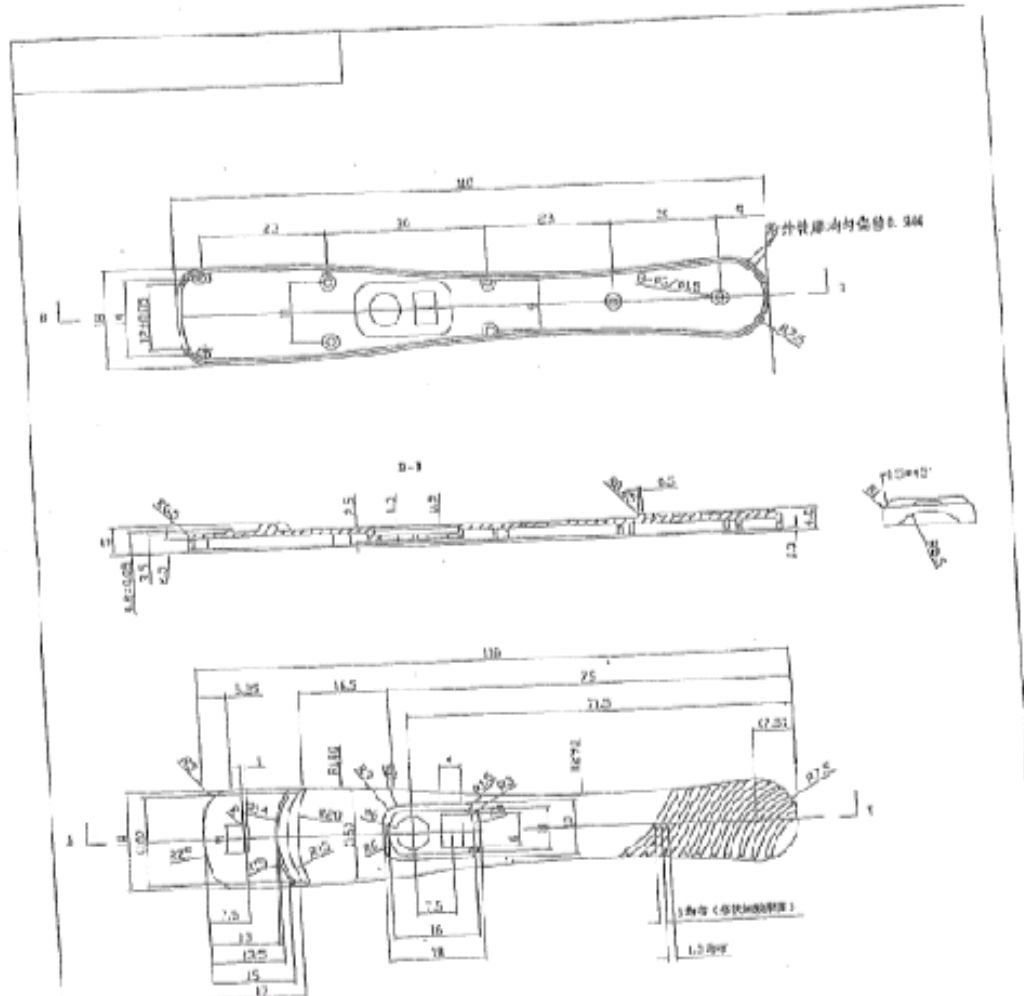


(WB 059)



ANNEXURE 17

(WB 060)



修改记录

插图

修改

旧图号

底图号

备注

设计

审核

工艺

图样	日期	修改文件号	签字	日期
设计				
校核				
审核				
工艺				

CVS (bCC) 棒上板

图样	日期	修改文件号	签字	日期
设计				
校核				
审核				
工艺				

1. 材料: 304;
2. 公差: IT12;
3. 产品表面经抛光;
4. 产品表面颜色及印刷字体确定;

5. 按图样要求加工。

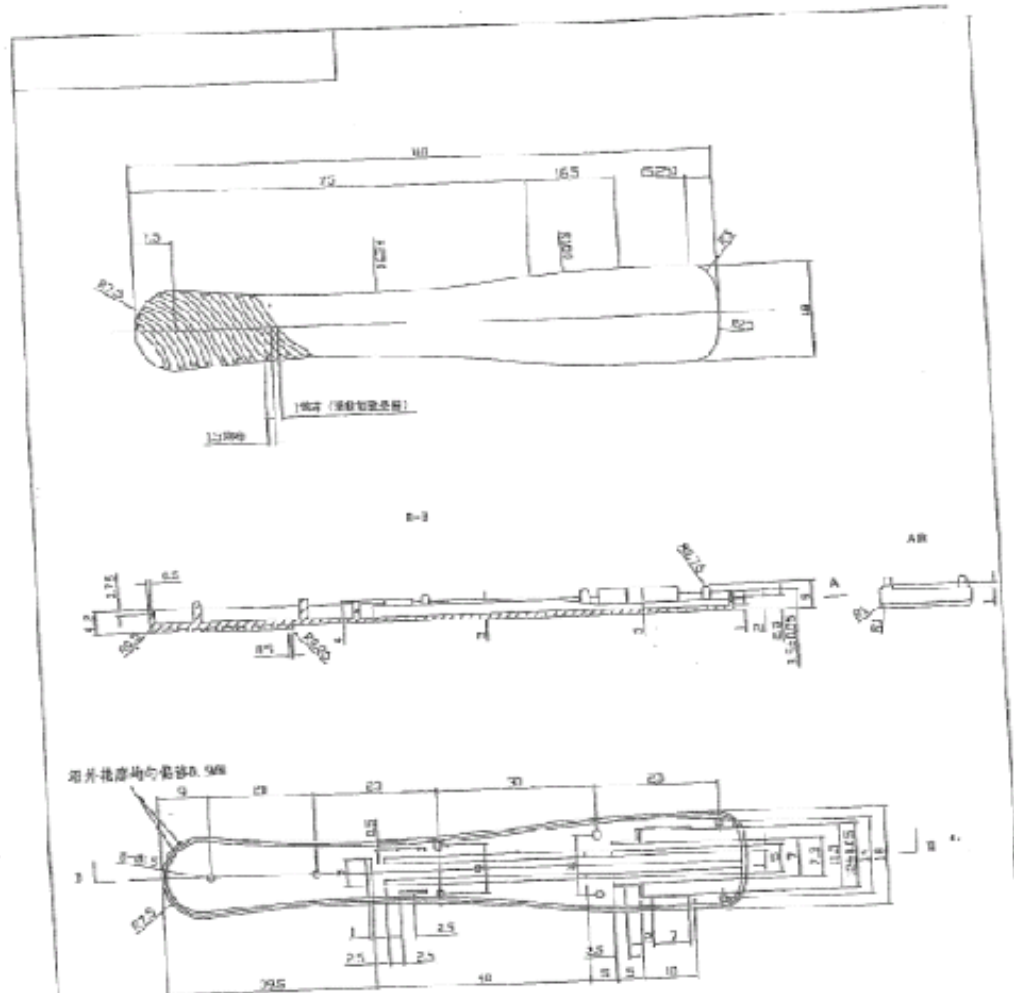
6. 新1450322

1201

1203
P324

ANNEXURE 18

(WB 061)



- 说明
1. 材料: A30;
 2. 零件名称: IT12;
 3. 产品表面轻微抛光;
 4. 产品表面颜色特定;

借用登记

设计

审核

旧版图号

新版图号

设计

审核

日期

CVS (hCG) 棒下板

Iron

设计

审核

日期

设计	审核	日期
设计	审核	日期
设计	审核	日期
设计	审核	日期

图样标记	数量	比例
图样标记	数量	比例
图样标记	数量	比例
图样标记	数量	比例

图样标记	数量	比例
图样标记	数量	比例
图样标记	数量	比例
图样标记	数量	比例

U2P2
P325

(WB 062)



