INNOGEN GROUP OF COMPANIES, Opposer, **-versus-** **ASTRAZENECA AB** (formerly AKTIEBOGALET ASTRA) Respondent- Patentee.	}	**IPC No. 11-2010-00307** Cancellation of: Patent No. 1-1994-48276 Date Granted: 22 August 2002 Title: **"NEW COMPOUNDS"**

NOTICE OF DECISION

ATTY. JORGE CESAR M. SANDIEGO
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GREETINGS:

Please be informed that Decision No. 2016 - 362 dated October 12, 2016 (copy enclosed) was promulgated in the above entitled case.

Taguig City, October 12, 2016.

MARILYN F. RETUTAL
IPRS IV
Bureau of Legal Affairs

INNOGEN GROUP OF COMPANIES,

Petitioner,

- versus -

ASTRAZENECA AB
(formerly AKTIEBOGALET ASTRA)

Respondent-Registrant.

x ----------x

IPC NO. 11-2010-00307

Cancellation of:
Patent No. 1-1994-48276
Date Granted: 22 August 2002

Title: **NEW COMPOUNDS**

Decision No. 2016 - 362

D E C I S I O N

INNOGEN GROUP OF COMPANIES (Petitioners)[1] filed a Petition for Cancellation of Philippine Patent No. 1-1994-48276 for "New Compounds" issued in the name of Respondent-Patentee, ASTRAZENECA AB[2] (Respondent-Patentee).

The Petition is grounded on the following: that the new compounds claimed in the said patent are not novel nor inventive and/or Claim 1 thereof is vague in the use of the term "Solid State." The grounds were expounded in the affidavit of Atty. Jorge Cesar M. San Diego[3], pertinent portions of which are quoted as follows:

> "2.1. One case that was referred to me is Philippine Patent No. 1-1994-48276 (48276 patent for brevity) issued in the name of Aktiebogalet Astra x x x
>
> "2.2. From my study of the said patent, it can not be denied that:
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> a.) Claim 1 is vague and in particular – the use of the term PURESOLID STATE;
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> b.) Assuming without admitting that claim 1 refers to the (-enantiomer) free from its racemate – the (+) enantiomer, it was

[1] Represented by Atty. Jorge Cesar M. San Diego with office address at 15M Torre Venezia, 170 Scout Santiago St. Quezon City
[2] Corporation duly organized and existing under the laws of Sweden with office address at SE-151 85 Molndal, Sweden.
[3] Attached in the Petition for Cancellation

held in the case of United Laboratories vs. Merck that the isolated enantiomer of a racemic mixture is not patentable

c.) The salt forms described in the claims are already known in the prior arts

d.) With the foregoing findings, all dependent claims (Claims 2, 3, 4 and 5) are also void.

e.) The "methods" in claims 6-10 are in fact not patentable.

SOLID STATE

"3.1 Claim 1 of the Philippine Patent No. 1-1994-48276 (48276 patent for brevity), sought to protect:

> A pharmaceutical formulation for oral administration comprising the pure solid state alkaline salt of the (-) enantiomer of 5 – methoxy – 2 [[[(4-methoxy-3, 5-dimethyl-2pyridinyl)methil]sulfinyl]-1H benzimida-zole and a pharmaceutically accepted carrier.

"3.2 However, a scrutiny of the description of the patent in question will reveal that the qualifying term in the claim i.e. PURE SOLID STATE was not even mentioned in the description /specification thereby rendering Claim 1 void for being vague. Being vague, claim 1 as worded is void as it failed to comply with the requirement of Section 14 Republic Act 165 (the law in effect when the application of this patent in issue was filed) in relation to Rule 63 of the Rules of Practice in Patent Cases (the implementing rules of RA 165) the provisions of which are hereto reproduced as follows:

> Sec. 14. The specification – the specification shall include:
>
> x x x
>
> (e) a distinct and explicit claim or claims of the subject matter which the applicant claims as new and seeks to have patented.
>
> RULE 63. Claim – a.) The specification must conclude with a claim particularly printing out and distinctly claiming the part, improvement or combination which the applicant regards as his invention.
>
> x x x
>
> (d) the claim or claims must conform to the invention as set forth in the description made in the specification, and the terms and phrases in the claims must filed (sic should be must find) clear support or antecedent basis in the said description so that meaning of the terms in the claims may be ascertainable by reference to the description.

"3.3. Thus, in view of the fact that the term PURE SOLID STATE in claim 1 was not defined or at least described, claim 1 is vague and consequently void.

