

IN THE HIGH COURT OF JUDICATURE AT MADRAS

RESERVED ON: 19.02.2021

PRONOUNCED ON: 01.04.2021

CORAM:

THE HONOURABLE MR.JUSTICE C.V.KARTHIKEYAN

O.A.No. 1082 of 2019

And

A.No. 9645 of 2019

And

A.Nos. 282 & 1616 of 2020

IN

C.S.No. 684 of 2019

O.A.No. 1082 of 2019:

1. Centaur Pharmaceuticals Pvt. Ltd.,
Cetaur House, Shantinagar, Vakola,
Santacruz (E), Mumbai 400 055
Represented by its Directors through Ms. Rakhi Kadam
Authorised Signatory.
2. Kibow Biotech Inc.
4781, West Chester Pike, Newtown Square,
PA 19073, United States of America
Represented by its Directors through Ms. Rakhi Kadam

... Plaintiffs

Vs.

1. La Renon Health Care Pvt. Limited.,
207-208 ISCON Elegance, Circle P,
Pralhad Nagar Cross Roads, SG Highway,
Ahmedabad 380 015
Represented by its Directors.
2. Stanford Laboratories Pvt. Ltd.,
5th Floor, Caddie Commercial Tower,
Aerocity, New Delhi 110 037
Represented by its Directors. ... Defendants

PRAYER IN O.A.No.1082/2019: This application filed under Order XIV Rule 8 of O.S Rules read with Order XXXIX Rules 1 & 2 and Section 151 CPC, to grant interim injunction restraining the respondents, their directors, shareholders, men, agents, partner, associate, officer, representative, servant and all other persons acting on respondents' behalf or in their interest from in any manner infringing the applicants' Patent No. 224100 by in any manner using the Patent No. 224100, and/or manufacturing, marketing, selling products infringing Patent No. 224100 whether under the name 'Cudo', 'Cudo Forte' and/or 'Probigress' or otherwise.

A.No. 9645 of 2019:

1. La Renon Health Care Pvt. Limited.,
207-208 ISCON Elegance, Circle P,
Pralhad Nagar Cross Roads, SG Highway,
Ahmedabad 380 015
Represented by its Directors.

2. Stanford Laboratories Pvt. Ltd.,
5th Floor, Caddie Commercial Tower,
Aerocity, New Delhi 110 037
Represented by its Directors.

... Applicants/Respondents/Defendants

Vs.

1. Centaur Pharmaceuticals Pvt. Ltd.,
Cetaur House, Shantinagar, Vakola,
Santacruz (E), Mumbai 400 055
Represented by its Directors through Ms. Rakhi Kadam
Authorised Signatory.
2. Kibow Biotech Inc.
4781, West Chester Pike, Newtown Square,
PA 19073, United States of America
Represented by its Directors through Ms. Rakhi Kadam

... Respondents/Applicants/Plaintiffs

PRAYER IN O.A.No.9645/2019: This application filed under Order XIV Rule 8 of O.S Rules read with Order XXXIX Rule 4 of CPC, to vacate the order of interim injunction granted in O.A.No. 1082 of 2019 in C.S.No. 684 of 2019 dated November 29, 2019.

A.No. 1616 of 2020:

1. Centaur Pharmaceuticals Pvt. Ltd.,
Cetaur House, Shantinagar, Vakola,
Santacruz (E), Mumbai 400 055
Represented by its Directors through Ms. Rakhi Kadam
Authorised Signatory.

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2. Kibow Biotech Inc.
4781, West Chester Pike, Newtown Square,
PA 19073, United States of America
Represented by its Directors through Ms. Rakhi Kadam

... Applicants/Plaintiffs

Vs.

1. La Renon Health Care Pvt. Limited.,
207-208 ISCON Elegance, Circle P,
Prahlad Nagar Cross Roads, SG Highway,
Ahmedabad 380 015
Represented by its Directors.
 2. Stanford Laboratories Pvt. Ltd.,
5th Floor, Caddie Commercial Tower,
Aerocity, New Delhi 110 037
Represented by its Directors.
- ... Respondents/Defendants

PRAYER IN O.A.No.1082/2019: This application filed under Order XIV Rule 8 of O.S Rules read with Order XXXIX Rule 2A and Section 151 CPC, to punish the respondents, their directors, shareholders, men, agents, partner, associate, officer, representative, servant and all other persons acting on respondents' behalf or in their interest for disobedience of the Order of this Hon'ble Court dated 29.11.2019 in O.A.No. 1082 of 2019 as modified on 13.12.2019.

A.No. 282 of 2019:

1. Centaur Pharmaceuticals Pvt. Ltd.,
Cetaur House, Shantinagar, Vakola,
Santacruz (E), Mumbai 400 055
Represented by its Directors through Ms. Rakhi Kadam
Authorised Signatory.

2. Kibow Biotech Inc.
4781, West Chester Pike, Newtown Square,
PA 19073, United States of America
Represented by its Directors through Ms. Rakhi Kadam

... Plaintiffs

Vs.

1. La Renon Health Care Pvt. Limited.,
207-208 ISCON Elegance, Circle P,
Prahlad Nagar Cross Roads, SG Highway,
Ahmedabad 380 015
Represented by its Directors.

2. Stanford Laboratories Pvt. Ltd.,
5th Floor, Caddie Commercial Tower,
Aerocity, New Delhi 110 037
Represented by its Directors. ... Defendants

PRAYER IN A.No.282/2019: This application filed under Order XIV Rule 8 of O.S Rules read with Order XXXIX Rule 2A and Section 151 CPC, to punish the respondents, their directors, shareholders, men, agents, partner, associate, officer, representative, servant and all other persons acting on respondents' behalf or in their interest for disobedience of the order of this Hon'ble Court dated 29.11.2019 in O.A.No. 1082 of 2019.

For Applicants/Plaintiffs in
A.Nos. 1616 & 282/2019, O.A.No.
1082 of 2019 and Respondents/
plaintiffs in
A.No. 9645/2019 : Mr. Vineet Subramani

For 1st Defendant in
A.Nos. 1616 & 282/2019,
O.A.No. 1082 of 2019 and
1st Applicant/
1st Defendant in A.No.
9645/2019 : Mr. P.H.Arvind Pandian
Senior Counsel
Assisted and Instructed by
Mr.T.Saikrishnan,
Mr. Adarsh Ramanujan &
Ms.Bitika Sharma

For 2nd Defendant in
A.Nos. 1616 & 282/2019,
O.A.No. 1082 of 2019 and
2nd Applicant/
2nd Defendant in A.No.
9645/2019 : Mr.Satish Parasaran
Senior Counsel
Assisted and Instructed by
Mr.T.Saikrishnan,
Mr. Adarsh Ramanujan &
Ms.Bitika Sharma

COMMON ORDER

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O.A.No. 1082 of 2019 had been filed by the plaintiff in the suit seeking an order of interim injunction restraining the defendants or anybody acting under them from infringing Patent No. 224100 in any

manner by using the Patent or manufacturing, marketing or selling products, infringing the Patent under the names Cudo', 'Cudo Forte' and / or 'Probigress'.

