

IN HIGH COURT OF JUDICATURE AT MADRAS

RESERVED ON : 03.09.2018

DELIVERED ON : 10.01.2019

CORAM

THE HONOURABLE MR.JUSTICE R.SUBBIAH

AND

THE HONOURABLE MR.JUSTICE C.SARAVANAN

W.P.No.1219 of 2014

and

M.P.No.1 of 2014

M/s.La Renon Health Care Pvt., Ltd.,
No.5, Aswamegh Estate,
Sarkhej-Bawla Highway,
Sarkhej, Ahmedabad-382 210,
Gujarat.

: Petitioner

1.Union of India,
Ministry of Commerce and Industry,
DIPP, Udyog Bhavan,
New Delhi - 110 001.

2.The Controller General of Patents,
Designs and Trademarks,
The Patent Office,
Bhoudhik Sampada Bhavan,
Near Antop Hill Head Post Office,
S.M.Road, Antop Hill,
Mumbai - 400 037.

WEB COPY

3.The Intellectual Property Appellate Board,
Guna Complex,
Teynampet,
Chennai - 600 018.

4.Kibow Biotech Inc.,
Represented by its Senior Vice President (R&D),
Dr.N.Ranganayhan,
New Town Business Centre,
4629, West Chester Pike,
Newton Square, A 19073 USA.

: Respondents

Prayer:Writ Petition filed under Article 226 of Constitution of India, to issue a writ of certiorarified mandamus, calling for the records pertaining to the order No.262 of 2013 of the 3rd respondent herein dated 13.11.2013 made in ORA No.29/2011/PT/MUM/ & M.P.No.90 of 2012 & 130/2012 in ORA No.29/2011/PT/MUM on the file of the 3rd respondent herein and to quash the same and to consequentially direct the 2nd respondent herein to revoke/cancel the registered Indian Patent No.224100 for the invention titled, "Compositions for Augmenting Kidney Function", granted by the 2nd respondent herein to the 4th respondent herein and to make suitable changes/entries in the register of patents maintained by the 2nd respondent herein.

For Petitioner : Mr.G.K.Muthukumarm Assisted by
Mr.A.Ram Kumar & Preethika
Ravichandrabaabu
for M/s.GMs Law Associates
For RR1 & 2 : Mr.K.Srinivasamoorthy, SPCCG
For RR3 : Mr.T.V.Krishnamachari
For RR4 :Mr.Vineet Subramani

ORDER

By the impugned order No. 262/2013 dated 13.11.2013 bearing reference No. ORA/29/2011/PT/MUM, the 3rd respondent Intellectual Properties Appellate Board (IPAB) has dismissed the Application for revocation of impugned Patent No.224100 dated 23.08.2006 of the 4th respondent.

2. The impugned patent was granted to the 4th respondent by the 2nd respondent based on PCT application filed by the 4th respondent claiming priority from US Patent Application No.10.672,622 filed on 30.09.2003.

3. Following claims are covered by the impugned patent:-

1. A composition for augmenting kidney function in a subject comprising at least one probiotic bacterium wherein said probiotic bacterium selected from Streptococcus thermophilus 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 thermophilus is strain KB4, KB19, or KB25.

3. The composition of 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 at least 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 protein, 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 probiotic.

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

4. In the specification it is stated that in normal, healthy humans, metabolic waste nitrogen is primarily excreted via the kidneys as urea, uric acid creatinine, etc., in the urine. However, in individuals with kidney disease, as well as a number of other diseases such as inborn errors in urea cycle enzyme deficit, waste nitrogen accumulates in the body thereby manifesting toxic symptoms. Hyperammonium can lead to mental retardation and, in severe cases, coma.

5. It is further explained that during a normal digestive process the gastrointestinal tract delivers nutrients and water to the bloodstream and eliminates some waste products and undigested materials through the bowel. The intestinal wall regulates absorption of nutrients, electrolytes, water and certain digestive aiding substances such as bile acids. The intestinal wall also acts as a semi-permeable membrane allowing small molecules to pass from the intestinal tract into the bloodstream and preventing larger molecules from entering the circulation.

6. Nitrogenous wastes such as urea, uric acid, creatinine and uric acid, along

with several other small and medium molecular weight compounds, flow into the small intestine and equilibrate across the small intestine epithelium. The intestinal bacteria flora can be reduced become unbalanced or be eliminated in patients undergoing antibiotic treatment and other therapies, and in individuals suffering from inflammatory intestinal diseases, kidney disease and liver disease.

7. The specification further states that during normal aging the Bifidobacteria population is reduced while the concentration of pathogenic and putrefactive bacteria concomitantly increases.

8. It is stated that the human gastrointestinal tract harbors a complex microbial ecosystem containing a large number and variety of bacteria. The resident bacterial population in the human gastrointestinal tract has a major impact on gastrointestinal function and thereby on human health and well-being.

9. Among these, some bacteria are opportunistic or considered to be detrimental and cause adverse conditions such as diarrhea, infections, gastroenteritis and endotoxaemia while some bacteria species are considered as “probiotic”, in that they perform beneficial functions for the human organism.

10. It is stated that the beneficial effects of microbes such as the

bifidobacterium species are in part due to their ability to ferment non-digestible sugars, known as prebiotics, present in the colon.

11. A prebiotic is a non-digestible food ingredient that beneficially affects the host by selectively stimulating the growth and /or the activity of one or a limited number of bacteria in the colon.

12. However, proper clinical management of renal, hepatic and gastrointestinal diseases or disorders actually requires alleviation of multiple symptoms. Accordingly, there was a need for alternative modalities of treatment for uremia. As per the specification one of the major deficits prior art approaches, however, is that they tend to address individual uremic solutes or toxins.

13. It is stated that the present invention provides compositions and methods for augmenting kidney function.

14. In the summary of invention, it has been disclosed that the invention is relating to augmenting kidney function using among the probiotic bacteria, bifidobacteria species are the most prominent. Bifidobacteria species, when in live and viable form, stipulate the immune system and exert a competitive exclusion of

pathogenic and putrefactive bacteria, reduce the amounts of ammonia and cholesterol in the blood, and promote absorption of minerals.

