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IN THE HIGH COURT OF DELHI

IA No. 11883/2006 in CS (OS) No. 2020 of 2006

Decided On: 22.02.2008

Appellants: **J. Mitra and Co. Pvt. Ltd.**
Vs.
Respondent: **Kesar Medicaments and Anr.**

Hon'ble Judges/Coram:
Sanjay Kishan Kaul, J.

Counsels:
For Appellant/Petitioner/plaintiff: A.M. Singhvi, Sr. Adv. Pratibha Singh an Pema Yeshey, Advs

For Respondents/Defendant: Pravin Anand and Sagar Chandra, Advs. for Respondent No. 2

Subject: Intellectual Property Rights

Acts/Rules/Orders:
Code of Civil Procedure (CPC) - Section 151, Code of Civil Procedure (CPC) - Order 39 Rule 1, Code of Civil Procedure (CPC) - Order 39 Rule 2; Patents Rules, 2003 - Rule 55; Patents Act, 1970 - Section 2, Patents Act, 1970 - Section 3, Patents Act, 1970 - Section 11, Patents Act, 1970 - Section 12, Patents Act, 1970 - Section 13, Patents Act, 1970 - Section 13(4), Patents Act, 1970 - Section 14, Patents Act, 1970 - Section 18, Patents Act, 1970 - Section 25, Patents Act, 1970 - Section 25(1), Patents Act, 1970 - Section 25(4), Patents Act, 1970 - Section 30, Patents Act, 1970 - Section 64, Patents Act, 1970 - Section 107, Patents Act, 1970 - Section 117A, Patents Act, 1970 - Section 117A(2); Patents Amendment Act, 2005

Cases Referred:
Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries PTC (Suppl.) (1) 731 (SC); Standipack Private Ltd. and Ors. v. Oswal Trading Co. Ltd and Ors. 1999 PTC (19) 479 (Del); National Research Development Corporation of India, New Delhi v. The Delhi Cloth and General Mills Co Ltd and Others AIR 1980 Delhi 132; Telemechanique and Controls (I) Ltd. v. Schneider Electric Industries SA 94 (2001) DLT 865; Technograph v. Mills and Rockley [1972] R.P.C 346, 355; Billcare Ltd. v. Amartara Pvt. Ltd 2007 (34) PTC 419 (Del); Shri Ravi Raj Gupta v. Acme Glass Mosaic Industries 56 (1994) DLT 673; Gillette Safety Razor Co. v. Anglo American Trading Co. Ltd. 30 of Patent, Design and Trademark Cases 465

Disposition:
Application allowed

Citing Reference:

Discussed	7
Mentioned	1

Case Note:
Intellectual Property Rights - Patent infringement - Validity of patent - Obviousness or anticipation - plaintiff filed an application for grant of interim injunction against Defendant for infringement of its patent stating that the Defendants were manufacturing a device similar to that of patented product and thus infringing plaintiff's patent - Defendants opposed same on ground that plaintiff's patent is not valid as the invention in respect of which the plaintiff had obtained the patent was a prior known art as it was obvious and anticipated - Hence, the present suit - Held, from a reading of the specifications, it prima facie appears that there are differences in the manner of flow adopted in the two devices, i.e., of US patents and plaintiffs patents - Device of the plaintiff is of a different construction and function and is not anticipated by U.S. Patents - Hence, the contention that the plaintiff's device was anticipated by U.S. patent Nos. 5006464 and 5541059 is not acceptable

Intellectual Property Rights - Patent infringement - Validity of patent - Presumption of - Relevant considerations - Defendant No. 2 argued that mere grant or sealing of a patent or decision rendered by the Controller on an opposition filed does not imply the validity of the patent - Held, Order of the patent controller granting the patent and the decision on the opposition cannot by itself give rise to a presumption of validity of the patent notwithstanding the investigation and examination made - While the actual user and duration of the patent may be one of the factors that may be taken into account, that factor alone cannot give rise to a presumption of validity of the patent - But for the purposes of temporary injunction Court can presume the same to be valid - Validity of patents presumed - Temporary injunction granted

Intellectual Property Rights - Patent infringement - Ground of obviousness - Mosaicing - plaintiff has averred that the attempt by Defendant No. 2 to prove the ground of obviousness by citing a number of citations constitutes mosaicing and same is not permissible as none of the documents is relevant to the said invention - Held, a defense of the Defendant to show that the various integers were already known separately and the combination thereof cannot be patented would amount to

mosaicing and is not permissible for determining the validity of the patent - Hence, in the present case, it would be not be permissible for the Defendant to rely on different documents disclosing different components/features of the product to plead that the product of the patent is known - None of the documents relied on by Defendant No. 2 in the present matter really anticipate all the components of the plaintiff's product - Hence, defense of mosaicing not applicable in the present case

Intellectual Property Rights - Patent - Infringement of - Validity of patent - Prior art - Gillette defense - Applicability - Defendant No. 2 placed reliance on the Gillette defense to submit that even if the product of Defendant No. 2 falls within the four corners of the plaintiff's patent, it would not amount to infringement as the impugned product is based on prior US Patents - Held, as per Gillette defense if Defendant could prove that the act complained of is what was disclosed in a prior publication, which can be relied on against the validity of the patent, and no patentable or substantial alteration has been made in respect thereof, then that will be a good defense in an action for alleged patent infringement - In the present case, perusal of the features of the impugned product of Defendant No. 2 shows that almost all the components of the said product are identical with the plaintiffs product - plaintiffs product do not appear to be based on the US Patents or the products of third parties - Further, documents relied on by Defendant No. 2 do not prima facie indicate that the product of the plaintiff was obvious or was anticipated - Hence, Gillette defense not acceptable

Civil - Patent infringement - Grant of interim injunction - Order 39 Rule 1 of Code of Civil Procedure, 1908 - Whether interim injunction for alleged patent infringement could be granted - Held, plaintiff has made out a prima facie case of patent infringement - Documents placed on record by Defendant No. 2 with respect to US Patents do not anticipate the product of the plaintiff - Use of patent being limited, irretrievable prejudice will be caused to the plaintiff if interim Orders are not granted - Balance of convenience lies in favor of the plaintiff - Application allowed

Ratio Decidendi:
"Order of the patent controller granting the patent and the decision on the opposition cannot by itself give rise to a presumption of validity of the patent."

"A defense of the Defendant to show that the various integers were already known separately and the combination thereof cannot be patented would amount to mosaicing and is not permissible for determining the validity of the patent."

"If Defendant could prove that the act complained of is what was disclosed in a prior publication, which can be relied on against the validity of the patent, and no patentable or substantial alteration has been made in respect thereof, then that will be a good defense in an action for alleged patent infringement."

"In a patent infringement action, if use of patent is limited and balance of convenience lies in favor of the plaintiff, irretrievable prejudice will be caused to the plaintiff if interim Orders are not granted."

JUDGMENT

Sanjay Kishan Kaul, J.

1. The present matter is concerned with a claim of infringement of the patent of the plaintiff in respect of 'a device for detection of antibodies to HepatIT is C Virus (for short, HCV) in human serum and plasma'. The early detection of HCV is stated to be critical as there is no vaccine for the same.

2. The plaintiff is stated to be a Private Limited Company engaged in the manufacture and sale of diagnostic kits and is also stated to be a holder of various patents, designs and trademarks in respect of its products. The plaintiff's application (I.A. No. 11883 of 2006) under Order 39, Rules 1 and 2 and Section 151 of the Civil Procedure Code (hereinafter referred to as the 'said Code') is for the issuance of a temporary injunction restraining the defendants from infringing the plaintiff's Patent No. 194638 dated 22nd September, 2006 in a suit for permanent injunction, rendition of accounts and damages.

3. The plaintiff further claims to be a pioneer company enjoying a major market share and a constant innovator in technological breakthroughs in the field of diagnostic devices in India. It is stated that the plaintiff had established an in-house Research and Development Department in 1987 which is duly registered and approved by the Department of Scientific and Industrial Research, Ministry of Science and Technology, Government of India.

4. It is averred that the plaintiff developed a diagnostic device namely HCV TRI-DOT in the field of rapid visual test for the qualitative detection of antibodies to HepatIT is C virus in human serum or plasma. Such device is stated to ensure specificity and sensitivity in carrying out the tests making them viable for detection of HCV infection in laboratories, clinics, blood banks etc. It is claimed that the said device is a 'fourth generation' device which is stated to detect the antibodies if present for 10-15 days. It was pointed out that the first generation devices could detect the antibodies if present for a period of more than three months, and the second generation devices in case of antibodies present for more than two months. In case of the third generation devices, this time period was reduced to one month.

5. The plaintiff company through its patent agents is stated to have applied for grant of patent in respect of the said product on 14-06-2000 with complete specifications comprising of various claims. The description of such invention has been given in claim 1 and 2 which is as under:

Claim No. 1

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A device for the detection of antibodies of HepatIT is C Virus in human serum and plasma comprising base, an absorbent pad made of cellulosic material having a thickness of 2.4 to 2.7 mm positioned on the said base, an immunofilteration membrane on the said pad made up of cellulosic material having a pore size of 0.8-1.5 micron and diameter of 12 mm having three coatings of homogenous mixture of different HCV recombinant antigens as herein described Chemically linked and physically mixed along with the dispensing agent as herein described spotted on the said immunofilteration membrane, a top cover fitted tightly and irremovably attached to said base having a central hole conforming to the circumference of said immunofilteration membrane provided with two test dots (T1 and T2) and one built in quality control dot (C) within the circumference of said immunofilteration membrane to render 100% sensitivity and 98.9% specificity of the sample under test.

Claim No. 2

A device as claimed in claim No. 1 wherein the said dispensing agent is weight/volume.