THE CASE OF UNITED LABORATORIES VS. MERCK;
THE SALT FORMS ARE KNOWN IN THE PRIOR ARTS:

"4 Assuming without admitting that Claim 1 in effect refers to the (-enantiomer) free from its racemate – the (+) enantiomer, it was held in the case of UNITED LABORATORIES VS. MERCK (Interpartes Case No. 548 x x x that the isolated enantiomer of a racemic mixture is not patentable.

"4.1 Furthermore, Claim 1 also claims as part of the invention – the alkaline salt of the (-)-enantiomer of 5- methoxy-2 [[(4-methoxy-3, 5-dimenthyl-2pyridinyl)methyl]sulfinyl-1H benzimidazole {hereinafter referred to as S-omeprazole}. On the otherhand, alkaline salts are identified to contain Na+, Mg2+, Li+, K+, Ca+, or N+(R)4 salt (please see Claim 3[page 39]; abstract page 1 of the 48276 patent; detailed description starting from line 18 of page 4 of the 28276 patent).

"4.2 On the other hand, the claimed molecule comprising of the alkaline salt of S-omeprazole is also not new / inventive and therefore not patentable on the ground that:

a.) starting from line 14 of page 2, the 48276 patent admits that the compound 5 – methoxy-2 [[(4-methoxy-3, 5-dmethyl-2pryrdinyl)methyl]sulfinyl]-1H benzimidazole (known as omeprazole) and its acceptable salts was described in EP 124 495 patent. x x x

b.) Starting from line 19 of page 2 of the 48276 patent, it was also revealed that omeprazole exist acrually as two optical isomers (enantiomers). Furthermore, page 3 of 48276 patent starting from line 18 has also admitted that the enantiomers of omeprazole has been described 9j J. Chromatography, 532 (1990), 305-19 and in a preparative scale in the German Patent was further discussed on page 3 of the 48276 patent starting from line 11.

c.) The two enantiomers mentioned in sub par. B) hereof were actually identified in the 48276 patent particularly starting from line 21 of page 4 as follows [the difference lies in the (-) and (+) orientation]:

i) (-) – 5- methoxy-2 [[(4-m3thoxy-3, 5-dimethyl-2pyridinyl)methyl]sulfinyl]-1H benzimidazole {S-omeprazole}; and
ii) (+)- 5-methoxy-2 [[(4-methoxy-3, 5-dimethyl-2pyridinyl)methyl]sulfinyl]-1H benzimidazole

d.) Going back to EP 124 495 xxx, it was described that the omeprazole molecule can also exists as salts in combination with Na+, Mg2+, Li+, K+,Ca+, or N+ (R)4 salt x x x

"4.3 Thus, summarizing the foregoing arguments, it is very clear that in EP 124495, if omeprazole exists enantiomers with the foregoing salt forms, it follows that the following molecules are known:

a) NA+, Mg2+, Li+,K+,Ca+or N+(R)4 salt of (-)-5-methoxy-2[[(4-methoxy-3, 5-dimethyl-2pyridinyl)methyl]sulfinyl]-1Hbenzimidazole {S-omeprazole}; and

b.) Na+,Mg2+,Li+,K+Ca+orN+®4 salt of (+) – 5 – methoxy-2 [[(4-methoxy-3,5-dimethyl-2pyridinyl)methyl]sulfinyl]-1H benzimidazole {S-omeprazole};

"4.4. It should be noted that the enantiomer (and its salt form) in par. A) hereof is practically identical to the enantiomer in it salt form claimed in the 48276 patent the only difference is the fact that in the 48276 patent, a particular enantiomer, i.e. the (-) enantiomer that was claimed separated from its racemate, the (+) enantiomer.

"4.5 According to the patent in question, "optically pure" means (-) enantiomer is free from the (+)enantiomer (please see line 1 of page 7 of the 48276 patent), then what is the meaning of solidstate in claim 1?

CLAIM 2. 3, 4 AND 5 ARE VOID BEING
DEPENDENT ON CLAIM 1 WHICH IS VOID

x x x

CLAIM 6-10 ARE NOT PATENTABLE

"6. According to Section 7 of RA 165, the law applied when the application that matured to Philippine Patent No. 1-1994-48276 was filed and eventually granted xxx the following matters can be patented:

a.) Machines
b.)Products and substances;
c.)Processes; and
d.) Improvement of the foregoing.