2. A.No. 9645 of 2019 had been filed by the defendants seeking to vacate the order of interim injunction granted on 29.11.2019.

3. The first plaintiff, Centaur Pharmaceuticals Pvt., Ltd., is a Company incorporated under the provisions of the Companies Act 1956. The second plaintiff Kibow Biotech Inc., is an international Biotech Company with address in United States of America. The first plaintiff is an Indian Pharmaceuticals Company and is an exclusive licensee in India and certain other countries of the second plaintiff with respect to Patent No. 224100.

4. The plaintiffs have filed the suit taking advantage of Sections 48, 68, 69, 104, 108 and 109 of the Patents Act, 1970 seeking a Judgment and Decree against the defendants, La Renon Health Care Pvt. Ltd., and Stanford Laboratories Pvt. Ltd., in the nature of a permanent injunction

restraining the defendants or anybody acting under them from infringing the Plaintiffs' Patent No.224100 or using the same or manufacturing or marketing products infringing the said Patent under the name 'Cudo', 'Cudo Forte' and / or 'Probigress' and also for a direction to take accounts of the defendants with respect to the infringing use of Patent No. 224100 and with respect to marketing and sales of the infringing products and for consequential reliefs of seizure and forfeiture and destruction of the products used by the defendants and for damages of Rs.1,00,00,000/- and for costs of the suit.

5. It is claimed that the second plaintiff was granted Patent No. 224100 on 29.09.2008 with 10 Claims for its invention to augment kidney function. They are entitled to manufacture, market, sell, license and use the product in India to the exclusion of everybody else. It is claimed that the invention has been granted patent internationally across all major jurisdictions.

6. The Patent is for an invention that assists or augments kidney function by the breakdown of uremic/nitrogenous toxins in the colon prior

to the transfer of the toxins to the kidneys. It is claimed that this would reduce stress on the kidney by reducing the amount of toxins that are passed on. This is important because the dissolved food is transmitted to the kidneys by the blood vessels for purification. The kidneys act as a filter to breakdown the toxins. If a person has a kidney disease or a weak kidney, then, the normal treatment is dialysis. The second plaintiff, by virtue of the Patent has invented a process to breakdown the toxins in the gut itself before the dissolved foods are passed to the kidneys. This is achieved through the delivery of specially chosen beneficial bacteria to a specific location in the gut in sufficient quantities enabling creation of a large bacterial colony which can breakdown the toxins even before the dissolved food is passed to the kidney.

7. Naturally, the entire process would involve in identifying the particular bacteria which can perform the task of braking down the toxins even before the dissolved food passes to the kidney. This bacteria must also have a beneficial effect by itself. It should not damage either the gut or any other internal organ. This also necessitated identifying a probiotic bacteria. The second plaintiff selected the strains of the probiotic bacteria,

Streptococcus Thermophilus. The next aspect was to identify the quantity of this particular bacteria to be delivered by a capsule so that they can reproduce and form a colony to breakdown the toxins. It also required that the bacteria should survive and therefore, specific non-living, non-digestible food ingredients like, specified oils, minerals, vitamins, will also have to be added along with the bacteria in the capsule. They must also be delivered to the correct location in the gut. If the capsule dissolves in the stomach then the acids in the stomach which are very strong would dissolve all the materials and therefore, the capsules must also have a strong enough enteric coating which would survive the digestive acids. Thereafter, the bacteria should be released at that particular place in the bowel which would give the maximum effect.

8. It has been claimed in the plaint that each one of these individual elements should also have marginal or nil effect on the body. There must not be, in simple terms, any side effect. With these specifications, the second plaintiff was granted Patent with 10 Claims.

9. The plaintiffs are aggrieved by the manufacturing and marketing of products under the name 'Cudo', 'Cudo Forte' and / or 'Probigress' by the defendants, which products, the plaintiffs claim have directly infringed the Patent of the plaintiffs. It must be pointed out that the brand name of the plaintiffs' product Renadyil.

10. The second defendant is the manufacturer and the first defendant is the marketer. It is claimed that they have infringed the Patent of the plaintiff. Along with the plaint, the plaintiffs have also filed a copy of the patent, the copy of the license agreement, a copy of the product brochures of the product of the plaintiffs. They have also produced the brochures of the product of the defendants.

11. It is claimed that the defendants, in their infringing products, are using the same strain of probiotic bacterium, Streptococcus Thermophilus, also contained in a capsule which would also dissolve in the same bowel area as the plaintiffs' product with the same purpose. It is claimed that though the defendants may vary the quantity of probiotic bacteria and mix it with other probiotics, still it would be an infringement

of the Patent of the plaintiffs. The plaintiffs have also filed along with the plaint, a laboratory analysis report, according, to which the products of the defendants were claimed to be less effective. It had been claimed that the defendants are offering low quality infringing products which not only impinges on the plaintiffs' exclusive rights but also causes distress of market confidence and also economic loss to the plaintiffs.

12. The second plaintiff had instituted C.S.No. 498 of 2011 but the leave granted was revoked on a technical ground. Original Side Appeals were dismissed for default. The plaintiffs claimed that the present suit is not barred.

13. However, after the said suit was instituted, the first defendant had initiated proceedings before the Intellectual Property Appellate Board to revoke the patent of the plaintiffs. That was dismissed and the validity of the Patent was upheld.

14. The first defendant filed W.P.No. 1219 of 2014 and a Division Bench of this Court dismissed the Writ Petition on 10.01.2019.

15. It had been further stated that the plaintiffs found that the infringing products of the defendants were being sold at various locations within the jurisdiction of this Court. It had been claimed that these actions of the defendants are causing loss to the plaintiffs.