Disodium Hydrogen Phosphate	:	10-100 millimolar;
Sodium Dihydrogent Phosphate	:	10-100 millmolar;
Protein Stabilizer	:	0.1-5%
Detergent	:	0.02-1%
Glycerol	:	10-20%
and Preservative	:	0.001-0.15%

and the balance being distilled water.

6. Such application post acceptance was notified in the Gazette on 20-11-2004 to which a pre-grant opposition was filed by defendant No. 2 on 21-03-2005. Such opposition was heard and dismissed vide order dated 23-08-2006 and finally the said patent was granted in favor of the plaintiff on 22-09-2006 as mentioned aforesaid. An appeal against the same being FAO 292-293/2006 was filed by defendant No. 2 wherein an ex-parte order was passed on 19.10.2006 directing that the order of the Assistant Controller of Patents and Designs be not given effect to until further orders. In the meantime, the Certificate of Registration of the said patent was duly obtained by the plaintiff on 15-10-2006.

7. The plaintiff also claims to be the forerunner in the market as regards the 'rapid visual test for qualitative detection of antibodies to HepatIT is C Virus in human serum or plasma' and in support of its claim has set out its sales in para 6 of the plaint.

8. It is also the submission of the plaintiff that the patent in respect of the said device has been granted in South Africa, Sudan and the UAE and in other jurisdictions, the same has entered the national phase and is pending and the fact of the patent being granted in other jurisdictions would reinforce the patentability and novelty of the said product.

9. It is the case of the plaintiff that on or about 11-10-2006, the plaintiff purchased the product of defendant No. 2 from defendant No. 1 being a proprietorship firm in the business of sale and purchase of various pharmaceutical and diagnostic products including the products so manufactured by defendant No. 2 and found that the product of defendant No. 2 was based and covered by the claims and invention provided in the complete specification of the plaintiff's said patent No. 194638.

10. It is submitted that all components of the plaintiff's test device HCV TRI- DOT form an integral part of defendant No. 2's product Signal HCV and for the purposes of elucidating the same, a comparative table is given in para 9 of the plaint which has been reproduced hereunder:

S. No.	Claims	plaintiff's Kit	Defendant's Kit	Remarks
	Claim 1			
1	A device for the detection of antibodies of HepatIT is C Virus in human serum and plasma	Yes	Yes	same
2	Comprising base, an absorbent pad made up of Cellulosic material positioned on the said base, an immunofilteration membrane placed on the said pad	Yes	Yes	same
3	HCV Recombinant Antigens as herein described Chemically linked and physically mixed along with the dispensing agent as herein described spotted on the said immunofilteration membrane	Yes (Antigen -Core, NS3, NS4, NS5)	Yes (Antigen Core, NS3, NS4, NS5)	Recombinant Antigens are the sane in both cases. The core is also the same and has to be in the desired ratio to achieve the desired sensitivity and specificity. (Page 4 pare of complete specification)
4	Immunofilteration membrane provided with two test dots and one built in quality control dot(C)	Yes with two test dot and one quality dot (T1 and T2) control dot(C)	Yes with one test dot and one quality dot (T control dot)(C)	The test dot is meant to diagnose to have one dot or two does not change the invention. Control dot is meant to indicate whether the device is in order or not.
5	Sensitivity and Specificity Sensitivity 100.00% 100.00% The sensitivity and specificity is directly related to Specificity 98.90% 100.00%			The antigens and core used and their ratio's thus approved by World Health Organization Not authenticated, by any organizat-ion. In both cases it is the same. Geneva (WHO test reports enclosed)

				supported by In house testing
	CLAIM 2			
1	Dispensing agent is a must to make a homogenous mixture of antigens and core	Yes	Yes	In both the cases the antigens and core are in the form of powder. Dispensing agent is needed to make a homogenous solution and coating the same on the membrane. In both the cases it is the same.
	CLAIM 3			
1	A Device as claimed in claim 1, wherein HCV peptides or recombinant HCV recombinant antigens are coated on the said membrane at the said T1 and T2 dots.	Yes	Yes	Recombinant antigens coated on one test dot(T) on membrane. The heart of the invention is coat antigens on the test dot whether two or one the second dot if provided gives a better performance as described in page 9 para 4 and figure 3c of Complete Specification
	CLAIM 4			
1	A device for the detection of antibodies of HepatIT is C Virus in human serum and plasma, substantially as herein described with reference to the accompanying drawings.	Yes (Fig 1 relates to the test device)	Yes (As shown in defendant's manual)	Claim 4 is directed to claim a device as described in the specification with reference to the drawings. The defendants device is completely covered under this claim.

11. It is thus the case of the plaintiff that the base, membrane, antigens used and the control dots and test dots in the product of defendant No. 2 are the same as those in the plaintiff's product. It is also submitted that the fact that the buffer solution, Protein A Conjugate and/or the plaintiff's device can be used interchangeably with those of defendant No. 2's buffer solution, Protein A Conjugate and/or the device establishes infringement of the plaintiff's patent.

12. The plaintiff avers that the infringement of its patent by the defendants is causing immense loss and irreparable damage to the plaintiff's rights. It is further averred that defendant No. 2 had knowledge of the plaintiff's patent and that the use of the plaintiff's invention by defendant No. 2 was intentional and willful. The defendants are also stated to be quoting low prices as compared to the plaintiff. Thus, the present suit has been filed with the application therein for an interim injunction against the defendants.

13. Defendant No. 2 has contested the present suit filing a written statement and a counter-claim being CC 2196/2006 on 25.11.2006 for the revocation of the plaintiff's patent no 194638 under Section 64 of the Patents Act, 1970 (hereinafter referred to as the 'said Act').

14. The submission made by defendant No. 2 is that it has been manufacturing and marketing its HepatIT is C Virus Detection Kit since December 2000. It is claimed that the said Kits are being manufactured by Defendant No. 2 in accordance with specifications from Accudx, USA which are in the public domain and that the manufacturing license had been obtained by defendant no 2 prior to the plaintiff's application for the grant of patent filed on 14.06.2000. It is stated that defendant No. 2 had obtained the 'first test and analytical license' to manufacture the HCV kit on 25.07.1997 and thereafter the second license on 24.02.1999, and the third test license on 27.06.2000.

15. The invalidity of plaintiff's patent No. 194638 is alleged on the grounds of prior publication, prior public knowledge and use in India, obviousness, not being an invention nor a patentable invention and lastly on the ground that the invention has not been sufficiently explained by the plaintiff.

16. Defendant No. 2 has submitted that the investigation conducted by the Controller under section 13 of the said Act is not conclusive on the question of anticipation which principle has been enunciated in sub section (4) of Section 13 of the said Act. It is the case of defendant No. 2 that the patent of the plaintiff is liable to be revoked on the ground of prior publication established by US Patent Nos. 5006464, 5541059 and 5160701. It is contended that the said US patents as also US patent Nos.5008080, 4920046, 5763159 and 5721095 and international patent No. W096/13590 make the patent claimed by the plaintiff obvious. It is submitted that each of the features of the patent specification, namely, the testing device, buffer solution and the protein A conjugate function independently of each other in a known way and thus the plaintiff's claims do not constitute an invention under Section 3(f) of the said Act.

17. It is also the case of defendant No. 2 that as a prior appeal against the order of the patent controller dated 23.08.2006 is pending and the said order is not to be given effect to in terms of the order dated 19.10.2006 of this Court, any act done pursuance to the order dated 23.08.2006 cannot be given effect to. It is alleged that the plaintiff has approached the court with unclean hands as the fact of the appeal being filed and the ex parte order therein were not disclosed by the plaintiff although the appeal had been filed prior to the present suit. Defendant No. 2 has thus prayed for the revocation of the patent of the plaintiff.

18. Insofar as defendant No. 1 is concerned, none entered appearance on behalf of defendant No. 1 despite service and the said defendant was proceeded ex parte vide order dated 08.11.2006.

19. I have heard learned Counsels for the parties. Mention of plaintiff's Product in the WHO Report

20. Learned senior counsel for the plaintiff submitted that the device of the plaintiff is the only one mentioned in the report of the WHO dated July 2001.

21. It was averred by defendant no 2 as regards the WHO report relied on by the plaintiff that the plaintiff has misrepresented that the WHO has approved and certified its product as it does not approve or certify. Defendant No. 2 also alleges that the plaintiff is wrongly claiming that its product had the best sensitivity and specificity. It was submitted that the WHO document of July 2001 has a product by the name of Serodia HCV which has a better sensitivity and specificity being 100 and 99.5 per cent respectively. The said report contains a disclaimer that 'the mention of specific companies and of certain manufacturers products does not

imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned'.

22. Learned Counsel for the plaintiff however contended that while defendant No. 2 has averred that other companies were manufacturing products similar to that of the plaintiff which find mention in the WHO Report, a perusal of the list would show that there are a number of differences in the various kits mentioned which is evident from a perusal of the testing parameters mentioned. The said report notes that RIBA HCV 3.0 and InnoLIA HCV are 'Strip Immunoblot' tests. Genedia HCV Rapid, which is an immunofiltration test has a specificity and sensitivity of 98.4 and 98.5 respectively which is different from the product of the plaintiff (4th generation) which has a sensitivity and specificity of 100 and 98.9 respectively. The said report also mentions the 3rd generation product of the plaintiff HCV Microlisa as having a sensitivity and specificity of 100 and 97.4 respectively. It was submitted that the Serodia Test is a ELISA Rapid test in which a 'microlitre particle agglutination assay is used for the qualitative detection of the anti-HCV' and the time taken to obtain results in the said test is 2 hours and 45 minutes.

