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The Controller of Patents & Designs
The Patent Office
Delhi.

Via E-mail/Courier
May 18, 2011

Kind Attn.: Dr. Nilanjana Mukherjee
Ld. Assistant Controller of Patents & Designs

Dear Sir,

Re: Patent Opposition Under Section 25(1) against
Patent Application No. **602/DEL/2007 dated March 20, 2007**
GILEAD SCIENCES, INC.....**Applicant**
INTERMED LABS PVT. LTD . .....**Opponent**
Our Ref : PII 318/AS/AM/Y/19062011

We submit herewith the **Written Arguments** on behalf of the opponent in duplicate based on the hearing held on April 6 and May 2, 2011 in connection with the above case.

A copy of the written arguments may be sent to the Patentee's attorney, if you so desire, but only after the receipt of their written arguments from the patentee. In the event, a copy of the opponent's written arguments is furnished to the patentee a copy of the patentee's written arguments should also be sent to the opponent.

The above documents may kindly be taken on record.

Yours faithfully,

Abhishek Sen
Of S. Majumdar & Co.
Opponent's Agent

23/05/11

27139

Encl. Written Argument (in duplicate)

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BEFORE THE CONTROLLER OF PATENTS,
DELHI

IN THE MATTER of Patent Application No: 602/DEL/2007 dated March 20, 2007

GILEAD SCIENCES, INC, ... **Applicant**

And

CDYMAX (INDIA) PHARMA LIMITED ..... **Opponent**

WRITTEN ARGUMENTS OF THE OPPONENT BASED ON THE HEARING HELD ON APRIL 6 AND MAY 2, 2011 AT PATENT OFFICE, DELHI

As directed by the Ld. Controller, Intermed Labs Pvt. Ltd, India, being the opponent in the present opposition proceedings hereby submits written arguments on the submissions made at the hearing with respect to the aforesaid opposition.

Before commencing with its submissions, the Opponent clarified that it's name has been changed from Intermed Labs Private Limited to Cdymax (India) Pharma Limited. The opponent also filed a petition dated April 2, 2011 stating the same.

The submissions at the hearing were made on the basis of the impugned application 602/Del/2007 and the pleadings of the parties.

PRELIMINARY SUBMISSIONS & OBJECTIONS

1. At the outset, it was categorically submitted by the opponent that the impugned application is a divisional to application no. 2076/DEL/1997, which pertains to substantially the same invention as the one under opposition.

2. The opponent also filed a representation under Section 25(1) against the parent application, being 2076/DEL/1997. Subsequently by an order dated July 30, 2009, 2076/DEL/1997 was rejected on the grounds of non-obviousness and not patentable under section 3(d).

3. It is submitted that the claims of the impugned application is substantially the same as those on the parent application. For ready reference, the opponent has tabulated the claims of the parent application (2076/DEL/1997) and the present one.

602/del/2007	**Corresponds to 2076/del/1997 (as amended)**	**Remarks**
1. (Independent)	1	Claimed compound is designated by the chemical class in the parent as against the generic term compound of formula 1(a) in the divisional
2.	2	All these claims of divisional are directly / indirectly dependant on claim 1.
3.	3	
4.	4	
5.	5	
6.	6	
7.	7	
8.	8	
9.	9	
10.	10	
11.		Dependant on claim 4 – refers to configuration of the chiral center

12.		Dependant on claim 4 – refers to configuration of the chiral center i.e. 90% R
13.	11	All these claims of divisional are directly / indirectly dependant on claim 1.
14.	12	
15.		
16.		
17.		
18.	13	
19.	14	
20.	15	
21.	16	
22.	17	
23.	18	
24.	-	Dependant on claim 1
25.	-	Dependant on claim 22 – refers to configuration of the chiral center i.e. 90% S
26. (Independent)	19	-
27. (slightly modified) – (Independent)	20	-
28.	21	-
29.	22	-
30.	-	Dependant on claim 27. Process description.
31.	-	Dependant on claim 30. Salts of 1 – sulfuric, phosphoric, lactic or citric.
32. (omnibus - product)	23 (omnibus)	
33. (omnibus - product)	-	
34. (omnibus - process)	24(omnibus)	
35. (omnibus)	-	

4. As evident from the above table, the scope of the subject matter claimed in both applications is essentially same. The opponent submitted that filing such a divisional application, wherein the claims are same in scope as that of the claims on the parent, was done with a malafide intent and in an attempt to mislead the Ld. Controller. It was submitted that the applicant being aware of the noninventiveness of the parent application, filed a divisional as a fall-back option in the event the parent application gets refused. As expected, the parent application was rejected based on the opposition filed by the opponent and with this application the applicants are getting another chance to revive the rejected claims.

5. It was also submitted that the impugned patent application is not truly a divisional application as per Section 16 of the Act, particularly sub-section 3 which clearly provides that, "The Controller may require such amendment of the complete specification filed in pursuance of either the original or the further application as may be necessary to ensure that neither of the said complete specifications includes a claim for any matter claimed in the other". The same objection was also found in the First Examination Report issued by the Patent Office under paragraph 4. Thus the present application does not qualify as a divisional application as the same was filed in contravention to provision of the Patent Act and should be outrightly rejected.

6. The opponent submitted that the Delhi PO has rejected quite a few applications, where the claims of the divisional were same as that of the parent application. Two such cases are mentioned below alongwith the relevant passages.

7. The Ld. Controller in the matter of patent application no. 832/DEL/2001 filed by M/s. BAYER AKTIENGESELLSCHAFT held as under.

> *The set of claims of the so called divisional application was same as that of the parent application including the claim 1 which the applicant intended to claim again..... I hereby refuse to consider the instant application as a divisional application u/s 16 of the Act as the same has not been filed in accordance with the provisions of the Patents Act.*

The Ld. Controller in the matter of patent application no. 748/DEL/2002 made by M/s. NOVARTIS AG later on assigned to (SYNGENTA PARTICIPATION AG) held as under.

The set of claims of the so called divisional application was same as that of the parent application including the claim 1 which the applicant intended to claim again....I hereby refuse to consider the instant application as a divisional application u/s 16 of the Act as the same has not been filed in accordance with the provisions of the Patents Act.

8. The opponent submitted that the claims of both applications recite substantially the same subject-matter and argued between the same parties before the Patent Office at Delhi, so the common law principle of "*Res-judicata*" applies here which has been grounded in Section 11 of The Code of Civil Procedure, 1908 and also general principles. In other words, the principle of *res-judicata* squarely applies to the present case as the parties involved in the proceeding pertaining the parent application, i.e. 2076/DEL/1997 are the same as the present one, also the subject- matter of the dispute being the claims are same in both proceedings and before the same Tribunal.

9. The opponent relied on the below judgments to support its contention on the principle of *res judicata.*

The High Court of Bombay in **Pandurabg Sakharam Vs. The Mahaarashtra Revenue Tribunal, Nagpur and Ors. [AIR1974Bom20],** discussed the doctrine of *res judicata* as under:

11. The doctrine of res judicata is a doctrine of repose and is grounded on public policy. It means that the things which were actually and directly in dispute and which were finally adjudicated upon should not be allowed to be reagitated. In a sense it postulates a principle of peace operative over the warring field of litigation and secures finality for justice. doctrine as is known to us had its origin in English common law principle its recent appraisal by that it stems out of law of estoppels and in essence is a doctrine of "issue - estoppel". In ***Edwards V. Edwards (1967) 2 All ER 1032*** *Sir Jocelyn Simon. P. observes:*

"All adjudication. like every piece of social engineering of desiderata, not all of which are easily made consistent. There should first, be the fullest and truest assessment of all relevant facts. There must however, secondly be some protection of individual privacy and liberty. Thirdly, and most relevant of all to this application it is desirable that disputes within society should be brought to an end as soon as is reasonably practical and should not be allowed to drag. That last principle finds expression in maxim which English law took over from the Roman law; it is in the public interest that there should be some end to litigation. The principle, for example applies in the doctrine which is known to lawyers as res judicata, in other words, once there is decision on a matter by a competent Court, it is binding on all courts of similar jurisdiction".

In ***Carl-Ziess-Stiftung V. Rayner (1966) 2 All ER 536****. its content is found to mean "an issue estoppel". The Court observes:*

"Within recent years the principle was developed so as to extend to what is now described as "issue estoppel" that is to say where in a judicial decision between the same parties some issue which was in controversy between the

parties and was incidental to the main decision has been decided, then that may create an estoppel per rem judicatam"."

12. As far as Indian Law is concerned, the principles of res judicata are firmly grounded into our system of judicial administration both under the code of Civil Procedure and also upon general principles. In ***Satyadhyan V. Smt. Deorajin Debi: [(1960)3SCR590]*** *the principles were applied on the need of giving a finality to judicial decisions. If a matter between two parties in one suit or proceeding has been decided and that decision has achieved finality either because no appeal was taken to a higher court or because the appeal was dismissed or no appeal lies, then neither party should be allowed in the future suit or the proceeding between the same parties to canvass the matter again. This is the core and concept of the rule. The principles however underlying the doctrine are available and as such applicable in other jurisdictions too for achieving finality and firmness to judicial process. Similarly a given controversy may stand concluded between two stages of the same litigation to the extent that Court, whether the trial Court or higher Court, having at an earlier stage decided the matter in one way will not allow the same parties to reagitate the matter again at a subsequent stage of the same proceeding...*

The Hon'ble Supreme Court of India in **Kunjan Nair Sivaraman Nair Vs. Narayanan Nair and Ors. [AIR2004SC1761]** at length discussed the principle of *res judicata* as under:

11. Rule of res judicata is contained in Section 11 of the Code. Bereft of all its explanations, namely, Explanations I to VIII, Section 11 is quoted below :
"11. Res judicata. - No court shall try any suit or issue in which the matter directly and substantially in issue has been directly and substantially in issue in a former suit between the same parties, or between parties under whom they or any of them claim, litigating under the same title, in a court competent to try such subsequent suit or the suit in which such issue has been subsequently raise, and has been heard and finally decided by such court."
12. "Res judicata pro veritate accipitur" is the full maxim which has, over the years, shrunk to mere "res judicata".
13. Section 11 contains the rule of conclusiveness of the judgment which is based partly on the maxim of Roman Jurisprudence "Interest reipublicae ut sit finis litium" (it concerns the State, that there be an end to law suits), and partly' on the maxim "Nemo debet bis vexari pro una at eadem causa" (no man should be vexed twice over for the same cause). The section does not affect the jurisdiction of the court but operates as a bar to the trial of the suit or issue, if the matter in the suit was directly and substantially in issue (and finally decided) in the previous suit between the same parties litigating under the same title in a court, competent to try the subsequent suit in which such issue has been raised.
14. The above position was noted in Deva Ram and Anr. v. Ishwar Chand and Anr. [AIR1996SC378].