15. In addition, Bifidobacteria have been suggested to exert a preventive action against colon cancer, by reducing the activity of some enzymes that convert procarcinogen substances into carcinogen substances.

16. It is stated that the lactic bacteria such as *Lactobacillus bulgaricus*, *Lactobacillus acidophilus*, *Lactobacillus casei*, *Lactobacillus plantarum* and *Streptococcus faecium* are useful. *Streptococcus thermophilus* are also probiotic. These bacteria produce antagonist effects against pathogenic microorganisms, stimulate the immune system, improve lactose digestion, perform a lipolytic activity making fats more digestible, reduce plasma values of cholesterol, protect the intestinal mucosa ensuring an even assimilation of the nutritive substances, produce polysaccharides that are active on some tumors, and reduce viability of some enzyme-producing microorganisms catalyzing conversion of procarcinogen substances into carcinogenic substances. There was augmenting kidney function.

17. The claim based on the above summary of the specification was challenged before the 3rd respondent by the petitioner on the ground that there was neither an invention nor any inventive step under the provisions of Section 2(1)(j) and 2(1)(ja) of the Patents Act.

18. According, to the petitioner the specification of the patent only disclosed the admixture of the integers and therefore patent ought not to have been granted to the 4th respondent.

19. It was further alleged that there was inadequate disclosure as the specification suffers from insufficient disclosure and the claims are not based on disclosure in the specification.

20. The specification of the alleged invention is obvious and therefore the patent granted was liable to be revoked in terms of Section 64(1)(h). In support of the said plea, the Petitioner particularly drew attention to the documents in the form of Exhibit B2, B3, C17, D5, D8 and X10 series.

21. It was also submitted that the specification does not disclose any technical

advancement over existing knowledge or prior art and it was obvious to a person skilled in the art.

22. In support of the same, the learned counsel for the petitioner placed reliance on the documents filed before the Appellate Board viz., Exs.B1, B2, B3, C3 a, C17, C17, C23, D1, D5, DD10 and X10, which are the extract from various patents granted to others and extracts from scientific journal dealing with probiotic.

23. Therefore, learned counsel for the petitioner submitted that the patent was liable to be revoked on account of obviousness.

24. According to the learned counsel for the Petitioner, the patent was the composition of the following six ingredients viz., One or more of Streptococcus Thermophilus Bacteria, strains KB4, KB19 and KB25, in a particular range i.e. 5 to 20 billion colony forming units (CFU),

1. Other ingredients being selected from

- (i) a. Carbohydrate
- (ii) b. Protein
- (iii) c. Fats
- (iv) d. Vitamin

(v) e.Mineral.

25. The learned Counsel submitted that there was no novelty in the invention and this Section (3)(e) of the Patent Act, defines an admixture as “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”.

26. Therefore, it was submitted that if a product is obtained by a mere admixture of ingredients resulting in aggregation of the properties of the components, it is barred from being patented. He therefore submitted patent granted to the 4th respondent ought to have been revoked by the 3rd respondent Appellate Tribunal.

27. Adding further, the learned counsel submitted that the impugned patent neither directly nor explicitly discloses a composition comprising a combination of *Streptococcus thermophilus* with other ingredients viz., vitamin, mineral, carbohydrate, protein and fats, as claimed, but talks of some other unconnected combinations.

28. Thus, the respondent No.4 has to provide a composition for augmenting

kidney function comprising a combination of Streptococcus thermophilus with other ingredients viz., vitamin, mineral, carbohydrate, protein and fats.

29. The learned counsel also submitted that the patent was obtained by a false suggestion and material suppression of facts, claiming that the claimed composition increases kidney function and it can be used for kidney patient.

30. It was submitted that patent was obtained by making a false representation that the prior patent applications were pending when in reality prior patent applications filed by the 4th respondent in the US was refused.

31. It was further submitted that the patent specification does not disclose as to how the composition increases kidney functions.

32. The learned counsel further submitted that claim 1 and dependable claims 2 - 10 are not patentable under Section 10(4) of the Patents Act.

WEB COPY

33. The learned Counsel summarized that though the petitioner had filed scientific literature before the 3rd respondent, the impugned order has been passed

in a summary manner without proper consideration.

34. It is submitted that the impugned order is non speaking and arbitrary and liable to be set aside. The learned counsel submitted that the impugned order deserves to be set aside and remanded back to the 3rd respondent for re-consideration and passing order denovo on merits. Finally, the learned counsel for the petitioner submitted that the 4th respondent has not deposited a sample of bacteria referred to in the specification as per proviso to Section 10(4) (d).

35. Countering the submission, the Learned Counsel for the 4th respondent submitted that the power of the Court under Article 226 of the Constitution of India to review an order of an inferior tribunal like the 3rd respondent was limited.

36. It was submitted that the Court cannot re-appreciate evidence and substitute the reasoning and judgment of the 3rd respondent as long as there was no infirmity in the procedure followed by it while passing the impugned order. In other words, it was submitted only if there was infirmity in the decision making process, the Court review an order under Article 326 of the Constitution of India.

37. It was submitted that the 3rd respondent has not committed any procedural irregularity and therefore the impugned order cannot be dissected and quashed.

Hence, it was prayed that the present writ petition was liable to be dismissed.

38. The learned counsel referred to the decision of the Hon'ble Supreme Court in **Basappa V. Nagappa** AIR 1954 SC 440 wherein it was held that in granting a writ of certiorari the superior court does not exercise the powers of an Appellate tribunal. It does not review or reweigh the evidence upon which the determination of the inferior tribunal purports to be based. It only demolishes the order which it considers to be without jurisdiction or palpably erroneous but does not substitute its own views for those of the inferior tribunal.

39. Reliance was also placed on the decision of the Hon'ble Supreme Court in **Estralla Rubber V. Dass Estate (P) Ltd.**, (2001) 8 Supreme Court Cases 97. While dealing with the scope of Art. 227, the Hon'ble Supreme Court held that an order of the Appellate Court can be set aside if it is based on no evidence at all or is perverse that no reasonable person would come to such a conclusion. In the present case, the impugned order was perfectly reasoned.