插图

抽 权

船底图号

底匡為号

堡 字

使 情

註 明

- 1、材料: ABS;
- 2、未注公差: IT14;
- 3、产品表面经微抛光;
- 4、产品颜色待定。

CVS (hDC) 棒套

from

签字	书记 刘敬	设计 文俊	签字 王 彪	日期
	设计	校对	签字	日期
设计	审核	工艺	日期	6.27.2

圖 牌 標 記	重 量	比 例
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[illegible]

	7
2	

共 4 張 第 3 張

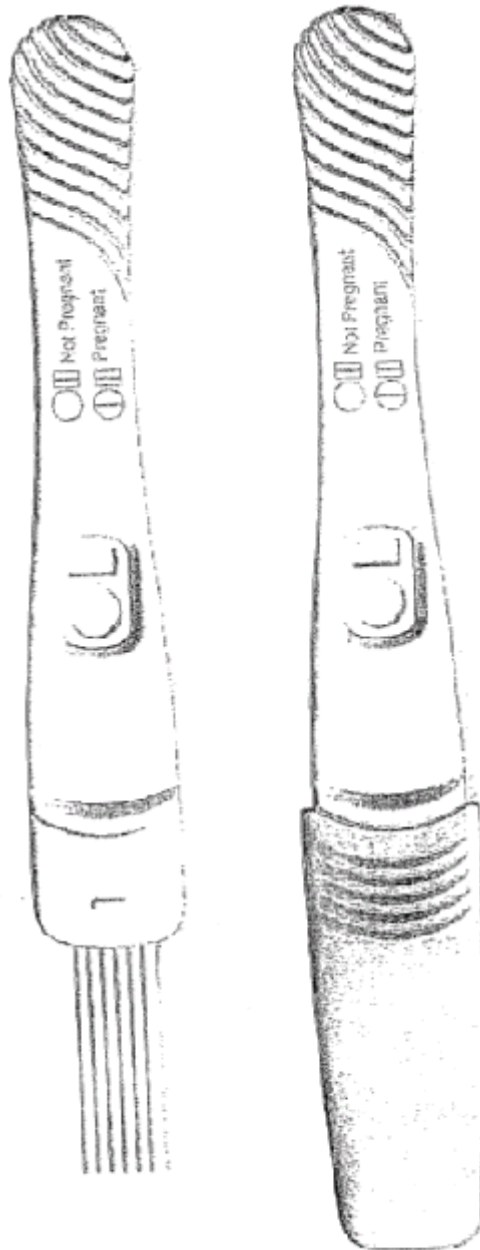
Let

33

Valz
PS2B

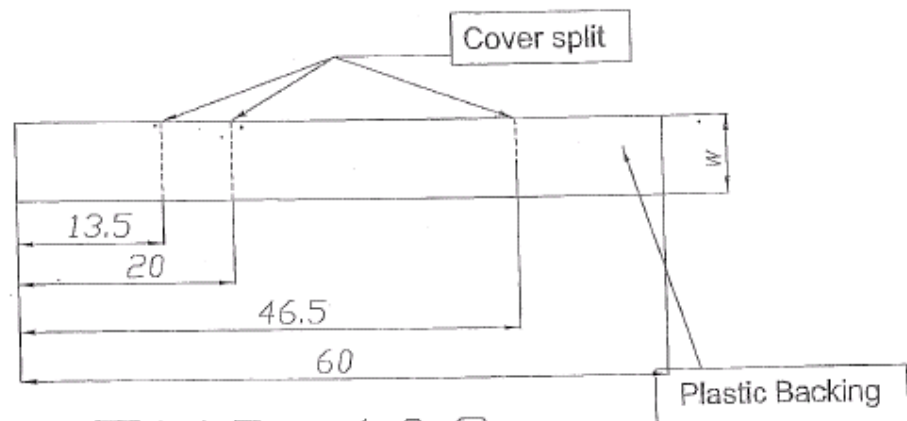
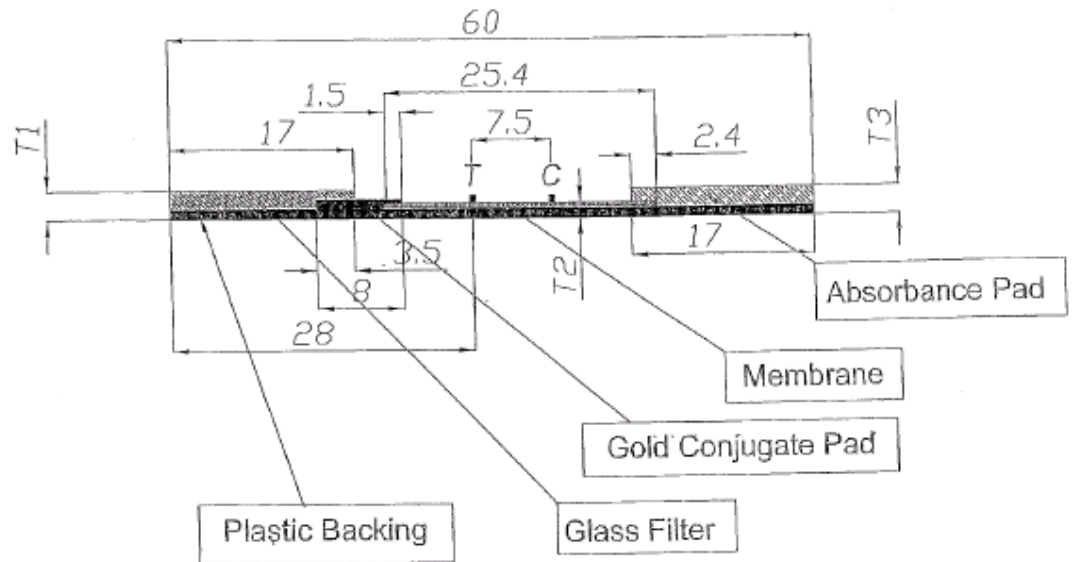
ANNEXURE 20

(WB 069)



ANNEXURE 21

(WB 071)



