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(T)OP(PT) No.45 of 2023

IN THE HIGH COURT OF JUDICATURE AT MADRAS

Reserved on : 09.07.2024

Pronounced on : 04.10.2024

CORAM:

THE HON'BLE MR.JUSTICE P.B.BALAJI

(T)OP(PT) No.45 of 2023
(ORA/35/2014/PT/CHN)

Embio Limited,
501, Sentinel,
Hiranandani Gardens,
Powai, Mumbai – 400076 India
Represented by its Managing Director,
Mr.Devesh Malladi.

.. Petitioner

.Vs.

1.Malladi Drugs & Pharmaceuticals Ltd.,
No.9, G.S.T.Road, St.Thomas Mount,
Chennai – 600 016, India.

2.The Controller of Patents,
Intellectual Property Office,
Intellectual Property Office Building,
G.S.T. Road, Guindy,
Chennai – 600 032.

.. Respondents

Prayer: This petition filed under Section 64 of the Patents Act, 1970,
prays for the following reliefs:

a) The Board may be pleased to declare that the impugned patent,
bearing No.249376 titled “A method for the preparation of new chiral



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beta-amino alcohols from r(-) - phenyl acetyl carbinol” in the name of M/s.Malladi Drugs and Pharmaceuticals Ltd., 52, Jawarlal Nehru Road, Ekkattuthangal, Chennai – 600 097, as invalid, unenforceable and non est in law; and further

b) Award exemplary cost in view of the inequitable conduct of the Patentee.

For Petitioner : Mr.Ramesh Ganapathy
for M/s Origin IP Solution

For Respondents
For R1 : Mr.Perumbulavil Radhakrishnan

For R2 : Mr.Girish
for Mr.M.Karthikeyan

ORDER

The Petitioner seeks revocation of the patent granted to the 1st Respondent.

2.I have heard Mr.Ramesh Ganapathy, learned Counsel for the Petitioner and Mr.Perumbulavil Radhakrishnan, learned Counsel for the 1st Respondent and Mr.Girish for Mr.M.Karthikeyan, learned Counsel



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for the 2nd Respondent. I have also perused the records as well as the Patent Controller's grant, with reasons, in favour of the 1st Respondent.

3.The learned Counsel for the Petitioner, Mr.Ramesh Ganapathy's submissions, summarised:

- Objections regarding novelty and inventive step were raised by the Controller himself.
- The 1st Respondent has not been able to show non-obviousness to the person skilled in the art or ordinarily skilled in the art.
- Petitioner is a person interested since both the Petitioner and the 1st Respondent are in the same industry, dealing with similar kind of medicines.
- 1st Respondent has not been able to show as to how the method is different from the prior arts.
- 1st Respondent's invention is a mere workshop improvement which is not sufficient under the law, to enable a grant of patent.
- 1st Respondent has not been able to produce any data to show technical advancement.



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4.The learned Counsel for the Petitioner would place reliance on the following decisions:

i) Ollos Biotech Private Limited v. Omega Ecotech Products India Limited and another, OP(PT) No.1 of 2023 dated 28.03.2024.

ii) Indian Institute of Technology, Madras v. The Controller of Patents & Designs, (T) CMA (PT) No.52 of 2023 dated 11.06.2024.

iii) Novartis AG v. Union of India and Others, reported in (2013) 6 SCC 1.

iv) F.Hoffmann-La Roche Ltd., &Anr. v. Cipla Ltd., reported in 2015 SCC OnLine Del 13619.

5.Per contra, Mr.Perumbalavil Radhakrishnan, learned Counsel for the 1st Respondent's arguments are summarised as follows:

- The 1st Respondent's patent was published as early as in 2007 and **the same was never opposed by any one**, including the Petitioner who has woken up after the grant.
- Though the Petitioner claims to be manufacturing Ephedrine, the claim remained on paper and the Petitioner has not produced any material to establish the claim and hence the Petitioner is not a



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‘person interested’.

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- Ephedrine is not the end product in the 1st Respondent’s invention and the 1st Respondent has shown as to how their process is completely different from that of the prior arts.
- The process involved in the 1st Respondent’s patent is a clear technological advancement in as much as new Active Pharmaceutical Ingredients (API) intermediates were produced.
- The 1st Respondent has shown inventive step in as much as adopting a process for compounds which is different from ephedrine and its salts.
- Insofar as Claim 2, in organic chemistry, in view of long periods of time involved, no specific range can be given and moreover range depends on various other factors.