WEB COPY

40. Learned Counsel further relied on the decision rendered in **Champagne**

Moet & Chandon V. Union of India (2011) 183 DLT 99 (DB) wherein it was held that while exercising the power of judicial review under Article 226 of the Constitution of India, the proceeding cannot be converted into an appeal. The judicial review is directed not against the decision but is confined to the examination of the decision making process. He submitted that there was no error in that can be pointed in the decision making process of the 3rd respondent/Appellate Board.

41. He further submitted that *Radhey Shyam V. Chabbi Nath (2015) 5 SCC 423* the Hon'ble Supreme Court held that., While Appellate or revisional jurisdiction is regulated by the statutes, power of superintendence under Article 227 is constitutional. Learned counsel for the 4th respondent referred to the decision of the Court in *Financial Times V. Times Publishing House (2016) 234 DLT 305*. There the Court observed that the Court while exercising supervisory jurisdiction over the order/decision of IPAB and the parameters of exercise of which jurisdiction are materially different from the parameters of Appellate jurisdiction and the scope of interference against the order of IPAB allowing or disallowing cross-examination, especially when it is made along with the final order would be very limited, confined may be to situations where this Court finds itself, on the evidence on record before the IPAB, to return any finding and requires further information to be elucidated from the witness.

42. The learned Counsel also drew our attention to the following two other cases laws on the scope of Art.226:

i) *AmminiKarnan V. IPAB* (2013) 2 LW 513:

ii) *Canara Bank V. Perumal* unreported WA(MD) 963/2012

43. Therefore, it was submitted that as there was no irregularity or perversity either in the proceedings or in the impugned order and further, the writ petition filed by the petitioner was liable to be dismissed with exemplary cost and the impugned order passed by the 3rd respondent Appellate Board has to be upheld.

44. The learned counsel submitted that a patented invention can be challenged by way of opposition under Section 25(1) of the Act or after grant of patent within one year under Section 25(2) or under Section 64(1) of the Act either before the 3rd respondent Appellate Tribunal or by way of counter claim in a suit for infringement.

WEB COPY

45. The learned counsel submitted that under Section 64(1) of the Parent Act,

1970 only a “person interested” can approach the Appellate Board for revocation of patent or by way of counter claim in a suit for infringement of patent before the High Court.

46. It was submitted that the scope of writ petition against an order of the Appellate Board passed under Section 64 and by way of counter claim in a suit is very different.

47. In the former, the scope is limited whereas the in suit by way of counter-claim it is wide. Though, the petitioner had an opportunity to contest the patent in C.S.No.498 of 2011, the petitioner chose to successfully resist the said suit by contesting the jurisdiction of this Court in the exercise of the original jurisdiction.

48. The leave granted by this Court in the said suit was revoked and the plaint was rejected on 20.02.2011 at the behest of the petitioner. Since the scope of review in writ proceeding was very limited, arguments on merits cannot be entertained.

WEB COPY

49. The learned counsel for the 4th respondent submitted that the petitioner cannot be considered as an “interested person” either for the purpose of Section 25(2)

or Section 64(1) of the Parents Act, 1970.

50. The petitioner having lost an opportunity to challenge the patent by way of counter-claim chose to invoke the jurisdiction of the 3rd respondent under Section 64 of the Act. Having invoked the jurisdiction of the 3rd Respondent, the Petitioner cannot re-agitate the validity of the patent on merits under Art. 226 of the Constitution of India.

51. It was submitted that a “person interested” would be a person who is adversely affected by the patent. The learned counsel submitted that “a person interested” would include any individual who desires to make independent use of either the invention itself(which has been patented), or desires to exploit the process (which has been patented) in his individual production capacity as held by the Hon'ble Supreme Court in **Alloys Wobben V. Yogesh Mehra** (2014) 15 SCC 360. It was submitted that in the present case, the petitioner was a mere marketing company and not a manufacturer and therefore was not an “interested person” for invoking the jurisdiction of the 3rd respondent under Section 64 of the Act.

52. It is submitted that anticipated grievance was no ground for filing the writ petition and therefore the writ petition is liable to be dismissed even at the

preliminary stage. He further submitted that even though the definition of “interested person” in Section 2(1)(t) is inclusive, it has to be read to mean only a person who is engaged in or in promoting research in the same field to which the invention relates and hence, the definition ought to be read in a restricted manner. In this connection, the learned counsel for the petitioner drew my attention to the following decisions:

- a. *Isabella Dilworth V. Commissioner of Stamps* (1899) A.C.99(PC).
- b. *South Gujarat Roofing & Tiles Manufacturing Association V. State of Gujarat* (1976) 4 SCC 601.
- c. *NDP Namboodripad V. Union of India*, (2007) 4 SCC 502.

53. It was therefore submitted that the petitioner was not an interested person for the purpose of revocation of patent under Section 64(1) of Patent Act, 1970.

54. On merits, the learned counsel for the 4th respondent submitted that the invention covered by Patent No.224100 is for an invention that assists or augments kidney function by carrying out the breakdown of uremic/nitrogenous toxins in the gut prior to transfer of the toxins to the kidney. There was neither prior art involved nor the patented invention was a admixture or lacks inventiveness on account of alleged obviousness or there was improper disclosure in the specification.

55. It is submitted that after extensive experimentation and testing, three specific of streptococcus thermophilus type of probiotic bacteria which are freely available in nature were selected i.e. KB4, KB19 and KB25 for producing the invented product.

56. They are delivered in a capsule along with other ingredients so that the bacteria can reproduce to form a sustainable colony in the bowel, to breakdown sufficient quantities of the toxins to achieve the desired result.

57. It was submitted that four patent applications were filed in the United States of America. He further submitted that all the prior US applications have been merged into one patent and are governed by Patent No. 7,998,470 and have not been abandoned. It was further submitted that only if there was suppression, revocation can be justified. Even this ground was not taken before the third respondent Appellate Board.

WEB COPY

58. Based on these applications, the 4th respondent filed PCT application under the Patent Cooperation Treaty, 1970. After proper scrutiny the same invention has

been patented in 33 different countries. It is submitted that the patent was not granted in India as a matter of routine but was also subjected to rigorous scrutiny.