"6.1. On the other hand, claims 6-10 refers to methods of use namely:

a.) Method of inhibiting gastric acid secretion...(Claim 6, 9 and 10)
b.) Method for the treatment of gastrointestinal (Claim 7, 8 and 10)

"6.2 Clearly, these methods are not machines and/or products and substances. The closest item on the list of patentable subject matter in the cited law is process. However, Section 8 of the same law mandates process not directed to the making or improving a commercial product is not patentable.

"6.3 Clearly, the methods in Claims 6 to 10 of the assailed patent are not patentable as there is no commercial product being manufactured or improved."

The petitioner's evidence consist of the following:

1. Exhibit "A" – the biodata of Atty. Jorge Cesar M. San Diego
2. Exhibit "B" – the copy of the patent sought to be cancelled

3. Exhibit "C" – the decision of the Philippine Patent Office in the case of United Laboratories, Inc. Westmont Pharamaceuticals, Inc. vs. Merck & Company, Inc. dated 10 June 1974
4. Exhibit "D" – copy of the European Patent document EP 124 495
5. Exhibit "E" – affidavit of Atty. Jorge Cesar M. San Diego

This Bureau issued a Notice to Answer on 18 January 2011 and served to Respondent-Patentee on 25 January 2011. On 24 May 2011, the Respondent-Patentee filed its Answer denying the material allegations in the Petition for Cancellation. Respondent-Patentee further alleged as follows:

> "3. Patent No. 1-1994-48267 was granted on 22 August 2002 which is almost Nine (09) years ago. In view of its considerable length of time that has elapsed since the date of grant of said patent, it is clear that petitioner has slept on whatever rights it may have to file the present petition. Otherwise stated, the present petition for cancellation is barred by laches.
>
> "4. Assuming for the sake of arguendo that petitioner has the legal capacity to sue and that the present case may properly be prosecuted against AstraZeneca AB, and assuming further that the present action is not barred by laches, still the instant petition is bereft of any merit whatsoever.
>
> "5. The Intellectual Property Office granted Patent No. 1-1994-048276 after undergoing substantive examination. The said patent was granted after a set of amended claims was filed with the said office. It was in compliance with the then handling Examiner's advice that the claims of Patent Application No. 1-1994-048276 be amended as to totally adopt those of the corresponding granted US Patent No. 5,714,504. x x x
>
> "6. Additionally, the subject matter of Patent No. 4-1994-048276 is covered by a family of granted U.S. Patents Nos. 6,143,771, 5,877,192, 6,875,872, and 5,693,818. x x x
>
> "7. Not only is the subject matter of Patent No. 1-1994-048276 covered by the aforesaid granted US Patents x x x it is covered by corresponding granted European Patents Nos. 1 020 460 and 1 020 462. x x x
>
> "8. Patent No. 1-1994-048276 DOES NOT in any manner refer to omeprazole which is a well known racemic compound. The invention covered by the subject patent actually refers to a composition for oral administration comprising a pure solid state alkaline salt of the (-)-enantiomer of omeprazole. It relates to novel compounds and NOT to the racemic compound omeprazole or its salts.
>
> "9. As stated under Field of Invention, the invention covered by Patent No. 1-994-048276 is directed to new compounds with high optical purity, their use in medicine and their use in the manufacture of pharmaceutical preparations. Its aim was to obtain compounds with

improved pharmacokinetic and metabolic properties which will give an improved therapeutic profile such as a lower degree inter-individual variation. The subject invention also provides a novel method for preparing the novel compounds.

"10. Needless to state, the compounds covered by Patent No. 1-1994-048267 are novel and inventive. Also, Claim 1 of the said patent is not in any manner vague as it clearly defines the invention as "a pharmaceutical formulation for oral administration comprising a pure solid state alkaline salt of the (-)-enantiomer of omeprazole and a pharmaceutical acceptable carrier."

"11. Based on the whole disclosure in the contested patent, the term "pure" is understood to relate to chemical purity of the compound in that the alkaline salt of the (-)-enantiomer of omeprazole is essentially free from chemical impurities to permit use in a pharmaceutical formulation" or that it is "sufficiently free from chemical impurities to permit its use in a pharmaceutical formulation."

"12. Claim 2, on the other hand, defines the solid state salt to be optically pure while Claim 4 states that the said solid state salt is in a substantially crystalline form.