16. The plaintiffs also claimed that they have effected sales from September 2018 till 31.03.2019 to an amount of Rs.2,13,61,622/- and from April 2019 to October 2019 to an amount of Rs.3,31,19,231/-. It had been stated that the Patent has commercial value. It had been stated that the plaintiffs had spent more than 20 years in developing the invention and in securing the Patent in India and other countries and in building a market for their product Renadyil. It had been claimed that the defendants are infringing the Patent of the plaintiffs deliberately. It is under these circumstances that the suit had been filed seeking the reliefs as stated above.

17. Along with the suit the plaintiffs also filed the application now under consideration, O.A.No. 1082 of 2019. This application came up for

consideration before a learned Single Judge of this Court and on 29.11.2019 an ex parte order of interim injunction till 13.12.2019 was granted. The defendants filed A.No. 9645 of 2019 to vacate the said order of ex parte injunction. It must also be mentioned that the matter was next listed on 13.12.2019 and the learned counsel for the plaintiffs stated that inspite of the grant of interim injunction, the defendants were continuing to violate the said order by not withdrawing the offending products from the market. Sales bills were also produced. Another learned Single Judge of this Court modified the interim order to the effect that the defendants shall sell the stock in hand the quantity of which were specifically mentioned with respect to 'Cudo Forte' and 'Probigress'. The defendants were also directed to maintain accounts for the said sales and submit them to the Court on the next hearing date on 14.02.2020. The defendants claim that they had submitted accounts as directed. However, the learned counsel for the plaintiffs stated that the plaintiffs had filed O.S.A.No. 35 of 2020. That was dismissed on 29.01.2020 with a direction to this Court to take up both the application for injunction and the application to vacate the injunction and hear them. The learned Single Judge in the course of the same order dated 14.02.2020 had also observed that in the meanwhile A.No. 282 of

2020 had been filed by the plaintiffs under Order 39 Rule 2-A CPC and also noted that the learned counsel for the plaintiffs had insisted that the Court should take up that particular application and that he was not ready to argue O.A.No. 1082 of 2020. The learned counsel for the defendants however stated that the applications with respect to injunction should be heard.

18. In view of these divergent representation, the learned Single Judge stated that the order passed on 29.11.2019 granting interim injunction shall be kept in abeyance till clarification is received from the Division Bench with respect to the orders passed in O.S.A.No. 35 of 2020.

19. The matter came up again on 01.07.2020 and on 06.07.2020. On 06.07.2020, it was brought to the knowledge of this Court that by order dated 28.02.2020, the Division Bench had observed that all the pending applications, namely, O.A.No. 1082 of 2019, A.No. 9645 of 2019, A.No. 282 of 2020 and A.No. 1616 of 2020 be heard together. The learned counsels were requested to complete pleadings and also exchange the same in advance and to advance arguments on 29.07.2020 at 2.15 p.m. On

29.07.2020 the matter was heard through video conference and issues were raised with respect to the documents filed which were also clarified.

20. The learned counsel for the plaintiffs then stated that he would get instructions from the plaintiffs whether arguments could be advanced through video conference. The matter was adjourned to 06.08.2020. On 06.08.2020, the learned counsel for the plaintiffs stated that the applications should be heard only after the lock down period was over. This representation was seriously objected by the learned Senior Counsels for the defendant.

21. An affidavit was directed to be filed by the plaintiffs in this regard. The matter was then posted to 27.08.2020. On 27.08.2020, an affidavit was filed by the Director of the first plaintiff who also claimed to be the Constituted Attorney of the second plaintiff. It was stated that hearing of the case may be deferred till regular hearings commenced. A clarification was sought on the status of the interim orders. It was made clear that no interim order had been granted either on that date, 27.08.2020 or on the preceding hearing date by this Court. The matter was then

reposted to 21.09.2020. The matter was then posted to 25.01.2021 at 3.30 p.m for advancing arguments through virtual hearing.

22. It was only thereafter that Mr. Vineet Subramani, learned Counsel for the plaintiffs, Mr.P.H.Arvind Pandian, learned Senior Counsel for the first defendant and the learned Senior Counsel Mr. Satish Pararasan, for the second defendant commenced to advance arguments.

23. In the affidavit filed in support of A.No. 1082 of 2019, the averments made in the plaint were reiterated by the deponent of the affidavit. The averments made in the plaint had already been reduced above.

24. In the affidavit filed in support of A.No. 9645 of 2019 which as stated above was an application seeking to vacate the order of interim injunction granted in O.A.No. 1082 of 2019 on 29.11.2019, it had been first stated that the Patent of the plaintiffs is invalid in law. It had been stated that the plaintiffs have not come to Court with clean hands, since they have expanded the scope of their patent to encompass the defendants' products and thereby give a colour as if the defendants are infringing Patent

No.224100. It had been pointed out that in the said patent, the count of streptococcus thermophilus was limited to be within a range of 5 billion to 20 billion colony forming units. It had been stated that however, the count of streptococcus thermophilus in 'Cudo Forte' was beyond 20 billion colony forming units. It was actually over and above 30 billion which fact is apparent from the brochure of the product. In the brochure, it had been given that the composition was streptococcus thermophilus, lactobacillus acidophilus and bifidobacterium longum and the count was 90 billion colony forming units. It had been stated that the products of the defendants are a composition of the above three probiotic bacterium whereas the plaintiffs' product is limited to only one probiotic bacteria, namely streptococcus thermophilus. It had been therefore stated that with respect to each one of the bacterial species the colony forming unit was greater than 30.0 billion. It had been stated that this fact has also been established by Laboratory analysis and the reports have also been filed. It had been stated that the reliance cannot be placed on the Laboratories reports filed by the plaintiffs.

25. It had been stated that the infringing product should be

mapped against the Patent claims and not against the plaintiffs' product. The test analysis reports relied on by the plaintiffs were seriously questioned in the affidavit. It was also pointed out that the defendants' products used a different strain of streptococcus thermophilus, namely DY205 as opposed to the strains in the suit patent, namely, KB4, KB19 OR KB25. It had also been stated that the other ingredients said to have been selected, namely, vitamins, minerals, carbohydrates, proteins and fats, which are said to be essential ingredients for the plaintiffs' product are not found in the defendants' product. It had therefore stated that the defendants' product do not come within the claims of the suit patent.

26. With respect to the averment that the challenge by the defendants before the Intellectual Property Appellate Board to the grant of Patent to the plaintiffs and the subsequent Writ Petition had both been dismissed, it had been stated that there is no presumption of validity of a Patent and that grant of Patent can still be challenged.