The Hon'ble IPAB, Chennai in **Hindustan Lever Limited Vs. Madhusudhan Industries Limited and Assistant Registrar of Trade Marks [2005(31)PTC214(IPAB)]**

2. The first respondent filed an application for registration of a trade mark consisting of words 'UJALA KING' with a device of Sun in Class 3 of the Trade and Merchandise Marks Act, 1958 (hereinafter referred to as the Act), in respect of soaps under application No.401336. The user claimed under that application is since December, 1975. In due course, the mark was advertised in the Trade Marks Journal No.1078 (Supplement) dated 8.5.1994 at page 6, under proviso to Section 20(1) of the Act. The appellant gave a notice on 27.7.1994 to oppose the registration of the mark on the ground that it is the proprietor of a well known trade mark 'SUNLIGHT' and also of the trade mark 'SUN'. The said marks are registered in various forms. The impugned mark is deceptively similar to its registered trade mark 'SUNLIGHT'. The word UJALA is descriptive of the goods like Soaps. The impugned mark is neither distinctive nor capable of distinguishing the goods of the applicant. The first respondent had earlier made an application for the same mark under No.342707 which was refused registration vide opposition No.BOM-6129. That decision of the Registry is res-judicata in the present matter. It opposed the mark under sections 9,11, 12(1), 18(1) and 18(4) of the Act. The first respondent filed its counter statement and the evidence. In due course, similarly the appellant filed its evidence. The Assistant Registrar heard the matter on 4.8.1997 and he inferred that the opposition is based on sections 9, 1, 12(1) and 18(1) of the Act. He heard arguments of the learned counsel for the appellant and the first respondent. He concluded that, by virtue of long user since 1975, the mark acquired distinctiveness and, as such, qualifies for registration under section 9 of the Act. In the matter of its examination under section 11(a), after having heard both the counsel, he concluded that both the marks are distinct and he inferred that even the goods are different. The first respondent's product is washing soap and is meant for the poor class society whereas the 'SUNLIGHT' soap is a product which is being bought by the rich people because of its high price. So the objection of the appellant fails under Section 11(a) of the Act and accordingly the objection under Section 11(e) also fails. In the matter of its examination under Section 12(1), in relation to application of two tests thereof, his conclusion was that the rival goods are of the same description, but, however, he found that the mark does not meet the second requirement as the rival marks are totally different from each other in respect of get up, colour scheme, etc. Thus, he concluded that the opposition under Section 12(1) also fails. He found the mark to be eligible under section 18(1) of the Act. Having found the mark to be entitled for registration under Sections 9,11(a),11(e), 12(1) and 18(1) of the Act, he proceeded with the examination of the mark under Section 12(3) of the Act and found that, in any case, the mark is also eligible under Section 12(3) of the Act. His conclusion about the application of the principle of resjudicata in the matter is that the Tribunal which he was then for the time being presiding over is an independent Tribunal and the proceedings of the matter under opposition No.BOM-6129 are not binding upon that Tribunal. He mentioned that the circumstances in the Bombay case might have been different and in the present case, he has made a physical examination of the packing material as well as the products of both the rival marks and according to his findings and analysis he reached the conclusion that the rival marks are totally different from each other. Thus, he dismissed the opposition and ordered for the registration of the mark.

8. Sub section 2 of Section 4 of the Trade and Merchandise Marks Act, 1958 can best be exemplified as the replica of an instrumentality having its philosophical deduction from the provisions under the Constitution. The Registrar remains to be one in spite of its various limbs known as the Joint Registrars, Deputy Registrars and Assistant Registrars as the Government of

India remains one in spite of the various civil servants to perform its functions at different levels. Since the institution of the Registrar is one of which the Assistant Registrar at Bombay and another Assistant Registrar at Ahmedabad happen to be integral part, one limb of that integrated personality cannot be seen as claiming that that particular limb is independent of the machinery as a whole. Here learned Assistant Registrar appears to be venturing in that direction. The Assistant Registrar is patently wrong in claiming that he is an independent Tribunal in itself. Independence of the Tribunal is undisputed, but, as the Tribunal of the Registrar as a whole and not of the specific nuts and bolts. It is essential that there must be some consistency amongst the functionaries discharging quasi-judicial functions. Otherwise on the rejection of an application by one authority, the applicant will be tempted to file a fresh application before another authority with or without modification and have a chance.

As evident from the underscored lines above, the applicant filed an application for a mark, which was same as a mark previously rejected by the Registry. The Opponent therein argued that the decision of the Registry in the previous matter is *res-judicata* on the present. The Assistant Registrar in his order granting the application stated that he is an independent Tribunal and therefore the principle of *res-judicata* will not hold good. The IPAB clearly stated that the Asst Registrar was wrong in assuming that he is an independent Tribunal in itself and that there must be some consistency amongst the functionaries discharging quasi-judicial functions.

In the present case, the claims of the parent and the present application (divisional) are same and the parent application being rejected by the Patent Office based on the same grounds as taken in the present one, the principles of res-judicata clearly applies. Thus the decision in the matter of patent application no. 2076/DEL/1997 is *res judicata* on the present one.

The Hon'ble Supreme Court of India in **Ramdev Food Products Pvt. Ltd. Vs. Arvindbhai Rambhai Patel and Ors. [(2006)8SCC726]** held as under.

42. We are also not in a position to accept the submission of Mr. Nariman that the MOU must be read with the deed of partnership or the deeds of retirement whereby and whereunder the firm 'Ramdev Masala' and 'Ramdev Exports' were permitted to use the word 'Ramdev'. What is registered is a logo wherein the words 'Ramdev' and 'Masala' are prominent. A person may be held to be permitted to carry on business in spices as contradistinguished from the permission to carry on manufacturing goods which are similar to that of the appellant, but in terms of the statutory provisions, the respondents were not legally permitted to sell its products in packages or labels which would be deceptively similar to that of the registered owner of a trade mark.

The right to manufacture masala and to sell the same with the registered logo, it will bear repetition to state, was assigned as far back in 1991. If the contention of the Senior Counsel is accepted, the said purpose would be lost.

In a case of this nature, therefore, ordinarly an injunction would issue. By reason of interpretation of MOU, trade mark cannot be infringed and further when the right of user has been relinquished, the same could not have been claimed by the respondents.

WAIVER

43. The matter may be considered from another angle. If the first respondent has expressly waived his right on the trade mark registered in the name of the appellant-Company, could he claim the said right indirectly? The answer to the said question must be rendered in the negative. It is well-settled that what cannot be done directly cannot be done indirectly. The term 'Waiver' has been described in the following words:

Waiver is the abandonment of a right in such a way that the other party is entitled to plead the abandonment by way of confession and avoidance if the right is thereafter asserted, and is either express or implied from conduct.... A person who is entitled to rely on a stipulation, existing for his benefit alone, in a contract or of a statutory provision may waive it, and allow the contract or transaction to proceed as though the stipulation or provision did not exist. Waiver of this kind depends upon consent, and the fact that the other party has acted upon it is sufficient consideration.... It seems that, in general, where one party has, by his words or conduct, made to the other a promise or assurance which was intended to affect the legal relations between them and to be acted on accordingly, then, once the other party has taken him at his word and acted on it, so as to alter his position, the party who gave the promise or assurance cannot afterwards be allowed to revert to the previous legal relationship as if no such promise or assurance had been made by him, but he must accept their legal relations subject to the qualification which he has himself so introduced, even though it is not supported in point of law by any consideration. [See 16 Halsbury's Laws (4th edn) para 1471] Waiver may sometimes resemble a form of election, and sometimes be based on ordinary principles of estoppel. [See 45 Halsbury's Laws (4th edn.) para 1269] In Indu Shekhar Singh and Ors. v. State of U.P. and Ors. MANU/SC/8125/2006 : AIR2006SC2432 , this Court held: "They, therefore, exercised their right of option. Once they obtained entry on the basis of election, they cannot be allowed to turn round and contend that the conditions are illegal"

In the cited case, right on a trademark was expressly waived by owner, who later tried to re-claim the same by indirect means. The Court held that such cannot be permitted as it is against the Law. In the present case too, the parent application having the same claims as the one under opposition was rejected by a well-reasoned decision. In view of that, the applicant's attempt to prosecute the present application is clearly a malafide action as it is trying to reclaim subject matter, which already forms part of prior art due to reasons herein.

Therefore the impugned application should be forthrightly rejected based on the preceding submissions.

10. The opponent submitted that the claims of the impugned application are similar to the parent application 2076/DEL/1997, please see table under

paragraph 3 for a comparative analysis of the claims. It was also submitted at the outset that the opponent wholly adopts the arguments as found in the written arguments concerning the parent application. A copy of the same is annexed hereto for ready reference.

11. The opponent specifically drew the attention of the Ld. Controller to page 5, line 20 of the specification which referred to the objects of the invention. The opponent further stressed that the main object of the alleged invention was centered on three objects viz as evident from page 33, line 12 onwards.

(i) the compounds should be chemically stable;

(ii) should have an adequate shelf-life and proper bio-distribution upon oral administration; and

(iii) should have bioavailability in beagle dogs that exceeds about 20%, preferably about 30%.

12. In this context it was submitted that the applicant has not provided any data to substantiate the enhanced efficacy of the compound claimed in the impugned application with respect to their effectiveness in human beings although the applicant has specifically indicated dosage for human use which could not have been arrived at without exhaustive trials. The question is why has the applicant not revealed the test data for humans but only with respect to beagle dogs.

13. The opponent submitted that Table 1 as found in the impugned specification concerned only the carbonate prodrugs whereas the scope of the invention was directed to both carbonate and carbamate prodrugs. This implies that the both the prodrugs are effectively interchangeable and that it is a mere attempt on the part of the applicant to enlarge the ambit of the invention. It was further emphasized that the demonstration was not with respect to both the forms though the carbamate prodrugs are indicated to be more stable in biological environments than the carbonates.

14. It was submitted that there were no secondary aspects and that all the product claims were effectively dependent on claim 1. Therefore all the dependent claims rise and fall with claim 1.

15. The opponent drew the attention of the Ld. Tribunal to page 7 of its representation specifically to paragraphs 5.1 and 5.2 which dealt with the

compounds claimed in the impugned application. The opponent further relied upon paragraph 5.3 which highlighted certain admissions of the applicant viz,

- The parental compounds having the structure $AOCH_2P(O)(OH)_2$ are well known and have demonstrated anti-viral activity;
- Per se, they are not part of this invention; and
- In general, A has the structure BQ wherein B is a purine or pyrimidine base or the aza and/or deaza analogs thereof and Q is a cyclic or acyclic aglycon. B is linked to Q through the purine 9 or pyrimidine 1 positions.

16. The opponent presented the definition and a brief explanation of a 'prodrug' and cited a relevant paragraph from an article entitled "Targeted Prodrug Design to Optimize Drug Delivery" published in 2000 which clearly taught that *"The term "prodrug" or "proagent" was first introduced by Albert (2) to signify pharmacologically inactive chemical derivatives that could be used to alter the physicochemical properties of drugs, in a temporary manner, to increase their usefulness and/or to decrease associated toxicity. Since Albert discussed the concept of prodrugs in the late 1950s, such compounds have also been called "latentiated drugs," "bioreversible derivatives," and "congeners," but "prodrug" is now the most commonly accepted term."* The opponent summarized that these bioreversible derivatives mask the parent drug, pass through the channels in vivo to which the parent drug is susceptible in effect functioning as a vehicle to deliver the parent drug without degradation to the patient in need.

17. The opponent submitted that its principal objection to the impugned application was obviousness and lack of inventive step. The opponent drew the attention of the Ld. Tribunal to paragraph 5.4 of its representation wherein the table illustrated the minor difference between the compounds claimed in the instant impugned application and those admittedly known in the prior art. It was stated that paragraph 5.5 of the representation highlighted that the hydroxyl group occurring the known parental compounds were substituted by the group 'Z' in the impugned application and also included the various values of 'Z' allegedly claimed in the impugned application. With respect to paragraph 5.6 of its representation, the opponent stated that the applicant has tried to protect the carbonate and carbamate prodrugs in view of the known parental compounds.