59. The essence of the patent is that specially selected probiotic bacteria and prebiotic by themselves would not have the desired beneficial effect unless they are delivered in the correct location in the gut to maximise the beneficial effect.

60. It was submitted that stomach acids are very strong and normally dissolve virtually all material which passed through it. Hence the 4th respondent had to choose the capsule with a specific level of enteric coating which can survive the digestive acids and receive the bacteria only at the gut location.

61. The learned counsel submitted that the onus lies on the petitioner to prove that the patent granted deserves to be revoked as held by the Bombay High Court in **FH & B Corp Versus Unichem Laboratories AIR 1969 1969 Bom 255.**

62. It was further submitted that Section 115 of the Act allows court to call for scientific expert to test the validity of the patent. However, the petitioner neither requested for appointment of scientific expert before the third respondent or before this court.

63. Instead for the first time and effort has been made by way of a rejoinder which is impermissible.

64. It was further submitted that writ proceeding is not a proceeding for the purpose of Section 115 of the Patent Act, 1970 and therefore scientific adviser cannot be appointed in course of review proceeding under Art. 226.

65. Learned counsel submitted that the argument that the patent has been granted to a mere admixture lacks creditability.

66. It was submitted that the invention was not a mere aggregation of the constituents, but a highly creative composition of elements each of which were chosen because they have a specific effect on each other and to have a specific role to play in the detoxification of uraemic/nitrogenous waste in the gut to augment kidney function prior to filtration by the kidney and thereby reduce the strain on the kidney. The patent cannot be discredited without any evidence or proof.

67. The learned counsel further submitted that Section 10 (4) (d) was not invoked before the third respondent Appellate Board and therefore same cannot be

pressed into service in the present case.

68. It was further submitted that the argument that the proviso Section 10 (4) (d) which mandates deposit of sample of the bacteria used in the patented process/product as per the Budapest Treaty was not violated as it is clear that a deposit of biological material is required only if the specification does not fully and particularly describe bacteria and if the biological material is not available to the public.

69. It was submitted that strains of the bacteria are available in the nature in abundance and therefore there was no need for deposit of the bacteria.

70. It was submitted that none of the documents really support the petitioner's plea. The petitioner has merely referred to title and few passages from the literature and even those passages were irrelevant and therefore the patent cannot be questioned based on these documents.

WEB COPY

71. In this connection, reliance was placed on the decision of the Court in *Alan Nuttal Ltd. Vs Fir.- Jado UK Ltd.* (2008) EWHIC 1311 (Pat) wherein it was that the

fact that the defendant cited a considerable number of items of prior art in support of their case on obviousness obviousness's was seldom a policy because if alleged invention's was obvious in the light of one particular item of prior art, it does not make the case any better that there were other items that were not quite as good.

72. To cite numerous piece of prior art in an obviousness case tends, if anything, to suggest that the invention was not obvious after all. There after citing several documents, the defendant ended up relying on just two citations's plus called general knowledge.

73. In the present case, the petitioner after citing 37 documents confined to 9 documents alone. Exhibit B1 is a Report of the International Search Authority. It is evident from FAQs published by the World Intellectual Property Organisation (WIPO), makes it clear that its opinion are not binding. Further, this document was also filed by the 4th respondent itself and it is only after a thorough scrutiny of the all the documents the subject patent was granted by the 2nd respondent.

WEB COPY

74. Exhibit B 2 is the patent granted for Frozen Desserts Formulations, i.e a method to make ice creams. It was submitted that none of the 60 claims in the said

patent relates to the use of probiotic bacteria for augmenting kidney function or even refer to Streptococcus Thermophilus. It was therefore submitted that the Exhibit B2 has no relevance.

75. Exhibit B3 Is the US Patent for Probiotic Compounds derived from Lactobacillus Casei Strain KE01. The said invention discloses preparation of Probiotic Lactobacillus derived from newly characterized strain of Lactobacillus Casei Strain KE01 and the object of the invention is to provide a new strain of Lactobacillus that has demonstrated the properties of probiotics. Thus, the said patented invention is irrelevant for the enquiry.

76. Exhibit C3 is the research notes on effect of feeding diets containing an antibiotic, a probiotic or yucca extract on growth and intestinal urease activity in broiler chicks. The research paper states that “suppressing urease activity and ammonia production can be beneficial for improving animal health and enhancing growth because ammonia locally produced by uleolysis in the intestinal mucosa can exert a significant damage to the surface cells. Thus, the study contained therein has no relevance to the case.

77. Exhibit C 17 titled “Critical Review-Dietary Modulation of the Human Colonic Microbiota: Introducing the Concept of Probiotics.” It was submitted that the

article has dealt with beneficial and positive effects of probiotics administered to human in a number of biomedical conditions. These include diarrhoea, constipation, colitis, recolonisation by pathogens, flatulence, gastroenteritis, gastric acidity, immuno stimulation, hyper- Cholesteroemia, hepatic encephalopathy and carcinogenesis.

78. It was submitted that Exhibit C 17 contains general information and not specific information as to the beneficial effects of each of the different varieties of probiotic bacteria and nor does it refer to kidney disease and its alleviation by use of bacteria particularly the select strain of Streptococcus thermophilus.

79. Similarly Exhibit C 23 is an extract from an article titled “Effect of Oral Administration of Freeze-dried Lactobacillus Acidophilus on Small Bowel Bacterial Overgrowth in Patients with End-Stage Kidney Disease: Reducing Uraemic Toxins and Improving Nutrition. It was submitted that the Petitioner has merely produced extract and not the entire article. The abstract shows that the study relates to showing of how to strains (“NCFM and BG2F04) of Lactobacillus Acidophilu can lower Dimethymine(DMA) and nitrosdiethyamine (NDMA) in the blood to nutrition. The document does not talk about Streptococcus Thermophilus augmenting kidney function.

80. It was submitted that in the Table 1 to exhibit D1, titled “Probiotics:100 years (1907-2007) after Elie Metchnikoff’s Observation, provided a list of ‘*proven probiotic microorganisms*’. This list does not include *Streptococcus thermophilus*. It is clear therefore that the beneficial effects of the *Streptococcus thermophilus* strains of probiotic bacteria were unknown at the time of publication, therefore making the 4th Respondent’s invention unique and the Patent non-obvious.