23. Learned Counsel averred that the kit being manufactured by defendant No. 2 is not approved by the WHO and in this behalf referred to the draft report submitted by the WHO. The said report notes that the final sensitivity and specificity of the said product is 100 and 98.9 per cent respectively which is identical to that of the plaintiff's product. It is also stated that the Phase I evaluation meets the WHO criteria to proceed to the Phase II level and the same will be published in the official WHO report of the commercially available assays to detect the anti-bodies to HCV in human serum/plasma.

24. The plaintiff placed reliance on a letter dated 17.05.2002 on behalf of the Department of Scientific and Industrial Research, Ministry of Science and Technology addressed to defendant No. 2 to contend that the said defendant did not have a research and development facility until as late as 2002. The said letter conveys the accordance of recognition to the said defendants RandD facility till 31.03.2004

25. A perusal of the WHO report of July 2001 shows that the said report does contain a disclaimer that the WHO is not recommending or endorsing any of the products mentioned therein in preference to other products of a similar nature. However, the report shows that the products mentioned therein including the plaintiffs HCV Tri-Dot (4th Generation) have been evaluated and the specificity and sensitivity of the plaintiff's 4th generation product has been noted to be 98.9 and 100 as claimed by the plaintiff.

26. The other products mentioned in the WHO report, being RIBA HCV 3.0 and InnoLIA HCV are 'Strip Immunoblot' tests, Genedia, which is an immunofiltration test has a lower specificity and sensitivity than that of HCV Tri-dot (4th Generation). The Serodia HCV test is stated to be a microlitre particle agglutination assay for the qualitative detection of Anti-HCV and not an immunofiltration test as is the case with the plaintiff's product.

27. The draft report of the WHO in respect of the product of defendant No. 2 shows that the WHO is in the process of evaluating the product of the said defendant.

28. I am of the view that the fact of the plaintiff's 4th generation product being mentioned in the WHO Report in which the product has been evaluated and its sensitivity and specificity noted is certainly one of the factors to be taken into account by this Court. Habitual infringement

29. It was contended by learned Counsel for the plaintiff that defendant No. 2 is a habitual infringer and has been copying the products of the plaintiff and is continuing to do so. It was stated that defendant No. 2 has filed an opposition in respect of almost all of the products of the plaintiff namely HCV Tri-dot (4th Generation), HCV Tri-dot (3rd Generation), Protein A Conjugate and Buffer Solution. Patent has been granted in respect of HCV Tri-dot (4th Generation) and HCV Tri-dot (3rd Generation) and the decision on the objections are pending as regards the Protein A Conjugate and Buffer Solution.

30. Insofar as the claim of the plaintiff that defendant No. 2 is a habitual infringer is concerned, the plaintiff and defendant No. 2 being competitors, such objections are being filed. It cannot be said from this material alone that defendant No. 2 has been habitually infringing the patents of the plaintiff. Suppression of Facts

31. Learned Counsel for defendant No. 2 has taken the plea that the plaintiff has in its plaint and argument suppressed certain facts including the appeal filed against the order of the controller granting patent to the plaintiff and the order dated 19.10.2006 granting stay against the operation of the order of the Assistant Controller. It is also alleged that the plaintiff has made no mention of the fact that it was approached by one Mr. Albert Chu about 8-10 years ago to license the technology related to the invention of the plaintiff or the prior products being manufactured and sold by EY Laboratories since 1996 as also their patents being US Patent Nos. 5006464 an 5541059. The fact of the abandonment of the plaintiff's patent claim in the US is also alleged to have been suppressed. It was averred that the plaintiff has been manufacturing and selling a similar bi-dot product prior to its patent application. Documents regarding any research done by the plaintiff in the context of the patented product have not been shown. It is averred that the PCT search report stating that the application of the plaintiff is obvious has also been suppressed.

32. Insofar as the appeal filed against the order dated 23.08.2006 of the Assistant Controller of patents is concerned, it was submitted by the plaintiff that the appeal was served upon the plaintiff only on 06.11.2006 while the present suit was filed on 28.01.2006 and thus the appeal or stay granted therein was not mentioned. Learned Counsel further submitted that the learned single judge hearing the appeal was not informed of the grant of patent and registration of the same. The plaintiff submitted that the order of the Assistant Controller of patents dismissing the pre-grant opposition of defendant No. 2 is one under Section 25(1) of the said Act and Section 117A(2) of the said Act provides for appeals to be filed before the appellate board only against orders under Section 25(4) of the said Act which are with regard to maintaining, amending or revoking a patent i.e., at the post grant stage. It is also stated that defendant No. 2 has filed a fresh application on 20.11.2006 seeking stay of the patent granted in favor of the plaintiff and on 21.11.2006, the learned single judge directed the filing of a reply to the said application and clarified that the suit may proceed in the meantime.

33. In respect of the abandonment of the patent application in the United States, learned Counsel pointed out

that the same has in fact been mentioned during the opening arguments. It was also submitted that the US patent was filed for the kit as a whole and not merely the device as in India and the same was abandoned as it was found not to be economically viable.

34. Learned Counsel submitted that the aspect of a bi-dot product being manufactured by the plaintiff was not argued during the oral submissions. It was also averred that Bi-Dot relates to a third generation device with a much lower sensitivity and specificity and is beyond the scope of the present litigation.

35. A plea has also been raised that the research and development documents are confidential in nature and the final manufacturing license granted to the plaintiff has been placed on record.

36. Learned Counsel for the plaintiff submitted in respect of the PCT report that the said report notes that as far as PCT Article 33(2) is concerned, Claims 1-13 of the plaintiff meet the criteria set out therein as the prior art does not anticipate the diagnostic kit as claimed. The said claims are also stated to meet the criteria in Article 33(4) of the PCT as the claimed the diagnostic kit can be used to detect antibodies to HepatIT is C in human serum and plasma. It was also submitted that the PCT application claiming priority was directed towards the complete kit as per the claims originally filed.

37. Insofar as the concealment of fact of the appeal filed against the order dated 23.08.2006 of the Patent Controller is concerned, it has been pointed out by learned Counsel for the plaintiff that the summons in the same were served on the plaintiff only on 6.11.2006 while the present suit was filed on 28.01.2006 and thus the same has not been stated in the plaint. This aspect however finds mention in the written statement to the counter claim. The fact thus could not have been mentioned in the appeal. While it is the plea of the plaintiff that appeals under Section 117A of the said Act can be filed only against orders under Section 25 of the said Act, it may be noticed that prior to the amendment of the said Act vide the Patents Amendment Act, 2005, to the provisions inter alias of Section 117A(2), which came into force from 2.04.2007, appeal could be brought against any order of the Controller under Section 25. Be that as it may, these aspects are to be considered by the Appellate Court. The order dated 21.11.2006 of the Appellate Court had clarified that the proceedings in the present suit may continue.

38. It was mentioned in the oral submissions in respect of the American Patent Application of the plaintiff that the same had been abandoned.

39. As regards the bi-dot product of the plaintiff, a perusal of the literature placed on record shows that the same is stated to be a a third generation product. The antigens stated to be used are highly purified recombinant antigens for Core, NS3, NS4 and NS5. the results are stated to be obtained within 5 minutes. While the bi-dot product is stated to utilise a unique combination of the said antigens, the proportions have not been specified. The specificity and sensitivity of the product are stated to be 1020/1022 EIA negative sera and 312/312 positive sera respectively. Further, the product is stated to be a third generation product which as transpired during the oral submissions detect antibodies if present for more than one month while the fourth generation product detects antibodies if present for 15 days. Thus, the fourth generation devices are an improvement over third generation devices as far as this aspect is concerned.

40. Insofar as the aspect of the documents showing research conducted by the plaintiff are concerned, i am of the view that sufficient material has been placed on record by the parties for a prima facie consideration of the case. These aspects may thus be considered during the trial.

41. A perusal of the PCT International Preliminary Examination Report shows that it also notes that the said claims 1-13 of the plaintiff's application lack inventive step under PCT Article 33(3). It is observed in the said report that claims 1-13 lack an inventive step under PCT Article 33(3) as being obvious over US patent Nos. 4,962,023, 5,008,080, and 5,958,790 each of which disclose a kit comprising a multi-layer test device that includes one or more test areas that can be coated with one or more antigens for the assay of antibodies in a sample and each discloses a colloidal gold label for the visualization of antigen antibody complexes as well as Protein A for the capture of IgG. The said report objects to certain individual claims on grounds of lack of clarity as the claims are indefinite. The International Search Report states that the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more documents of particular relevance, such combination being obvious to a person skilled in the art. It may be useful to reproduce the relevant provisions of PCT Article 33 which are as under:

> Article 33
>
> 1. The objective of the international preliminary examination is to formulate a preliminary and non-binding opinion on the questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), and to be industrially applicable.
>
> 2. For the purposes of the international preliminary examination, a claimed invention shall be considered novel if it is not anticipated by the prior art as defined in the Regulations.
>
> 3. For the purposes of the international preliminary examination, a claimed invention shall be considered to involve an inventive step if, having regard to the prior art as defined in the Regulations, it is not, at the prescribed relevant date, obvious to a person skilled in the art.
>
> 4. For the purposes of the international preliminary examination, a claimed invention shall be considered industrially applicable if, according to its nature, it can be made or used (in the technological sense) in any kind of industry. "Industry" shall be understood in its broadest sense, as in the Paris Convention for the Protection of Industrial Property.

