SMITHKLINE BEECHAM PLC,
Respondent-Appellant,

-versus-

NATRAPHARM, INC.,
Petitioner-Appellee.
x----------x

Appeal No. 14-07-33

Inter Partes Case No. 14-2006-00024
Cancellation of Letters Patents
No. 1-1996-52993
Issued on 05 May 2005
Filed: 30 April 1996
Title: Method for Treatment

DECISION

SMITHKLINE BEECHAM PLC ("Appellant") appeals Decision No. 2007-61, dated 31 May 2007, of the Director of the Bureau of Legal Affairs ("Director") which granted the petition of NATRAPHARM, INC. ("Appellee") to cancel Letters Patent No. 1-1996-52993 issued in favor of the Appellant.

Records show that the Appellee filed on 27 February 2006 a "VERIFIED PETITION FOR CANCELLATION"[1] alleging the following:

1. Subject invention is not patentable for lacking in novelty as defined under either Sections 7 and 9, Chapter II of Rep. Act No. 165 ("RA 165")[2] or under Sections 23 and 24 of Rep. Act No. 8293, known as the Intellectual Property Code of the Philippines ("IP Code");

2. Subject invention is not patentable for lacking in inventive step under either Sec. 7 of RA 165 or Sec. 26 of the IP Code;

3. Patent and non-patent documents were in existence more titan one (1) year prior to the filing (priority) date of the subject invention that the dosages claimed in the subject patent are obvious to a person skilled in the art;

4. There is no significant improvement in the efficacy of the present invention as compared to that of the prior art; the routine experimentation which appears to be the main factor that contributed to the subject invention is deemed to be within the knowledge of one who possesses ordinary skills in the art at the time of the filing (priority) date of the patent application;

5. All the indications and suggestions in the prior arts clearly lead the skilled person to the teaching of the subject invention and there is nothing unexpected or surprising in the subject invention as it is obvious to a person of ordinary skilled in the art to develop the dosage form as claimed therein in view of the disclosures, suggestions and incentives earlier mentioned; and
6. The present case was filed under the old patent law and it was not appropriate to use as a basis for allowance of the subject invention European or Australian patents as their laws are not similar to the old patent law.

The Appellee submitted the following evidence to support the petition:

1. Affidavit of Jorge Cesar M. Sandiego (including annexes), executed on 06 June 2006;[3]
2. Affidavit-Testimony of Agnes S. Heruela-Casiding, executed on 05 June 2006;[4]
3. GB 2005 538 A — UK Patent Application published on 25 April 1979[5]
4. WO/1991/015197 Pharmaceutical Formulation — an international application under the Patent Cooperation Treaty, Publication Date: 17 October 1991[6]
5. US Patent No. 4,537,887 dated 27 August 1985.[7]

6. Printed publications and studies on amoxicillin-clavulanic pharmaceutical formulation;[8] and
7. Transcript of Stenographic Notes on the 13 June 2006 hearing of Civil Case No. 06-373 in Regional Trial Court (RTC) Makati City, Branch 138;[9]

The Appellant filed on 06 October 2006 a “VERIFIED ANSWER" alleging the following:

1. Letters patent carry a presumption of validity and clear and convincing evidence is necessary to cancel it;

2. The references cited by the Appellee neither prove nor support the unfounded allegation of lack of novelty and lack of inventive step;

3. The illustrative rulings in various foreign cancellation cases involving the subject invention support the findings of novelty and inventive step of the letters patent; and

4. The Appellee has clearly and convincingly failed to carry its burden of proof regarding the allegations of lack of novelty and lack of inventive step of Letters Patent No. 1-1996-52993.