6.The learned Counsel for the 1st Respondent placed reliance on the following decisions:

i)*Aloys Wobben and another*, reported in (2014) 15 SCC 360.

ii)*Agfa Nv &Anr. V. Assistant Controller of Patents and Designs*, reported in 2023 (95) PTC



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336(Del).

iii) *Societe Des Produits Nestle SA v. Controller of Patents and Design & Anr*, reported on 2023(95) PTC 445(Del).

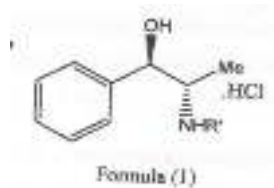
iv) *M/s. La Renon Health Care Pvt. Ltd., Gujarat v. Union of India & others*, reported in CDJ 2019 MHC 868.

v) *F. Hoffman-La Roche Ltd. and another v. Cipla Ltd.*, reported in 2012 SCC OnLine Del 4704.

7. I have carefully considered the submissions advanced by the learned counsel on either side. I have also kept in mind the principles laid down by the Courts in the cases relied on by both the Counsel.

8. The 1st Respondent's claim is as follows:-

1) A method for the preparation of new optically pure 1-phenyl-2 (N-alkyl/arylamino) propanol hydrochlorides (Formula 1) with 100% optical purity,





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wherein R' is alkyl ($C_2 - C_{10}$) Phenylalkyl ($C_7 - C_{10}$) , phenyldialkyl, Cycloalkyl ($C_7 - C_{10}$) , heterocyclic ring containing nitrogen, sulfur or oxygen (ethyl, i-propyl, n-butyl, tert-butyl, cyclohexyl).

2) A process for the preparation of 1-phenyl-2-(N-alkyl/arylamino) propanol hydrochlorides (formula 1) with 100% optical purity from R-Phenyl acetyl carbinol involving the preparation of imino derivative of R-(-)-phenyl acetyl carbinol with alkyl/aryl amines followed by asymmetric reduction using noble metal catalyst in the presence of organic solvents, which comprises of

i) adding of phenyl acetyl carbinol dissolved in organic solvent into a hydrogenator.

ii) adding of water and noble metal catalyst to the resulting solution of step (i) followed by cooling to a temperature in the range of 0° C to 25° C.

iii) adding of aryl/alkyl amine dissolved in organic solvent to the step (ii) solution



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iv) passing the hydrogen into the hydrogenator to maintain a pressure of 1 atm to 10 atm till consumption of hydrogen ceases at a temperature in the range from -30°C to $+100^{\circ}\text{C}$ preferably $10-15^{\circ}\text{C}$ for a period of 15 min to 10 h and further maintaining at a temperature in the range of -30°C to $+100^{\circ}\text{C}$ for a period ranging from 15 min to 24 h.

v) filtering the solution to recover the catalyst and separating organic layer and aqueous layer of the filtrate.

vi) drying the solvent layer containing the product 1-phenyl-2-(N-alkyl/arylamino) propanol obtained in step v with salt drying agent before concentrating under vacuum.

vii) adding of ether to the resulting mass obtained in step (vi) and acidifying by passing dry HCl gas to pH in the range 1.0 to 6.0 to obtain the crude (+) or (-)-1-phenyl-2-(N-alkyl/arylamino) propanol as HCl salt

viii) recrystallising the crude product obtained in step (vii) using organic solvent or water.

3) A process according to claim 2 wherein, R-(-) phenyl acetyl carbinol used in step (i) is selected from (+) or (-) or $\pm$ phenyl acetyl carbinol and the solvent used is selected from organic solvents or water, preferably toluene.



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4) A process according to claim 2 wherein, the catalyst used in step (ii) for reduction is chosen from noble metals, preferably platinum and cooling the resulting solution to a temperature range of 0° C to 30° C preferably 10° C.

5) A process according to claim 2 wherein, alkyl/aryl amine used in step (iii) is selected from i-propyl, cyclohexyl, phenyl, n-butyl, R-phenylethyl, S-phenylethyl, benzyl dissolved in toluene.

6) A process according to claim 2 wherein, the hydrogenator in step (iv) is pressurized using hydrogen in the range of 1 atm to 10 atm preferably 6 atm till consumption of hydrogen ceases at a temperature in the range from – 30° C to + 100° C preferably 10-15 ° C for a period of 15 min to 10 h, preferably 2h and is maintained further under stirring for a period of 15 min to 10h preferably 4h at a temperature ranging from -30° C to 100 ° C preferably 10-15 ° C.

7) A process according to claim 2 wherein step (v) solution is filtered to recover the catalyst followed by separation of organic layer containing the product from the aqueous layer of the filtrate.