"13. Claim 3 and 5 define the compound in the claimed formulation to be specific pure solid state salts of the (-) –enantiomer of omeprazole, such as sodium and magnesium salts and other salts of the (-)-enantiomer of omeprazole. The working examples in the contested patent also show the preparation of chemically and optically pure sodium and magnesium salts of the (-)-enantiomer of omeprazole as well as their use in the preparation of pharmaceutical formulation.

"14. Claim 6 and 7 refer to the medical use of the claimed formulation comprising a pure(-)-enantiomer of omeprazole and a pharmaceutically acceptable carrier. Thus, the alkaline salt of the (-)-enantiomer of omeprazole is essentially free from chemical impurities to permit its use in a pharmaceutical formulation in medical treatment.

"15. Claim 8 to 10, inclusive, refer to the medical use of the claimed formulation comprising a pure (-)-enantiomer of omeprazole and a pharmaceutically acceptable carrier. Thus, the pure (-)-enantiomer of omeprazole is essentially free from chemical impurities to permit use in a pharmaceutical formulation in medical treatment.

"16. Petitioner's reliance on the case of United Laboratories vs. Merck, Inter-Partes Case No. 548, is quite misplaced. This case finds no application in the case at bar. The facts of this case simply do not obtain in the present controversy.

"17. The pure solid state alkaline salts of the (-)-enantiomer of omeprazole covered by Patent No. 1-1994-048276 are NOVEL compounds which show surprising and advantageous properties vis-à-vis the general thinking in the prior art references.

"18. Suffice it to state that the result shown in the US Declaration submitted to the U.S. Patent and Trademark Office during the

examination of the subject invention's corresponding granted U.S. Patent No. 5,714,504 x x x cannot be obvious especially taking into account that the general understanding at the time was that omeprazole and the enantiomers of omeprazole were of equal potency x x x

"19. The data in the aforesaid US Declaration shows the advantageous effect of a pure solid state alkaline salt of the (-)-enantiomer of omeprazole over the racemic compound omeprazole as well as over the (+)-enantiomer. All compounds were administered as sodium salt. The Declaration also show data on administration of magnesium salt of the (-)-enantiomer.

"20. On the other hand, petitioner's reliance on European Patent No124495, German Patent Application No. DE 40 35 455 and J. Chromatography, 532 (1990), pages 305-319, in raising the issue of novelty and seeking the cancellation of Patent No. 1-1994-048276 is, to say the least, highly misplaced. These prior art references have all been cited and discussed in the backgound of the invention covered by Patent No. 1-1994-048276. Indeed, these prior art references are not new to the Respondent-Patentee which is very much well aware of their existence and content.

"21. It must be emphasized at this juncture that none of the prior art references relied upon by the petitioner disclosed the novel pharmaceutical composition for oral administration comprising a pure solid state alkaline salt of the (-)-enantiomer of omeprazole.

"22. Neither are the pure enantiomers of omeprazole such as the pure (-)-enantiomer of omeprazole, nor an alkaline salt of the pure (-)-enantiomer of omeprazole, known in the aforesaid prior art references.

"23. European Patent No. 124495 generally refers to the racemic compound omeprazole and some its acceptable salts are described in this prior art reference, none of the enantiomers of omeprazole or any salts of the enantiomers are, however, disclosed therein.

"24. Indeed, European Patent No. 124495 describes certain salts of omeprazole, i.e. racemic compounds. It does not, however, in any manner whatsoever propose or suggest separation of the racemic compound into a single enantiomers. Neither is there any suggestion or proposal therein of any property of a pure solid state alkaline salt of the (-)-enantiomer of omeprazole, especially not the advantageous properties found for an alkaline salt of the (-)-enantiomer of omeprazole over the racemic omeprazole and the (+)-enantiomer of omeprazole.

"25. Thus, clearly, European Patent No. 124495 does not describe anyone of the novel compounds claimed in Patent No. 1-1994-048276. Specifically, it does not disclose any pure solid state alkaline salts of the (-)-enantiomer of omeprazole and does not suggest or disclose the surprising merits of the claimed compounds over omeprazole and the (+)- enantiomer of omeprazole, all compounds administered as sodium salt. Perhaps more importantly, this prior art reference does not contemplate that the (-)-enantiomer of omeprazole could have any

properties which differ from those of the (+)-enantiomer or the racemic compounds.

"26. Similarly, a pure solid state alkaline salt of (-)-enantiomer of omeprazole or the pure (-)-enantiomer of omeprazole (non-salt form) has not been described in or known from German Patent Application No. DE 4035445. Neither has it been described in, or known from, J. Chromatography 532 (1990).