42. The PCT preliminary examination report indicates that claims 1-13 of the plaintiff lack an inventive step but are novel and can be considered industrially applicable. It may however be noticed that the said report is in respect of the diagnostic kit of the plaintiff. Furthermore, Article 33(1) of the PCT states that 'the objective of the international preliminary examination is to formulate a preliminary and non binding opinion on the aspects of novelty, industrial applicability and non obviousness. Article 35(2) of the PCT states that the International Preliminary Report would not contain any statement on the patentability or unpatentability of the claimed

invention according to any national law. The International Search Report (7th Nov. 2002) is again with regard to the 'Diagnostic Kit for Invitro detection of HepatIT is C'. The said International Preliminary Examination Report thus cannot be said to have much bearing in considering the validity of the patent.

Presumption of Validity

43. Defendant No. 2 argued that the mere grant or sealing of a patent or decision rendered by the Controller on an opposition filed does not imply the validity of the patent. In this behalf, learned Counsel placed reliance on the judgment of the Apex Court in Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries PTC (Suppl.) (1) 731 (SC) wherein it was observed that the grant and sealing of the patent or the decision of the Controller on the opposition application does not guarantee the validity of the patent and the same can be challenged before the High Court on various grounds in infringement proceedings. This position is expressly provided by Section 13(4) of the said Act. Again in Standipack Private Ltd. and Ors. v. Oswal Trading Co. Ltd and Ors. 1999 PTC (19) 479 (Del), learned single judge (as he then was) noted that the Delhi High Court has held in an infringement act relating to a patent, the plaintiff has to make a prima facie case about the existence of a monopoly right and its infringement by the defendant. The court must look at the whole case of the patentee and the strength of the defense under Sections 107 and 64 of the said Act. It has also been observed that no presumption of validity attaches to a patent granted by the Controller under the Act notwithstanding examination and investigation made under sections 12 and 13.

44. It was averred by learned Counsel for the plaintiff however that as the pre-grant opposition filed by defendant No. 2 had been dismissed by a technical body, at least at the interlocutory stage there cannot be presumption against the validity of the patent and the presumption of validity could be dislodged only at the stage of trial. It was submitted that the entire process of opposition and the final decision on the same would have a significant bearing on the validity of the patent as the patent of the plaintiff would have been rigorously examined by the patent office as specified in the said Act and the process of grant of patent being a long and tedious one, it would be evidence of the fact of a prima facie finding of an expert body that the invention is a valid one. The grounds of examination include 'anticipation'. Learned Counsel referred to the provisions of the said act to point out the procedure followed for scrutiny and examination. It was also submitted that Section 13(4) of the said Act is only a statutory indemnification.

45. Learned Counsel referred to the provisions of Sections 11-13 of the said Act to highlight the process of scrutiny of patent application and Section 14 in respect of the consideration of the report by the patent controller. Further Rule 55 of the Patents Rules, 2003 provides the procedure with regard to opposition proceedings. Section 18 of the said Act is in respect of the powers of the Patent Controller in case of anticipation and provides inter alias that where it appears to the Controller that the invention has been anticipated in the manner provided by the said act, he may refuse the application unless the applicant either shows to the satisfaction of the Controller that the priority date of the claim of the complete specification is not later than the date on which the relevant document was published or the applicant amends his complete specification to the satisfaction of the controller. A reference was also made to the grounds of revocation under Section 64 available and the provisions of Section 107 of the said Act which provides that every ground on which a patent may be revoked under under section 64 shall be available as a defense in a suit for infringement.

46. Learned Counsel also submitted that while a pre-grant opposition under the said Act can be filed by any person, a post grant opposition can be filed only by a 'person interested' which includes a 'person engaged in, or in promoting, research in the same field as that to which the invention relates' [Section 2(q)].

47. Learned Counsel for the plaintiff placed reliance on the judgment in National Research Development Corporation of India, New Delhi v. The Delhi Cloth and General Mills Co Ltd and Others MANU/DE/0304/1979 : AIR 1980 Delhi 132 wherein a learned single judge of this Court observed that if the patent is sufficiently old and has been worked, the court would for the purpose of temporary injunction, presume the patent to be a valid one and if the patent is more than six years old, and there has been actual user, it would be safe for the court to proceed upon this presumption. It was thus submitted that as the patent in the present case is six years old, the validity of the same must be presumed. The said judgments have been considered in the judgment of a division bench of this Court in Telemechanique and Controls (I) Ltd. v. Schneider Electric Industries SA MANU/DE/1264/2001 : 94(2001)DLT865 .

48. A perusal of the provisions of Sections 11-12 of the said Act shows that where a request for examination is made by an applicant or person interested, the examiner is to make a report in respect of whether the application, specification and other documents meet the requirements of the said Act and rules, whether there is a lawful ground of objection to the grant of patent under the Act, the result of the investigations on the ground of anticipation and other matters that may be prescribed. Further Section 13 requires the examiner to make an investigation into whether the invention claimed is anticipated by publication before the date of filing of the applicant's complete specification in any specification filed in pursuance of an application for a patent made in India or whether the invention is claimed in the claim of any other complete specification published on or after the date of filing of the applicant's complete specification being a specification filed in pursuance of an application for a patent made in India and dated before or claiming a priority date earlier than that date. The examiner is also required to make an investigation as to whether the invention has been anticipated in any publication in India or elsewhere in any other document. Section 13(4) however provides that such examinations or investigations are not to be deemed to warrant the validity of any patent. Rule 55 of the Patents Rules, 2003 requires the examiner to consider the statement and evidence filed by the applicant and in case a hearing is requested, to consider the representation and submissions made and thereafter give a decision as to whether the patent is to be granted, refused or the complete specification be amended.

49. It is well settled as held in the decisions in Bishwanath Prasad Radhey Shyam and Standipack Private Ltd. cases (supra) that the grant of a patent alone does not give rise to a presumption of validity of the patent notwithstanding the examination and inspection carried out by the Patent Controller and the validity of the patent can be challenged in infringement proceedings on the same grounds on which revocation can be claimed under Section 64 of the said Act. Section 13(4) of the said Act provides inter alia, that the examination and investigation conducted shall not be deemed in anyway to warrant the validity of the patent. The decision on the opposition application also does not imply the validity of the patent.

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50. The decision in M/s National Research Development Corporation of India case (supra) is to the effect that where a patent has been in existence for sufficiently long and has been worked, for the purposes of temporary injunction at least the court can presume the same to be valid.

51. Although the examiner looks into various aspects and makes a rigorous examination of the patent application and opposition thereto, in view of the decisions in Bishwanath Prasad Radhey Shyam and Standipack Private Ltd cases (supra), the order of the patent controller granting the patent and the decision on the opposition cannot of itself give rise to a presumption of validity of the patent notwithstanding the investigation and examination made and the same can be challenged. Insofar as the decision in M/s National Research Development Corporation of India case (supra) is concerned while the actual user and duration of the patent may be one of the factors that may be taken into account, I am of the view that that factor alone cannot give rise to a presumption of validity of the patent. This Court would thus have to look into the merits of the case of the plaintiff as also the defense put forth by the defendant. Prior knowledge and use of technology by Defendant No. 2

52. It is the case of defendant No. 2 that it has been manufacturing the impugned product according to specifications provided by AccuDx USA. It was submitted that the said defendant had entered into a technology transfer agreement on 31.07.1997 with AccuDx in respect of the device comprising a base, absorbent pad made of nitrocellulose material, an immunofiltration membrane and a top cover having a central hole. The reagents in the kit are stated to include Buffer solution, Colloidal solution, Protein A Conjugate and Anti-Human IgG and the agreement is stated to deal with both 'flow through' and 'Elisa' Device.

53. Insofar as the aspect that only three antigens are mentioned in the technology transfer agreement is concerned, it is the submission of defendant No. 2 that the technology with AccuDx pertaining to antigens was not advanced and the defendant learned from and purchased the antigens from one Devaron, Inc, USA. Learned Counsel referred to an email sent to defendant No. 2 regarding shipments sent to the said defendant. One of the products mentioned is 'DEV 21- 25 (Cat# 301-21-25-2) ' which includes HCV Core, NS3, NS4 and NS5.

54. Learned Counsel submitted that while the plaintiff has taken the stand that it is the combination and ratio of the antigens which is the subject matter of the patent, the proportion of antigens has not been mentioned in the patent document. Learned Counsel alleged that the plaintiff has been changing its stance as regards the antigens used in the patented product. While initially it was argued by the plaintiff that the antigens used are new, the stand was changed later that the antigens are not disputed but the combination, proportion and ratio is the subject matter of the patent.

55. The submission of the plaintiff that the documents do not relate to the product in question has also been disputed by defendant No. 2 and it was averred that the brochures and materials attached to the licenses and applications explain the technology being used by defendant No. 2 which is the same as is being used in the impugned product. In this behalf, reference was made to the applications stated to be filed by defendant No. 2 for the grant of the licenses. The first application dated 26.04.1997 is with respect to the 'SIGNAL Flow Through anti-HCV Test Kit for in-vitro detection of antibodies in the HepatIT is C virus'. The said kit is stated to consist of a 'plastic cassette containing a membrane spotted separately with synthetic and recombinant HCV peptide and Anti-Human Immunoglobin'; and a wash buffer, signal reagent, negative control. The annexures to the application also detail the procedure of manufacturing the said components and the specificity and sensitivity of the product is estimated to be 100 per cent. However, there is no mention of the specific antigens used. Another application dated 17.07.1997 with regard to the said product for the grant of permission for manufacture of the said product for examination, test or analysis. The draft labels stated to be attached to the application include the label for the SIGNAL HCV Flow- Through Anti-HCV Spot/ Immunodot Test Kit'. In respect of this application, a letter dated 25.07.1997 was sent on behalf of the Food and Drugs Control Administration granting the license up to 24.07.1998. A third application is stated to have been sent on 17.02.1999 for the manufacture of products including the 'Signal Flow through Anti-HCV Spot Immunodot Test Kit' for examination, test or analysis. license in respect of this application was granted vide a letter dated 24.02.1999. A request for evaluation of the 'Signal HCV Flow Through Anti-HCV spot immunodot test kit' is stated to have been made vide an application dated 06.03.2000. On 27.06.2000 again license was granted to Defendant No. 2 in respect of another application filed by the said defendant on 12.06.2000 for a license for examination, test or analysis.