27. With respect to balance of convenience, it had been stated that the products of the defendants have been in the market since 2012 much

prior to the actual sales of the product Renadyil of the plaintiffs which entered the market only in the year 2018. It had been stated that therefore the balance of convenience is in favour of the defendants since from the year of grant of the Patent in the year 2008 till 2018, the year the plaintiffs have not worked the Patent. It had been stated that the defendants have been catering to the needs of more than 10,000 patients since 2012.

28. It had also been stated that the Claim No.1 of the suit Patent was substantially different from the claim as filed before the Patent Office in 2008. It had been stated that originally the probiotic bacteria included several bacterium and when the Patent Office returned the same stating that there was no novelty, the plaintiff had limited the probiotic bacterium to only streptococcus thermophilus. It had been claimed that the plaintiff cannot now claim infringement if the defendants uses the bacteria which had been left out consequent to objections by the Registry.

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29. It had been further stated that the defendants' product / drug, 'Cudo Forte' was manufactured and marketed under the license from the

Drug Controller under the Drugs and Cosmetics Act and Rules 1945, where the plaintiffs' product is a nutraceutical covered under the Food Safety and Standards Act, 2006. The defendants claimed that the order of interim injunction should be vacated.

30. Heard arguments advanced by Mr. Vineet Subramani, learned Counsel for the plaintiff and Mr. P.H. Arvind Pandian, learned Senior Counsel for the first defendant and Mr. Satish Parasaran, learned Senior Counsel for the second defendant.

31. I have carefully considered the materials available on record.

32. The plaintiffs have approached the Court under Sections 48, 68, 69, 104, 108 and 109 of the Patents Act, 1970.

33. Section 48 relates to the rights of patentees. It is as follows:-

“48 Rights of patentees. -Subject to the other provisions contained in this Act and the

conditions specified in section 47, a patent granted under this Act shall confer upon the patentee-

(a) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India

(b) where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India ”

34. Section 47 relates to the conditions to which grant of patents are subjected to. Section 47 is as follows:-

“47 Grant of patents to be subject to certain conditions. -The grant of a patent

under this Act shall be subject to the condition that-

(1) any machine, apparatus or other article in respect of which the patent is granted or any article made by using a process in respect of which the patent is granted, may be imported or made by or on behalf of the Government for the purpose merely of its own use;

(2) any process in respect of which the patent is granted may be used by or on behalf of the Government for the purpose merely of its own use;

(3) any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils; and

(4) in the case of a patent in respect of any medicine or drug, the medicine or

drug may be imported by the Government for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government or any other dispensary, hospital or other medical institution which the Central Government may, having regard to the public service that such dispensary, hospital or medical institution renders, specify in this behalf by notification in the Official Gazette. ”

35. Section 68 of the Patents Act relates to assignments. It is as follows:-

“68 Assignments, etc., not to be valid unless in writing and duly executed. —An assignment of a patent or of a share in a patent, a mortgage, licence or the creation of any other interest in a patent shall not be valid unless the same were in writing and the agreement between the parties concerned is reduced to the form of a document embodying all the terms and conditions governing their rights and obligations and duly

executed ”.

36. Section 69 of the Patents Act relates to registration of assignments, transmissions, etc.,. It is as follows:-

“69 Registration of assignments, transmissions, etc. -

(1) Where any person becomes entitled by assignment, transmission or operation of law to a patent or to a share in a patent or becomes entitled as a mortgagee, licensee or otherwise to any other interest in a patent, he shall apply in writing in the prescribed manner to the Controller for the registration of his title or, as the case may be, of notice of his interest in the register.

(2) Without prejudice to the provisions of sub-section (1), an application for the registration of the title of any person becoming entitled by assignment to a patent or a share in a patent or becoming entitled by virtue of a mortgage, licence or other instrument to any other interest in a patent may be made in the prescribed manner by the assignor, mortgagor,

licensor or other party to that instrument, as the case may be. ”

(3) Where an application is made under this section for the registration of the title of any person the Controller shall, upon proof of title of his satisfaction,-

(a) where that person is entitled to a patent or a share in a patent, register him in the register as proprietor or co-proprietor of the patent, and enter in the register particulars of the instrument or even by which he derives title; or

(b) where that person is entitled to any other interest in the patent, enter in the register notice of his interest, with particulars of the instrument, if any, creating it:

Provided that if there is any dispute between the parties whether the assignment, mortgage, licence, transmission, operation of law or any other such transaction has validly vested in such person a title to the patent or any share or interest therein, the Controller may refuse to take any action under clause (a) or, as the case may be, under clause (b) until the rights of the parties have been determined by a

competent court.

(4) There shall be supplied to the Controller in the prescribed manner for being filed in the patent office copies of all agreements, licences and other documents affecting the title to any patent or any licence thereunder authenticated in the prescribed manner and also such other documents as may be prescribed relevant to the subject-matter: Provided that in the case of a licence granted under a patent, the Controller shall, if so requested by the patentee or licensee, take steps for securing that the terms of the licence are not disclosed to any person except under the order of a court.

(5) Except for the purposes of an application under sub-section (1) or of an application to rectify the register, a document in respect of which no entry has been made in the register under sub-section (3) shall not be admitted by the Controller or by any court as evidence of the title of any person to a patent or to a share or interest therein unless the Controller or the court, for reasons to be recorded in writing, otherwise directs.”

37. Section 104 relates to the jurisdiction to the Court. It is as follows:-

“104 Jurisdiction. -No suit for a declaration under section 105 or for any relief under section 106 or for infringement of a patent shall be instituted in any court inferior to a district court having jurisdiction to try the suit:

Provided that where a counter-claim for revocation of the patent is made by the defendant, the suit, along with the counter-claim, shall be transferred to the High Court for decision.”

38. Section 108 deals with the reliefs that can be granted in suits for infringement. It is as follows:-

“108 Reliefs in suit for infringement. - ”

(1) *The reliefs which a court may grant in any suit for infringement include an injunction (subject to such terms, if any, as the court thinks fit) and, at the option of the plaintiff, either damages or an account of profits.*

(2) The court may also order that the goods which are found to be infringing and materials and implements, the predominant use of which is in the creation of infringing goods shall be seized, forfeited or destroyed, as the court deems fit under the circumstances of the case without payment of any compensation.] “

39. Section 109 relates to the right of the exclusive licensee to take proceedings against infringement. It is as follows:-

“109 *Right of exclusive licensee to take proceedings against infringement. -*

(1) The holder of an exclusive licence shall have the like right as the patentee to institute a suit in respect of any infringement of the patent committed after the date of the licence, and in awarding damages or an account of profits or granting any other relief in any such suit the court shall take into consideration any loss suffered or likely to be suffered by the exclusive licensee as such or, as the case may be, the

profits earned by means of the infringement so far as it constitutes an infringement of the rights of the exclusive licensee as such.