FHC-103

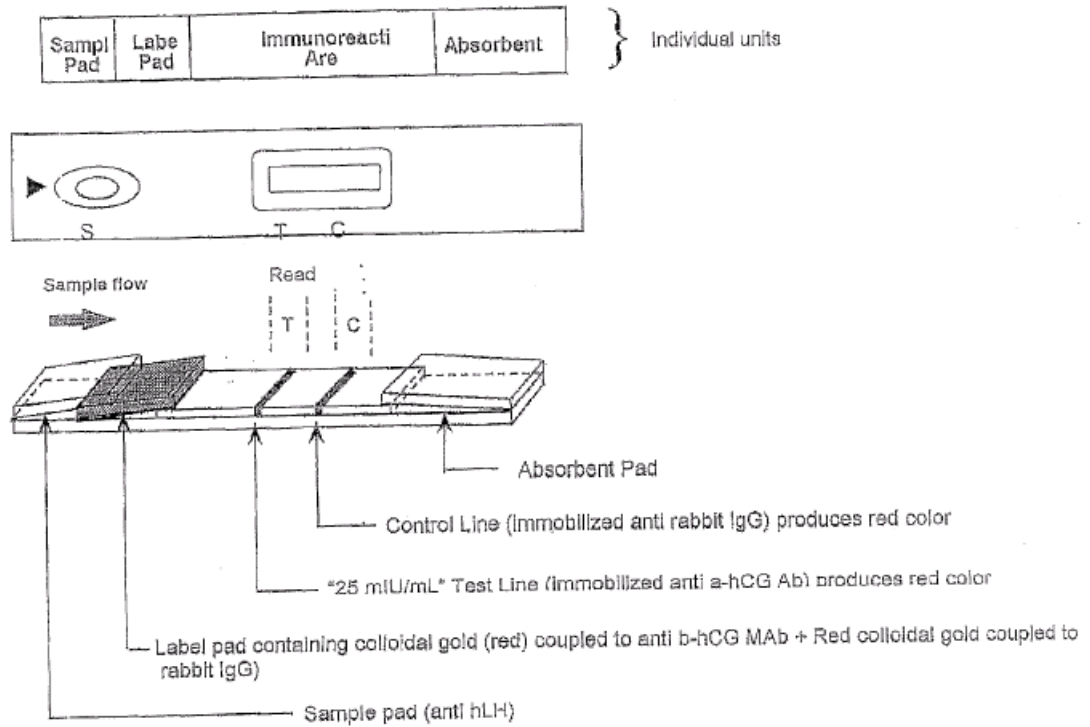
Unit:mm
Scale:2:1

T1	T2	T3	W
1.0-1.5	0.4-0.8	1.0-1.5	6.8-7.5

ANNEXURE 22

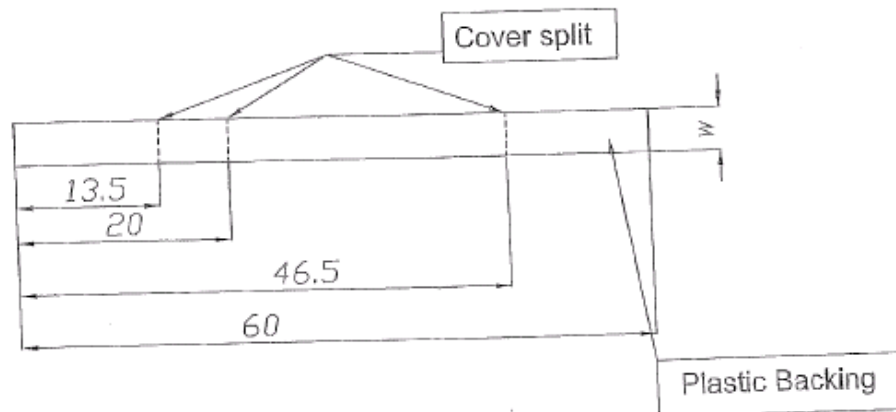
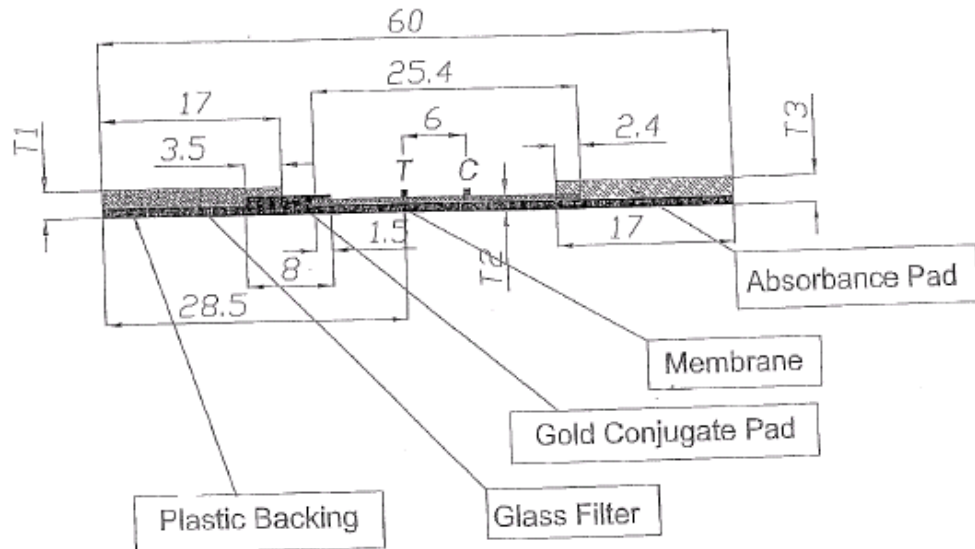
(WB 013)

hCG Urine test device: 25 mIU/mL, R_r control line



ANNEXURE 23

(WB 016)



FHC-102

Unit:mm
Scale:2:1

T1	T2	T3	W
1.0-1.5	0.4-0.8	1.0-1.5	2.5-6.0

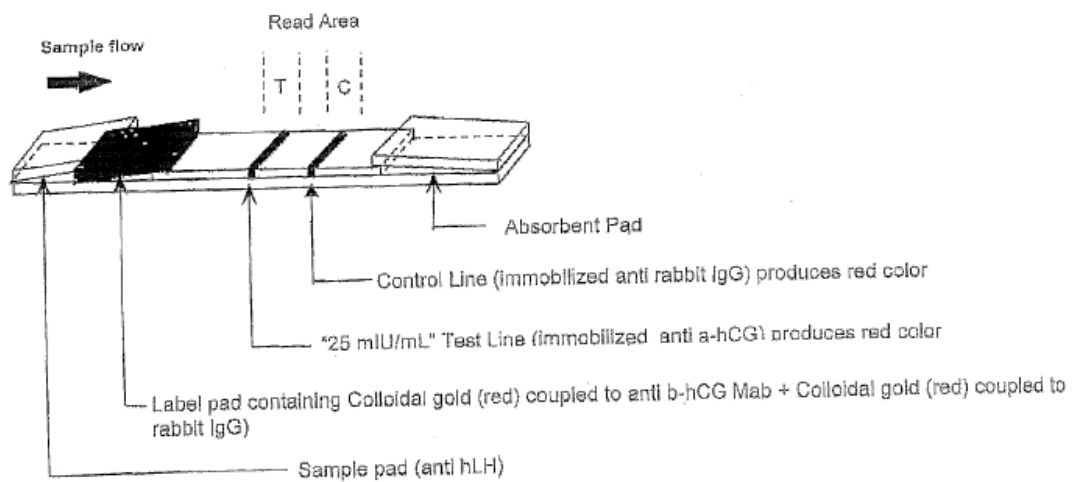
ANNEXURE 24

(WB 074)

hCG Urine test strip: 25 mIU/mL, result & control lines

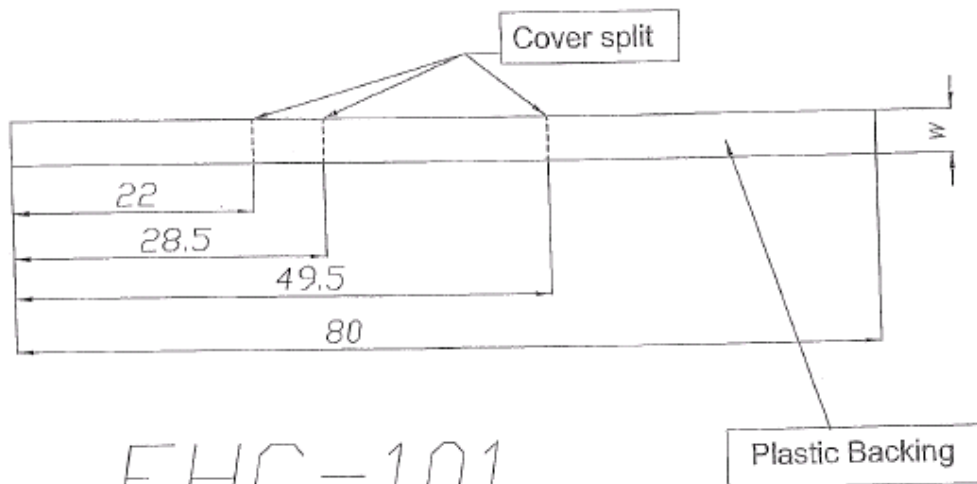
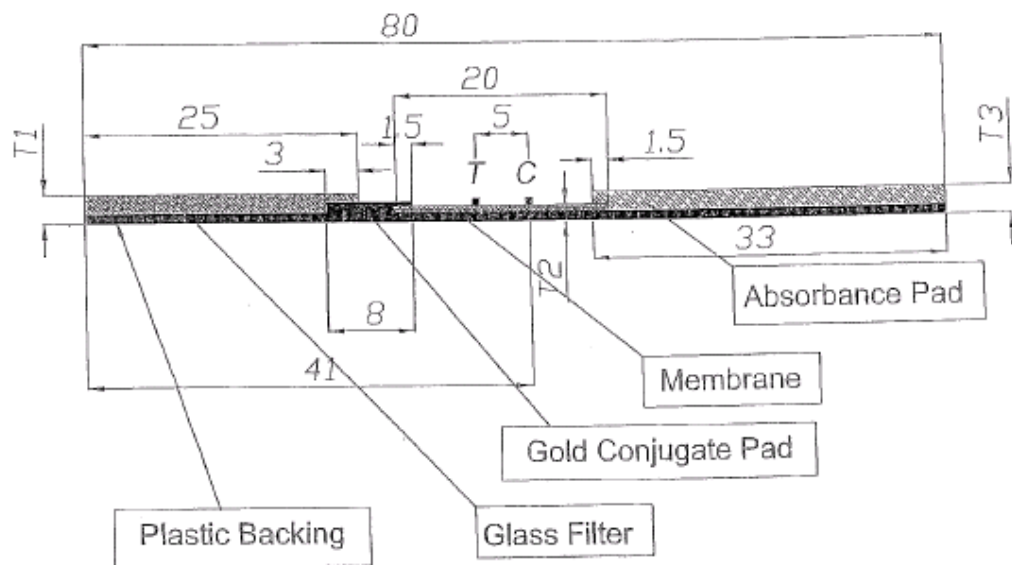
Sample Pad	Label Pad	Result Area	Absorbent
------------	-----------	-------------	-----------