8) A process according to claim 2 wherein, organic solvent layer in step (vi) containing the product is dried with solid drying agent preferably



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anhydrous sodium sulphate before concentrating under vacuum.

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9) A process according to claim 2 wherein, the resulting mass in step (vii) is acidified by passing dry hydrochloride gas to pH in the range 1.0 to 6.0 preferably 3.0 to obtain the crude (+) or (-) - 1- phenyl-2-(N-alkyl aryl amino) propanol hydrochloride.

10) A process according to claim 2 wherein the solvent used in step (viii) for recrystallisation is selected from organic solvents or water preferably isopropyl alcohol.

9.The 1st Respondent's patent application pertains to the method in Claim 1 and process in Claim 2 being the main claims and the remaining claims, all being dependant claims. The application was filed on 25.06.2007 and was notified on 18.10.2011.

10.Initially the Patent application met with preliminary objections from the Controller vide First Examination Report and in response to the same, the 1st Respondent replied with its explanations and also amended the claims twice, on 03.06.2011 and 14.09.2011 respectively and finally granted the patent for the first 2 claims, viz., the method and the process



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as detailed hereinabove already.

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11.The subject matter of the said patent granted to the 1st Respondent is “*A method for the preparation of new chiral beta-amino alcohols from R(-)-phenyl acetyl carbinol*”

12.The specific case of the Petitioner is that the Petitioner is the world’s second largest manufacturer of Ephedrine and Pseudoephedrine salts with bulk manufacturing facility. Attacking the patent granted to the 1st Respondent on the ground of lack of novelty, under Section 64(1)(e) of the Patents Act, 1970, the Petitioner contends that there has been substantial research in this particular area and specifically referring to prior arts, European Patent No.EP 1 142 864 A1, US Patent Nos.US2,509,309 & US2004/0249212 A1, the Petitioner would contend that the invention claimed by the 1st Respondent is not novel since the process, steps, reactants, temperature range, catalyst used and pressure employed are all found in prior arts.



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13. With regard to lack of inventive step under Section 64(1)(f), the Petitioner alleges that the use of phenyl acetyl carbinol as the starting compound for synthesis of α -amino alcohol has been seen in the prior arts and it is obvious to any person skilled in the art to arrive at the final compound using noble metal catalyst.

14. It is also the further case of the Petitioner that the impugned Patent neither involved any technical advancement nor has any economic significance. Moreover, the process is well known in chemistry and does not go beyond the normal progress of technology, but merely follows the prior arts.

15. The Petitioner further contends that the 1st Respondent has not shown any significant improvement relating to efficacy of the product or a new product arising from the process or even a new reactant involved in such a new process. The 1st Respondent has also not sufficiently described the invention which is one of the important criterion for getting grant of a patent.



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16.The said allegations of the Petitioner are resisted by the 1st

Respondent claiming that the 1st Respondent is a leading manufacturer of API in the cough and cold segment as well as having a dominant presence in various other segments, right from the year 1980 onwards. The 1st Respondent also contests the claim of the Petitioner to be 'an interested person' on the ground that merely claiming to be a leading manufacturer of Ephedrine would not make the Petitioner, 'a person interested'.

17.The further case of the 1st Respondent is that the claims were amended twice and the grant of patent was thereafter and the Petitioner can no longer rely on the claims originally filed by the 1st Respondent and citing the same, attack the grant.

18.Regarding lack of novelty, the 1st Respondent contends that the process disclosed to synthesis stereo selective isomer is novel and inventive and the same is not found in the prior arts. The technical advancement claimed is the high optical purity achieved, and the process involved is for intermediates of new API's. The Petitioner's claim,



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according to the 1st Respondent is only based on irrelevant and immaterial prior arts.

19.Let me examine the relevant case laws on the subject, before I proceed to apply the ratio laid down in the said cases, as applicable to the facts of the present case.

20.In *Ollos Biotech's* case (referred herein supra), this Court held on the facts of the said case that no comparative data was provided and the complete specification lacked experimental data to support an inference of technical advancement.

21.In *IIT, Madras's* case (referred herein supra), this Court held that in order to surmount the test of inventive step, the claimed invention must possess two main characteristics, viz., i) it should exhibit technical advancement as compared to the existing knowledge or have economic significance in the industry or both of the above; and ii) the purported technical advance must not be obvious to a person skilled in the art.



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22.In *Novartis's* case (referred herein supra), the Hon'ble Apex Court held that in the case of medicines, therapeutic efficacy should be shown and mere existence of advantages or beneficial properties would not be relevant. It further held that mere change of form with properties inherent to that form would not qualify as 'enhancement of efficacy' of a known substance.