(2) In any suit for infringement of a patent by the holder of an exclusive licence under sub-section (1), the patentee shall, unless he has joined as a plaintiff in the suit, be added as a defendant, but a patentee so added as defendant shall not be liable for any costs unless he enters an appearance and takes part in the proceedings. ”

40. The second plaintiff Kibow Buotech Inc. is an international biotechnology company. It is claimed that they specialise in the development of scientifically formulated and clinically tested probiotic dietary supplements with a focus on renal disease and gut health. In simple terms, they specialise in developing bacteria which have a beneficial effect as a dietary supplement with a focus on renal (kidney) related disease and gut health.

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41. The first plaintiff is an Indian Pharmaceuticals Company and it is claimed that it is an exclusive licensee in India and in certain other countries with respect to Patent No. 224100. The License Agreement dated

06.03.2018 had been filed as document to the plaint. This fact has not been seriously disputed by the defendants. In effect, it would mean that both the plaintiffs will have a common cause of action if they come across infringement of the Patent No.224100. They now complain that the defendants have infringed the said Patent. The second defendant is said to be manufacturing the infringing products for and on behalf of the first defendant, who markets the said products. The second defendant is said to be a subsidiary of the first defendant. It is for that reason that both have been impleaded as defendants in the suit.

42. The plaintiffs claim that in line with their specialisation in developing probiotic dietary supplements, they had, after extensive experimentation and testing, identified strains of probiotic bacteria streptococcus thermophilus as being a supplement in the breakdown of toxins which are present in the food diets and this breakdown would reduce the strain on the kidneys . It is claimed that this selection and identification of probiotic bacteria itself is a critical part of the patent. This particular probiotic bacteria had been selected from the numerous and infinite probiotic bacterium available. The plaintiffs have further developed the

manner in which the streptococcus thermophilus can be beneficially used. It must be kept in mind that their research was focused on renal disease and gut health. To reduce the strain of kidneys particularly if they are affected, the plaintiffs have found that if a particular strain of streptococcus thermophilus is transmitted in a capsule with strong enteric coating along with nutrients to serve as food for survival, and if they are placed in a particular region in the gut, they would assist in the breakdown of the toxins which are present in the foods taken by any normal human being and this breakdown of toxins would reduce the strain on the kidneys. It would also augment the functioning of the kidneys. In effect, the plaintiffs have invented a particular medicine, for which they have given the brand name Renadyil, which would reduce the strain on the kidneys and would be of assistance to those who suffer from kidney related diseases for which the normal treatment is dialysis which is not only expensive but also time consuming.

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43. The plaintiffs have been granted the following claims:-

“1. A composition for augmenting

kidney function in a subject comprising at least one probiotic bacterium wherein said probiotic bacterium selected from streptococcus thermophiles at about 5 billion to about 20 billion colony forming units of said at least one probiotic bacterium other ingredient being selected from vitamin, mineral, carbohydrate, protein and fats.

(2) The composition of claim 1, wherein the Streptococcus thermophiles is strain KB4, KB19, or KB25.

(3) The composition if claim 1, further comprising at least one vitamin component and at least one mineral component;

(4) The composition of claim 1, further comprising an enteric coating;

(5) The composition of claim 1, wherein said composition is a nutritional food or nutritional food product further comprising at least one carbohydrate, at least one fat ingredient, and atleast one protein ingredient;

(6) The composition of claim 5 wherein the carbohydrate ingredient is dextrose, sucrose, fructose, lactose, maltose, galactose, sugar

alcohols, such as sorbitol, mannitol and xylitol, invert sugar syrups, brown sugar, corn syrup, corn syrup solids, honey, molasses, brown sugar, maple syrup, fruit juices, stevia, or an artificial sweetener;

(7) The composition of claim 5, wherein the fat ingredient is olive oil, canola oil, palm oil, coconut oil, sunflower oil, peanut oil, vegetable oil, lecithin, fish oil, cotton seed oil, soybean oil, lard, monoglycerides, diglycerides, butter, margarine, and other animal, vegetable and marine fats or milk fats;

(8) The composition of claim 5, wherein the protein ingredient is cereal proteins, milk proteins, egg proteins, animal proteins, vegetable proteins, whey proteins, bean proteins, lactalbumin-casein co-precipitate, calcium caseinate, sodium caseinate, purified or refined grades of casein and soy proteins, or peanuts;

(9) The composition of claim 5, further comprising at least one vitamin component, at least one mineral component, and at least one prebiotic; and

(10) The composition of claim 9, wherein the prebiotic ingredient is a fructo-oligosaccharide, a galacto – oligosaccharide, a soy – oligosaccharide, a xylo-oligosaccharide, an ismalto – oligosaccharide, jerusalem artichoke flour, rolled oats, banana fiber, a pectin and pectic polysaccharide, a mannan, a pentosan, a beta-glucan a rabinan or a galactan. ”

44. In effect, if the above claims are read as a whole, it would indicate that (1) streptococcus thermophilus with the strain KB4, KB19, or KB25, with (2) about 5 billion to about 20 billion colony forming units, together with (3) other ingredients to be selected from vitamins, minerals, carbohydrates, proteins and fats which would indicate that there is atleast one vitamin component and one mineral component, (4) are enclosed in a capsule with a strong enteric coating, constituting a nutritional food which would also include atleast one carbohydrate atleast one fat ingredient and atleast one protein ingredient (5) is consumed and (6) is released in a particular area in the gut, then it would (7) breakdown the uremic/nitrogenous in the gut itself before the dissolved foods are passed to

the kidneys.

45. The sum and substance of Patent No. 224100 of the plaintiffs is as above.

46. It is claimed by the defendants that the product of the plaintiffs and their products are totally different. In this connection, comparison had been drawn to the fact that the product 'Cudo Forte' not only contains streptococcus thermophilus but also contains two other bacterium, namely, lactobacillus acidophilus and bifidobacterium longum. It is also pointed out that the colony forming units, which are restricted between 5 billion and 20 billion in the streptococcus thermophilus used by the plaintiff is about 30 billion and more in the streptococcus thermophilus used by the defendants. Apart from that, the other two bacteria also have colony forming units and as a whole, the three bacterium contain 90 billion colony forming units. It had been further pointed out that there should be no comparison between the plaintiffs' products and the defendants' products but rather a comparison between the defendants' products and the claims given in the Patent of the plaintiffs' products.