The Appellant submitted the following evidence:

1. Affidavit of Nikko P. Quevada, executed on 20 September 2006;[10]
2. Copies of decisions /rulings in various foreign cancellation cases;[11]
3. Affidavit of Richard M. Rivera, executed on 31 March 2006; [12]
4. Power of Attorney executed by Peter John Giddings on 06 September 2006;[13]
5. Affidavit of Crisanta J. Palafox, executed on 30 October 2006;[14] and
6. Transcript of Stenographic Notes on the 26 June 2006 hearing of Civil Case No. 06-373 in RTC Makati City Branch 138.[15]

After the appropriate proceedings, the Director ruled that Letters Patent No. 11996-52993 lacks novelty and inventive step. According to the Director, the subject matter was described in patent documents W091/15197 and US Patent 4,537,887 which ante dates the filing date of the subject invention and that the Appellee established by clear and convincing evidence the obviousness of the invention.

Dissatisfied, the Appellant filed an "APPEAL" on 05 July 2007 reiterating its position that the Appellee has not overturned the presumption of validity of the Letters Patent No. 1-1996-52993 by clear and convincing evidence. The Appellant contends that the invention is novel and not obvious. The Appellant asserts that lack of novelty or anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference or embodied in a single prior art device or practice and that lack of inventive step requires that the claimed invention should have been obvious to a person skilled in the art at the time of the filing date or priority date of the application claiming the invention. The Appellant cites the rulings in foreign jurisdictions upholding the novelty and inventive step of its invention.

Commenting on the appeal[16], the Appellee contends that it has sufficiently overturned the presumption of validity of the Appellant's patent by adducing clear and convincing evidence. The Appellee maintains that to prove lack of novelty, it is not required that each and every element of the claimed invention be disclosed in a single prior art device or practice but it is sufficient that the elements are inherent or implicit to a person skilled in the art. According to the Appellee, the tablet and solution form for adult formulation can be easily converted into solution form for pediatric solution and such conversion is well within the knowledge of ordinary person skilled in the art. The Appellee claims that the Appellant's invention is obvious and lacks inventive step and that a pharmacist is an ordinary person skilled in the art of dosage formulation. The Appellee avers that the subject invention is not patentable under the provisions of RA 165 and the IP Code.

The main issue to be resolved in this case is whether the Director was correct in ordering the cancellation of Letters Patent No. 1-1996-52993.

Sec. 61 of the IP Code provides that any interested person may upon payment of the required fee petition to cancel a patent on any of the following grounds:

(a) That what is claimed as the invention is not new or patentable;

(b) That the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by any person skilled in the art; or

(c) That the patent is contrary to public order or morality.

The relevant question, therefore, is whether the Appellant's invention is new or patentable.

In resolving the issue of patentability of an invention, it is important to look at the claims of the subject invention. The claims of an invention define the matter for which protection is sought.[17] The claims of the Appellant's invention are the following:

"Claims

"1. A method of treating bacterial infections in pediatric patients which method comprise administering to a patient in need thereof an antibacterially effective amount of a formulation comprising amoxicillin trihydrate and potassium clavulanate in combination, in a weight ratio 7:1. The weights being expressed as the free parent acids amoxicillin and clavulanic acid, the formulation being administered twice daily (bid), at a dosage of between 20 and 70 mg/kg/day of amoxicillin and a pro rata amount of clavulanic acid.

"2. A method as claimed in claim 1 in which the dosage regimen is 70 + 10%/mg/kg/day amoxicillin in combination with 10 + 10% mg/kg/day clavulanic acid.

"3. A method as claimed in claim 1 in which the dosage regimen is 45 + 10%/mg/kg/day amoxicillin in combination with 6.4 + 10% mg/kg/day clavulanic acid.

"4. A method as claimed in claim 1 in which the dosage regimen is 35 + 10%/mg/kg/day amoxicillin in combination with 5 10% mg/kg/day clavulanic acid.

"5. A method as claimed in claim 1 in which the dosage regimen is 25 + 10%/mg/kg/day amoxicillin in combination with 3.6 + 10% mg/kg/day clavulanic acid.