} Individual units mylabackin



ANNEXURE 25

(WB 075)



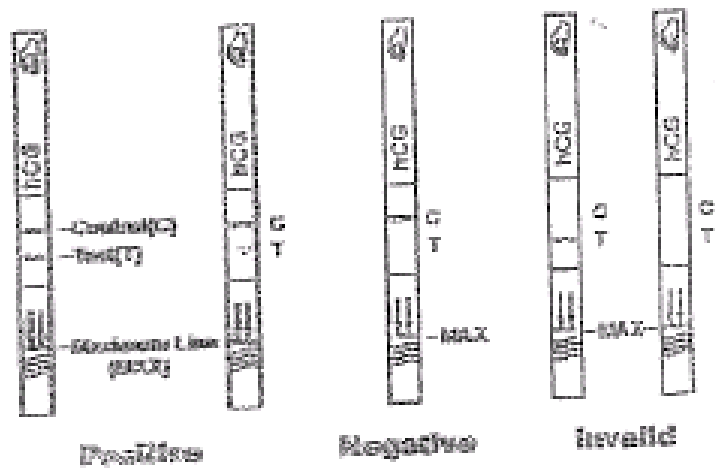
FHC-101

Unit:mm
Scale:2:1

T1	T2	T3	W
1.0-1.5	0.4-0.8	1.0-1.8	2.5-5

ANNEXURE 26

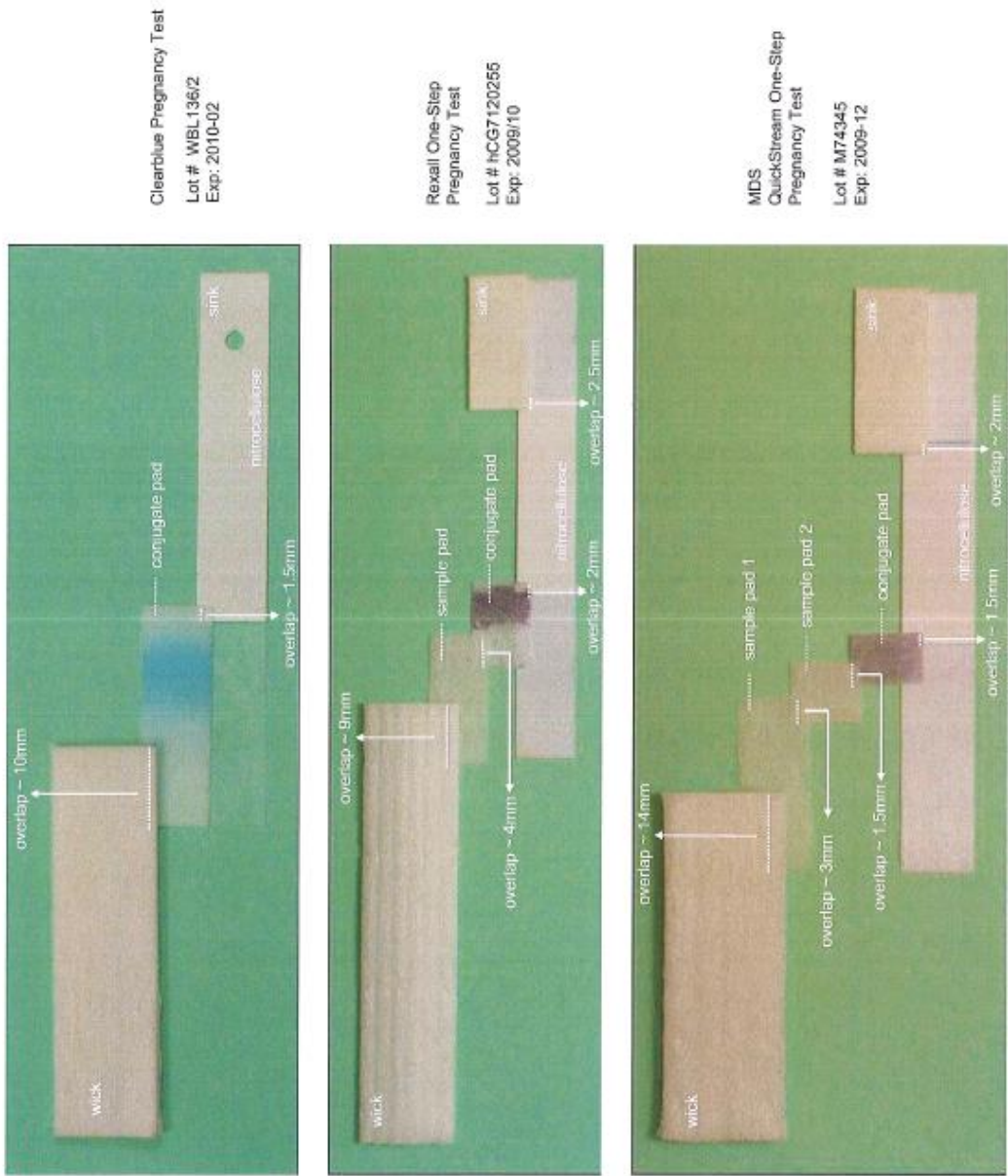
(WB 072)