47. It had been very strongly argued that streptococcus thermophilus is a commonly available bacteria and therefore the claim of the plaintiffs that they had identified the same after hard research has to be rejected since there can be no claim for Patent in a commonly available product. In this connection, reliance had been placed on Section 3(c), Section 3(e) and Section 3(j) of the Patents Act 1970.

48. Section 3 stipulates what are not inventions under the Act.

49. Section 3(c), (e) & (j) are as follows:-

“3 What are not inventions. -The following are not inventions within the meaning of this Act,-

.....

.....

(c) the mere discovery of a scientific principle or the formulation of an abstract theory [or discovery of any living thing or non-living substances occurring in nature];

.....

(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

....

(j) plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;

..... ”

50. Placing strong reliance on the above provisions, it is the contention of the learned Senior Counsels on behalf of the defendants that bacteria is a living thing and discovery of a scientific formulation of a living thing cannot be categorised as an invention under Section 3(c) of the Act. It had also been stated that a mere mixture of various components, in this case of vitamins, minerals, carbohydrates, fats and proteins would again not be an invention in accordance with Section 3(e) and it had been further stated that discovery of a living thing occurring in nature cannot be claimed to be an invention by the defendants.

51. Reliance had also been placed on Section 64(1)(d) of the Patent Act. Section 64 relates to revocation of Patents and one of the grounds for revocation of a patent is that the subject of any claim of the complete specification is not an invention within the meaning of the Act.

52. Section 64(1)(d) is as follows:-

“64 Revocation of patents. -

(1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, 149 [be revoked on a petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High Court] on any of the following grounds that is to say-

.....
(d) that the subject of any claim of the complete specification is not an invention within the meaning of this Act;

..... ”

53. Drawing attention to this provision and to Sections 3(c) and 3(e), it had been very strongly argued that the plaintiffs can never claim to have invented anything new. They have only identified the bacteria which is a living thing already present in nature and have added it with vitamins, minerals, carbohydrates, fats and proteins, which are also obviously already available and have created only an admixture and it had therefore been stated that the plaintiffs can never claim privilege in inventing a new product requiring protection from infringement.

54. Unfortunately, a careful reading of the documents presented show that these are the very grounds which had been taken by the defendants in their application before the Intellectual Property Appellate Board when they sought revocation of the Patent. Their challenge was unsuccessful. They filed a Writ Petition before this Court. It came up before a Division Bench and again their challenge was rejected. During the course of arguments, it had been very fairly stated by the learned counsel on record for the defendants that they had also filed a Special Leave Petition before the Hon'ble Supreme Court wherein also they had suffered an order of dismissal. Therefore, at this stage, while examining whether the

plaintiffs have made out a prima facie case for grant of protection, it may not be proper on the part of this Court to examine whether the plaintiffs' product can be categorised as an invention and whether streptococcus thermophilus will pass the test of being discovered after research, though already available, and whether usage of ingredients as food, namely, carbohydrates, proteins, minerals, vitamins and fats would negate it from being categorised as an invention or whether it could be categorised as a common health preparation much like the preparation in any house hold kitchen.

55. I am afraid it could not be so categorised as a mixture of readily available products.

56. There are numerous bacterium available. Some of them are beneficial some of them are not beneficial. To identify a beneficial bacteria, namely, a probiotic bacteria from among numerous choices and thereafter, determining the particular strain of such bacteria and thereafter determining the required colony forming units requires research and further research. It is not a discovery made over night.

57. One specific bacteria had been identified. This would mean that numerous others would have been tested and rejected.

58. The further contention fact that there are differences between the defendants' product and the claims made and granted is an issue which will have to be decided during only the course of trial.

59. Both sides have produced Laboratory reports. This Court at this stage of the proceedings cannot rely on one report and reject the other as being of no value. Both the reports will have to be proved in the manner known to law.

60. The significant crucial fact is determining who as between the plaintiffs and defendants, first identified this particular bacteria, Streptococcus thermophilus in the first instance. The defendants have not produced any materials to show that they had identified the specific bacteria earlier to the plaintiffs' discovery of the said bacteria.

61. There is however one further factor to be considered namely, the defendants' contention that the plaintiffs have not been in the market till the year 2018 and the defendants had substantially captured the market by that time. The explanation given by the plaintiffs is that they were having a presence in India through online marketing and later in the year 2018 have entered the market by across the sales counter through prescriptions because the first plaintiff had been appointed as an exclusive licensee of the second plaintiff. With respect to the sales turn over of both the plaintiffs or the defendants, evidence is required to substantiate them. It would be highly inappropriate to rely on statements made in affidavit when they should be proved in the manner known to law.

62. Reliance had been made by the learned Senior Counsels for the defendants on Section 13(4) read with Section 107 of the Patent Act, 1970.

Section 13 (4) is as follows:-

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“13. Search for anticipation by previous publication and by prior claim.-

(4) The examination and investigations

required under section 12 and this section shall not be deemed in any way to warrant the validity of any patent, and no liability shall be incurred by the Central Government or any officer thereof by reason of, or in connection with, any such examination or investigation or any report or other proceedings consequent thereon.

Section 107 is as follows:-

107 Defences, etc ., in suits for infringement. -

(1) In any suit for infringement of a patent every ground on which it may be revoked under section 64 shall be available as a ground for defence.

(2) In any suit for infringement of a patent by the making, using or importation of any machine, apparatus of other article or by the using of any process or by the importation, use or distribution or any medicine or drug, it shall be a ground for defence that such making, using, importation or distribution is in accordance with any one or more of the conditions specified in section 47.”

63. If the defendants claimed that they are entitled to the grounds available under Section 107 then, they would have to await commencement of trial and to lead evidence. That is the crux of the issue. The plaintiffs have a Patent granted lawfully, recognised and grant upheld by the Intellectual Property Appellant Board which recognition has been upheld by the Division Bench of this Court and which recognition has also been affirmed by the Hon'ble Supreme Court. I hold that the defendants will have to await trial.