"27. It is worthy to not that German Patent Application No. DE 4035445 as well as its corresponding PCT applications never matured into a granted patent. All these applications were allowed to lapse and/or abandoned by the applicant therein.

"28. More importantly, German Patent Application No. DE 4035445 does not provide the (-)-enantiomer or any or the enantiomers of omeprazole. The attempts of the applicant therein to obtain the single enantiomers of omeprazole using the method described in the said patent application failed and the same could not be used to produce pure enantiomers of omeprazole. Clearly, this prior art reference does not disclose pure compounds, much less any specific alkaline salt of a pure compound. It does not disclose the (-)-enantiomer of omeprazole.

"29. Not even the combination of European Patent No. 124495 and German Patent Application No. DE 4035445 disclose the new compounds covered by Patent No. 1-1994-048276.

"30. Finally, as petitioner itself admits, methods of treatment were patentable under Republic Act 165, as amended. Needless to state, the subject patent was filed, prosecuted and granted during the effectivity of the said law.

"31. In filing the instant petition for cancellation, petitioner's motive is highly suspect. Respondent-Patentee's Nexium™ tablet comprises magnesium salt of esomeprazole (the(-)-enantiomer of omeprazole) and Nexium™ i.v. comprises sodium salt of esomeprazole."

The Respondent-Patentee submitted the following exhibits as evidence:

1. Exhibit "1" – authenticated special power of attorney executed by Mr. Benjamin McDonald
2. Exhibit "2" to "2-A" - authenticated affidavit of Mr. Sverker von Unge
3. Exhibit "3" – copy of U.S. Patent No. 5,714,504
4. Exhibit "4" – copy of U.S. Patent No. 6,143,771
5. Exhibit "5" – copy of U.S. Patent No. 5,877,192
6. Exhibit "6" – copy of U.S. Patent No. 6,875,872
7. Exhibit "7" – copy of U.S. Patent No. 5,693,818
8. Exhibit "8" – copy of European Patent 1 020 460
9. Exhibit "9" – copy of European Patent 1 020 461

10. Exhibit "10" – certified true copy of the declaration executed by Tommy Anderson, Ph.D filed with U.A. Patent and Trademark Office

During the Preliminary Conference on 10 November 2011, the Petitioner failed to appear and was declared to have waived its right to file the position paper. Subsequently, the Respondent-Patentee filed its position paper and the case was submitted for decision.

At the outset, the Respondent-Patentee contends: that the petitioner has no legal capacity to sue for failure to allege the requisite legal circumstances; that the petition was brought against an entity that is not a real party in interest since it was filed against Aktiebogalet Astra and not AstraZeneca AB; and the present action is barred by laches for having been filed almost nine (9) years from the issuance of the patent.

Before proceeding to discuss the substantive issue in the instant case, this Bureau will tackle first the above formal objections espoused by the Respondent-Patentee.

Firstly, this Bureau finds that the instant petition has substantially complied with the formal requirements under the law. Republic Act No. 165 which is the law governing at the time of the application of the instant patent or even the current Intellectual Property Code, only require that the petition for cancellation of patent must be in writing, verified by the petitioner or any person on his behalf and shall specify the grounds upon which it is based and including statements of facts relied upon.[4] The mistake in the name of the party impleaded is not fatal since the petition clearly indicated the particular patent registration being assailed. Moreover, the Respondent-Patentee also admitted that the initially impleaded Aktiebogalet Astra was its former name. In fact, records show that Respondent-Patentee was still using the name Aktiebogalet Astra when it first filed the application of the instant patent.

With regard to the Respondent-Patentee's claim that the instant petition should be barred by laches, the same is equally unavailing. In *Regalado v. Go*[5], the Supreme Court defined laches as the failure or neglect for unreasonable and unexplained length of time, to do that which, by exercising due diligence, could or should have been done earlier, it is negligence or omission to assert a right within a reasonable length of time, warranting presumption that the party entitled to assert it either has abandoned it or declined to assert it. In this case, the elements of laches are not present.

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[4] Section 30, R.A. 165 and Section 62, R. A. 8293
[5] G.R. No. 167988, 6 February 2007

Proceeding with the main issue, which is, whether the subject patent for the new compounds covered by Philippine Patent No. 1-1994-48276 should be cancelled for having vague claim or for lacking of novelty and/or inventive steps.