23.The Division Bench of the Hon'ble Delhi High Court, in *F.Hoffmann's* case (referred herein supra), held that any inventive step of an invention must not be obvious to a person skilled in the art. The Hon'ble Delhi High Court further held that a new form is neither the same substance nor the same product and if one does show enhancement in efficacy, he would be entitled to grant of a patent for the new form. The Division Bench also held that obviousness is a question of law based on facts and the burden to prove is on the party which alleges, however after the party which alleges makes out a prima facie case, the burden shifts on the inventor to disprove obviousness.

24.In *Aloys Wobben's* case (referred herein supra), the Hon'ble



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Supreme Court dealt with 'interested person' and held that a person interested would include a person who has a direct, present and tangible interest with a patent and the grant of the patent would adversely affect his rights and would include a person 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.

25.In *Agfa's* case (referred herein supra), the Hon'ble Delhi High Court held, referring to Terrell on Law of Patents, 16th Ed., proof of common knowledge is given by witnesses competent to speak upon the matter, who, to supplement their own recollections, may refer to standard works upon the subject which were published at that time and which were known to them, and regarding inventive steps, the invention should be considered as a whole and it would not be sufficient to draw a conclusion that a claimed invention is obvious merely because individual parts of the claim taken separately are known or might be found to be obvious.

26.In *Societe's* case (referred herein supra), the Hon'ble Delhi High



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Court held that when prior arts cited are more than 20 years older than the patent in question, having been available for a long time and an apparently minor development meeting a long felt want may be shown to be non-obvious because, although prior art has been available, the development was not hit upon by others.

27.In *M/s.La Renon's* case (referred herein supra), the Division Bench of this Court held that when a patent has already been granted, the onus is on the person wishing to challenge its validity and that onus has to be discharged on a balance of probabilities and also held that the onus of establishing invalidity on any of the grounds cannot be shifted to the patentee.

28.Keeping in mind the above principles, first and foremost, it is to be examined whether the Petitioner is an interested person competent to challenge the grant in favour of the 1st Respondent. Section 2(t) of the Patents Act, 1970 defines a “person interested” to include a person engaged in, or in promoting, research in the same field as that to which the invention relates.



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29.The specific case of the Petitioner is that the Petitioner is a manufacturer of Ephedrine and Pseudoephedrine salts and also having a bulk manufacturing facility. The 1st Respondent also manufactures API (Active Pharmaceutical Ingredients) including DL-Ephedrine HCl, DL-Methylephedrine HCl, Pseudoephedrine and salts. As held by the Hon'ble Apex Court in *Aloy Wobben's* case (referred herein supra), the term 'person interested' is not static and even if he 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 of time, he may assume the character or disposition of a 'person interested'.

30.Section 64 of the Patents Act, 1970 deals with revocation of patents. The validity of a patent can be challenged or sought to be revoked by any person interested on the grounds mentioned in sub-sections 1(a) to 1(q). Even according to the 1st Respondent, the Petitioner is a competitor and therefore, it cannot be said that the Petitioner is not a 'person interested'. The language employed in Section 2(t) does not require that the person interested should be only in manufacturing in the same field.



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31.This Court also in *M/s.La Renon's* case (referred herein supra), held that 'person interested' is an inclusive definition and merely because the Petitioner is not a manufacturer, he cannot be shut out from filing an application for revocation under Section 64(1). Therefore, in the facts and circumstances of the case discussed hereinabove, I have no hesitation to hold that the petition at the instance of the Petitioner is maintainable under Section 64 of the Act.

32.Moving on to the next two-fold objections that the 1st Respondent's patent lacks novelty and inventive step, especially in the light of the prior art, I shall proceed to examine the facts of the present case and the rival contentions put forth, in the light of the settled legal position.

33.The EP 1 142 864 A1 deals with a process where L-(R)-Phenylacetylcarbinol reacts with primary aralkylamine under catalytic reduction conditions using catalysts like platinum or palladium with the reactions being carried out using lower alcohols as solvents, achieving 82% optical purity with a yield of isolated pure L-erythro (1R,2S)-2-



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amino-1-phenylpropan-1-ol of 42.3%.

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34. In the 1st Respondent's patent, the yield is in the range of 60% - 70% with a purity of more than 99% and optical purity of close to 100%. Thus, the 1st Respondent has certainly shown technical advance over the prior art in the European patent.