64. It had been stated by the learned Senior Counsels for the defendants that the particular strain of streptococcus thermophilus used in the products of the defendants is DY205 and not KB4, KB19 OR KB25 as found in the Streptococcus thermophilus used by the plaintiffs. Even before entering into a discussion on the differing strains, the very fact that streptococcus thermophilus had been used by the defendants itself shows that the defendants have followed the discovery made by the plaintiffs centering on streptococcus thermophilus as a probiotic bacteria which can be used for the specific purpose of alleviating the pain of those, who suffer

from kidney related disease. The defendants will have to explain as to how they centered on streptococcus thermophilus. Thereafter, they can justify that their products have a different strain and therefore are totally different. The products of the plaintiffs and the products of the defendants do the same function. Their base is streptococcus thermophilus. This probiotic bacteria was zeroed in by the plaintiffs in the first instance. Therefore, the pendulum swings in favour of the plaintiffs. The other issues can be taken up only during trial. The defendants must realise that going through the trial process is the proper procedure to negate the claim of the plaintiffs.

65. Both the learned counsel for the plaintiffs and the learned Senior Counsels for the defendants relied on *F.Hoffman La Roche Ltd., & Anr. V. Cipla Ltd.*, reported in (2015) 225 DLT 391 (DB).

66. Paragraph No. 68 is as follows:-

“68. In the case of (52 F.3d 967 also 517 US 370) *Herbert Markman Vs. Westview the Courts held that an infringement analysis entails*

two steps:-

(a) First step is to determine the meaning and scope of the patent claims asserted to be infringed.

(b) Second step is to compare the properly construed claim with the device accused of infringing.

(xv) The parts of the claim include its preamble, transition phrase and the body. The transition phrase' includes terms like:-

- (a) Comprising;
- (b) Consisting;
- (c) Consisting essentially of;
- (d) Having;
- (e) Wherein;
- (f) Characterised by;

Of these terms some are open ended, such as 'comprising' which means that if the claim contains three elements 'A', 'B' and 'C' it would still be an infringement for someone to add a fourth element 'D'.

Further some terms are close ended such as 'consisting of', i.e. in a claim of three elements, 'A', 'B' and 'C' a defendant would infringe if he

has all three elements. In case the defendant adds a fourth element 'D' he would escape infringement.

(xvi) Each claim has a priority date so that in a group of claims in a specification you could have multiple priority dates. This only means that if a patent application with certain priority date and claims was followed by another application with different claims and different priority dates, then if they were consolidated or cognate with another application, each claim would retain the original priority date [Section 11(1)].”

67. It must be pointed out that the Division Bench while laying down the principles had the benefit of documents, which had passed tests of admissibility and relevancy and had been proved in the manner known to law. Here that is not the case. The Division Bench also had the benefit of the witnesses speaking about the facts stated. Again that is not the case herein. Even otherwise, the Division Bench had clearly stated that transition phrases like 'comprising' are open ended. In the claims of the plaintiffs herein, an open ended phrase 'comprising' has been used in claims 3, 4, 5 and 9. Any addition would be an infringement. The defendants

should realise this.

68. The learned counsel for the defendants also relied on *Actavis V. Eli Lilly* reported in [2017] UKSC 48. Again a reference to paragraph 9 would indicate that trial had concluded and the Judgment was passed on analysis of evidence. There was a trial which went for four days, and thereafter Judgment was delivered. The matter went to the Court of Appeal and thereafter, it came up before the United Kingdom Supreme Court. Unfortunately, in the instant case, the parties have not yet shown any inclination to examine witnesses and put documents to test. The plaintiffs and the defendants have not yet had the opportunity of speaking the facts stated in the pleadings on oath and their statements being tested on cross examination. The documents produced have not been proved in manner known to law.

69. In Paragraph No.88 of the Judgment, it had been contended that a patentee should make it clear that he was not seeking to contend that a patent, if granted, would extend its scope to the variant which he now claims infringes on his patent. This observation has been relied on by the learned Senior Counsels pointing out the difference in the strains between

streptococcus thermophilus used by the plaintiffs and used by the defendants and also the difference in the colony forming units. Again I would hold that the parties should speak about all these facts during trial on oath and subject themselves to cross examination.

70. There is one further fact, namely, the allegation that the plaintiffs have not been in the market for atleast seven years between 2012 to 2018. The learned Senior counsel for the defendants relied on *AIR 1997 Del 79 [Franz Xavier Huemer V. New Uash Engineers]* with specific reference to paragraph Nos. 8 to 21. In that case, the plaintiff had registered 5 Patents in India in 1985. In February 1994 he came to know about the defendants' products. He then filed a suit.

71. The defendant claimed that he had been in textile business since 1969 and had developed his own machines after two years of hardwork. It had been found as a fact that the power of attorney in favour of the agent of the plaintiffs was dated two days after the date of filing of the suit. More over, the machines of the defendants had been advertised from 1992 and therefore, the claim that the plaintiffs came to know about it

in the year 1994 was disbelieved. It was held by a Division Bench of the Delhi High Court that the plaintiffs' patent was an unused Patent and grant of protection for the same may not be proper.

72. In the instant case, the plaintiffs have stated that there had been online sales of the products of the plaintiffs and thereafter the first plaintiff was appointed as exclusive licensee of the second plaintiff and sales across the counter commenced. This explanation cannot be compared with a fact situation in the cited Judgment where the plaintiff had come to Court after 10 years of the defendants' product being in the market which fact was pointed out by the Hon'ble Division Bench. Here the second plaintiff had infact instituted an earlier suit in the year 2011. The defendants may take advantage of that fact again during trial. But again, we are now at the interlocutory stage.

73. It had also been pointed out that the balance of convenience is in favour of the defendants since they have been in business for a number of years.

74. Reliance has been placed on *[Wander Ltd. & Anr. Vs. Antox*

India Pvt. Ltd.,] reported in **1990 (Supp) SCC 727** and more particularly to paragraph No.9. Paragraph No. 9 is as follows:-

“9. Usually, the prayer for grant of an interlocutory injunction is at a stage when the existence of the legal right asserted by the plaintiff and its alleged violation are both contested and uncertain and remain uncertain till they are established at the trial on evidence. The court, at this stage, acts on certain well settled principles of administration of this form of interlocutory remedy which is both temporary and discretionary. The object of the interlocutory injunction, it is stated

“...is to protect the plaintiff against injury by violation of his rights for which he could not adequately be compensated in damages recoverable in the action if the uncertainty were resolved in his favour at the trial. The need for such protection must be weighed against the corresponding need of the defendant to be protected against injury resulting from his having been prevented from exercising his own legal

rights for which he could not be adequately compensated. The court must weigh one need against another and determine where the 'balance of convenience' lies."