ANNEXURE 27

Comparison of pregnancy test strips

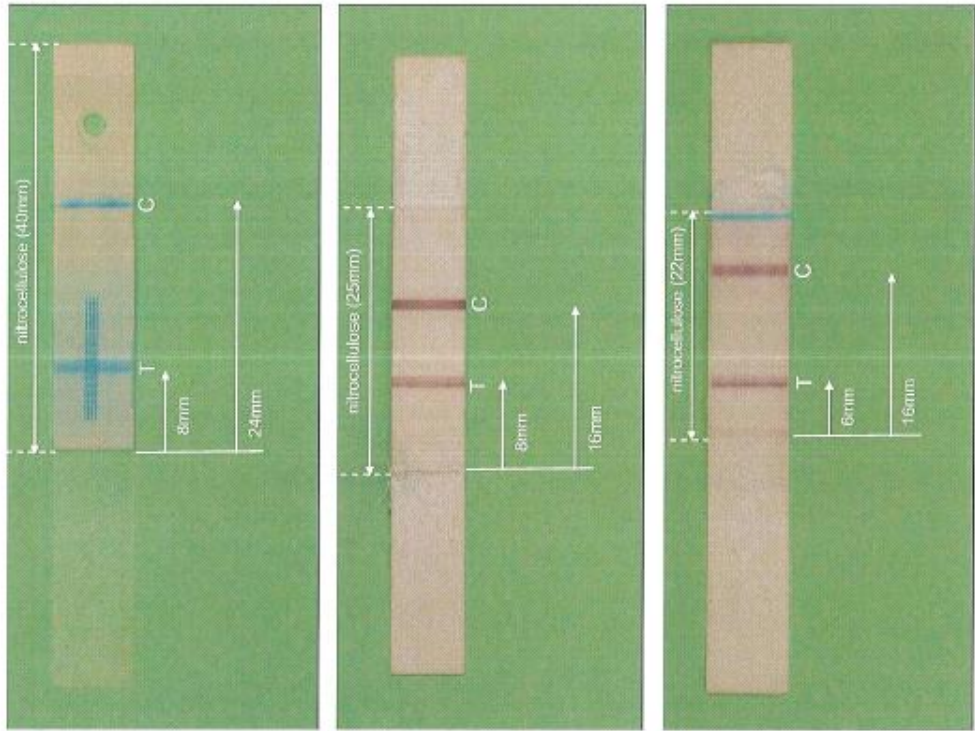
File 7



ANNEXURE 28

File 34

A comparison of midstream pregnancy tests run in 400mIU/ml hCG



Clearblue
Pregnancy Test
Lot # WEN171/2
Exp: 2010-09

Rexall One-Step
Pregnancy Test
Lot # hCG7120255
Exp: 2009/10

MDS QuickStream
One-Step Pregnancy Test
Lot # A80359
Exp: 2010-02

Devices run in buffer containing
400mIU/ml hCG batch B400/637

ANNEXURE 29

A comparison of midstream pregnancy tests run in 400mIU/ml hCG



Devices run in buffer containing 400mIU/ml hCG batch B400/637

File: BR/Patent Design Regs/ Final Photo Shoot / File 33 Midstream CB4 & Rexall & MDS QuickStream RUN devices. ppt

ANNEXURE 30

File: BR/P/Patient Design Regs Final Photo Shoot/Unrun devices CB6 Rexall & MDS/ File 1 CB6 Rexall and MDS Midstream unrun devices with caps.ppt

A comparison of pregnancy tests

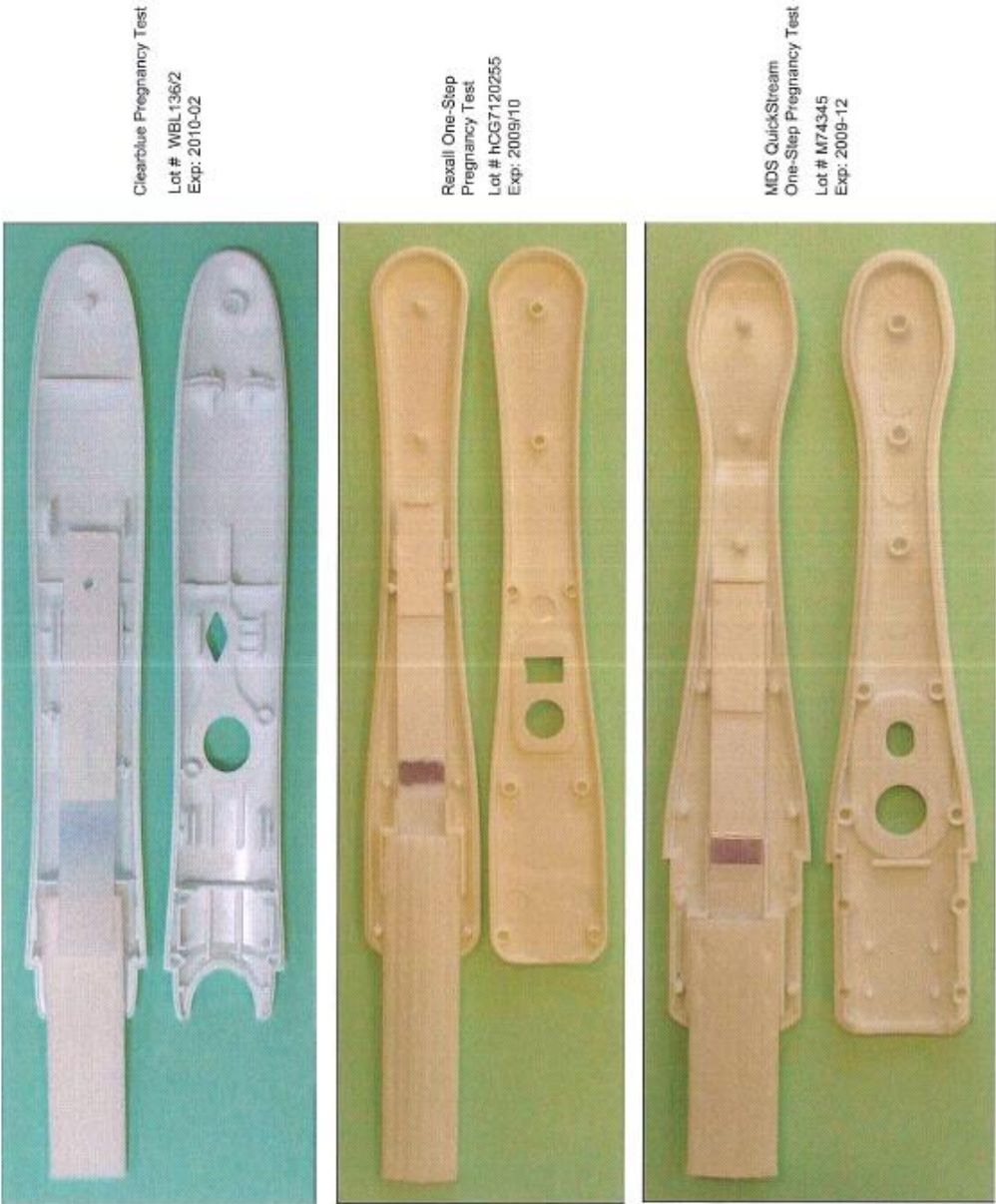


File 1

ANNEXURE 31

File 3

A comparison of pregnancy tests

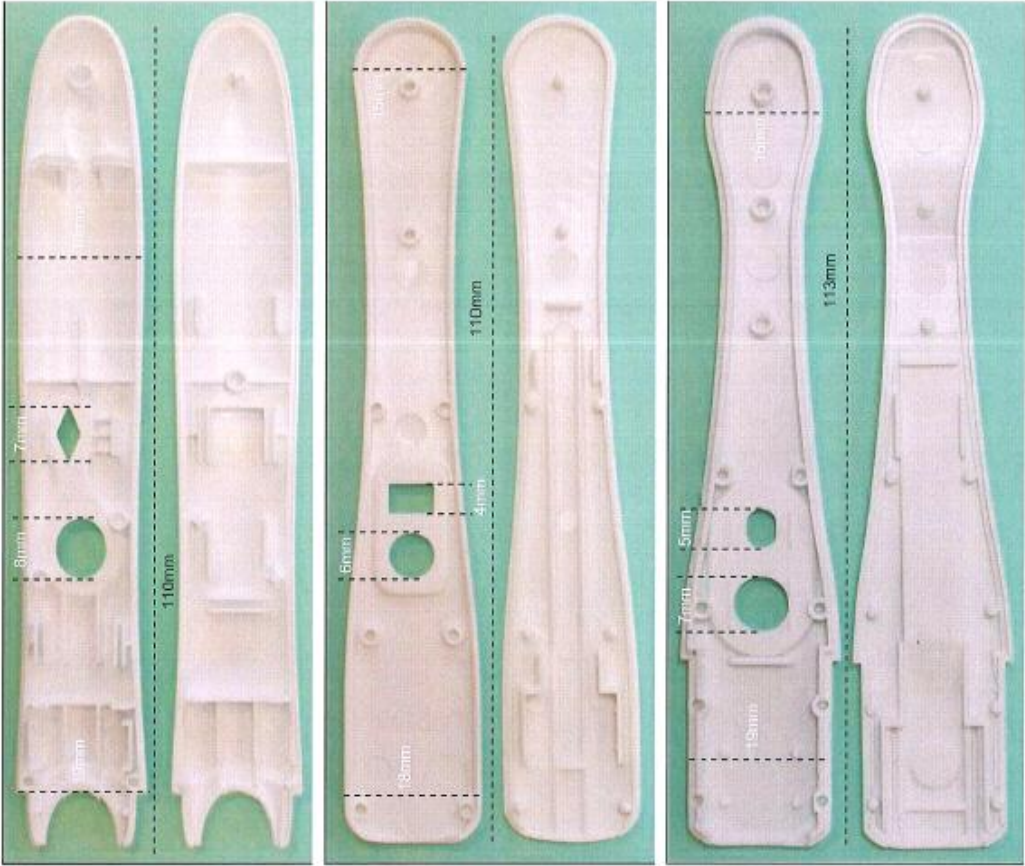


ANNEXURE 32

File: BR/Patent Design Regs Final Photo Shoot\Unrun devices CB6 Rexall & MDS\File 4 CE6 Rexall and MDS Midstream cases.ppt