81. Further, the article deals with the possible reduction of formation of kidney stones: “*The use of probiotic preparation VSL #3 and experimental Oxalobacter formigenes have shown that it is possible to influence urinary oxalate excretion and potentially reduce urinary super-saturation levels and the formation of kidney stones*” and makes no other reference to uremia, removal of uremic toxins or augmenting kidney function.

82. It was submitted that it is clear therefore that the focus of the research set out in Document D1 relates to reduction of kidney stones, and not to augmenting kidney function by hydrolysis of uremic toxins in the gut prior to filtration by the kidney.

83. It was submitted that as per exhibit D5, there is a lack of ‘good evidence’ on the beneficial effects of probiotics on gut flora:

“While there is no doubt that gut flora can protect the host against intestinal disease, we lack good evidence from controlled clinical trial that the organisms currently being used as probiotics are those that are responsible for the beneficial effects of the gut flora. More trials are needed to establish the efficacy of those probiotics which are currently on the market” What is also desperately needed is more research on the way probiotics work.

84. It was submitted that this document supports the inventiveness of the Respondent's Patent, as there was no pre-existing research in the area as reported in the exhibit D5 relied upon by the petitioner.

(i) Exhibit X10 -titled Effect of Administration of Fermented Milk Containing whey protein concentrate to rats and healthy men on serum lipids relates to the preparation of fermented milk-curd, which is fortified without protein concentrate. It has no relevance whatsoever to alleviating kidney disease or reducing stress on the kidney by pre-hydrolysing uremic/ itrogenous toxins in the gut, prior to filtration by the kidney.

“The effect of fermented milk supplemented with whey protein concentrate on the serum lipid level of rats was investigated.”

This is reiterated:

“Although the main focus of the present study was to investigate the effect of fermented milk supplemented with WPC on the serum lipids of rats and humans, further study on the serum cholesterol lowering factor would be needed to resolve the mechanism. ...Thus we conclude that it is possible to manufacture fermented milk with WPC and fermented by optimum lactic acid bacteria, having both a serum lipid improvement effect and a hyposensitive effect on humans as well as animals. These results indicate the potential of development of fermented milk with multiple therapeutic effects.”

85. It was thus submitted that it would be clear that each of the above documents clearly contradict the Petitioner's allegations that the Respondent's Patent is obvious or lacks inventiveness. The very fact that none of the documents even suggests that probiotic bacteria may be used to augment kidney function by carrying out the breakdown of toxin in the gut prior to filtration itself is sufficient evidence to prove the novelty and inventiveness of the Respondent's Patent.

WEB COPY

86. Learned counsel for the 4th respondent therefore submitted that each of the documents cited during the hearing clearly contradict the case that was

projected during hearing.

87. The very fact that none of the documents suggest probiotic bacteria were used for augmenting kidney function by carrying out the breakdown of toxins in the gut prior to filtration itself is sufficient evidence to prove the novelty and inventiveness in the patent.

88. Learned counsel submitted that this case is not fit for remanding the case back to the third respondent Appellate Tribunal. Having failed to lead proper evidence either before the third respondent Appellate Board or in this proceeding, the petitioner cannot ask for third opportunity to lead fresh evidence in the remand proceedings.

89. It was submitted that the petitioner was given a fair opportunity before the Court also. However, no attempt was made to make out a precise case and therefore requested for dismissal of the case with cost.

WEB COPY

90. Heard both sides and perused the documents filed in support of the writ petition and the impugned order.

91. The purpose of government monopoly under the provisions of the Patent Act, 1970 in the form of grant of patent to an inventor and the scope of this Court under Article 226 of the Constitution of India has to be kept in mind in this case.

92. The patent system is based on a “bargain”, or quid pro quo. An inventor is granted an exclusive right in a new and useful invention for a limited period in exchange for disclosure of the invention so that society can benefit from this knowledge.

93. The patent bargain encourages innovation and advances science and technology. This is the fundamental policy and rationale for grant of monopoly in the form of patent. The claim in a Patent limits the monopoly while the specification explains the invention. Thereto, specification has to be describe the invention and the changes over the existing art.

94. In *Tubes, Ld. v. Perfecta Seamless Steel Tube Company, Ld.* (1902), 20 R.P.C 77, Lord Halsbury observed as under:

“ . . . if one has to look at first principles and see what the meaning of a Specification is . . . why is a Specification

necessary? It is a bargain between the State and the inventor: the State says, “If you will tell what your invention is and if you will publish that invention in such a form and in such a way as to enable the public to get the benefit of it, you shall have a monopoly of that invention for a period of fourteen years.” That is the bargain. The meaning which I think, in my view of the Patent Law, has always been placed on the object and purpose of a Specification is that it is to enable, not anybody, but a reasonably well informed artisan dealing with a subject-matter with which he is familiar, to make the thing, so as to make it available for the public at the end of the protected period. [Emphasis added.] Lord Halsbury’s view was cited with approval by Dickson J. (as he then was) in *Consolboard*, at para. 523.

[34] Therefore, adequate disclosure in the specification is a precondition for the granting of a patent. As Hughes J. stated in *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142, 63 C.P.R. (4th) 406, at para. 74:

Thus, one must both advance the state of the art and disclose that advance in order to gain the patent monopoly. Failing to do so, thus invalidating the monopoly, can be in the form of one or more of several matters such as, the “invention” was not new, or the so-called invention was “obvious” or the disclosure was “insufficient” or “what you

disclosed doesn't support the monopoly that you claim”.

95. In return for such disclosure, patent is granted to the inventor for a specified period provided so that the patented invention is also worked in the country without undue delay and if there is any infringement by anybody, the patent holder invokes the rights under the Act to protect the claims in the patent.

96. In other words, there is an element of quid pro quo. In return for full disclosure and promise to work the patent in commercial scale in the country, a monopoly is given by the Government so that the patented invention is available to consumers at a cheaper cost and is available for being used at the end of the term of the patent.

97. Patent is not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article. This is the statutory mandate of Section 83 of the Act which reads as under:

“83. General principles applicable to working of patented inventions.

—Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had

to the following general considerations, namely—

(a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;

(b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;

(c) that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;

(d) that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;

(e) that patents granted do not in any way prohibit the Central Government in taking measures to protect public health;

(f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving

title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and

(g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.”

98. If the invention that has been patented has not been put to use by way of production and manufacture in India, the purpose for which the Patent was granted would stand defeated.

99. The intention of the law is not to merely confer monopoly to an inventor to make disclosure in the specification and make claims and to flood the market without actual manufacture in the country.

100. If the patented product is manufactured on overseas soil and imported into the country, the monopoly cannot remain. There could be compulsory licensing.

101. The 4th respondent has licensed the manufacture in India through a third party manufacturer. It appears that the patented product is both manufactured and marketed in the country.

102. The 4th respondent has thus complied with the said requirement, as the product is not merely marketed in India.

103. The Hon'ble Supreme Court of India in the case of **Biswanath Prasad RadheyShyam vs. Hindustan Metal Industries**, AIR 1982 SC 1444, held as follows:-

“It is noteworthy that the grant and sealing of the patent, or the decision rendered by the Controller in the case of opposition, does not guarantee the validity of the patent, which can be challenged before the High Court on various grounds in revocation or infringement proceedings. It is pertinent to note that this position, viz. the validity of a patent is not guaranteed by the grant, is now expressly provided in Section 13(4) of the Patents Act, 1970.”

104. Therefore, even though patent has been granted it can be revoked at any time. The preliminary objection of the 4th respondent is that the petitioner is not a “interested person” and therefore revocation proceeding at its behest before the 3rd respondent was not maintainable.

WEB COPY

105. In **Aloys Wobben v. Yogesh Mehra**, (2014) 15 SCC 360 , the Hon'ble Supreme Court held that “A corrective mechanism is also available to “any person interested”, to assail the grant of a patent under Section 64(1) of the Patents Act.

This is in addition, to a similar remedy provided to “any person interested”, under Section 25(2) of the Patents Act. In the above scenario, it is necessary to first appreciate the true purport of the words “any person interested”. The term “person interested” has been defined in Section 2(1)(t) of the Patents Act. Unless the context otherwise requires, in terms of Section 2(1)(t) aforementioned, a “person interested” would be one who is ... “engaged in, or in promoting, research in the same field as that to which the invention relates”. Simply stated, a “person interested” would include a person who has a direct, present and tangible interest with a patent, and the grant of the patent adversely affects his above rights. ***A “person interested” would include any individual who desires to make independent use of either the invention itself (which has been patented), or desires to exploit the process (which has been patented) in his individual production activity. Therefore, the term “any person interested” is not static.*** The same person may not be a “person interested” when the grant of the patent concerned was published, and yet on account of his activities at a later point in time, he may assume such a character or disposition. It is, therefore, that Section 64 of the Patents Act additionally vests in “any person interested”, the liberty to assail the grant of a patent, by seeking its revocation.

106. As far as *locus standi* of the petitioner is concerned, we are of the view that the petitioner indeed had a locus standi to challenge the patent before the third respondent Appellate Board under Section 64(1) of the Act. The definition of person interested in Section 2(t) of the Act is inclusive and therefore cannot be read in a restricted manner.

107. Further, the Petitioner cannot be shut out from invoking the jurisdiction of the 3rd respondent for revoking the patent merely because it is not a manufacturer.

108. At the same time, merely because a prior infringement proceeding had been initiated for alleged infringement of the subject Patent *ipso facto* does not mean a infringer can have the patent successfully revoked by raising untenable grounds without proper evidence.

109. The petitioner who was accused of infringing the impugned patent has a right under Section 64(1) of the Act to challenge the patent though such challenge has to be on well founded and recognized principle of law under the Act.

110. The Petitioner has filed scores of 43 documents. Ten documents were filed along with the application for rectification and 33 later to substantiate prior art.

111. After filing these documents were filed, before the 3rd respondent, the petitioner submitted that it is for the 4th respondent to peruse and distinguish their irrelevance.

112. In our view, though patent granted by a patent office is revocable under the provisions of the Act under Section 64 of the Act, yet the burden of proof to establish the grounds was with the petitioner.

113. The patent having been granted, the onus is on the person wishing to challenge its validity. That onus has to be discharged on a balance of probabilities. The onus of establishing invalidity on any of the grounds cannot be shifted to the patentee.

114. Under Section 114 of the Indian Evidence Act, 1872, there is a presumption that all judicial and official acts have been regularly performed. In the case of P.J. Ratnam vs. D. Kanikaram&Ors., AIR 1964 SC 244, the Supreme Court of India held that there would be a presumption of regularity in respect of official

and judicial acts and it will be for the party who challenges such regularity to plead and prove his case.

115. In **Narayan Govind Gavate&Ors. Vs. State of Maharashtra &Ors.**, (1977) 1 SCC 133, the Supreme Court held that “true presumptions, whether of law or of fact, are always rebuttable. In other words, the party against which a presumption may operate can and must lead evidence to show why the presumption should not be given effect to. If, for example, the party which initiates a proceeding or comes with a case to Court offers no evidence to support it, the presumption is that such evidence does not exist. And, if some evidence is shown to exist on a question in issue, but the party which has it within its power to produce it, does not, despite notice to it to do so, produce it, the natural presumption is that it would, if produced, have gone against it. Similarly, a presumption arises from failure to discharge a special or particular onus.”

116. Unlike under Section 31 of Trade Marks Act, 1999, wherein Registration of a trade mark is considered to be a prima facie evidence of its validity, under the Patents Act, 1970, the patent is vulnerable as per the interpretation of Section 13 (4) of Patents Act, 1970 by the Supreme Court of India in Biswanath Prasad.

117. The petitioner cannot shift the burden either on the 4th respondent or on the 3rd respondent Appellate Board. The Petitioner had an opportunity to let in evidence of an expert to substantiate the grounds for revocation. However, the petitioner failed to do so.

118. The third respondent Appellate Board being an ultimate fact finding authority was handicapped. The petitioner could not expect the Board to come to its rescue even if the Board has a Technical member. It is not for the 3rd respondent Appellate Board to infer invalidity based on deluge of 43 documents filed by the petitioner.