The interlocutory remedy is intended to preserve in status quo, the rights of parties which may appear on a prima facie case. The court also, in restraining a defendant from exercising what he considers his legal right but what the plaintiff would like to be prevented, puts into the scales, as a relevant consideration whether the defendant has yet to commence his enterprise or whether he has already been doing so in which latter case considerations somewhat different from those that apply to a case where the defendant is yet to commence his enterprise, are attracted."

75. In that case, the learned Single Judge had determined the prior user and had thereafter refused to grant any interim relief. The Division Bench came to a different conclusion. The Judgment of the Division Bench was interfered with by the Hon'ble Supreme Court. The discretion of the learned Single Judge was recognised by the Hon'ble Supreme Court. Here,

on the facts of this case, when the application for injunction was first moved, *ex parte* interim injunction was granted. Thereafter, the defendants sought permission to sell the products which were already available in the market. That permission was alone granted. The factors for grant of injunction however still remain. They have not altered.

76. I would therefore fall back on making the injunction already granted absolutely. I would relegate the parties to trial. The object of the Commercial Courts Act is focused on quick determination of the issues raised in the plaint rather than to meander around interlocutory applications.

77. In view of these reasons, (1) O.A.No. 1082 of 2019 is allowed and injunction is granted till disposal of the suit. (2) A.No. 9645 of 2019 is dismissed. (3) No order as to costs.

78. With respect to A.No. 282 of 2020 and A.No. 1616 of 2020, which are applications filed under Order XXXIX Rule 2A of the Code of Civil Procedure, the Division Bench had directed that both these applications should also be disposed.

79. The plaintiffs will have lead evidence with respect to violation of injunction order by the defendants. The defendants may rebut such evidence. These issues cannot be decided on the basis of affidavits. The allegations will have to be proved in manner known to law. The documents have to pass the tests of admissibility and relevancy. They will have to be proved. The defendants must be granted an opportunity to graze the witness box and explain how they are not in contempt.

80. However, in deference to the directions of the Division Bench, a perusal of the records show that exparte interim injunction was first granted. On the very next hearing date, the defendants sought permission to sell the products which were already in the market. Permission was granted. In the meanwhile, the plaintiffs filed an application for contempt. When the interim injunction application was sought to be taken up by the

learned Senior Single Judge, the learned counsel for the plaintiffs insisted that the application for contempt should be heard. Thereafter, clarifications were sought from the Division Bench. The order of injunction was kept in abeyance.

81. By way of an affidavit, again clarification was sought from this Court by the plaintiffs. This Court had made it clear that this Court had not granted injunction. The matter was again taken up before the Division Bench. The plaintiffs have been the cause for much confusion with respect to these two applications. They should have sought permission to lead evidence which they could avail at the time for trial along with the suit. On the basis of the affidavits filed, I hold that any opinion much less prima facie opinion regarding the reliefs sought in these applications cannot be arrived at.

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82. It would only be in the interest of both the parties that a fresh beginning is made with the plaintiffs being vigilant of any breach of the order passed today in their application for injunction whereby injunction has been granted till disposal of the suit. They cannot harp on the past.

83. I would therefore close both the applications since a finding can never be given on applications under Order XXXIX Rule 2-A Code of Civil Procedure on the basis of the averments made in affidavits and denials in counter affidavits.

84. In the result, A.No. 282 of 2020 and A.No. 1616 of 2020 are both closed. No order as to costs.

85. Finally,

- (i) O.A.No. 1082 of 2019 is allowed and injunction as prayed for is granted till disposal of suit;
- (ii) A.No. 9645 of 2019 is dismissed.
- (iii) A.No. 282 of 2020 is closed.
- (iv) A.No. 1616 of 2020 is closed.
- (v) No order as to costs.

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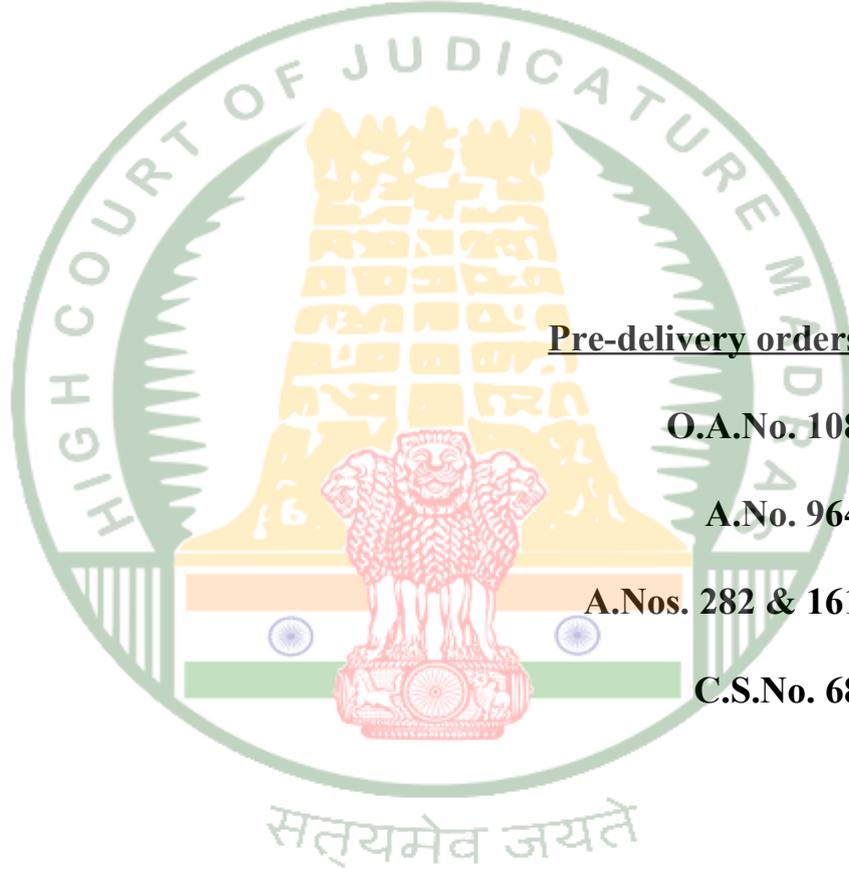
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C.V.KARTHIKEYAN. J,

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Pre-delivery orders made in

O.A.No. 1082 of 2019

And

A.No. 9645 of 2019

And

A.Nos. 282 & 1616 of 2020

IN

C.S.No. 684 of 2019

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