18. With reference to paragraphs 5.7, 5.8, 5.9 and 5.10 of its representation, the opponent stated that these paragraphs discussed the object of invention of the impugned application and table 1 given on page 62 wherein the applicant claims to have provided bioavailability data which allegedly is the basis of claiming the inventive merit in the impugned application.

19. The opponent further presented to the Ld. Tribunal that the test of obviousness rests in the fact as to whether a person skilled in the art would be successful in bridging the teachings of the prior art to arrive at the claimed invention. It was further stated that obviousness may be judged either on the basis of prior art documents or with the aid of an expert in the field who would be able to predict the closeness between the prior art and the claimed invention. It was further stated that the applicant's response to documents D3, D4 and D5 of the representation indicating that these documents were a part of the US prosecution history were of little relevance to the present proceedings since the Indian patent office will not decide the present proceedings on the basis of the proceedings before the USPTO and the onus rests on the applicant to establish that the impugned application was not obvious in view of the teachings of D3, D4 and D5. It was further stated a person skilled in the art would combine the teachings of these documents to arrive at the claimed invention and will simultaneously conduct trials for similar compounds to check their performance. It was further stated that to ascertain inventive merit an expert in the field needs to justify that the intervention by the person skilled in the art to the existing state of the art is unexpected.

20. The opponent stated with reference to D1 of the representation that the said document was published in 1995 and was in the name of the same applicant as that of the impugned application and Dr. William Lee is a co-inventor of D1. It was further submitted that a product patent was not possible in India prior to 01.01.1995 and the process also is not protected by a patent. The subject application covers the alleged invention which is designed at recreating monopoly which could not have been done in respect of pharmaceutical products prior to 01.01.1995. Therefore, the applicant has merely come forward with cosmetic alterations and claims a patent for a non-patentable subject matter.

21. The opponent further referred to page 11 paragraph 6.5 of the Applicant's reply statement wherein the applicant has clearly denied the case made out by

the opponent establishing that the impugned application is obvious on the face of the teachings of D1. While the applicant denied and disputed the case of the opponent the pleadings of the applicant wholly fails to address the case of obviousness of the opponent. The applicant has failed to make any comments in support of the same implying that the opponent's arguments regarding the obviousness of the impugned application in view of D1 do hold ground.

22. The opponent further submitted that even statements in the applicant's response are worded as 'submissions'. The legal effect of submissions vis-à-vis statements was explained and submitted at the hearing and accordingly the reply statement has no authenticity and ought to be ignored and not relied upon.

PRIOR PUBLIC USE / PRIOR KNOWLEDGE

23. This ground was withdrawn by the opponent stating that the same will not be relevant to the present proceedings in the light of the willful omission of the ground of anticipation at the time of filing the opposition to the subject application.

NOT AN INVENTION / NOT PATENTABLE

24. It was submitted that the impugned application does not satisfy the criterion of inventive step since an advantage in use is not proportional to technical advancement. The opponent relied upon the arguments under the ground of obviousness and the same is not repeated for the sake of brevity. The aspect of bioavailability tests conducted on beagle dogs was stated to be inaccurate since the same could not be extrapolated to humans in light of fact that the compounds of the alleged invention were meant for administration to a human.

Section 3(d)

25. The opponent submitted that the main objects of the impugned application are given on page 33 line 12 of the detailed description viz chemical stability, storage stability and proper biodistribution. The opponent relied upon the definition of the expression *"efficacy"* as observed by the Judges of the Hon'ble Madras High Court which reads *"the ability of a drug to produce the desired therapeutic affect"*. It was submitted by the opponent that the nucleotide analogs

of the alleged invention however did not offer any therapeutic advantage but only advantage in terms of mode of safe delivery by masking of the parent nucleotide. This feature therefore falls within the scope of non-patentable invention defined by section 3(d) and therefore ought to be rejected.

CASE LAWS RELIED UPON BY THE OPPONENT

The opponent relied upon the "Case Law of the Boards of Appeal of the European Patent Office, Fifth Edition, December 2006" which on page 121 Paragraph 2 cites

> *"According to board of appeal case law (see T 1/80, OJ 1981, 206; T 20/81, OJ 1982, 217; T 24/81, OJ 1983, 133; T 248/85, OJ 1986, 261),* ***the assessment of inventive step has to be based on the objective, not subjective, achievement of the inventor.*** *By starting out from the objectively prevailing state of the art, the technical problem is to be determined on the basis of objective criteria and consideration given to whether or not the disclosed solution was obvious to the skilled person. Although the problem and solution approach is not mandatory, its correct application facilitates the objective assessment of inventive step.* ***The correct use of the problem and solution approach rules out an ex post facto analysis which inadmissibly makes use of knowledge of the invention (T 564/89, T 645/92, T 795/93, T 730/96 and T 631/00).*** *In principle, therefore, the problem/solution approach is to be used; however, if exceptionally some other method is adopted, the reasons for departing from this generally approved approach should be stated."*

The last paragraph on the said page relates to the determination of the closest prior art and reads as:

> *In accordance with the problem and solution approach, the boards have developed certain criteria for identifying the closest prior art to be treated as a starting point. After the relevant prior art has been identified, careful consideration must be given to the question whether, in the case concerned, the skilled person, taking into account all the available information on the technical context of the claimed invention, would have had good reason to take this prior art as the starting point for further development.* ***The boards have repeatedly pointed out that the closest prior art for assessing inventive step is normally a prior art document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural Inventive step modifications*** *(T 606/89, T 686/91, T 834/91, T 482/92, T 298/93, T 380/93, T 59/96, T 730/96, T 650/01).* ***A further criterion for the selection of the most promising starting point is the similarity of technical problem*** *(see T 495/91, T 570/91, T 439/92, T 989/93, T 1203/97, T 263/99). The determination of the closest prior art is therefore an objective and not a subjective exercise. It is made on the basis of the notional skilled man's objective comparison of the subject-matter, objectives and features of the various items of prior art leading to the identification of one such item as the closest (T 1212/01). The prior art has to be assessed from the point of view of*

the skilled person on the priority date applicable (T 24/81, OJ 1983, 133; T 772/94, T 971/95).

Relying on the aforesaid findings of the EPO Board of Appeals, the opponent submitted that the document D1 is the closest prior art in terms of structural features and similarity of technical problem. It was further submitted that the impugned application is a mere extension of D1 subsequently failing to contribute any technical advancement.

The opponent relied on the decision in ***Astrazeneca UK Limited v. GM Pharma Ltd.***, wherein the requirement of comparative tests vis-à-vis the closest prior art was again stated by the Ld. Tribunal, in the following words:

*The opponent relied on the European Board of Appeal decision T 181/82 which held that "**an effect which may be said to be unexpected can be regarded as an indication of inventive step; where comparative tests are submitted as evidence of this, there must be the closest possible structural approximation - in a comparable type of use - to the subject-matter of the invention.** In paragraph 5 of the same decision, it states:*

*To be relevant, such comparative tests must meet certain criteria. These include the choice of a compound disclosed in the application and of a comparative substance taken from the state of the art; at the same time, **the pair being compared should possess maximum similarity with regard to structure and application. Given the similar properties to be expected in view of the structural similarity of two substances, evidence of an abrupt improvement can be regarded as unexpected.** The greater the structural difference between the compounds being compared, the less unexpected are any differences in their effects. So if a meaningful statement is to be made in order to render an inventive step possible, compounds having a maximum structural resemblance must be compared with one another.*

Following the above basis, I find that the compound of Table 3 within example 34 comes structurally closer to the claimed compounds than any of the compounds of examples 26, 41 and 64 of the prior art in disclosing the same 3',4'-substituent and 7 – methoxy substituent. Therefore, compound 5 within example 34 is the closest prior art, which would require minimum structural modifications in order to reach the compounds claimed in the present invention.

The requirement for a comparison with the closest prior art is based on the principle of the structural dependence of the properties of chemical substances i.e. on the fact that these properties reflect the structure of the substances.

Therefore, it is very difficult accept the applicant's claim of 16 fold potency of the compounds of the present invention against the compound disclosed in the prior art because the comparison provided is not against the closest prior

art. Even if I agree with the arguments of the applicant that the basic group at the 6th position makes an important contribution to the properties and activities of the claimed compounds, the compound 5 of the table 3 within example 34 of the prior art should have been used as comparative test compound, as the said compound 5 of Table 3 within example 34 of the prior art differs from the claimed compound in the presence of basic group at the claimed 6-position. This could have provided a suitable platform for the demonstration of the surprising effect of the claimed compound vis-à-vis the said example compound 5 of the example 34 (Table 3). This could have proved that the surprising or the unexpected properties of the claimed compound is associated with a basic group at 6th position of the ring. In absence of any test comparative test data provided vis-à-vis compound 5 of example 34 of the prior art, the applicant's claim that the compound of the present invention are 4 to 16 times potent as compared to the prior art reference is not very convincing.

I agree with the opponent's contention that for ***the demonstration of 'technical advancement' must be shown to have been achieved by a claimed invention vis-à-vis the prior art by way of demonstrating the presence of an unexpected effect over the closest prior art****.....Therefore, I have no doubt that the applicant has failed to provide comparative test data vis-à-vis the structurally closest compound of the prior art.*

The opponent relied upon European Board of Appeal decision **T_1101/98** which relates to a similar case of obviousness in prodrug strategy of anticonvulsant sulfamates wherein

The Appellant's submissions were essentially as follows: Documents (1) and (2) were selected from a search made with hindsight knowledge of the invention. Their combination was the result of an ex post facto analysis and did not indicate a genuine lack of inventive step. The solution to the problem of providing further potentially improved anticonvulsant compounds by the provision of a ***prodrug form*** *of the compound of document (1) was not obvious. There were many possible modifications of the compound of document (1) which would have occurred to the skilled reader and, indeed, document (1) described a number of derivatives of said compound, but not a prodrug. Table 1 showed that the activity of the 2,3:4,5-bis-O-(1-methylethylidene)-â-D fructopyranose sulfamate was decreased by substitution at the sulphonamide N. This taught away from the invention. None of the sulphonamide compounds disclosed in document (2) had any similarity to the fructopyranose imidate derivatives of the application in suit. Without experiment, it could not have been predicted that in vivo these derivatives would not be toxic, nor that they would undergo satisfactory hydrolysis to active sulphonamide. For these reasons, the conclusion by the Examining Division of lack of inventive step of claim 1 in the light of the combined disclosure of documents (1) and (2) was unfounded." The Board in the case held that "The closest prior art to the subject-matter of claim 1 is document (1). It discloses that 2,3:4,5-bis-O-(1-methylethylidene)-â-D fructopyranose sulfamate (ie. The molecule, from which some of the compounds of claim 1 are derived) has potent anticonvulsant activity. A study of some analogs thereof is carried out to ascertain those features associated with biological activity. It is found that derivatives carrying methyl or phenyl substitutions on the sulfamate group (Chart I, compounds 1 to 3) have an*

anticonvulsant activity lower than the fructopyranose sulfamate itself, or no anticonvulsant activity at all, as measured ***in vivo*** *by the standard MES test carried out on mice.*

Thus, at the priority date, the skilled person was aware from document (1) of the anticonvulsant activity of the fructopyranose sulfamate, and from document (2), that imidate derivatives of sulfonamide drugs would behave as prodrugs. In the Board's judgment, it was obvious when wanting to obtain derivatives of the fructopyranose sulfamate, while keeping the anticonvulsant activity, to combine the teachings of both these documents i.e. to make N-sulfonyl imidate derivatives of said fructopyranose sulfamate. The Appellant argued that such a combination could only be done with hindsight knowledge of the content of the application as filed. However, as the usefulness of transforming drugs into prodrugs in order to solve the type of problems solved in the instant application was already known as early as 1975 (references 1 to 3, page 2071 of document (2)), this argument cannot be accepted.