35. In the US Patent, US2,509,309, the process disclosed is for preparation of ephedrine salts, The yield achieved is 42.5% or thereabouts using ethyl as a catalyst and using nickel predominantly. In the US Patent, US2004/0249212 A1, phenylacetylcarbinol is reacted with liquid methylamine or methylamine in THF, using liquid carbon dioxide as solvent. This prior art does not disclose any yield or purity and optical purity of the isolated product.

36. Comparing the 1st Respondent's patent to even the above prior arts, it is clear that the process involved in the 1st Respondent's patent is certainly different and also better than the teachings of all the three prior arts.



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37.Regarding novelty also, the 1st Respondent has evolved a process whereby the reaction time is lesser and also produces better results, especially drastic higher yield as well as optical purity of the isolated product being far superior to what is achieved in the prior arts. The reaction conditions are also far simpler than the ones followed in the prior arts. Novelty is exhibited by the isolation of α -Amino alcohol as HCl salt in organic solvent leading to selective crystallisation of Erythro(1R, 2S) isomer.

38.In fact, from the claims, I notice that the primary object of the invention itself is to provide a new synthetic route and a new process for synthesis of optically pure hydrochlorides by a reduction using platinum as a catalyst and in the presence of organic solvents and also isolate optically pure phenyl propanol hydrochlorides in a higher yield as well as in optically pure form in the range of more than 99% and even able to reach 100%. Thus, both inventive step and novelty have been shown by the 1st Respondent over the prior arts cited and relied on by the Petitioner.



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39.The 1st Respondent has also provided sufficient examples before the Patent Controller in order to illustrate the invention which is a process of preparation of new chiral α -amino alcohols which are useful intermediates in the synthesis of anticoagulant drugs. Therefore, I do not find any merit in the contention that the 1st Respondent has not provided sufficient data or comparison relevant to the patent.

40.As held in *Agfa's* case (referred herein supra), the invention has to be considered as whole and dissecting the invention into parts and finding individual parts to be obvious to hold that the invention itself is obvious, is not the right approach to be adopted. In doing so, it is evident from the foregoing discussions that the patent granted to the 1st Respondent is not hit by Section 3(d) of the Act.

41.Also the EP Patent is of the year 1999 and the US Patent is also of the year 1950 and applying the ratio laid down in *Societe's* case (referred herein supra), the prior arts being much earlier to the patent in question and when the 1st Respondent has shown some advancement over the earlier prior arts and the very fact that despite the prior arts being



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in existence, none has been able to come up with the invention of the 1st

Respondent all these long years, by itself shows that there is no obviousness in the claimed invention.

42.The further fact that the Controller has examined the patent application and raised various objections, including prior arts, all of which have been overcome by the 1st respondent, before being granted the patent also shows that the Controller has applied his mind and only after a thorough examination of all the claims made by the 1st Respondent, that too after amending the claims twice, the patent has been granted. I do not find any illegality or perversity in the grant, in order to invalidate the same on the grounds raised by the Petitioner.

43.Yet another reason for not acceding to the Petitioner's claim, coupled with the findings arrived hereinabove, is the fact that the 1st Respondent was granted the patent on 18.10.2011 and its term relates back to the date of application, viz., 25.06.2007 and the 1st respondent's patent term is in its fag end, with a little over two years left. I have also not seen any strong materials having been put forth by the Petitioner to



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invalidate the grant. There is some merit in the argument of the 1st

Respondent's Counsel that despite the publication in 2007, no objection was taken for several years. Moreover, in such cases of post -grant challenge, the burden is only on the Petitioner to establish that the grant requires to be revoked for not being novel or not showing any inventive step. The Petitioner's attempts to cite prior arts to challenge the grant in favour of the 1st Respondent are not worthy enough for this Court to revoke the grant of patent in favour of the 1st Respondent which was only after a thorough examination of the same by the Controller. Merely because, the Petitioner, being a competitor of the 1st Respondent is entitled as a 'person interested' to challenge the patent, post grant, the said right is not automatic and unless the Petitioner establishes strong grounds for revocation by citing relevant prior arts and also show how the subject patent is not novel and that it lacks inventive step or does not show any technical advance, the Petitioner is not entitled to succeed. Having already found that the Petitioner has not been able to discharge the burden upon it, there is no necessity to revoke the grant in favour of the 1st Respondent.



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44.For all the above reasons, I do not see any merit in the petition
and the same deserves to be dismissed.

45.In fine, the Original Petition is dismissed. However, there shall
be no order as to costs.

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To

The Controller of Patents,
Intellectual Property Office,
Intellectual Property Office Building,
G.S.T. Road, Guindy,
Chennai – 600 032.

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