56. It is stated that defendant No. 2 was able to obtain the commercial license and commenced manufacture of the said product in December 2000. In support of this submission, reference was made to invoices. An invoice dated 18.12.2000 mentions 'Signal Flow Through HCV'.

57. It is averred that as the specification filed by the plaintiff on 14.06.2000 was incomplete and the complete specifications were filed only on 14.06.2001, defendant No. 2 could not have copied the patented product as the same was being exported by them since 2000. Defendant No. 2 claims to have obtained knowledge of the product only after it was published in 2004 after which an opposition was filed. Learned Counsel averred that while the plaintiff has claimed that it commenced the sales of its product in June or July 2000, no documents have been filed in support of the claim. Also, no documents have been filed showing any research conducted towards developing the said product.

58. Learned Counsel for the plaintiff however, referred to the patent specification to contend that the ratio of the antigens used had been set out therein which is as under:

> The said antigens can be mixed taking
>
> ```
> Core:  40-60 nannogram
> NS3: 100-150 nannogram
> NS4: 150-200 nannogram
> NS5: 150-200 nannogram
> ```

59. Insofar as the contention of defendant no 2 that it is manufacturing its product based on technology

obtained from AccuDx is concerned, it is the submission of the plaintiff that the device of AccuDx uses only two antigens being NS3 and Core while the plaintiff's device employs 4 antigens. It was also alleged by the plaintiff that the argument was an afterthought and the technology transfer agreement had not been placed on record at the first instance and was placed on record only with the replication to the written statement to the counter claim. Moreover the said agreement relates to ELISA tests and the manner in which dots appear in defendant No. 2's device is different from the device of AccuDx. The clause in the said technology transfer agreement on its 'Scope' mentions the 'production protocol of HCV Elisa Tests'. It was submitted without prejudice that the defendant can follow the technology of AccuDx which is different from the product of the plaintiff.

60. In response to defendant No. 2's argument that it had imported the mixture of antigens from Devaron, it was submitted by the plaintiff that it is the combination, proportion and ratio of the said antigens which is the subject matter of the said patent.

61. In respect of the application for manufacturing license of defendant No. 2 is concerned, it was averred by the plaintiff that the application filed in 1997 was a general application for a device and the product being manufactured by the said defendant now is completely different from the product in respect of which the application was filed.

62. Learned Counsel averred that defendant No. 2 is attempting to confuse the manufacturing licenses and documents for its other devices. The device in respect of which the plaintiff has a grievance is the HCV Signal Rapid Device and not the other types of devices namely the HCV Comb Test and the HCV Elisa Test also available for the diagnosis of the HepatIT is C Virus. It is thus alleged that the documents submitted by defendant No. 2 reveals that the applications and approvals for different products have been intermingled.

63. Learned Counsel urged that the said defendant had not pleaded any knowledge of technology of the product in the present case at any time in the entire opposition proceedings before the patent office. The plaintiff avers that the plea that defendant No. 2 has been manufacturing the impugned device since 1997 was not taken before the patent controller in the said proceedings. It was also submitted that there has no whisper in the pre-grant opposition to either the technology of AccuDx being used or to the applications dated 26.02.1997 or 17.07.1997 and the same appear to be an afterthought.

64. The plaintiff has also alleged that there are a number of discrepancies in the documents filed. A table of the alleged discrepancies has been filed by the plaintiff which is as under:

```
Application dated 26.4.97
Application dated 17.7.97
Application dated 30.11.2000

Recombinant and Synthetic protein
Recombinant and Synthetic peptides
Recombinant antigens (NS3, NS4, NS5 and Core). This is identical to plaintiff's patent.

HCV antibodies IgG, IgM, IgA are visualised.
HCV antibodies IgG, IgM, IgA are visualized
Only IgG is visualized

Antibodies have to react with Colloidal Gold and Protein A and Protein G
Antibodies have to react with Colloidal Gold and Protein A and Protein G
Colloidal Gold Protein A signal reagent

Reagents 1,2,3,4 and 5 are include in the kit
Reagents 1,2,3,4 and 5 are included in the kit
Reagents 1,2 and 3 are included in the kit

Items contained in the kit:
  i) Test device
 ii) Wash buffer
iii) Signal reagent
 iv) Negative control
  v) Positive control

Items contained in the kit:
  i) Test device
 ii) Wash buffer
iii) Signal reagent
 iv) Negative control
  v) Positive control

Items contained in the kit:
  i) Test device
 ii) Wash buffer
iii) Signal reagent
```

65. A reference was made to the inspection report (National Institute of Biologicals, March 1999) in respect of the products of defendant No. 2 which includes the 'Signal HCV Flow Through Anti HCV Spot Immunodot test kit' to contend that the product is a spot test on a strip. The said report mentions that 'the spot test strip for HIV, HbSAg and HCV has been designed in a way that the spots appearing on the strip after the test are not permanently fixed and may fade away or disappear after some time'. Learned Counsel also referred to the final manufacturing and marketing approval (11-12-2000) granted to defendant No. 2 to submit that the same was also subject to conditions.

66. Learned Counsel for the plaintiff submitted that no device would take a period of three years for the requisite approvals. It was also averred that the fact that the draft report of the defendant followed the

defendant's kit only in 2000 after one of the senior employees of the plaintiff involved in the manufacture of the said product had joined defendant No. 2 in May 2001 shows that the said defendant did not possess the technology in 1997. Further, the application for manufacturing permission was first made on 30.11.2000 but the license was not filed on record and the manufacturing permission was filed only after an objection was taken in the written statement to the counter claim. It was also submitted that the sales figures filed by defendant No. 2 are since December 2000.

67. Learned Counsel for the plaintiff alleged that the literature attached with the final application filed before the Drug Controller appears to be an afterthought and the same does not bear signatures as in all the other annexures attached to the application filed before the patent controller.

68. A reading of the technology transfer agreement dated 31.07.1997 shows that as per the scope of the agreement set out therein, AccuDx is stated to have information regarding 'critical areas related to the manufacturing of immunofiltration based diagnostic kits'. The example with regard to HepatIT is C diagnostic Kits provided includes the device, single solution blocking/wash buffer, formulation of colloidal gold conjugate diluent, antigen mixture, large scale production and production protocol of HCV Elisa tests. The description of final product (HCV Spot Assay) states that it is 'an immunofiltration assay with over 99.5 % sensitivity and specificity' and having a filtration device with recombiant NS3, NS4 and Core proteins of HCV, procedure control spot containing anti-human lgG, FC fragment, wash buffer, colloidal gold protein A conjugates etc. The brochure of Hep C Spot HepatIT is C (HCV) Rapid Test (which has been developed by AccuDx) states in the 'principle of the assay' that the recombinant proteins corresponding to NS3 and Core of HepatIT is C are bound to the membranes of the filtration device. The said agreement thus mentions only three antigens being Core, NS3 and NS4 and the said Hep C Spot Device appears to utilize only two antigens (NS3 and Core) unlike the device of the plaintiff on which a mixture of four antigens are used. Moreover, a perusal of the notice of opposition of defendant No. 2 to the plaintiff's patent application shows that the agreement with AccuDx has not been mentioned therein.

69. Although the reagent stated to be imported by defendant No. 2 from Devaron, Inc. Dev 21-25 (Cat# 301-21-25-2) contains all four antigens i.e., Core, NS3, NS4 and NS5, the combination in which the said antigens have been mixed has not been specified. The particular proportion in which the antigens have mixed is specified in the patent specification of the plaintiff and appears to be one of the salient features of the plaintiffs invention.

70. A comparison of the applications dated 26.04.1997, 17.07.1997 and 30.11.2000 that there are certain distinctions. In the items contained in kit. While the applications dated 26.04.1997 and 17.07.1997 the include positive control and negative control in the kits, the Kit in the application dated 30.11.2000 does not contain the said two reagents. The initial applications do not mention the antigens used while the application dated 30.11.2000 mentions the combination of Core, NS3, NS4 and NS5 antigens. The product with respect to which applications have been filed by defendant No. 2 thus appears to have undergone certain changes from the date of the initial application on 24.04.1997. Another aspect to be taken note of is that the inspection report of the National Institute of Biologicals with regard to the device of defendant No. 2 mentions the 'spot test strip' which indicates that the device has also undergone certain changes. The device thus currently being manufactured by defendant No. 2 cannot be said to be the same as the one in respect of which licenses were sought in 1997. The device of the defendant as well as the antigens used and the use of colloidal gold protein A as well as the items included in the kit of the said defendant has undergone changes since the initial applications for licenses were filed. The agreement with AccuDx also does not refer to the combination of antigens now being used by the said defendant. Defendant no 2 cannot thus plead that they have been manufacturing a similar device since the year 1997 and that they had knowledge of the technology prior to the patent application of the plaintiff. Prior Publication and Obviousness

71. Learned Counsel for defendant No. 2 submitted that prior publications being US patent Nos. 5,006,464 and 5,541,059 establish that the product in respect of which the plaintiff has obtained a patent was known in the art.