The Board accepts that it could not be predicted with certainty whether, in vivo, imidate derivatives of fructopyranose sulfamate would be toxic or not, nor whether they would undergo satisfactory hydrolysis. Yet, the combined teachings of documents (1) and (2) would lead the skilled person in an obvious manner to make imidate derivatives and testing them would be a matter of routine as shown in document (1) which discloses that the anticonvulsant activity test is a standard test dating from 1952 (page 881, right hand column, "Anticonvulsant testing"). There is, thus, no inventive activity linked to preparing or testing these compounds.

The opponent relied upon **Aventis Pharma vs. Lupin Pharmaceuticals**, Federal Circuit, 2006-1530 wherein the Court of Appeals held as under.

The district court held that Lupin failed to meet its burden of proof by clear and convincing evidence that a person of ordinary skill in the art would have been motivated to purify 5(S) ramipril into a composition substantially free of other isomers. Invalidity Opinion at 74–75. The district court saw this as a close case based principally on the absence of a clear and convincing showing of motivation. Since the date of that decision, however, the Supreme Court decided KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007), which counsels against applying the "teaching, suggestion, or motivation" ("TSM") test as a "rigid and mandatory formula[]." See KSR, 127 S. Ct. at 1741. ***It remains necessary to show "'some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness,'" but such reasoning "need not seek out precise teachings directed to the specific subject matter of the challenged claim."*** *See id. (quoting In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006)). Requiring an explicit teaching to purify the 5(S) stereoisomer from a mixture in which it is the active ingredient is precisely the sort of rigid application of the TSM test that was criticized in KSR.*

In the chemical arts, we have long held that ***"structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a prima facie case of obviousness."*** *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd., No. 06-1329, slip op. at 9 (Fed. Cir. June 28, 2007) (quoting In re Dillon, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc)); see also In re Papesch, 315 F.2d 381 (C.C.P.A. 1963). The "reason or motivation" need not be an explicit teaching that the claimed compound will have a particular utility; it is sufficient to show that the claimed and prior art compounds possess a "sufficiently close relationship . . .*

to create an expectation," in light of the totality of the prior art, that the new compound will have "similar properties" to the old. Dillon, 919 F.2d at 692; see also In re Wilder, 563 F.2d 457, 460 (C.C.P.A. 1977) ***("[O]ne who claims a compound, per se, which is structurally similar to a prior art compound must rebut the presumed expectation that the structurally similar compounds have similar properties."). Once such a prima facie case is established, it falls to the applicant or patentee to rebut it, for example with a showing that the claimed compound has unexpected properties. Dillon, 919 F.2d at 692.***

The opponent relied on the following decisions of the Indian patent office, where applications on prodrugs were rejected for being non-inventive. The below decisions clearly state that unless some technical advancement is shown over the existing at the time of the invention, inventions cannot be said to involve an inventive step. Moreover, both the below applications were rejected under Section 3(d) as the prodrugs claimed therein failed to exhibit therapeutic efficacy.

In the matter of an application for patent No. **924/DELNP/2006**, the Ld. Controller rejected the application for lack of inventive step and under Section 3(d) as under.

10. Findings and conclusions
(.....)
The claimed compound of formula A is in fact a double prodrug of the compound of formula B. i.e., the claimed compound of formula A (BIBR-1048 MS) is only converted into the actual effective compound, namely the compound of formula B, in the specification. Compound B, the pharmaceutically active compound, is also referred to in the document D8 as BIBR-953 ZW.
As can be seen from the above, document D1 to D8 discloses in combination all the features defined in independent claim 1 and dependent claims 2-4 .Hence the subject-matter of claim 1 is not new and lack of inventive step under Section 2(1) j of the Act.
Dependent claims 2-4 do not contain any features which, in combination with the features of any claim to which they refer meet the requirements of the Section 2(1) j of the Act. in respect of inventive step.

II. (.....) It is stated by the applicant that the claimed compound has got the better solubility compared to its closest prior art compound mentioned in Document D1 to D8.
However the applicant has not provided any argument and experimental proof of any enhancement of the above properties and significant improvement in therapeutic efficacy, i.e. to say no comparative experimental data is available in the specification to prove the improvements are significant and the new form is efficacious than the earlier one. In such circumstances of failure to prove efficacy the compound as claimed is merely a new form of the known substance which is not Patentable U/S 3(d) of the Patent Act. Merely difference in solubility data does not serve the purpose of complying the requirement of section 3(d).

The process claimed in dependent claim 3&4 also not fully supported in the specification.
In the entire description of the invention the new therapeutic effect of the new forms is not disclosed. Hence it is concluded that the new crystalline form II exhibit the same efficacy as the Documents D1 to D8.

Therefore the applicant has failed in proving that the alleged invention does not attract the provisions under Section 3(d) of the Patents Act.

In the matter of an application for patent No. **712/DEL/2002**, the Ld. Controller rejected the application for lack of inventive step and under Section 3(d) as under.

I find that various cited documents especially US4808716 and US5663159 synthesise the parent compound (PMEA) as a crystalline solid. Since the compound of the invention (AD) is an ester form of the parent compound (PMEA) no inventive technical advancement can be attributed to the alleged invention. I have analysed the results as provided by the applicants regarding improved stability of the alleged compound. I have observed that the applicants have not provided a comparative data with respect to the amorphous/parent compound of the alleged invention. In the absence of the same an inventive step cannot be established.

Section 3(d)

AD appears to be merely a new form of a known substance characterized by a XRD pattern and other physical characteristics of the compound. I observe that even though the applicants have submitted that it is incorrect to assume that polymorphs or derivatives of all compounds inherently exhibit the same activity as the parent compound and have refuted such a generalization in the field of pharmacology. They further submitted that the efficacy and activity are a function of various factors and their interplay. Efficacy is also judged on the basis of bioavailability, dissolution rates, stability, side effects, toxicity and the like. These parameters depend on the factors such as processing technologies, forms of the substance, position of substituent, etc. The agents for the applicants reiterated that the forms of AD claimed in the present application are inventive over amorphous forms of AD since they possess superior dissolution rates and superior stability which significantly improve their technical and pharmacological efficacy. Thus the claimed invention is non-obvious and possess inventive step and is entitled to grant of patent. However I observe that nowhere in the Complete specification it is suggested, indicated or substantiated that the use of the characterized crystalline form results in increased biological activity or enhanced therapeutic efficacy in comparison with the biological activity and therapeutic efficacy as shown by the known and reported forms of AD. No such comparative data that substantiates the enhancement in efficacy as compared to the earlier known amorphous forms is provided in the 712/DEL/2005.
In this regard the opponent referred the Judgment passed by Hon,ble High court of Judicature at Madras in the case of Novartis AG Vs Union of India and others the court defined what is therapeutic efficacy and efficacy
I have analyzed the results as provided by the applicants regarding improved stability of the alleged compound. I have observed that the applicants have not provided a comparative data with respect to the

amorphous/parent compound of the alleged invention. Also no improvement in the therapeutic efficacy of AD as compared to its parent compound (PMEA) has been provided. In fact both the compounds (AD) is used to treat viral infections which is also the activity shown by the parent compound (PMEA). In view of above I state that the subject matter for application no. 712/DEL/2002 is not patentable under section 3(d).

INSUFFICIENCY

26. It was submitted by the opponent that the arguments put forth with respect to the aforesaid grounds in its representation will be relied upon.
The opponent's principal objection was lack of inventive step and obviousness of the impugned application on the basis of failure on the part of the applicant to rebut the obviousness over D1 in light of the structural similarity of the compounds taught in D1 and those allegedly claimed in the impugned application, failure to explain obviousness as taught by D3, D4 i.e. formation of prodrug and the gradual in vivo hydrolysis.

27. The opponent states that the case sought to be made by the applicant is based on the assumption that none of the cited prior art documents discloses the carbamate and carbonate prodrugs of PMPA and therefore the claimed invention cannot be held obvious and lacking an inventive step over the prior art. It is submitted that a prior art reference which presumably disclosed or taught carbamate or carbonate prodrugs of PMPA would be prejudicial to the novelty of the alleged invention. The applicant's contention that the prior art does not render the claimed carbonate and carbamate prodrugs of PMPA obvious because none of the prior art references discloses these specific prodrugs of PMPA appears to equate the standard of proof required for establishing anticipation with the standard of proof required for establishing obviousness, which is incorrect in law.

28. It is submitted that the ground of obviousness/lack of inventive step is operative when the prior art does not exactly teach the invention claimed by the applicant but such invention is obvious to a person skilled in the art having regard to the closest prior art and the knowledge available in the art. It is respectfully submitted that the alleged invention claimed by the applicant in the impugned application is clearly obvious and does not involve an inventive step in view of the prior art cited by the opponent and placed at length at the hearing. It is further submitted that the alleged invention in the impugned application under opposition

is liable to be rejected on this ground alone. The arguments set forth by the applicant are miserably insufficient for overcoming a case of obviousness and lack of inventive step. It is further submitted that the arguments set forth by the applicant do not attempt to address as to why the claimed invention directed to carbonate and carbamate prodrugs of PMPA would not have been obvious to a person skilled in the art in view of the strong showing of obviousness presented in the preceding paragraphs.

OPPONENT'S COMMENTS ON THE EXHIBITS FILED BY THE APPLICANT

The opponent submitted that at paragraph 6.63 of its reply, the applicant has relied upon Exhibit 2 to substantiate the higher bioavialability of the claimed compound. The patentee states "in retrospective comparison of the individual patient data, it was apparent that for given plasma AUC (area under curve, or amount)" of tenofovir, the viral load drop observed after the oral administration of TDF was greater than that observed with IV tenofovir."

The applicant also relied upon Exhibits 3 and 4, copies of which were handed out at the hearing. It is stated that as apparent from the title and text of Exhibit 3, it clearly pertains to adefovir dipivoxil, which is not the subject matter of the present invention. Therefore said document is of no relevance in the present matter.

Exhibit 4, entitled "determining the antiviral activity of tenofovir disoproxil fumarate in treatment-naïve chronically HIV-1-infected individuals" also pertains to tenofovir fumarate (TDF). Moreover such document reports the study results of TDF being used in combination with other antiviral agents. And the monotherapy studies suggested that the efficacy of TDF was similar to prevailing antiviral drugs.

It was submitted that the present application pertains to carbamate and carbonate prodrugs of tenofovir, there is no specific discussion on the performance of the fumarate salt. Moreover, it is significant to note that the fumarate salt of tenofovir is subject matter of another application, namely, 896/DEL/2002 (rejected by decision dated July 30, 2009), the fact that the applicants made a separate application for the fumarate salt of tenofovir implies that this specific salt form is in no way related to inventive concept the present application. Both the documents relied upon by the applicant pertain to the

fumarate salt of tenofovir (TDF). It is submitted that these documents have been cited clearly with intent to mislead the Ld. Tribunal. Such reliance upon misleading documents to establish the inventive step of an invention is an out-and-out malafide act on the part of the applicants.