sized

A comparison of pregnancy tests : upper and lower case parts

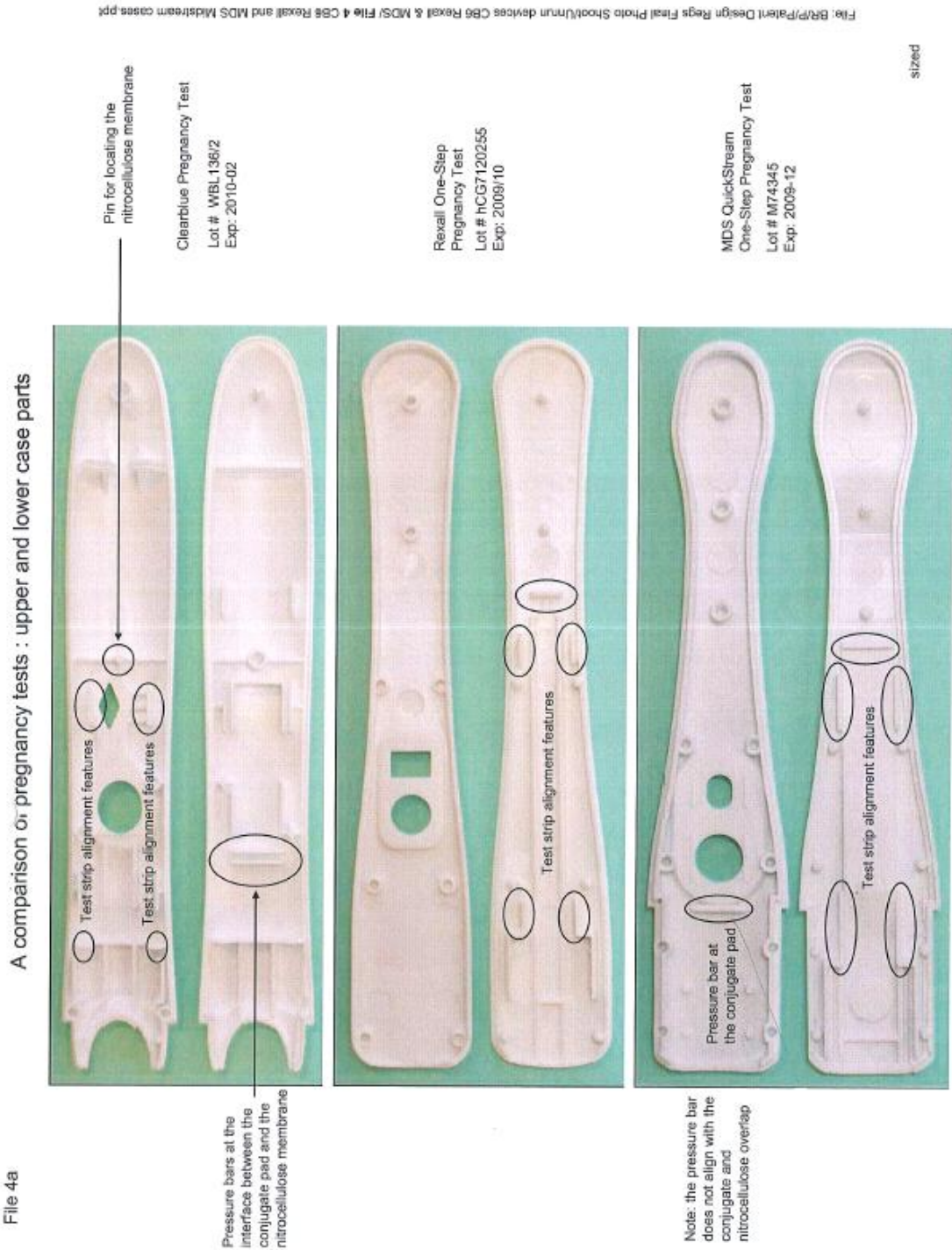


Clearblue Pregnancy Test
Lot # WBL136/2
Exp: 2010-02

Rexall One-Step
Pregnancy Test
Lot # HCG7120255
Exp: 2009/10

MDS QuickStream
One-Step Pregnancy Test
Lot # M74345
Exp: 2008-12

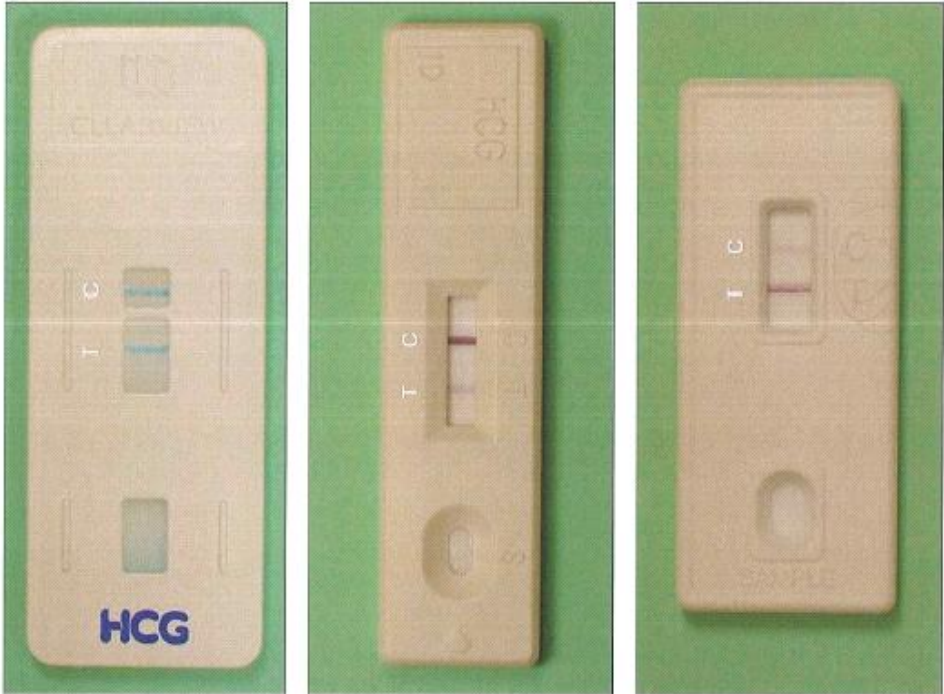
ANNEXURE 33



ANNEXURE 34

File 31 A comparison of Clearview vs. Quik-Check vs. MDS QuickCard hCG tests