72. US patent No. 5,006,464 is in respect of 'Directed Flow Diagnostic Device and Method'. It is stated to be 'an improved method for analyte assay in liquid samples, wherein a porous membrane with an immobilized receptor which ls capable of directly or indirectly binding to the analyte is separated from a body of absorbent material capable of absorbing the liquid sample by a septum capable of substantially separating the porous membrane from the absorbent body while substantially directing the flow of the liquid sample from the porous membrane to the absorbent body'. Learned Counsel contended that the device of the plaintiff contains the same physical elements except the 'septum' and nothing has been mentioned in the plaintiff's specification as to the effect of non use of the septum. It is stated that the device mentioned in the patent can be used for a number of diseases including HepatIT is A and B. It was however submitted that HepatIT is C had not been mentioned as the same had not been discovered at the time of the patent.

73. In this regard, it was submitted by the plaintiff that the device of the plaintiff is of a different construction and function and is not anticipated by US Patent No. 5,006,464. The said patent is in relation to a device that can be used to make a diagnostic kit for the treatment of various diseases listed in the patent specification of the said patent and does not relate to any specific disease. The said device employs a directed flow and uses a separating septum with a hole to direct the flow of the liquid while the plaintiff's device employs a rapid flow through system. In this behalf, a reference was also made to the letter of Mr. Albert Chu (18.04.2007), the owner of the said patent. It is stated in the said letter that there are many companies using the lateral flow techniques in India but 'the direct flow from J Mitra still dominates the whole India market'. It was thus contended that the non use of the septum in the plaintiff's device makes it different from the said US patent and the manner of flow of the liquid is different. A reference was also made to the decision of the learned Assistant Patent Controller on the pre-grant opposition of defendant No. 2 wherein it was observed with regard to US Patent No. 5006464 that 'As can be understood from the claims of USA specification 5006464, it is a device for analyte assay in liquid samples comprising a porous membrane with an immobilized receptor capable of binding the analyte and separated from a body of absorbent material capable of separating the porous membrane from the absorbent body while directing the flow of the liquid sample from the porous membrane to the absorbent body. The device of the impugned patent application has altogether different construction and function to perform. Therefore, I disagree with the contention of the Opponent that US Patent

No. 5006464 anticipates the impugned application. '

74. Learned Counsel for defendant No. 2 submitted that US Patent 5,54,1059 which is in respect of an 'Immunoassay Device Having an Internal Control of Protein A and methods of using the same' mentions the use of the control dot in an immunoassay device with the help of colloidal gold, Protein A Conjugate and Anti-Human IgG; the use of one or more test dots on which antigens are coated and the use of known antigens for the detection of various diseases. The said patent mentions the HepatIT is C Virus.

75. In respect of US Patent No. 5,54,1059, the plaintiff contended that the said device also used a septum and the ratio in which antigens were used in the said device was not disclosed. The said device again is a general one which can be used to manufacture test devices for various diseases. It was also contended that the manner of flow as well as the manner in which dots appear in the said device are different from that of the plaintiff's product. A reference was made to the description of drawings in the patent document to contend that the manner of coating and bars employed in the said US patent make the device different. The description is as under:

> BRIEF DESCRIPTION OF THE DRAWINGS
>
> FIG.1 shows the members surface of an immunoassay device having a circular control substance area and a circular antigen area.
>
> FIG.2 shows the membrane surface of an immunoassay device having a bar-shaped control substance area and two separate antigen areas on either side of the control substance area.
>
> FIG.3 shows the membrane surface of an immunoassay device having a circular rim of control substance and an antigen area within the circular rim.
>
> FIG.4 shows the membrane surface of an immunoassay device having a dotted circular rim of control substance and an antigen area within the dotted circular rim.
>
> FIG.5 shows the membrane surface of an immunoassay device having a control horizontal bar of control substance and two vertical bars of a first and second antigen.
>
> FIG.6 shows the membrane surface of an Immunoassay device having a horizontal bar of control substance and a vertical bar of antigen.
>
> FIG.7 shows the membrane surface of an immunoassay device having a central capture antibody area, an upper antigen area, and a lower control substance area.

76. In respect of US patent No. 5541059, the Patent Controller in the opposition proceedings observed that the same 'relates to an analytical device for use in an immunoassay for the detection of a first analyte antibody in a liquid sample comprising a permeable membrane. This device is in no way define the construction of the impugned invention'.

77. The specification of US Patent No. 5006464 shows that the same is a device and method for analyte assay in liquid samples wherein a septum separates a porous membrane with an immobilized receptor which is capable of directly or indirectly binding to the analyte from a body of absorbent material capable of absorbing into a liquid sample. The 'disclosure of the invention' notes that the septum is typically in the form of a sheet having one or more selected ports capable of substantially separating the porous membrane from the absorbent body while directing the flow of the liquid sample from the membrane to the absorbent body. The septum thus appears to have the effect of directing the flow of the sample. The plaintiff's device does not contain a septum and the manner of flow therein is not a directed flow. The letter of Mr. Albert Chu mentions that the 'direct flow from J Mitra' still dominates the market. However, the specific product has not been mentioned. However, from a reading of the specifications, it prima facie appears that there are differences in the manner of flow adopted in the two devices. The impact of such difference in manner of flow is not clear and would have to be examined during the course of the trial.

78. Insofar as US Patent 5,541,059 is concerned, a perusal of the claims show that the said patent is in respect of a device and methods employing non antibody control substances. The device comprises a solid phase with a permeable membrane having a lower surface and upper surface. The antigens and non antibody control substances are coated on different areas on the surface. There is thus no mixture of antigens used as is used in the plaintiffs device. The construction of the device also appears to be different from that of the plaintiff's device.

79. Thus, it cannot be said at least prima facie that the plaintiff's device is anticipated by US patent Nos. 5006464 and 5541059. Similar Products being manufactured by Third Parties

80. It was averred by Defendant No. 2 that a product namely HCV Scan similar to the product of the plaintiff and the impugned product of the defendant is manufactured by one EY laboratories, the CEO of which is one Mr. Albert Chu who is the owner of US Patent Nos. 5,006,464 and 5,541,059. Another product HCV Spot is being manufactured by the said EY Industries through one Gene Lab. The products are stated to have been in the market since 1996 and 1995 respectively.

81. The HCV Scan is stated to be 'a rapid, simple, qualitative test for the detection of antibodies to HepatIT is C Virus, in human serum or plasma' and is intended to be used only as an initial screening test.

82. Learned Counsel also placed reliance on a letter dated 7.04.2007 written by Mr. Albert Chu to defendant No. 2 stating that he had met the head manager of the plaintiff 8-10 years ago and asked him to license the patent of EY Laboratories but was ignored. It is also stated that HCV Spot was introduced into India by Gene lab and the product was copied by the plaintiff. In the said letter it is claimed that EY laboratories is the first company to have developed the rapid test using gold colloidal in mid 1980. The lateral flow and reversible flow device are also stated to have been developed by defendant No. 2. Learned Counsel submitted that Mr. Albert Chu had also alleged that the plaintiff had infringed his patents.

83. Learned Counsel also referred to the brochure for Murex anti-HCV (Version III) which is stated to be a rapid enzyme immunoassay for the detection of antibodies to HepatIT is C Virus in human serum or plasma. The said test is stated to utilize antigens from the putative core (C,structural), Protease/helicase (NS3, non structural), NS4 (non structural) and replicase (NS5) regions of the virus to provide a sensitive diagnostic test. The components of the said test include antigen coated wells (one plate or five plates each made up of 12 strips of eight wells coated with purified HCV antigens), sample diluent, Negative Control, Anti-HCV Positive Control, Conjugate Diluent (buffer containing inorganic sales and protein with 0.05 % Bronidox) and Conjugate (freeze dried horseradish peroxidase labeled mouse monoclonal antibody to human IgG in a protein base).

84. Another document pertains to UBI-HCV, EIA which is again stated to be 'an immunoassay which employs synthetic peptides for the detection of antibodies to HCV in human serum or plasma'. It is stated that the UBI HCV EIA employs an immunoabsorbent, which consists of synthetic peptides corresponding to highly antigenic segments or core NS3, NS4 and NS5 regions of the hepatIT is C virus, bound to the wells of the microplate. The reagent components include specimen diluent, anti-HCV non-reactive control, Anti HCV Weakly Reactive Control, Anti HCV Strongly reactive Control, Microplates, Wash Buffer Concentrates, Conjugate Diluent, OPD (O-Phenylenediamine-2HCl), OPD Diluent, Stop Solution, and Dilution microplates.

85. A reference was also made to a brochure of 'HepatIT is C Virus Encoded Antigen Ortho ELISA Test System with Enhanced Sample Added Verification'. In the said test three recombinant HepatIT is C virus encoded antigens are stated to be used namely c22-3, c20G and NS5.

86. Another document relied upon is of Innogenetics NV which is with regard to INNOTEST HCV AbIV. The objective of INNOGENETICS is stated to be to design a 4th generation assay with increased sensitivity for Core, NS3 and NS4 antibodies using HCV antigens with improved reactivity, and antigens derived from the most prevalent HCV genotypes. In the said test the antigens are stated to be derived from the Core (2 different epitope clusters), NS3, NS4A, NS4B, as well as NS 5A regions.

87. Learned Counsel for defendant No. 2 thus submitted that the features of the plaintiff's patent being a base, an absorbent pad of Cellulosic material, an immunofiltration membrane having coatings of homogenous mixture of different HCV Recombiant antigens, a top cover fitted to the base having a central hole and two test dots and a control dot are clearly understood from the US patent Nos. 5,006,464 and 5,541,059 and HCV Scan and HCV Spot which are products of EY Laboratories.

88. Learned Counsel for the plaintiff, submitted in respect of the products HCV Scan and HCV Spot that the said products use a different type of flow through mechanism from that of the plaintiffs product.