The Letters Patent sought to be cancelled relates to a new compound composed of the single enantiomers of omeprazole used for inhibiting gastric acid secretion in mammals and man, and for treatment of gastric-acid related diseases and gastrointestinal inflamatory diseases in mammal and man.[6] The particular claims in the patent are quoted as follows:

> 1. A pharmaceutical formulation for oral administration comprising a pure solid state alkaline salt of the (-) – enantiomer of 5-methoxy-2[[(4-m3thoxy-3, 5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and a pharmaceutically acceptable carrier.
> 2. The pharmaceutical formulation according to Claim 1 wherein the solid state salt is optically pure.
> 3. The pharmaceutical formulation according to Claim 1, wherein the alkaline salt is a Na^+, Mg^+, Li^+, K^+, Ca^{2+} or N^+ $(R)^4$ salt.
> 4. The pharmaceutical formulation according to Claim 1, wherein the solid state salt is in substantially crystalline form.
> 5. The pharmaceutical formulation according to claim 1 wherein the alkaline salt is a sodium or magnesium salt.
> 6. A method of inhibiting gastric acid secretion comprising the oral administration of a pharmaceutical formulation comprising a therapeutically effective amount of a pure solid state alkaline salt of the (-) –enantiomer of 5-methoxy-2[[(4-methoxy-3, 5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and a pharmaceutical acceptable carrier.
> 7. A method for the treatment of gastrointestinal inflamatory disease comprising the oral administration to a mammal including man in need of such treatment of a pharmaceutical formulation comprising a therapeutically effective amount of a pure solid state alkaline salt of the (-) –enantiomer of 5-methoxy-2[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and a pharmaceutically acceptable carrier.
> 8. A method for the treatment of gastrointestinal inflammatory disease comprising the oral administration to a mammal including man in need of such treatment a composition comprising an effective amount of the pure (-) – enantiomer of 5 – methoxy – 2 [[(4 - methoxy-3, 5-dimethyl -2-pyridinyl) methyl] sulfinyl] -1H - benzimidazole and a pharmaceutical carrier.
> 9. A method of inhibiting gastric acid secretion comprising the oral administration of a pharmaceutical composition comprising an effective amount of pure (-) – enantiomer of 5-methoxy-2[[(4-methoxy-3, 5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole and a pharmaceutical carrier.
> 10. The method of claim 6 or 7 wherein the alkaline salt is a Na^+, Mg^+, Li^+, K^+, Ca^{2+} or N^+ $(R)^4$ salt.

The petitioner argues that the term "Pure Solid State" in claim 1 of the instant patent was not defined or described, making it vague and

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[6] Philipine Patent No. 1-1994-48276, p. 7

consequently void. On its part, the Respondent-Patentee claims that the term "pure" relates to chemical purity of the compound in which the alkaline salt of the (-)-enantiomer of omeprazole is "essentially free from chemical impurities to permit use in a pharmaceutical formulation" or that it is "sufficiently free from chemical impurities to permit its use in a pharmaceutical formulation." Respondent-Patentee also added that successive claims[7] define the solid state to be optically pure, solid state salts and in a substantially crystalline form.

This Bureau agrees with the Respondent-Patentee. Rule 63 of the Rules of Practice in Patent Cases[8] in relation to Section 14 of Republic Act No. 165,[9] only requires that the terms and phrases in the claims should find clear support or antecedent basis in the patent description so that the meaning of the term may be ascertainable. A reading of the patent descriptions and specifications would show that the term "pure solid state" under Claim 1 of the invention refers to the optically pure alkaline salt of the (-)-enantiomer of omeprazole.

The Petitioner also contends that the instant patent should be cancelled for being unpatentable due to lack of novelty and/or inventive steps. It cited the decision of Director of Patent of the Philippine Patent Office in the case United Laboratories, Inc. et. al vs. Merck & Company, Inc.[10] (United Laboratories case, for brevity) dated 10 June 1974 regarding Philippine Letters Patent No. 3555 for *Isomers of Phenyl Alanine Derivatives*. It further argues that the subject new compounds are salt forms already known in the prior arts citing European Patent EP 124 495 and German Patent Application DE 40 35 455.