Devices run in buffer containing 400mIU/ml hCG batch B400/637



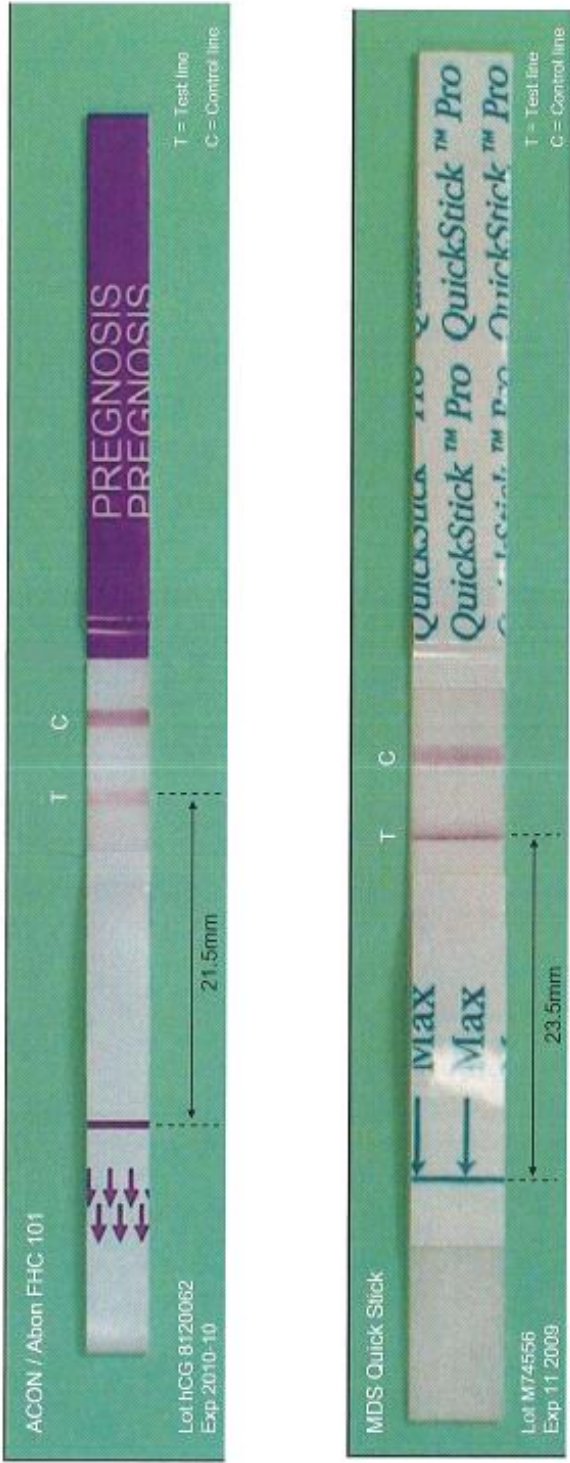
Clearview hCG
Lot # HG0062
Exp: 2009-06

Quik-Check
Pregnancy Test
Lot # hCG7080187
Exp: 2009-07

MDS
QuickCard
Pregnancy Test
Lot # B2373
Exp: 03-2004

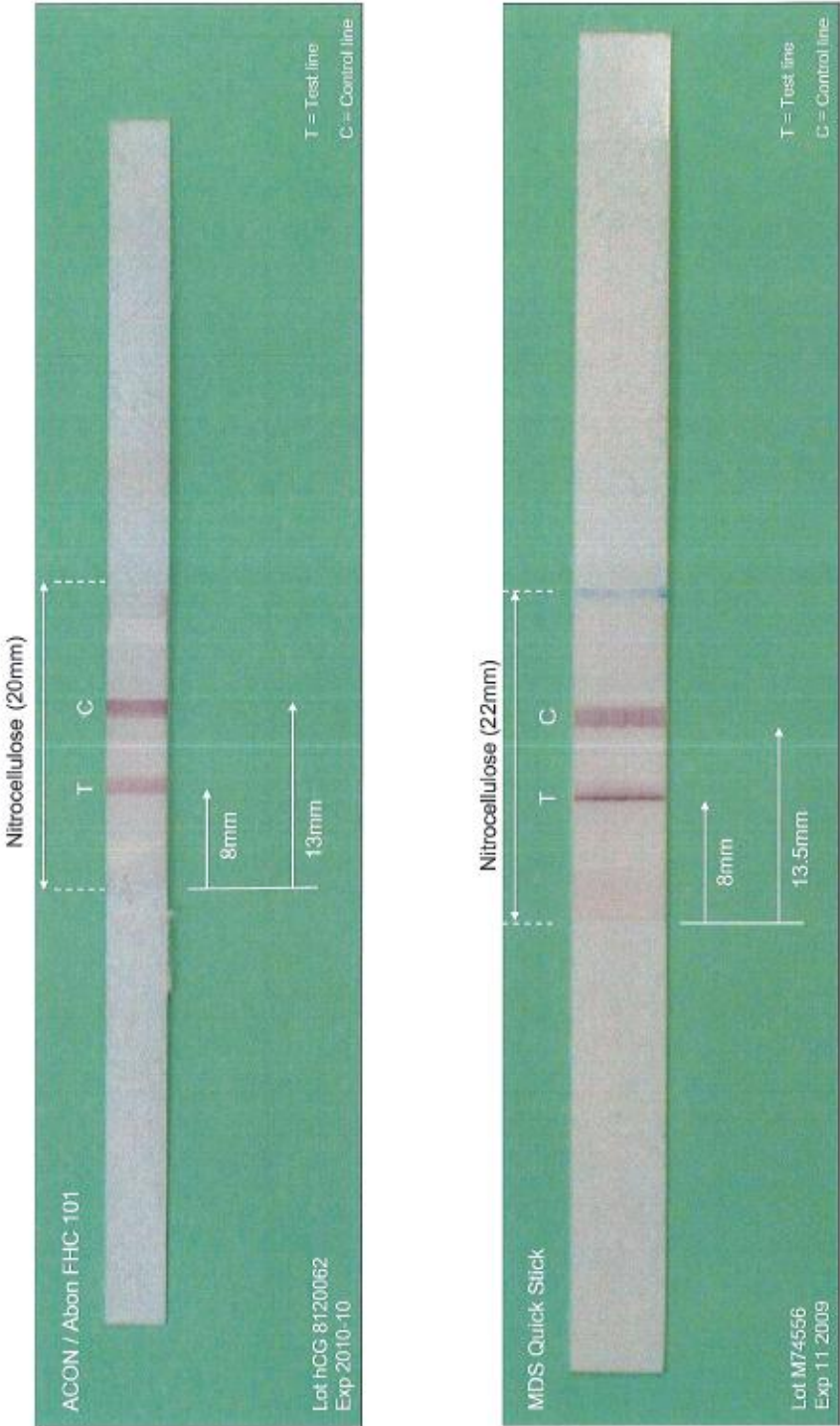
T = Test line
C = Control line

File 29 A comparison of ACON / Abon FHC 101 & MDS QuickStick pregnancy test strips