89. The contention of the plaintiff in respect of the 'Murex Anti-HCV' Test that the same is an ELISA test and is an immunoabsorbent linked assay while the plaintiff's test is not an enzyme linked immunoassay. Learned Counsel submitted that the UBI HCV is also an enzyme linked immunoabsorbent assay. As regards the 'HepatIT is C virus encoded antigen (Ortho Elisa) ', it was contended that the same is also an Elisa test and is also an enzyme linked immunoabsorbent assay. In the Elisa test the substrate and conjugate are to be used to give the desired results and the test takes two hours to be completed.

90. In respect of the Innogentics test, learned Counsel submitted that the same was in respect of an ELISA test and not a flow through test which is the case in the present patent.

91. The brochure in respect of HCV SCAN shows that it comprises HCV Scan device, non reactive control, strong reactive control, weak reactive control gold conjugate, diluent, blocking buffers, wash buffers and stop solution. The brochure does not mention the antigens used in the product.

92. A reading of the brochure of Murex anti-HCV (Version III) test shows that it is an enzyme linked immunoassay and in the said test, the diluted sample is incubated in microwells coated with highly purified antigens containing sequences from putative Core, NS3, NS4 and NS5 regions of HCV. The structure of the device appears to be different from that of the plaintiffs device and the process involves three periods of incubation which is not required in the plaintiff's test. The reagents used include a positive control and negative control besides the antigen coated wells, sample diluent, conjugate diluent and conjugate. A stop solution is also used. The plaintiffs device is not an enzyme linked test and does not require incubation. The positive control, and negative control are not used in the plaintiffs device.

93. As regards the UBI-HCV test, the same is again an enzyme linked immuno assay unlike the plaintiffs device. The said test employs the anti-HCV non- reactive control, Anti HCV Weakly Reactive Control, Anti HCV Strongly reactive Control, Microplates, Wash Buffer Concentrates, Conjugate Diluent, OPD (O-Phenylenediamine-2HCl), OPD Diluent, Stop Solution, and Dilution microplates. Also, the said test is an ELISA Test. The process includes incubation for 30 minutes and thereafter again for 15 minutes each at two stages. The microplates, Anti HCV Weakly Reactive Control, Anti HCV Strongly reactive Control, stop solution etc are not part of the plaintiff's device. The plaintiff's test is a rapid test.

94. The 'HepatIT is C Virus Encoded Antigen Ortho ELISA Test System with Enhanced Sample Added Verification' relied on by defendant No. 2 is an ELISA test as the name itself indicates and uses c22-3, c20G and NS5 antigens and thus the said product cannot be said to anticipate the plaintiff's product which is a rapid flow through test using Core, NS3, NS4, and NS5 antigens.

95. The INNOTEST HCV AbIV which is a 4th generation test is an ELISA test and not a rapid test as is the case with the plaintiff's device.

96. Thus, the product of the plaintiff is different from the products being manufactured by third parties referred to being Murex Anti-HCV, the UBI-HCV test, INNOTEST HCV AbIV and HepatIT is C Virus Encoded Antigen Ortho ELISA Test which contain different components from that of the plaintiffs product and are Elisa tests and cannot be said to be anticipated by the said products. Mosaicing

97. The plaintiff has averred that the attempt by defendant No. 2 by citing a number of citations constitutes mosaicing. In this behalf a reference was made to Terrell on Patents (sixteenth Ed., 2006) wherein it has

been observed with regard to mosaicing that

> The mosaicing of individual documents or prior uses is not permissible, unless it can be shown that the skilled person, confronted with a particular citation, would turn to some other citation to supplement the information from the first.
>
> Whether he would do so is a question of fact. Lord Reid said in Technograph v. Mills and Rockley [1972] R.P.C 346 :
>
> > When dealing with obviousness, unlike novelty, it is permissible to make a 'mosaic" out of the relevant documents, but it must be a mosaic which can be put together by an contention unimaginative man with no inventive capacity.

98. Learned Counsel for the plaintiff also placed reliance on the order dated 23.08.2006 of the patent controller wherein it has been observed that 'the contention of the Opponents to prove the ground of obviousness by way of mosaic of citations in absence of detailed discussion is not acceptable as none of the documents is relevant to the said invention'.

99. In the decision of this Court in Billcare Ltd. v. Amartara Pvt. Ltd MANU/DE/0889/2007 : 2007 (34) PTC 419 (Del), it was observed in respect of mosaicing that it would not a be a defense of the defendant to show that the various integers were already known separately and the combination thereof cannot be patented as it would amount to mosaicing which is not permissible for determining the validity of the patent.

100. It was submitted by learned Counsel for defendant No. 2, on the other hand, that the documents on which the said defendant has relied do not amount to mosaicing and if a person skilled in the art were to read the US patents, he would be able to come out with the device in respect of which patent has been obtained by the plaintiff. Learned Counsel contended that by a reading of US patent no 5541059, any skilled person would be able to learn about a device comprising a base, absorbent pad, an immunofiltration membrane and top cover with a hole having a multiple coating on the membrane; use of a control dot with the help of colloidal gold, Protein A Conjugate and anti human IgG; coating of antigens on the test dots, and on further inquiries, about HCV SCAN and HCV Spot and thus come up with the device. It was also submitted that mosiacing can be a defense for prior publication but not for obviousness.

101. Insofar as the aspect of mosaicing is concerned, the legal position as set out in the judgment in Billcare Ltd. case (supra), it would not be a defense to show that the various components in the patented product are known separately. The combination of such components may be patentable.

102. Thus, it would be not be permissible for the defendant to rely on different documents disclosing different components/features of the product to plead that the product of the patent is known. None of the documents relied on by defendant No. 2 in the present matter really anticipate all the components of the plaintiff's product. Prior Working of the Device by the plaintiff

103. Learned Counsel for the plaintiff submitted that while defendant No. 2 has alleged that the plaintiff has worked the said device prior to the filing of the patent application based on the WHO report of January 2001, the WHO Report does not show that the said product was being manufactured prior to June 2000. The plaintiff claims that the said report relates to third generation Tri-Dot and it is stated that newer versions of the product would be covered in a subsequent report.

104. Learned Counsel further submitted that Section 30 of the said Act specifically exempts manufacturing and submission to government authorities from testing and evaluation from anticipation. The said provision is as under:

> 30. Anticipation by previous communication to Government. An invention claimed in a complete specification shall not be deemed to have been anticipated by reason only of the communication of the invention to the Government or to any person authorised by the Government to investigate the invention or its merits, or of anything done, in consequence of such a communication, for the purpose of the investigation.

105. The market approval for the commercial sale of the said product after testing in respect of the product of the plaintiff was given on 24.07.2000. The date of expiry of the batch evaluated of the said product in the WHO Report is stated to be Nov. 2001 and the Shelf life is mentioned as 12 months.

106. Insofar as the prior working of the device by the plaintiff is concerned, it may be noticed that while the report referred to by learned Counsel for defendant No. 2 of January 2001 mentions HCV Tri-dot as one of the products tested, the subsequent report of July 2001 mentions 4th Generation HCV Tri-dot as one of the products evaluated. The cumulative list of commercially available assays in the said report mentions both the HCV Tri-dot and 4th Generation HCV Tridot assays. Nothing has been placed on record to show that the two tests are similar or that there is no distinction between the same. The WHO report (January 2001) however, does not mention whether the 'HCV Tri-dot' is a third generation product.

107. Section 30 of the said Act exempts the communication of the invention either to the government or a person authorised by the Government for the investigation of the invention or its merits from challenge on the ground of anticipation.

108. The batch of HCV Tri-dot 4th Generation evaluated by the WHO evaluated was manufactured in November 2000 which is after the date of the patent application. There is no other material on record which shows that the 4th Generation HCV Tri-dot was being manufactured by the plaintiff prior to the date of the patent application. Thus, it cannot be said from the material on record that the plaintiff has worked the impugned product prior to the date of the application. Explanation of Product insufficient

109. It is also claimed that the plaintiff has not sufficiently explained its invention and a number of essential features of the invention including inter alia, the proportion of the mixture of antigens; the use of the protein A

colloidal gold conjugate; HCV peptides and anti-human IgG and the antigens used to produce the T1 and T2 dots and the advantage of using two dots; whether the claims are directed to a single assay or to a plurality of tests; whether the test and control dots are part of the immunofiltration membrane or the top of the device and whether the membrane may be completely coated with antigens has not been explained in the main claim/other claims of the patent specification. It is averred that claim 2 of the plaintiff's claim does not relate to the features of the device and that as the indicated buffers are composed of compounds commonly used in buffer formulations, and the making of buffers is routinely optimized for its intended use in the art, claim 2 'identifying the embodiments of the claimed device' is obvious and lacks inventive step. Defendant No. 2 has asserted that the claims of the plaintiff are inconsistent as while in one instance it has been stated that the entire filter is to be coated with the antigen mixture, another instance states that only two dots are coated with the said mixture. Defendant No. 2 thus contends that the claims of the plaintiff's specification are 'drawn' to any device that would meet the structural limitations of claim 1 and renders 100 per cent sensitivity and 98.9 per cent specificity. It is claimed that the plaintiff has provided a general set of antigens that may be used in the claimed device but has not provided any demonstration as to the specificity or sensitivity of the set of antigens. Also, the effect of applying a number of coatings to the immunofiltration material has not been indicated in the claims.

110. Learned Counsel for the plaintiff submitted that the patent specification of the plaintiff's product clearly mentions the prior art and also explains the invention in the said product. It has been mentioned therein that the extant kits do not provide the desired specificity and sensitivity and the importance of precise and accurate diagnosis has been highlighted. It is noted that the fourth generation assays were introduced to achieve 98.9. per cent results for specificity and 100 per cent results for sensitivity. The specification states that in order to achieve 100 per cent reliable results and overcome the drawback of false results, the fourth generation tests utilized a greater range of antigens from the subtype level of HCV Core antigens, HCV NS3 antigens, HCV NS4 antigens and HCV NS3 antigens regions of HCV genome. The exact composition of the dispensing agent and specific composition of the buffer solution has been stated in the specification and the specific quantities of colloidal gold and Protein A have been spelt out. The plaintiff thus claimed that the patent specifications sets out the minutest details for the manufacture of the said product and the same can be manufactured without much effort.