The Respondent-Patentee claims that EP 124495 refers only to racemic compound of omeprazole and does not describe the enantiomers of omeprazole or any salts of the enantiomers. Respondent-Patentee added that EP 124495 does not propose or suggest separation of the racemic compound into its single enantiomers nor disclose the pure alkaline salts of the (-) –enantiomer of omeprazole. It further contends that the German Patent Application No. DE 40 35 455 nor the cited Journal of Chromatography[11] did not describe the pure alkaline salt of (-)-enantiomer

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[7] Claims 2-4, Letters Patent 1-1994-048276

[8] Rule 63. Claim – a) The specification must conclude with a claim particularly printing out and distinctly claiming the part, improvement or combination which applicant regards as his invention. x x x
(d) the claim or claims must conform to the invention as set forth in the description made in the specification and the terms and phrases in the claims must find clear support or antecedent basis in the said description so that the meaning of the terms in the claims may be ascertainable by reference to the description

[9] Section 14. The specification. – The specification shall include:
(a) the title of the invention;
(b) A brief statement of its nature and purpose;
(c) A brief explanation of the drawings, where there are drawings;
(d) A complete and detailed description of the invention in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which the invention relates to make and practice the invention; and
(e) A distinct and explicit claim or claims of the subject matter which the applicant claims as new and seeks to have patented.

[10] Inter-Partes Case No. 548, 10 June 1974

[11] J. Chromatography vol 532, 1990

or its non-salt form. It further claims that even the combination of EP 124495 and DE 4035455 did not disclose the pure compound (-)-enantiomer of omeprazole.

Republic Act No. 165, the applicable law in the instant case provides:

> Sec. 7. *Inventions patentable.* – Any invention of a new and useful machine, manufactured product or substance, process, or an improvement of any of the following, shall be patentable.
>
> Sec. 8. *Inventions not patentable.* – An invention shall not be patentable if it is contrary to public order or morals, or to public health or welfare, or if it constitutes a mere idea, scientific principle or abstract theorem not embodied in an invention as specified in section seven hereof, or of any process not directed to the making or improving of a commercial product.
>
> Sec. 9. *Invention not considered new or patentable.* – An invention shall not be considered new or capable of being patented if it was known or used by other in the Philippines before the invention by the inventor named in an application for patent for the invention, or if it was patented or described in any printed publication in the Philippines or any foreign country more than one year before the application for a patent therefore; or if it had been in public use or on sale in the Philippines for more than one year before the application for a patent therefore; or if it is the subject matter of a validly issued patent in the Philippines granted on an application filed before the filing of the application for patent therefore.

For an invention to be patentable, it must be new and must have the characteristics of inventiveness. A patent is new with reference to the cited prior arts, when the claims of the subject patent include every element in the prior art reference. It means that each and every element of the claimed invention must be disclosed in the prior art.[12] The presence of even the slightest difference between what is claimed and what is disclosed in the prior art would not constitute anticipation from the said prior art.[13]

In this case, there is no anticipation as the subject invention refers to a different compound from the cited prior arts. EP 124 495 refers to the racemic compound of omeprazole while the instant patent deals with the pure (-)-enantiomer of omeprazole. A racemic is a compound with a mixture of (+)-enantiomer and (-)-enantiomer. Thus, a pure compound compose of a single kind of enantiomer is different from the mixture composed of the two different types of enantiomers. Moreover, the separation of the two racemates in the racemic omeprazole is not taught or even suggested in EP 124 495. The compound in its stabilized salt form is not described in the references J. Chromatography[14] and DE 40 35 455.

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[12] W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F 2d 1540, 220 USPQ 303, Fed. Cir. 1983, Lexis 13701.
[13] Wegner, Patent Law in Biotechnology, Chemicals & Pharmaceuticals, 2nd ed., 1994, p 159-160
[14] vol. 532, 1990

Hence, the optically pure compound of (-)-enantiomer is considered novel with reference to the cited prior arts.

The doctrine of anticipation is explained in the World Intellectual Property Organization (WIPO) publication entitled, "Philippine Law on Patents, Trademark and Copyright (Background Reading Material on Intellectual Property, Philippine National Supplement)"[15], to wit:

> The rule is that the specification of the first patent must be such that persons skilled in the art could construct the invention described in the subsequent patent without the exercise of a creative faculty or further experimentation. An existing patent which did not bear within its four corners adequate directions for the practice of the patent in suit did not anticipate it.
>
> In the chemical arts, there are thousands of chemical compounds which could be synthesized on paper, their utilities predicted and their chemical structures and molecular weights determined and designated. If these references did not describe the manner of making or producing them but referred to compounds which were creation in theory only, they could not be cited to bar issuance of patent for lack of novelty.