The opponent states that the opposed application ought to be rejected in toto in view of the present opposition where the various grounds have been made out and established beyond doubt.

Dated this 18th day of May 2011.

Abhishek Sen
Of S.Majumdar & Co
Opponent's Agent

BEFORE THE CONTROLLER OF PATENTS,
DELHI

IN THE MATTER of Patent Application No: 602/DEL/2007 dated March 20, 2007

GILEAD SCIENCES, INC, ... **Applicant**

And

CDYMAX (INDIA) PHARMA LIMITED ..... **Opponent**

WRITTEN ARGUMENTS OF THE OPPONENT BASED ON THE HEARING HELD ON APRIL 6 AND MAY 2, 2011 AT PATENT OFFICE, DELHI

As directed by the Ld. Controller, Intermed Labs Pvt. Ltd, India, being the opponent in the present opposition proceedings hereby submits written arguments on the submissions made at the hearing with respect to the aforesaid opposition.

Before commencing with its submissions, the Opponent clarified that it's name has been changed from Intermed Labs Private Limited to Cdymax (India) Pharma Limited. The opponent also filed a petition dated April 2, 2011 stating the same.

The submissions at the hearing were made on the basis of the impugned application 602/Del/2007 and the pleadings of the parties.

PRELIMINARY SUBMISSIONS & OBJECTIONS

1. At the outset, it was categorically submitted by the opponent that the impugned application is a divisional to application no. 2076/DEL/1997, which pertains to substantially the same invention as the one under opposition.

2. The opponent also filed a representation under Section 25(1) against the parent application, being 2076/DEL/1997. Subsequently by an order dated July 30, 2009, 2076/DEL/1997 was rejected on the grounds of non-obviousness and not patentable under section 3(d).

3. It is submitted that the claims of the impugned application is substantially the same as those on the parent application. For ready reference, the opponent has tabulated the claims of the parent application (2076/DEL/1997) and the present one.

602/del/2007	**Corresponds to 2076/del/1997 (as amended)**	**Remarks**
1. (Independent)	1	Claimed compound is designated by the chemical class in the parent as against the generic term compound of formula 1(a) in the divisional
2.	2	All these claims of divisional are directly / indirectly dependant on claim 1.
3.	3	
4.	4	
5.	5	
6.	6	
7.	7	
8.	8	
9.	9	
10.	10	
11.		Dependant on claim 4 – refers to configuration of the chiral center

12.		Dependant on claim 4 – refers to configuration of the chiral center i.e. 90% R
13.	11	All these claims of divisional are directly / indirectly dependant on claim 1.
14.	12	
15.		
16.		
17.		
18.	13	
19.	14	
20.	15	
21.	16	
22.	17	
23.	18	
24.	-	Dependant on claim 1
25.	-	Dependant on claim 22 – refers to configuration of the chiral center i.e. 90% S
26. (Independent)	19	-
27. (slightly modified) – (Independent)	20	-
28.	21	-
29.	22	-
30.	-	Dependant on claim 27. Process description.
31.	-	Dependant on claim 30. Salts of 1 – sulfuric, phosphoric, lactic or citric.
32. (omnibus - product)	23 (omnibus)	
33. (omnibus - product)	-	
34. (omnibus - process)	24(omnibus)	
35. (omnibus)	-	

4. As evident from the above table, the scope of the subject matter claimed in both applications is essentially same. The opponent submitted that filing such a divisional application, wherein the claims are same in scope as that of the claims on the parent, was done with a malafide intent and in an attempt to mislead the Ld. Controller. It was submitted that the applicant being aware of the noninventiveness of the parent application, filed a divisional as a fall-back option in the event the parent application gets refused. As expected, the parent application was rejected based on the opposition filed by the opponent and with this application the applicants are getting another chance to revive the rejected claims.

5. It was also submitted that the impugned patent application is not truly a divisional application as per Section 16 of the Act, particularly sub-section 3 which clearly provides that, "The Controller may require such amendment of the complete specification filed in pursuance of either the original or the further application as may be necessary to ensure that neither of the said complete specifications includes a claim for any matter claimed in the other". The same objection was also found in the First Examination Report issued by the Patent Office under paragraph 4. Thus the present application does not qualify as a divisional application as the same was filed in contravention to provision of the Patent Act and should be outrightly rejected.

6. The opponent submitted that the Delhi PO has rejected quite a few applications, where the claims of the divisional were same as that of the parent application. Two such cases are mentioned below alongwith the relevant passages.

7. The Ld. Controller in the matter of patent application no. 832/DEL/2001 filed by M/s. BAYER AKTIENGESELLSCHAFT held as under.

> *The set of claims of the so called divisional application was same as that of the parent application including the claim 1 which the applicant intended to claim again..... I hereby refuse to consider the instant application as a divisional application u/s 16 of the Act as the same has not been filed in accordance with the provisions of the Patents Act.*

The Ld. Controller in the matter of patent application no. 748/DEL/2002 made by M/s. NOVARTIS AG later on assigned to (SYNGENTA PARTICIPATION AG) held as under.

The set of claims of the so called divisional application was same as that of the parent application including the claim 1 which the applicant intended to claim again....I hereby refuse to consider the instant application as a divisional application u/s 16 of the Act as the same has not been filed in accordance with the provisions of the Patents Act.

8. The opponent submitted that the claims of both applications recite substantially the same subject-matter and argued between the same parties before the Patent Office at Delhi, so the common law principle of "*Res-judicata*" applies here which has been grounded in Section 11 of The Code of Civil Procedure, 1908 and also general principles. In other words, the principle of *res-judicata* squarely applies to the present case as the parties involved in the proceeding pertaining the parent application, i.e. 2076/DEL/1997 are the same as the present one, also the subject- matter of the dispute being the claims are same in both proceedings and before the same Tribunal.

9. The opponent relied on the below judgments to support its contention on the principle of *res judicata.*

The High Court of Bombay in **Pandurabg Sakharam Vs. The Mahaarashtra Revenue Tribunal, Nagpur and Ors. [AIR1974Bom20],** discussed the doctrine of *res judicata* as under:

11. The doctrine of res judicata is a doctrine of repose and is grounded on public policy. It means that the things which were actually and directly in dispute and which were finally adjudicated upon should not be allowed to be reagitated. In a sense it postulates a principle of peace operative over the warring field of litigation and secures finality for justice. doctrine as is known to us had its origin in English common law principle its recent appraisal by that it stems out of law of estoppels and in essence is a doctrine of "issue - estoppel". In ***Edwards V. Edwards (1967) 2 All ER 1032*** *Sir Jocelyn Simon. P. observes:*

"All adjudication. like every piece of social engineering of desiderata, not all of which are easily made consistent. There should first, be the fullest and truest assessment of all relevant facts. There must however, secondly be some protection of individual privacy and liberty. Thirdly, and most relevant of all to this application it is desirable that disputes within society should be brought to an end as soon as is reasonably practical and should not be allowed to drag. That last principle finds expression in maxim which English law took over from the Roman law; it is in the public interest that there should be some end to litigation. The principle, for example applies in the doctrine which is known to lawyers as res judicata, in other words, once there is decision on a matter by a competent Court, it is binding on all courts of similar jurisdiction".

In ***Carl-Ziess-Stiftung V. Rayner (1966) 2 All ER 536****. its content is found to mean "an issue estoppel". The Court observes:*

"Within recent years the principle was developed so as to extend to what is now described as "issue estoppel" that is to say where in a judicial decision between the same parties some issue which was in controversy between the

parties and was incidental to the main decision has been decided, then that may create an estoppel per rem judicatam"."

12. As far as Indian Law is concerned, the principles of res judicata are firmly grounded into our system of judicial administration both under the code of Civil Procedure and also upon general principles. In ***Satyadhyan V. Smt. Deorajin Debi: [(1960)3SCR590]*** *the principles were applied on the need of giving a finality to judicial decisions. If a matter between two parties in one suit or proceeding has been decided and that decision has achieved finality either because no appeal was taken to a higher court or because the appeal was dismissed or no appeal lies, then neither party should be allowed in the future suit or the proceeding between the same parties to canvass the matter again. This is the core and concept of the rule. The principles however underlying the doctrine are available and as such applicable in other jurisdictions too for achieving finality and firmness to judicial process. Similarly a given controversy may stand concluded between two stages of the same litigation to the extent that Court, whether the trial Court or higher Court, having at an earlier stage decided the matter in one way will not allow the same parties to reagitate the matter again at a subsequent stage of the same proceeding...*

The Hon'ble Supreme Court of India in **Kunjan Nair Sivaraman Nair Vs. Narayanan Nair and Ors. [AIR2004SC1761]** at length discussed the principle of *res judicata* as under:

11. Rule of res judicata is contained in Section 11 of the Code. Bereft of all its explanations, namely, Explanations I to VIII, Section 11 is quoted below :
"11. Res judicata. - No court shall try any suit or issue in which the matter directly and substantially in issue has been directly and substantially in issue in a former suit between the same parties, or between parties under whom they or any of them claim, litigating under the same title, in a court competent to try such subsequent suit or the suit in which such issue has been subsequently raise, and has been heard and finally decided by such court."
12. "Res judicata pro veritate accipitur" is the full maxim which has, over the years, shrunk to mere "res judicata".
13. Section 11 contains the rule of conclusiveness of the judgment which is based partly on the maxim of Roman Jurisprudence "Interest reipublicae ut sit finis litium" (it concerns the State, that there be an end to law suits), and partly' on the maxim "Nemo debet bis vexari pro una at eadem causa" (no man should be vexed twice over for the same cause). The section does not affect the jurisdiction of the court but operates as a bar to the trial of the suit or issue, if the matter in the suit was directly and substantially in issue (and finally decided) in the previous suit between the same parties litigating under the same title in a court, competent to try the subsequent suit in which such issue has been raised.
14. The above position was noted in Deva Ram and Anr. v. Ishwar Chand and Anr. [AIR1996SC378].