111. A reference was also made to the observations of the Assistant Patent Controller in the order dated 23.08.2006 wherein it was observed that the opponents had nowhere stated that they were unable to understand the invention and a person having knowledge of the cited document which was in public domain cannot make such allegations. The ground of insufficient and fair description was rejected in the said order.

112. A perusal of the complete specification of the plaintiff's patent shows that the same mentions the limitations of the assays of the first, second and third generations and the need for a fourth generation test. The implication of the appearance of dots at the control dot and the two test dots has been indicated. The specification also mentions the composition of the dispensing media, the buffer solution and the proportion of the antigens. The composition of the mixture of antigens has also been set out in the specification as noted herein-above. In respect of the anti human IgG, it has been stated in the specification that the same is coated on the membrane for the appearance of the dot at the quality in built control dot. It is stated that the protein A conjugate is added which binds the Fc portion of the HCV antibodies to give distinct colour near the test region. Again the HCV peptides and recombinant HCV antigens is poured over for the indication of the dots. The specification prima facie appears to have sufficiently explained the various components of the device and the impact of the said components/features. Gillette defense/ Fletcher Moulton defense

113. Learned Counsel for Defendant No. 2 placed reliance on the Gillette defense to submit that even if the product of defendant No. 2 falls within the four corners of the plaintiff's patent, it would not amount to infringement as the impugned product is based on prior US Patents. Reliance was placed on the judgment of R.C. Lahoti J (as he then was) in Shri Ravi Raj Gupta v. Acme Glass Mosaic Industries MANU/DE/0651/1994 : 56(1994)DLT673 . In this case, a reference was made to the Terrell on Patents (1982 Edn, pp.170-171) wherein the Gillette defense is summed up as under:

> 6.41 'Infringement not Novel' (Gillette defense)
>
> Since no relief could be obtained in respect of an invalid patent, if the defendant could prove that the act complained of was merely what was disclosed in a publication which could be relied on against the validity of the patent, without any substantial or patentable variation having been made, he had a good defense'

114. In Gillette Safety Razor Co. v. Anglo American Trading Co. Ltd, Vol. 30., Reports of Patent, Design and Trademark Cases p. 465, Lord Moulton observed as under:

> I am, Therefore, of opinion that in this case the Defendants' right to succeed can be established without an examination of the terms of the Specification of the plaintiffs' Letters Patent. I am aware that such a mode of deciding a Patent case is unusual, but from the point of view of the public it is important that this method of viewing their rights should not be overlooked. In practical life it is often the only safeguard to the manufacturer. It is impossible for an ordinary member of the public to keep watch on all the numerous Patents which are taken out and to ascertain the validity and scope of their claims. But he is entitled to feel secure if he knows that that which he is doing differs from that which has been done of old only in non-patentable variations, such as the substitution of mechanical equivalents or changes of material shape or size. The defense that 'the alleged infringement was not novel at the date of the plaintiff's Letters Patent' is a good defense in law, and it would sometimes obviate the great length and expense of Patent cases if the defendant could and would put forth his case in this form, and thus spare himself the trouble of demonstrating on which horn of the well-known dilemma the plaintiff had impaled himself, invalidity or non-infringement. '

115. A perusal of the decision in the cases of Ravi Raj Gupta and Gillette Safety Razor Co. cases (supra) shows that where it is shown that the act complained of is what was disclosed in a prior publication, which can be relied on against the validity of the patent, and no patentable or substantial alteration has been made in respect thereof, there is a good defense. As far as the documents relied on by defendant No. 2 are concerned,the same do not prima facie indicate that the product of the plaintiff is obvious or was anticipated. A perusal of the features of the impugned product of defendant No. 2 however shows that almost all the components of the said product save for minor differences in the number of dots and number of drops of samples and reagents added are identical with the plaintiffs product. They do not appear to be based on the US Patents or the products of third parties relied on by the plaintiff.

Defendant No. 2's Product Different

116. Defendant No. 2 submitted that its product is different from that of the plaintiff and in order point out the differences between the two products had relied on a chart filed by it. The said chart inter alias mentions the following dissimilarities:

Point

plaintiff's HCV TRI DOT

Defendants SINGLE HCV

System

THREE Dot system (ONE control dot and TWO test dots)

Two Dot System (ONE control dot and ONE test dot)

Homogeneous mixture of antigen coated on membrane

Three coating of different homogeneous mixtures of antigens i.e. Core, NS3, NS4 and NS5 are prepared and one coated for test dot T1 and another one coated for test dot T2. (TWO test dot)

One homogeneous mixture with the unique combination of antigens i.e. Core, NS3, NS4 and NS5 is prepared and coated on test dot T only. (ONE test dot) Test Procedure

1. Addition of 3 drops of wash buffer to the test device.

1. Addition of 2 drops of wash buffer to the test device.

2. Addition of 1 drop of Sample to the test device.

2. Addition of 2 drops of sample to the test device.

3. Addition of 5 drops of wash buffer to the test device.

3. Addition of 2 drops of wash buffer to the test device.

4. Addition of 2 drops of colloidal gold conjugate to the test device.

4. Addition of 2 drops of colloidal gold conjugate to the test device.

5. Addition of 5 drops of wash buffer to the test device.

5. Addition of 3 drops of wash buffer to the test device.

The entire procedure in addition of 16 drops of sample/reagents for results to outcome. The entire procedure is addition of 11 drops of sample/reagents for results to outcome. The concentration of reagents utilized for carrying out the assay is different in its own means. The adln the decision of this Court in Billcare Ltd. v. Amertara Pvt. Ltd MANU/DE/0889/2007 : 2007 (34) PTC 419 (Del), it was observed It was submitted by learned Counsel for defendant No. 2, on the other hand, that the documents on which the said defendant has relied do not amount to mosaicing and if a person skilled in the art were to read the US patents, he would be able to come out with the device in respect of which patent has been obtained by the plaintiff. Learned Counsel contended that by a reading of US patent no 5541059, any skilled person would be able to learn about a device comprising a base, absorbent pad, an immunofiltration membrane and top cover with a hole having a multiple coating on the membrane; use of a control dot with the help of colloidal gold, Protein A dition of reagents is standardized as per the above shown protocol and is unique to get the outcome from the clinical specimen. Any change or deviation in the quantity of these reagents shall give erroneous and ambiguous result.

Interpretation of positive result

Appearance of either of the two test dots or both the test dots along with the the control dot means reactive or positive result. Appearance of single test dot along with the control dot means reactive or positive result.

117. The plaintiff however, contended that the only difference between the products of the plaintiff and defendant No. 2 the presence of two test dots in the product of the plaintiff and only one test dot in the product of defendant No. 2 and the differences in the number of drops (of the buffer, sample and the colloidal gold conjugate) to be added set out in the chart submitted by defendant No. 2 cannot be said to be a differentiating factor in the two products. It was submitted that the presence of two dots only increases the capability to capture the antibody.

118. Insofar as this aspect is concerned, the chart submitted by defendant No. 2 points out the differences in the number of test dots (one in the device of defendant No. 2 as opposed to two dots in the device of the plaintiff), the number of coatings of the antigen mixture (three coatings of different homogeneous antigen mixture in on the test dots in the device of the plaintiff and one homogenous mixture with 'unique' combination of antigens coated in the device of defendant No. 2) and the number of drops of the sample, wash buffer and colloidal gold added at various stages of the said test. There is no sufficient Explanation forthcoming as to the effect of the differences in the number of drops of the wash buffer, sample and colloidal gold added during the various stages of the test nor as to the effect of the number of coatings and nature of mixture used or as to how these differences make the two devices or the process different. The components used in the two devices being the the base, membrane, control dots and test dot/s, buffer solution, Protein A Conjugate, the antigens used etc are similar. The specificity and sensitivity of the devices of the plaintiff and defendant No. 2 as per the WHO reports are also identical. Thus, a finding cannot be reached on the submissions made at this stage that the product of defendant No. 2 is distinct from that of the plaintiff. Conclusion

119. In view of the aforesaid, I am of the view that the plaintiff has made out a prima facie case. The documents placed on record by defendant No. 2 with respect to US Patent Nos.5,006,464 and 5,541,059 and the products of third parties do not anticipate the product of the plaintiff. There are differences in the products in respect of various features such as structure, antigens used, time period required for the test and some of the tests being Elisa test as opposed to the rapid test of the plaintiff as noticed herein above. The claim of defendant No. 2 that it was manufacturing the same product in pursuance to an agreement entered into with AccuDx can also not be accepted as the product mentioned in that agreement employs different antigens. The material on record does not show prima facie that any fourth generation product has been worked by the plaintiff prior to its patent application. The use of patent being limited, irretrievable prejudice will be caused to the plaintiff if interim orders are not granted. The balance of convenience lies in favor of the plaintiff as the plaintiff's patent cannot be permitted to be infringed.

120. Thus, the application of the plaintiff under Order 39 Rules 1 and 2 of the said Code is allowed and the defendants, their promoters, directors, servants, agents, dealers, distributors are retrained from manufacturing, selling, offering for sale or in any other manner dealing with the impugned product SIGNAL HCV or any other product vocative of the plaintiff's patent No. 194638. Parties are left to bear their own costs.

121. Needless to say, any observations made herein will not affect the final adjudication of the case.