119. In **Hindustan Ferodo Ltd.** [(1997) 2 SCC 677], the Hon'ble Supreme Court explained the function of the Tribunal. It held as follows:-

It is not the function of the Tribunal to enter into the arena and make suppositions that are tantamount to the evidence that the party before it has failed to lead. Articles in question in an appeal are shown to the Tribunal to enable the Tribunal to comprehend what it is that it is dealing with. It is not an invitation to the Tribunal to give its opinion thereon, brushing aside the evidence before it. The technical knowledge of members of the Tribunal makes for better appreciation of the record, but not its substitution.”

120. The petitioner has not produced any evidence of an expert before the third respondent Appellate Board to substantiate its plea that the invention is a mere “admixture” or that the Patent was liable to be revoked on the grounds stated in the petition filed by it.

121. To appreciate the evidence filed in support of the petition for revocation of patent, the petitioner should have played a pro active role by either producing an expert or an expert’s affidavit and if necessary such expert could have been subjected to cross examination.

122. In **Madan Gopal Kakkad v. Naval Dubey, (1992) 3 SCC 204**, it was held that “A medical witness called in as an expert to assist the Court is not a witness of fact and the evidence given by the medical officer is really of an advisory character given on the basis of the symptoms found on examination. The expert witness is expected to put before the Court all materials inclusive of the data which induced him to come to the conclusion and enlighten the Court on the technical aspect of the case by explaining the terms of science so that the Court although, not an expert may form its own judgment on those materials after giving due regard to the expert’s opinion because once the expert’s opinion is accepted, it is not the

opinion of the medical officer but of the Court”. Though the above view was rendered in the context of tape, the reasoning is relevant in the present case as well.

123. If it was found that the petitioner had made out a case on merits, the 3rd respondent Appellate Board could have also called for an expert’s view under Section 115 of the Act. However, it is obvious petitioner miserably failed to even establish a prima facie case on the strength of the materials placed by it before the 3rd Respondent Appellate Board.

124. Though, the 3rd respondent it has given a finding that the impugned patent aids in the carrying out of the kidney function i.e. removal of waste and toxins and augments kidney function and not the functioning of the kidney *per se*. It is evident that such finding could not have been given without the help of a scientific adviser and/or technical expert’s evidence.

125. In fact, the 3rd respondent appellant Board cannot give a finding as it had no basis to come to the above conclusion. At best the 3rd respondent Appellate Board could have held that the materials filed by the petitioner was insufficient to revoke the patent as under 64 of the Patent Act. Therefore, to that extent these observations in paragraph 32 of the impugned order is liable to be expunged.

126. The third respondent Appellate Board has held that all the disclosure in the specification goes against the contention that the composition is a mere admixture.

127. In the proceedings before the third respondent Appellate Board, the petitioner has stated that the patent was liable to be revoked under Section 64 (1) (d), (e), (f), (h), (i), (j), (k) and (q).

128. The 3rd respondent Appellate Tribunal has considered each of the grounds taken before it and has rejected the case made out by the petitioner. It has held that mere reference to probiotics cited patents were not sufficient to infer prior art.

129. Technical submission made on Exhibit B2, C3, C17 and C 23 and E-series *et cetera* cannot be addressed before us as the Petitioner has not established their relevance before the 3rd respondent Appellate Tribunal.

130. Despite insufficient pleadings, third respondent Appellate Board considered the arguments advanced by the petitioner only to find that none of the submissions of the petitioner were relevant for revoking the patent.

131. Though the impugned patent had only 10 claims at the time of grant of patent, the petitioner had questioned all the 20 claims which were originally filed by the 4th respondent while filing the patent application before the 2nd respondent. Thus, the challenge itself was vague and without proper reading of the specification and the claim.

132. In our view, the third respondent Appellate Board has correctly observed that it is for the applicant to prove the case and it is not sufficient to make bald assertions in the pleadings and mere filing documents is not sufficient in revocation proceeding under Section 64(1)(d)(e) and (f).

133. Therefore, documents vide exhibit B2, C3, C17 and C23 and E-series et cetera cannot be even otherwise relied upon to substantiate the case.

134. Further, the petitioner has resorted to mosaicking by choosing few sentences from different documents to make it seem as if claims and the specifications in the impugned patent were contrary to the provisions of the Act and therefore the patent was liable to be revoked.

135. We are also convinced that the petitioner attempted to piece together a number of prior documents in order to produce an anticipation of the invention which is impermissible for the purpose of defeating claims.

136. In **Von Heyden Vs Neustadt** [(1880) 50 LJ Ch 126], the defendant pleaded anticipation and way of his evidence extracted paragraphs from a large number of publication as was done by the petitioner here.

137. The court there held that if it was this mosaic of extracts, from annals and treaties spread over a series of years, to prove the defendants' contention, that contention stands thereby self condemned.

138. The manner in which the rectification application by the fourth respondent came to be filed also shows that there was no precision in the application for revocation.

139. Further the ground relating obviousness was raised not in the pleading before the third respondent Appellate Board. It was made for the first time at the time of hearing before the third respondent Appellate Board.

140. As the petitioner has not made of the case before the 3rd respondent Appellate Board for revocation of the patent, we see no reason why the request of the petitioner at this stage should be entertained to remand the case to give it third opportunity to establish the case.

141. Further, elaborate submissions were made on the technical aspects relating to the invention on behalf of the either parties herein. It is not for us to decipher the specification and claims in the impugned patent to arrive at a different conclusion based on the submissions advanced by the Petitioner. We cannot substitute the finding of facts arrived by the 3rd respondent Appellate Board.

142. We are however of the view that the scope of review in a writ jurisdiction being limited we cannot substitute the finding of the 3rd respondent Appellate Tribunal based on those submission.

143. We are not exercising Appellate Court's Jurisdiction under Article 226 of the Constitution of India. On the other hand, we have to examine the impugned order from the perspective of a Court exercising supervisory jurisdiction under Article 226 of the Constitution of India. The scope of writ petition against an order of

the third respondent Appellate Board is limited. We can only examine whether there was any infirmity in the procedure adopted by the third respondent Appellate Tribunal while passing the impugned order.