The Hon'ble IPAB, Chennai in **Hindustan Lever Limited Vs. Madhusudhan Industries Limited and Assistant Registrar of Trade Marks [2005(31)PTC214(IPAB)]**

2. The first respondent filed an application for registration of a trade ma[illegible] consisting of words 'UJALA KING' with a device of Sun in Class 3 of the Trade and Merchandise Marks Act, 1958 (hereinafter referred to as the Act), in respect of soaps under application No.401336. The user claimed under that application is since December, 1975. In due course, the mark was advertised in the Trade Marks Journal No.1078 (Supplement) dated 8.5.1994 at page 6, under proviso to Section 20(1) of the Act. The appellant gave a notice on 27.7.1994 to oppose the registration of the mark on the ground that it is the proprietor of a well known trade mark 'SUNLIGHT' and also of the trade mark 'SUN'. The said marks are registered in various forms. The impugned mark is deceptively similar to its registered trade mark 'SUNLIGHT'. The word UJALA is descriptive of the goods like Soaps. The impugned mark is neither distinctive nor capable of distinguishing the goods of the applicant. The first respondent had earlier made an application for the same mark under No.342707 which was refused registration vide opposition No.BOM-612[illegible] That decision of the Registry is res-judicata in the present matter. It opposed the mark under sections 9,11, 12(1), 18(1) and 18(4) of the Act. The first respondent filed its counter statement and the evidence. In due course, similarly the appellant filed its evidence. The Assistant Registrar heard the matter on 4.8.1997 and he inferred that the opposition is based on sections 9, 1, 12(1) and 18(1) of the Act. He heard arguments of the learned counsel for the appellant and the first respondent. He concluded that, by virtue of long user since 1975, the mark acquired distinctiveness and, as such, qualifies for registration under section 9 of the Act. In the matter of its examination under section 11(a), after having heard both the counsel, he concluded that both the marks are distinct and he inferred that even the goods are different. The first respondent's product is washing soap and is meant for the poor class society whereas the 'SUNLIGHT' soap is a product which is being bought by the ric[illegible] people because of its high price. So the objection of the appellant fails under Section 11(a) of the Act and accordingly the objection under Section 11(e) also fails. In the matter of its examination under Section 12(1), in relation to application of two tests thereof, his conclusion was that the rival goods are of the same description, but, however, he found that the mark does not meet the second requirement as the rival marks are totally different from each other in respect of get up, colour scheme, etc. Thus, he concluded that the opposition under Section 12(1) also fails. He found the mark to be eligible under section 18(1) of the Act. Having found the mark to be entitled for registration under Sections 9,11(a),11(e), 12(1) and 18(1) of the Act, he proceeded with the examination of the mark under Section 12(3) of the Act and found that, in any case, the mark is also eligible under Section 12(3) of the Act. His conclusion about the application of the principle of resjudicata in the matter is that the Tribunal which he was then for the time being presiding over is an independent Tribunal and the proceedings of the matter under opposition No.BOM-6129 are not binding upon that Tribunal. He mentioned that the circumstances in the Bombay case might have been different and in the present case, he has made a physical examination of the packing material as well as the products of both the rival marks and according to his findings and analysis he reached the conclusion that the rival marks are totally different from each other. Thus, he dismissed the opposition and ordered for the registration of the mark.

8. Sub section 2 of Section 4 of the Trade and Merchandise Marks Act, 1958 can best be exemplified as the replica of an instrumentality having its philosophical deduction from the provisions under the Constitution. The Registrar remains to be one in spite of its various limbs known as the Joint Registrars, Deputy Registrars and Assistant Registrars as the Government

India remains one in spite of the various civil servants to perform its functions at different levels. Since the institution of the Registrar is one of which the Assistant Registrar at Bombay and another Assistant Registrar at Ahmedabad happen to be integral part, one limb of that integrated personality cannot be seen as claiming that that particular limb is independent of the machinery as a whole. Here learned Assistant Registrar appears to be venturing in that direction. The Assistant Registrar is patently wrong in claiming that he is an independent Tribunal in itself. Independence of the Tribunal is undisputed, but, as the Tribunal of the Registrar as a whole and not of the specific nuts and bolts. It is essential that there must be some consistency amongst the functionaries discharging quasi-judicial functions. Otherwise on the rejection of an application by one authority, the applicant will be tempted to file a fresh application before another authority with or without modification and have a chance.

As evident from the underscored lines above, the applicant filed an application for a mark, which was same as a mark previously rejected by the Registry. The Opponent therein argued that the decision of the Registry in the previous matter is *res-judicata* on the present. The Assistant Registrar in his order granting the application stated that he is an independent Tribunal and therefore the principle of *res-judicata* will not hold good. The IPAB clearly stated that the Asst Registrar was wrong in assuming that he is an independent Tribunal in itself and that there must be some consistency amongst the functionaries discharging quasi-judicial functions.

In the present case, the claims of the parent and the present application (divisional) are same and the parent application being rejected by the Patent Office based on the same grounds as taken in the present one, the principles of res-judicata clearly applies. Thus the decision in the matter of patent application no. 2076/DEL/1997 is *res judicata* on the present one.

The Hon'ble Supreme Court of India in **Ramdev Food Products Pvt. Ltd. Vs. Arvindbhai Rambhai Patel and Ors. [(2006)8SCC726]** held as under.

42. We are also not in a position to accept the submission of Mr. Nariman that the MOU must be read with the deed of partnership or the deeds of retirement whereby and whereunder the firm 'Ramdev Masala' and 'Ramdev Exports' were permitted to use the word 'Ramdev'. What is registered is a logo wherein the words 'Ramdev' and 'Masala' are prominent. A person may be held to be permitted to carry on business in spices as contradistinguished from the permission to carry on manufacturing goods which are similar to that of the appellant, but in terms of the statutory provisions, the respondents were not legally permitted to sell its products in packages or labels which would be deceptively similar to that of the registered owner of a trade mark.
The right to manufacture masala and to sell the same with the registered logo, it will bear repetition to state, was assigned as far back in 1991. If the contention of the Senior Counsel is accepted, the said purpose would be lost.

In a case of this nature, therefore, ordinarly an injunction would issue. By reason of interpretation of MOU, trade mark cannot be infringed and further when the right of user has been relinquished, the same could not have been claimed by the respondents.

WAIVER

43. The matter may be considered from another angle. If the first respondent has expressly waived his right on the trade mark registered in the name of the appellant-Company, could he claim the said right indirectly? The answer to the said question must be rendered in the negative. It is well-settled that what cannot be done directly cannot be done indirectly. The term 'Waiver' has been described in the following words:

Waiver is the abandonment of a right in such a way that the other party is entitled to plead the abandonment by way of confession and avoidance if the right is thereafter asserted, and is either express or implied from conduct.... A person who is entitled to rely on a stipulation, existing for his benefit alone, in a contract or of a statutory provision may waive it, and allow the contract or transaction to proceed as though the stipulation or provision did not exist. Waiver of this kind depends upon consent, and the fact that the other party has acted upon it is sufficient consideration.... It seems that, in general, where one party has, by his words or conduct, made to the other a promise or assurance which was intended to affect the legal relations between them and to be acted on accordingly, then, once the other party has taken him at his word and acted on it, so as to alter his position, the party who gave the promise or assurance cannot afterwards be allowed to revert to the previous legal relationship as if no such promise or assurance had been made by him, but he must accept their legal relations subject to the qualification which he has himself so introduced, even though it is not supported in point of law by any consideration. [See 16 Halsbury's Laws (4th edn) para 1471] Waiver may sometimes resemble a form of election, and sometimes be based on ordinary principles of estoppel. [See 45 Halsbury's Laws (4th edn.) para 1269] In Indu Shekhar Singh and Ors. v. State of U.P. and Ors. MANU/SC/8125/2006 : AIR2006SC2432 , this Court held: "They, therefore, exercised their right of option. Once they obtained entry on the basis of election, they cannot be allowed to turn round and contend that the conditions are illegal"

In the cited case, right on a trademark was expressly waived by owner, who later tried to re-claim the same by indirect means. The Court held that such cannot be permitted as it is against the Law. In the present case too, the parent application having the same claims as the one under opposition was rejected by a well-reasoned decision. In view of that, the applicant's attempt to prosecute the present application is clearly a malafide action as it is trying to reclaim subject matter, which already forms part of prior art due to reasons herein.

Therefore the impugned application should be forthrightly rejected based on the preceding submissions.

10. The opponent submitted that the claims of the impugned application are similar to the parent application 2076/DEL/1997, please see table under

paragraph 3 for a comparative analysis of the claims. It was also submitted at the outset that the opponent wholly adopts the arguments as found in the written arguments concerning the parent application. A copy of the same is annexed hereto for ready reference.

11. The opponent specifically drew the attention of the Ld. Controller to page 5, line 20 of the specification which referred to the objects of the invention. The opponent further stressed that the main object of the alleged invention was centered on three objects viz as evident from page 33, line 12 onwards.

(i) the compounds should be chemically stable;

(ii) should have an adequate shelf-life and proper bio-distribution upon oral administration; and

(iii) should have bioavailability in beagle dogs that exceeds about 20%, preferably about 30%.

12. In this context it was submitted that the applicant has not provided any data to substantiate the enhanced efficacy of the compound claimed in the impugned application with respect to their effectiveness in human beings although the applicant has specifically indicated dosage for human use which could not have been arrived at without exhaustive trials. The question is why has the applicant not revealed the test data for humans but only with respect to beagle dogs.

13. The opponent submitted that Table 1 as found in the impugned specificatic concerned only the carbonate prodrugs whereas the scope of the invention was directed to both carbonate and carbamate prodrugs. This implies that the both the prodrugs are effectively interchangeable and that it is a mere attempt on the part of the applicant to enlarge the ambit of the invention. It was further emphasized that the demonstration was not with respect to both the forms though the carbamate prodrugs are indicated to be more stable in biological environments than the carbonates.

14. It was submitted that there were no secondary aspects and that all t' product claims were effectively dependent on claim 1. Therefore all the dependent claims rise and fall with claim 1.

15. The opponent drew the attention of the Ld. Tribunal to page 7 of its representation specifically to paragraphs 5.1 and 5.2 which dealt with the

compounds claimed in the impugned application. The opponent further relied upon paragraph 5.3 which highlighted certain admissions of the applicant viz,

- The parental compounds having the structure $AOCH_2P(O)(OH)_2$ are well known and have demonstrated anti-viral activity;
- Per se, they are not part of this invention; and
- In general, A has the structure BQ wherein B is a purine or pyrimidine base or the aza and/or deaza analogs thereof and Q is a cyclic or acyclic aglycon. B is linked to Q through the purine 9 or pyrimidine 1 positions.

16. The opponent presented the definition and a brief explanation of a 'prodrug' and cited a relevant paragraph from an article entitled "Targeted Prodrug Design to Optimize Drug Delivery" published in 2000 which clearly taught that *"The term "prodrug" or "proagent" was first introduced by Albert (2) to signify pharmacologically inactive chemical derivatives that could be used to alter the physicochemical properties of drugs, in a temporary manner, to increase their usefulness and/or to decrease associated toxicity. Since Albert discussed the concept of prodrugs in the late 1950s, such compounds have also been calle "latentiated drugs," "bioreversible derivatives," and "congeners," but "prodrug" is now the most commonly accepted term."* The opponent summarized that these bioreversible derivatives mask the parent drug, pass through the channels in vivo to which the parent drug is susceptible in effect functioning as a vehicle to deliver the parent drug without degradation to the patient in need.

17. The opponent submitted that its principal objection to the impugned application was obviousness and lack of inventive step. The opponent drew the attention of the Ld. Tribunal to paragraph 5.4 of its representation wherein th table illustrated the minor difference between the compounds claimed in the instant impugned application and those admittedly known in the prior art. It was stated that paragraph 5.5 of the representation highlighted that the hydroxyl group occurring the known parental compounds were substituted by the group 'Z' in the impugned application and also included the various values of 'Z' allegedly claimed in the impugned application. With respect to paragraph 5.6 of its representation, the opponent stated that the applicant has tried to protect the carbonate and carbamate prodrugs in view of the known parental compounds.

18. With reference to paragraphs 5.7, 5.8, 5.9 and 5.10 of its representation, the opponent stated that these paragraphs discussed the object of invention of the impugned application and table 1 given on page 62 wherein the applicant claims to have provided bioavailability data which allegedly is the basis of claiming the inventive merit in the impugned application.