Thus, mere theoretical knowledge of the existence of a compound or mixture without the actual disclosure of the manner of making or producing them is not enough to prevent an issuance of the patent for lack of novelty.

With regard to the question of inventiveness or the requirement of inventive step, the test is whether the invention is not obvious to a person skilled in the art at the time of the filing date or priority date of the application. The person skilled in the art is presumed to be an ordinary practitioner aware of what was common general knowledge in the art at the relevant date. A person of ordinary skill in the art is presumed to be one who thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate, whether by patient, and often expensive, systematic research or by extraordinary insights, it makes no difference which.[16]

In the instant case taking in consideration the available references and the common general knowledge in the art during the relevant time, this Bureau finds that the subject invention has satisfied the requirements of inventiveness under the law. The Respondent-Patentee has sufficiently proven that, at the time of the filing of the application for patent and its priority date, the racemic omeprazole was not separated into its racemates for usage in the treatment of gastro-intestinal inflammatory disease or to inhibit gastric acid secretion in mammals and man. Moreover, there is no motivation for person skilled in the art to formulate the optically pure salt

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[15] Ignacio S. Sapalo, 1992

[16] Standard Oil Company vs. American Cyanamid Company, 774 F. 2d 448, 454 (Fed. Cir. 1985)

of esomeprazole for the said treatment especially with the known difficulty in separating the racemates of omeprazole.[17] It was only when the Respondent-Patentee conducted its clinical study showing a more than expected improvement in pharmacokinetics and interindividual variation on optically pure (-)-enantiomer of omeprazole when compared with the racemic salt of omeprazole. These unexpected findings are contrary to the prior art teaching on pharmacodynamic effect, which was previously demonstrated in gastric glands to be the same for the two enantiomers.[18]

The Petitioner's mere reliance on the United Laboratories case[19] is unavailing. In the cited case, the former Director of Patent based the decision on his findings that the prior art in the said case had sufficiently disclosed the racemic character of the compound and established that the said racemic mixtures were capable of resolution by conventional processes.[20] The particular discussion are quoted, as follows:

> Considered in the light of the foregoing explanation, I would agree with the respondent-patentee and sustain its view if the Pfister and Stein Patent did not show or indicate that the compounds therein described and claimed are racemic, in re Williams, 36 CCPA 756 171 F2d 80 USPQ 150, or while indicating that the compounds are racemic, they can not be separated into their optical antipodes by normal methods, Sterling Drug, Incorporated v. Watson, 135 F Supp. 172, 108 USPQ 37. It is here emphasized that the racemic mixtures of Pfister and Stein are capable of resolution by conventional processes to produce the claimed isomers including those methods taught by Karrer, Organic Chemistry, 2nd Ed., page 32 (Exh. "B")[21]

In the instant case, Petitioner failed to prove that the racemic mixtures herein can be separated by conventional processes. In contrast, the Respondent-Patentee has sufficiently shown that the subject compounds were not anticipated by the prior arts and the difficulty in the separation of the racemates of omeprazole would prevent an ordinary person skilled in the art to produce the claimed invention.[22]

Verily, the Philippine Patent No. 1-1994-48276 issued in the name of Respondent-Patentee has the presumption of validity. Hence, the burden of proving the invalidity is on the party who petition for its cancellation and the burden is a heavy one which is met only by clear and satisfactory proof which overcomes every reasonable doubt.[23] There is a presumption that the Office has correctly determined the patentability of the invention and such action must not be interfered with in the absence of competent evidence to

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[17] Respondent-Patentee's Answer, p. 8,
[18] Exhibit "10" of Respondent-Patentee p. 3
[19] Inter-Partes Case No. 548 supra
[20] Exhibit "C" of Petitioner, pp. 324-325,
[21] *ibid*
[22] Respondent-Patentee's Answer, p. 8
[23] Manzano vs. CA et. al., G.R. No. 113388, September 5, 1997

the contrary. The evidence presented by the Petitioner is not enough to overthrow the presumption of validity of accorded to the letters patent.

WHEREFORE, premises considered, the instant Petition for Cancellation to the Letters Patent with Registration No. 1-1994-48276 is hereby **DENIED**. Let the filewrapper of Letters Patent with Registration No. 1-1994-48276 be returned together with a copy of this **DECISION** to the Bureau of Patent (BOP) for appropriate action.

SO ORDERED.

Taguig City, 12 OCT 2016

Leonardo Oliver Limbo
Adjudication Officer
Bureau of Legal Affairs