144. We do not find any infirmity in the procedure adopted by the third respondent Appellate Tribunal while passing the impugned order. The impugned order also cannot be termed to palpably erroneous order on account of error on the face of record. We therefore find no grounds to intervene.

145. We are therefore inclined to dismiss the above writ petition and accordingly dismiss the writ petition. No cost.

(R.P.S.J.,)

(C.S.N.J.,)

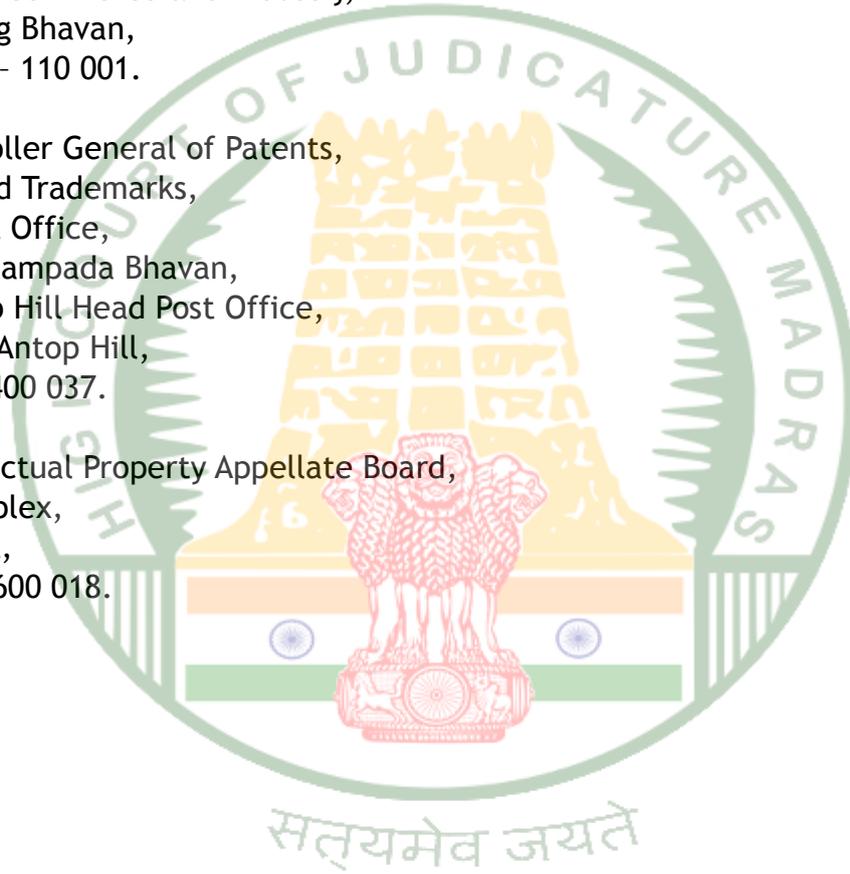
सत्यमेव जयते 10.01.2019

Internet : Yes / No
Index : Yes / No
Speaking : Non Speaking order
Arul/kkd

WEB COPY

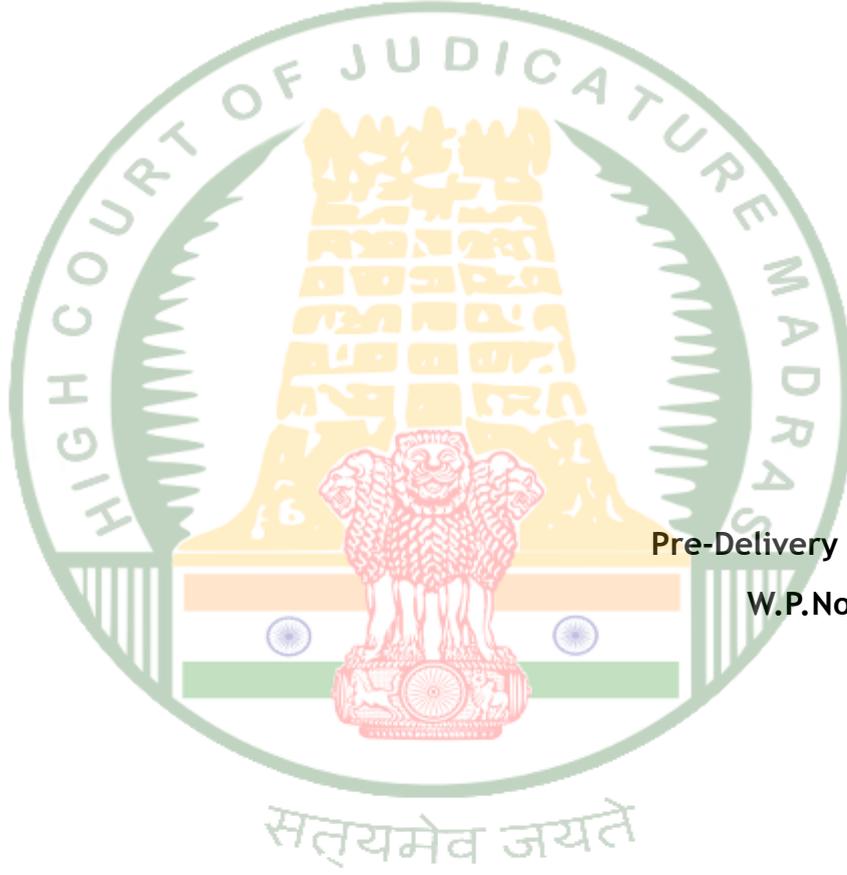
To

1. Union of India,
Ministry of Commerce and Industry,
DIPP, Udyog Bhavan,
New Delhi - 110 001.
2. The Controller General of Patents,
Designs and Trademarks,
The Patent Office,
Bhouthik Sampada Bhavan,
Near Antop Hill Head Post Office,
S.M.Road, Antop Hill,
Mumbai - 400 037.
3. The Intellectual Property Appellate Board,
Guna Complex,
Teynampet,
Chennai - 600 018.



WEB COPY

R.SUBBIAH, J.
and
C.SARAVANAN, J.
Arul/kkd



Pre-Delivery Order made in
W.P.No.1219 of 2014

WEB COPY

10.01.2019