19. The opponent further presented to the Ld. Tribunal that the test of obviousness rests in the fact as to whether a person skilled in the art would be successful in bridging the teachings of the prior art to arrive at the claimed invention. It was further stated that obviousness may be judged either on the basis of prior art documents or with the aid of an expert in the field who would be able to predict the closeness between the prior art and the claimed invention. It was further stated that the applicant's response to documents D3, D4 and D5 of the representation indicating that these documents were a part of the US prosecution history were of little relevance to the present proceedings since the Indian patent office will not decide the present proceedings on the basis of the proceedings before the USPTO and the onus rests on the applicant to establish that the impugned application was not obvious in view of the teachings of D3, D4 and D5. It was further stated a person skilled in the art would combine the teachings of these documents to arrive at the claimed invention and will simultaneously conduct trials for similar compounds to check their performance. It was further stated that to ascertain inventive merit an expert in the field needs to justify that the intervention by the person skilled in the art to the existing state of the art is unexpected.

20. The opponent stated with reference to D1 of the representation that the said document was published in 1995 and was in the name of the same applicant as that of the impugned application and Dr. William Lee is a co-inventor of D1. It was further submitted that a product patent was not possible in India prior to 01.01.1995 and the process also is not protected by a patent. The subject application covers the alleged invention which is designed at recreating monopoly which could not have been done in respect of pharmaceutical products prior to 01.01.1995. Therefore, the applicant has merely come forward with cosmetic alterations and claims a patent for a non-patentable subject matter.

21. The opponent further referred to page 11 paragraph 6.5 of the Applicant's reply statement wherein the applicant has clearly denied the case made out by

the opponent establishing that the impugned application is obvious on the face of the teachings of D1. While the applicant denied and disputed the case of the opponent the pleadings of the applicant wholly fails to address the case of obviousness of the opponent. The applicant has failed to make any comments in support of the same implying that the opponent's arguments regarding the obviousness of the impugned application in view of D1 do hold ground.

22. The opponent further submitted that even statements in the applicant's response are worded as 'submissions'. The legal effect of submissions vis-à-vis statements was explained and submitted at the hearing and accordingly the reply statement has no authenticity and ought to be ignored and not relied upon.

PRIOR PUBLIC USE / PRIOR KNOWLEDGE

23. This ground was withdrawn by the opponent stating that the same will not be relevant to the present proceedings in the light of the willful omission of the ground of anticipation at the time of filing the opposition to the subject application.

NOT AN INVENTION / NOT PATENTABLE

24. It was submitted that the impugned application does not satisfy the criterion of inventive step since an advantage in use is not proportional to technical advancement. The opponent relied upon the arguments under the ground of obviousness and the same is not repeated for the sake of brevity. The aspect of bioavailability tests conducted on beagle dogs was stated to be inaccurate since the same could not be extrapolated to humans in light of fact that the compounds of the alleged invention were meant for administration to a human.

Section 3(d)

25. The opponent submitted that the main objects of the impugned application are given on page 33 line 12 of the detailed description viz chemical stability, storage stability and proper biodistribution. The opponent relied upon the definition of the expression *"efficacy"* as observed by the Judges of the Hon'ble Madras High Court which reads *"the ability of a drug to produce the desired therapeutic affect"*. It was submitted by the opponent that the nucleotide analogs

of the alleged invention however did not offer any therapeutic advantage but only advantage in terms of mode of safe delivery by masking of the parent nucleotid This feature therefore falls within the scope of non-patentable invention defined by section 3(d) and therefore ought to be rejected.

CASE LAWS RELIED UPON BY THE OPPONENT

The opponent relied upon the "Case Law of the Boards of Appeal of the European Patent Office, Fifth Edition, December 2006" which on page 121 Paragraph 2 cites

> *"According to board of appeal case law (see T 1/80, OJ 1981, 206; T 20/81 OJ 1982, 217; T 24/81, OJ 1983, 133; T 248/85, OJ 1986, 261),* ***the assessment of inventive step has to be based on the objective, not subjective, achievement of the inventor.*** *By starting out from the objectively prevailing state of the art, the technical problem is to be determined on the basis of objective criteria and consideration given to whether or not the disclosed solution was obvious to the skilled person. Although the problem and solution approach is not mandatory, its correct application facilitates the objective assessment of inventive step.* ***The correct use of the problem and solution approach rules out an ex post facto analysis which inadmissibly makes use of knowledge of the invention (T 564/89, T 645/92, T 795/93, T 730/96 and T 631/00).*** *In principle, therefore, the problem/solution approach is to be used; however, if exceptionally some other method is adopted, the reasons for departing from this generally approved approach should be stated."*

The last paragraph on the said page relates to the determination of the closest prior art and reads as:

> *In accordance with the problem and solution approach, the boards have developed certain criteria for identifying the closest prior art to be treated as a starting point. After the relevant prior art has been identified, careful consideration must be given to the question whether, in the case concerned, the skilled person, taking into account all the available information on the technical context of the claimed invention, would have had good reason to take this prior art as the starting point for further development.* ***The boards have repeatedly pointed out that the closest prior art for assessing inventive step is normally a prior art document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural Inventive step modifications*** *(T 606/89, T 686/91, T 834/91, T 482/92, T 298/93, T 380/93, T 59/96, T 730/96, T 650/01).* ***A further criterion for the selection of the most promising starting point is the similarity of technical problem*** *(see T 495/91, T 570/91, T 439/92, T 989/93, T 1203/97, T 263/99). The determination of the closest prior art is therefore an objective and not a subjective exercise. It is made on the basis of the notional skilled man's objective comparison of the subject-matter, objectives and features of the various items of prior art leading to the identification of one such item as the closest (T 1212/01). The prior art has to be assessed from the point of view of*

the skilled person on the priority date applicable (T 24/81, OJ 1983, 133; T 772/94, T 971/95).

Relying on the aforesaid findings of the EPO Board of Appeals, the opponent submitted that the document D1 is the closest prior art in terms of structural features and similarity of technical problem. It was further submitted that the impugned application is a mere extension of D1 subsequently failing to contribute any technical advancement.

The opponent relied on the decision in ***Astrazeneca UK Limited v. GM Pharma Ltd.***, wherein the requirement of comparative tests vis-à-vis the closest prior art was again stated by the Ld. Tribunal, in the following words:

*The opponent relied on the European Board of Appeal decision T 181/82 which held that "**an effect which may be said to be unexpected can be regarded as an indication of inventive step; where comparative tests are submitted as evidence of this, there must be the closest possible structural approximation - in a comparable type of use - to the subject-matter of the invention.** In paragraph 5 of the same decision, it states:*

*To be relevant, such comparative tests must meet certain criteria. These include the choice of a compound disclosed in the application and of a comparative substance taken from the state of the art; at the same time, **the pair being compared should possess maximum similarity with regard to structure and application. Given the similar properties to be expected in view of the structural similarity of two substances, evidence of an abrupt improvement can be regarded as unexpected.** The greater the structural difference between the compounds being compared, the less unexpected are any differences in their effects. So if a meaningful statement is to be made in order to render an inventive step possible, compounds having a maximum structural resemblance must be compared with one another.*

Following the above basis, I find that the compound of Table 3 within example 34 comes structurally closer to the claimed compounds than any of the compounds of examples 26, 41 and 64 of the prior art in disclosing the same 3',4'-substituent and 7 – methoxy substituent. Therefore, compound 5 within example 34 is the closest prior art, which would require minimum structural modifications in order to reach the compounds claimed in the present invention.

The requirement for a comparison with the closest prior art is based on the principle of the structural dependence of the properties of chemical substances i.e. on the fact that these properties reflect the structure of the substances.

Therefore, it is very difficult accept the applicant's claim of 16 fold potency of the compounds of the present invention against the compound disclosed in the prior art because the comparison provided is not against the closest prior

art. Even if I agree with the arguments of the applicant that the basic group at the 6th position makes an important contribution to the properties and activities of the claimed compounds, the compound 5 of the table 3 within example 34 of the prior art should have been used as comparative test compound, as the said compound 5 of Table 3 within example 34 of the prior art differs from the claimed compound in the presence of basic group at the claimed 6-position. This could have provided a suitable platform for the demonstration of the surprising effect of the claimed compound vis-à-vis the said example compound 5 of the example 34 (Table 3). This could have proved that the surprising or the unexpected properties of the claimed compound is associated with a basic group at 6th position of the ring. In absence of any test comparative test data provided vis-à-vis compound 5 of example 34 of the prior art, the applicant's claim that the compound of the present invention are 4 to 16 times potent as compared to the prior art reference is not very convincing.

I agree with the opponent's contention that for ***the demonstration of 'technical advancement' must be shown to have been achieved by a claimed invention vis-à-vis the prior art by way of demonstrating the presence of an unexpected effect over the closest prior art****..... Therefore, I have no doubt that the applicant has failed to provide comparative test data vis-à-vis the structurally closest compound of the prior art.*

The opponent relied upon European Board of Appeal decision **T_1101/98** which relates to a similar case of obviousness in prodrug strategy of anticonvulsant sulfamates wherein

The Appellant's submissions were essentially as follows: Documents (1) and (2) were selected from a search made with hindsight knowledge of the invention. Their combination was the result of an ex post facto analysis and did not indicate a genuine lack of inventive step. The solution to the problem of providing further potentially improved anticonvulsant compounds by the provision of a ***prodrug form*** *of the compound of document (1) was not obvious. There were many possible modifications of the compound of document (1) which would have occurred to the skilled reader and, indeed, document (1) described a number of derivatives of said compound, but no prodrug. Table 1 showed that the activity of the 2,3:4,5-bis-O-(1-methylethylidene)-â-D fructopyranose sulfamate was decreased by substitution at the sulphonamide N. This taught away from the invention. None of the sulphonamide compounds disclosed in document (2) had any similarity to the fructopyranose imidate derivatives of the application in suit. Without experiment, it could not have been predicted that in vivo these derivatives would not be toxic, nor that they would undergo satisfactory hydrolysis to active sulphonamide. For these reasons, the conclusion by the Examining Division of lack of inventive step of claim 1 in the light of the combined disclosure of documents (1) and (2) was unfounded." The Board in the case held that "The closest prior art to the subject-matter of claim 1 is document (1). It discloses that 2,3:4,5-bis-O-(1-methylethylidene)-â-D fructopyranose sulfamate (ie. The molecule, from which some of the compounds of claim 1 are derived) has potent anticonvulsant activity. A study of some analogs thereof is carried out to ascertain those features associated with biological activity. It is found that derivatives carrying methyl or phenyl substitutions on the sulfamate group (Chart I, compounds 1 to 3) have an*

anticonvulsant activity lower than the fructopyranose sulfamate itself, or : / anticonvulsant activity at all, as measured ***in vivo*** *by the standard MES test carried out on mice.*

Thus, at the priority date, the skilled person was aware from document (1) of the anticonvulsant activity of the fructopyranose sulfamate, and from document (2), that imidate derivatives of sulfonamide drugs would behave as prodrugs. In the Board's judgment, it was obvious when wanting to obtain derivatives of the fructopyranose sulfamate, while keeping the anticonvulsant activity, to combine the teachings of both these documents i.e. to make N-sulfonyl imidate derivatives of said fructopyranose sulfamate. The Appellant argued that such a combination could only be done with hindsight knowledge of the content of the application as filed. However, as the usefulness of transforming drugs into prodrugs in order to solve the type of problems solved in the instant application was already known as early as 1975 (references 1 to 3, page 2071 of document (2)), this argument cannot be accepted.