Devices run in buffer containing
400mIU/ml hCG batch B400/637

File 30 A comparison of ACON/Abon FHC 101 & MDS QuickStick pregnancy test strips

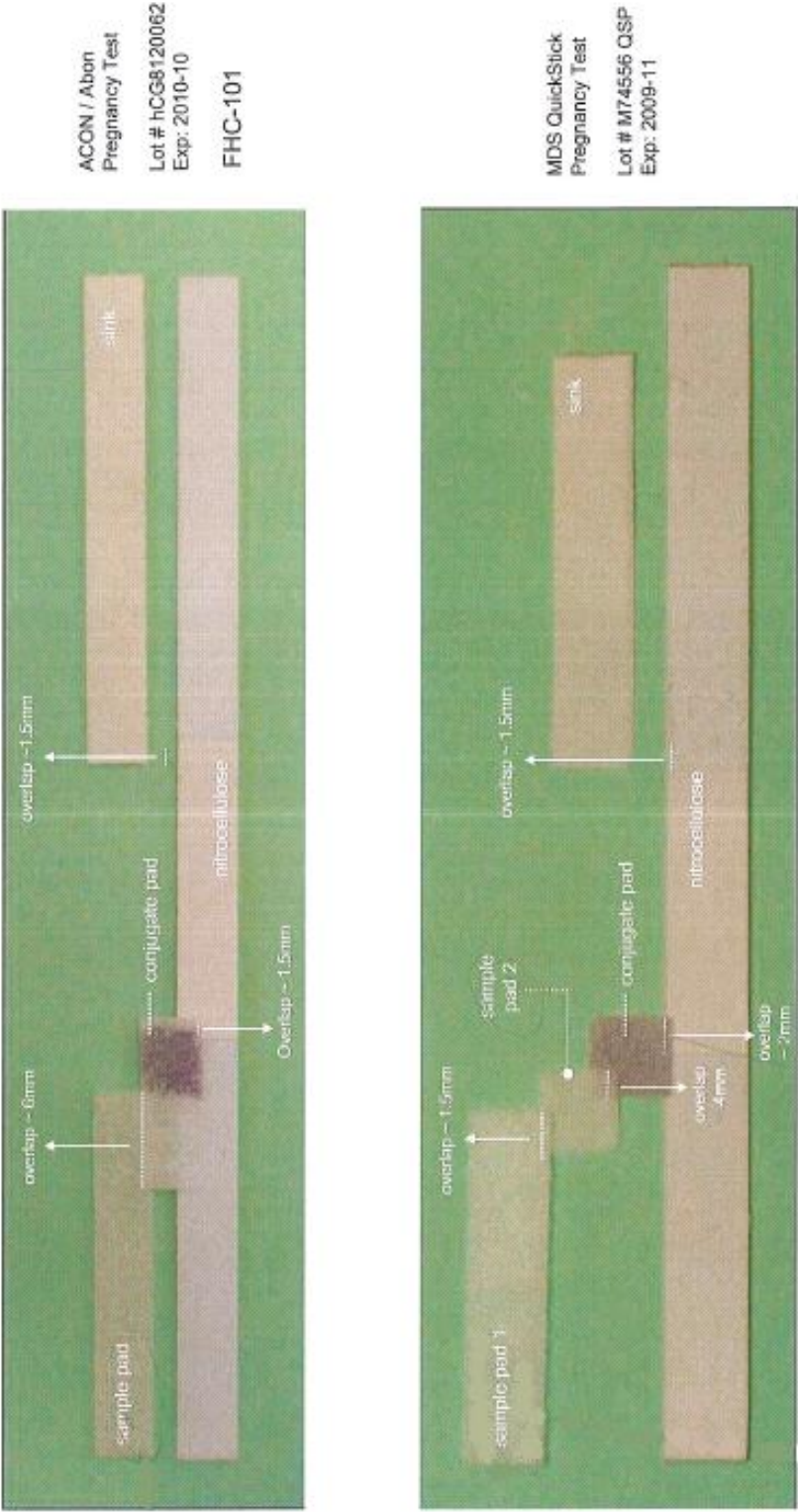


Devices run in buffer containing
400mIU/ml hCG batch B400/637

File: BR/Patent Design Regs/ Final Photo Shoot / File 30 ACON Abon FHC 101 vs. MDS QuickStick whole RUN devices ppt

ANNEXURE 37

File 28 A comparison of pregnancy test strips – MDS QuickStick & ACON / Abon (FHC-101) vs. MDS QuickCard



ANNEXURE 38

File 27

A comparison of pregnancy test strips – MDS QuickStick & ACON / Abon (FHC-101) vs. MDS QuickCard



ANNEXURE 39

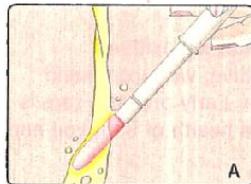
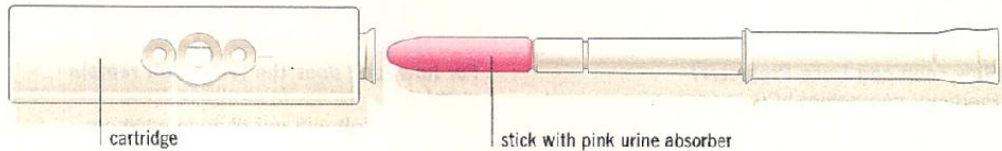
Predictor

P R E G N A N C Y T E S T

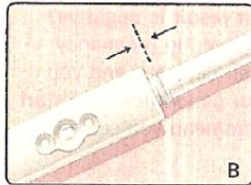
GREATER REASSURANCE

EASY EXTRA CHECKS

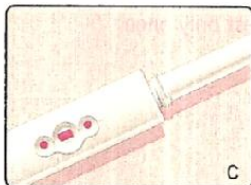
Predictor is a reliable and easy to use pregnancy test, that can be used anytime of the day and as early as the day your period is due.



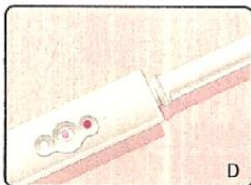
A



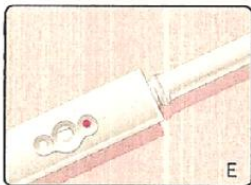
B



C



D



E

1. How to perform the test

Take the test out of the foil wrapper. (You don't need the small sachet, this is just to preserve the test against moisture.)

Pull the stick out of the cartridge.

Hold the pink urine absorber in your urine stream for at least 1 second (visual A).

Replace the stick into the cartridge. Make sure that the test is closed completely (visual B).

Now wait 4 minutes before reading the result.

2. The test is working

You will soon see a colour moving across all windows. This shows that the test is working (visual C).

3. Reading the result

PREGNANT

If after 4 minutes a dot has appeared in the large, middle window you are pregnant (visual D).

Even if this dot is very light, it still means you are pregnant.

NOT PREGNANT

If after 4 minutes there is no dot in the large, middle window you are not pregnant (visual E).

After 4 minutes: extra checks for greater reassurance

If after 4 minutes a dot is visible in the small **right** window this tells you that you have performed the test correctly.

If after 4 minutes the small **left** window has cleared completely, this means that the test is ready and the result cannot change anymore.

ANNEXURE 40

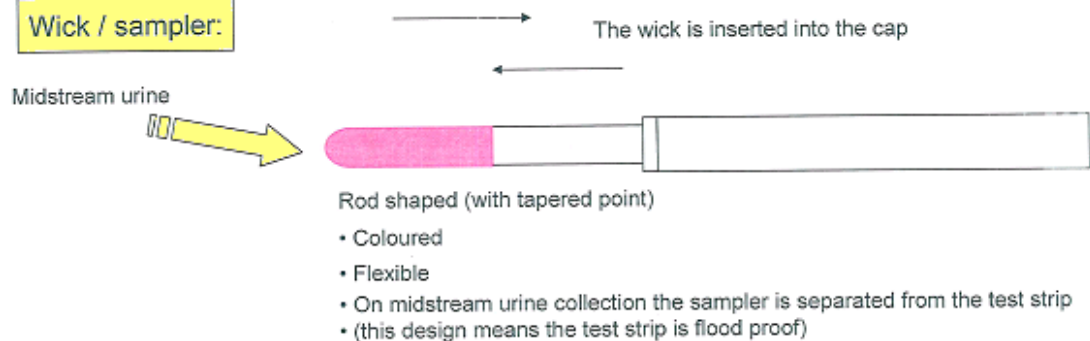
Cap:

Test results develop in 3 windows within the cap:



- Cap (contains the test strip)
- Result is seen as spots
- Test windows are unglazed (this unique design will not suffer from splashing as the urine is applied to the separate sampler)

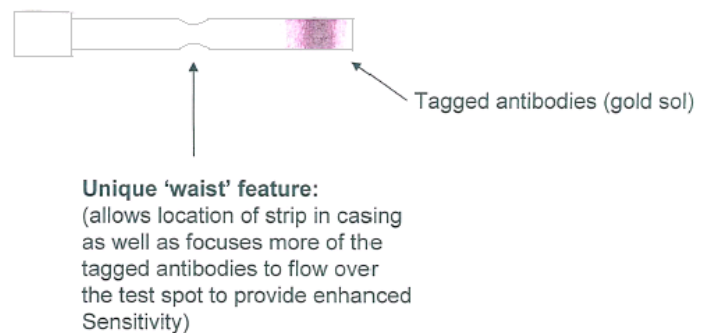
Wick / sampler:



Test Strip

Test and control spots form on paper (not nitrocellulose)

Test strip is **not supported** with plastic backing



Wick lies over the test strip (compact design)

ANNEXURE 41