The Board accepts that it could not be predicted with certainty whether, in vivo, imidate derivatives of fructopyranose sulfamate would be toxic or not, nor whether they would undergo satisfactory hydrolysis. Yet, the combined teachings of documents (1) and (2) would lead the skilled person in an obvious manner to make imidate derivatives and testing them would be a matter of routine as shown in document (1) which discloses that the anticonvulsant activity test is a standard test dating from 1952 (page 881, right hand column, "Anticonvulsant testing"). There is, thus, no inventive activity linked to preparing or testing these compounds.

The opponent relied upon **Aventis Pharma vs. Lupin Pharmaceuticals**, Federal Circuit, 2006-1530 wherein the Court of Appeals held as under.

The district court held that Lupin failed to meet its burden of proof by clear and convincing evidence that a person of ordinary skill in the art would have been motivated to purify 5(S) ramipril into a composition substantially free of other isomers. Invalidity Opinion at 74–75. The district court saw this as a close case based principally on the absence of a clear and convincing showing of motivation. Since the date of that decision, however, the Supreme Court decided KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007), which counsels against applying the "teaching, suggestion, or motivation" ("TSM") test as a "rigid and mandatory formula[]." See KSR, 127 S. Ct. at 1741. ***It remains necessary to show "'some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness,'" but such reasoning "need not seek out precise teachings directed to the specific subject matter of the challenged claim."*** *See id. (quoting In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006)). Requiring an explicit teaching to purify the 5(S) stereoisomer from a mixture in which it is the active ingredient is precisely the sort of rigid application of the TSM test that was criticized in KSR.*

In the chemical arts, we have long held that ***"structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a prima facie case of obviousness."*** *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd., No. 06-1329, slip op. at 9 (Fed. Cir. June 28, 2007) (quoting In re Dillon, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc)); see also In re Papesch, 315 F.2d 381 (C.C.P.A. 1963). The "reason or motivation" need not be an explicit teaching that the claimed compound will have a particular utility; it is sufficient to show that the claimed and prior art compounds possess a "sufficiently close relationship .*

to create an expectation," in light of the totality of the prior art, that the new compound will have "similar properties" to the old. Dillon, 919 F.2d at 692; see also In re Wilder, 563 F.2d 457, 460 (C.C.P.A. 1977) ***("[O]ne who claims a compound, per se, which is structurally similar to a prior art compound must rebut the presumed expectation that the structurally similar compounds have similar properties."). Once such a prima facie case is established, it falls to the applicant or patentee to rebut it, for example with a showing that the claimed compound has unexpected properties. Dillon, 919 F.2d at 692.***

The opponent relied on the following decisions of the Indian patent office, where applications on prodrugs were rejected for being non-inventive. The below decisions clearly state that unless some technical advancement is shown over the existing at the time of the invention, inventions cannot be said to involve an inventive step. Moreover, both the below applications were rejected under Section 3(d) as the prodrugs claimed therein failed to exhibit therapeutic efficacy.

In the matter of an application for patent No. **924/DELNP/2006**, the Ld. Controller rejected the application for lack of inventive step and under Section 3(d) as under.

10. Findings and conclusions
(.....)
The claimed compound of formula A is in fact a double prodrug of the compound of formula B. i.e., the claimed compound of formula A (BIBR-1048 MS) is only converted into the actual effective compound, namely the compound of formula B, in the specification. Compound B, the pharmaceutically active compound, is also referred to in the document D8 as BIBR-953 ZW.
As can be seen from the above, document D1 to D8 discloses in combination all the features defined in independent claim 1 and dependent claims 2-4 .Hence the subject-matter of claim 1 is not new and lack of inventive step under Section 2(1) j of the Act.
Dependent claims 2-4 do not contain any features which, in combination with the features of any claim to which they refer meet the requirements of the Section 2(1) j of the Act. in respect of inventive step.

II. (.....) It is stated by the applicant that the claimed compound has got the better solubility compared to its closest prior art compound mentioned in Document D1 to D8.
However the applicant has not provided any argument and experimental proof of any enhancement of the above properties and significant improvement in therapeutic efficacy, i.e. to say no comparative experimental data is available in the specification to prove the improvements are significant and the new form is efficacious than the earlier one. In such circumstances of failure to prove efficacy the compound as claimed is merely a new form of the known substance which is not Patentable U/S 3(d) of the Patent Act. Mere difference in solubility data does not serve the purpose of complying the requirement of section 3(d).

The process claimed in dependent claim 3&4 also not fully supported in the specification.
In the entire description of the invention the new therapeutic effect of the new forms is not disclosed. Hence it is concluded that the new crystalline form II exhibit the same efficacy as the Documents D1 to D8.

Therefore the applicant has failed in proving that the alleged invention does not attract the provisions under Section 3(d) of the Patents Act.

In the matter of an application for patent No. **712/DEL/2002**, the Ld. Controller rejected the application for lack of inventive step and under Section 3(d) as under.

I find that various cited documents especially US4808716 and US5663159 synthesise the parent compound (PMEA) as a crystalline solid. Since the compound of the invention (AD) is an ester form of the parent compound (PMEA) no inventive technical advancement can be attributed to the alleged invention. I have analysed the results as provided by the applicants regarding improved stability of the alleged compound. I have observed that the applicants have not provided a comparative data with respect to the amorphous/parent compound of the alleged invention. In the absence of the same an inventive step cannot be established.

Section 3(d)

AD appears to be merely a new form of a known substance characterized by a XRD pattern and other physical characteristics of the compound. I observe that even though the applicants have submitted that it is incorrect to assume that polymorphs or derivatives of all compounds inherently exhibit the same activity as the parent compound and have refuted such a generalization in the field of pharmacology. They further submitted that the efficacy and activity are a function of various factors and their interplay. Efficacy is also judged on the basis of bioavailability, dissolution rates, stability, side effects, toxicity and the like. These parameters depend on the factors such as processing technologies, forms of the substance, position of substituent, etc. The agents for the applicants reiterated that the forms of AD claimed in the present application are inventive over amorphous forms of AD since they possess superior dissolution rates and superior stability which significantly improv their technical and pharmacological efficacy. Thus the claimed invention is non-obvious and possess inventive step and is entitled to grant of patent. However I observe that nowhere in the Complete specification it is suggested, indicated or substantiated that the use of the characterized crystalline form results in increased biological activity or enhanced therapeutic efficacy in comparison with the biological activity and therapeutic efficacy as shown by the known and reported forms of AD. No such comparative data that substantiates the enhancement in efficacy as compared to the earlier known amorphous forms is provided in the 712/DEL/2005.
In this regard the opponent referred the Judgment passed by Hon,ble High court of Judicature at Madras in the case of Novartis AG Vs Union of India and others the court defined what is therapeutic efficacy and efficacy
I have analyzed the results as provided by the applicants regardin improved stability of the alleged compound. I have observed that the applicants have not provided a comparative data with respect to the

amorphous/parent compound of the alleged invention. Also no improvement in the therapeutic efficacy of AD as compared to its parent compound (PMEA) has been provided. In fact both the compounds (AL, is used to treat viral infections which is also the activity shown by the parent compound (PMEA). In view of above I state that the subject matter for application no. 712/DEL/2002 is not patentable under section 3(d).

INSUFFICIENCY

26. It was submitted by the opponent that the arguments put forth with respect to the aforesaid grounds in its representation will be relied upon.
The opponent's principal objection was lack of inventive step and obviousness of the impugned application on the basis of failure on the part of the applicant to rebut the obviousness over D1 in light of the structural similarity of the compounds taught in D1 and those allegedly claimed in the impugned application, failure to explain obviousness as taught by D3, D4 i.e. formation of prodrug and the gradual in vivo hydrolysis.

27. The opponent states that the case sought to be made by the applicant is based on the assumption that none of the cited prior art documents discloses the carbamate and carbonate prodrugs of PMPA and therefore the claimed invention cannot be held obvious and lacking an inventive step over the prior art. It is submitted that a prior art reference which presumably disclosed or taught carbamate or carbonate prodrugs of PMPA would be prejudicial to the novelty of the alleged invention. The applicant's contention that the prior art does not render the claimed carbonate and carbamate prodrugs of PMPA obvious because none of the prior art references discloses these specific prodrugs of PMPA appears to equate the standard of proof required for establishing anticipation with the standard of proof required for establishing obviousness, which is incorrect in law.

28. It is submitted that the ground of obviousness/lack of inventive step is operative when the prior art does not exactly teach the invention claimed by the applicant but such invention is obvious to a person skilled in the art having regard to the closest prior art and the knowledge available in the art. It is respectfully submitted that the alleged invention claimed by the applicant in the impugned application is clearly obvious and does not involve an inventive step in view of the prior art cited by the opponent and placed at length at the hearing. It is further submitted that the alleged invention in the impugned application under opposition

is liable to be rejected on this ground alone. The arguments set forth by the applicant are miserably insufficient for overcoming a case of obviousness and lack of inventive step. It is further submitted that the arguments set forth by the applicant do not attempt to address as to why the claimed invention directed to carbonate and carbamate prodrugs of PMPA would not have been obvious to a person skilled in the art in view of the strong showing of obviousness presented in the preceding paragraphs.

OPPONENT'S COMMENTS ON THE EXHIBITS FILED BY THE APPLICANT

The opponent submitted that at paragraph 6.63 of its reply, the applicant has relied upon Exhibit 2 to substantiate the higher bioavialability of the claimed compound. The patentee states "in retrospective comparison of the individual patient data, it was apparent that for given plasma AUC (area under curve, or amount)" of tenofovir, the viral load drop observed after the oral administration of TDF was greater than that observed with IV tenofovir."

The applicant also relied upon Exhibits 3 and 4, copies of which were handed out at the hearing. It is stated that as apparent from the title and text of Exhibit 3, it clearly pertains to adefovir dipivoxil, which is not the subject matter of the present invention. Therefore said document is of no relevance in the present matter.

Exhibit 4, entitled "determining the antiviral activity of tenofovir disoproxil fumarate in treatment-naïve chronically HIV-1-infected individuals" also pertains to tenofovir fumarate (TDF). Moreover such document reports the study results c. TDF being used in combination with other antiviral agents. And the monotherapy studies suggested that the efficacy of TDF was similar to prevailing antiviral drugs.

It was submitted that the present application pertains to carbamate and carbonate prodrugs of tenofovir, there is no specific discussion on the performance of the fumarate salt. Moreover, it is significant to note that the fumarate salt of tenofovir is subject matter of another application, namely, 896/DEL/2002 (rejected by decision dated July 30, 2009), the fact that th. applicants made a separate application for the fumarate salt of tenofovir implies that this specific salt form is in no way related to inventive concept the present application. Both the documents relied upon by the applicant pertain to the

fumarate salt of tenofovir (TDF). It is submitted that these documents have been cited clearly with intent to mislead the Ld. Tribunal. Such reliance upon misleading documents to establish the inventive step of an invention is an out-and-out malafide act on the part of the applicants.

The opponent states that the opposed application ought to be rejected in toto in view of the present opposition where the various grounds have been made out and established beyond doubt.

Dated this 18th day of May 2011.

Abhishek Sen
Of S.Majumdar & Co
Opponent's Agent