"6. A method as claimed in claim 1 for treating acute otitis media.

"7. A pediatric pharmaceutical formulation in the form of a dry powder which is reconstituted into a multiple dosage suspension with water or other suitable aqueous media, comprising amoxicillin trihydrate and potassium clavulanate in combination, in weight ratio of 7:1, the weights being expressed as the free parent acids amoxicillin and clavulanic acid, which formulation, when reconstituted, comprise amoxicillin in an amount of from 150 to 450 mg/5ml of liquid aqueous suspension and clavulanic acid in an amount of from 25 to 75 mg/5m1 of liquid aqueous suspension.

"8. A formulation as claimed in claim 7 which when reconstituted comprises 200 + 10% mg/5ml amoxicillin and 28.5 + 10% mg/5ml amoxicillin, or 400 + 10% mg/5ml amoxicillin and 57 + 10% mg/5ml clavulanic acid.

"9. A multiple dosage pharmaceutical formulation in the form of a liquid aqueous suspension comprising 200 + 10% mg of amoxicillin and 28.5 + 10% mg/5rn1 clavulanic acid/5 ml suspension, or 400 + 10% mg/5ml amoxicillin and 57 + 10% mg/clavulanic acid/5 ml suspension (the weights being expressed as the free parent acids amoxicillin and clavulanic acid), in a nominal ratio of 7:1.

"10. A formulation as claimed in claim 7 or 9 in which the proportion of amoxicillin and clavulanic acid is from 35-60wt%, in a dry formulation for make up with aqueous media into a suspension formulation.

"11. A formulation claimed in claim 7 or 9 which is substantially free of mannitol.

"12. A formulation having a composition within + 10% of the formulae listed below, expressed as mg/5ml dose of reconstituted aqueous suspension:

Ingredient	Mg/5ml	Mg/5ml
Amoxycillin trihydrate	408.0	204.0
Potassium clavulanate	61.56	30.78
Xanthan gum	12.5	12.5
Collodial silica	25.0	25.0

Succinic acid	0.84	0.84
Orange flavour	26.25	26.25
Golden Syrup Flavour	23.75	23.75
Aspartame	12.5	12.5
Hydroxypropylmethycellulose	79.65	79.65
Silicon dioxide	to 885.5	to 537.5

While the title of the invention is "METHOD OF TREATMENT" the invention also claims protection for the pharmaceutical formulations used in the invention. Thus, Claim Nos. 1 to 6 are claims for methods of treating bacterial infections in pediatric patients while Claim Nos. 7 to 12 are claims for the relevant pediatric pharmaceutical formulations. As pointed out by the Appellant, the essential features of its Letters Patent are the following:

32.1. The methods of the invention are for treating bacterial infections in pediatric patients and the compositions are for pediatric use.

32.2. The formulations are either in the form of a liquid oral suspension or as a dry powder or granule formulation for reconstitution into a liquid aqueous suspension.

32.3. The compositions comprise a combination of amoxicillin and clavulanic acid at a ratio of 7:1.

32.4. The dosage to be administered is from 20 to 70 mg/kg/day of amoxicillin and pro rata amounts of clavulanic acid.

33. The methods of the invention are directed to administration of the formulations twice daily (bid).[18]

On the issue of whether the Appellant's invention is new

Sections 23 and 24 of the IP Code contain the provisions on novelty.

SEC. 23. Novelty. - An invention shall not be considered new if it forms part of a prior art.

SEC. 24. Prior Art. - Prior art shall consist of:

24.1. Everything which has been made available to the public anywhere in the world, before the filing date or the priority date of the application claiming the invention; and

24.2. The whole contents of an application for a patent, utility model, or industrial design registration, published in accordance with this Act, filed or effective in the Philippines, with a filing or priority date that is earlier than the filing or priority date of the application: Provided, That the application which has validly claimed the filing date of an earlier application under Section 31 of this Act, shall be prior art with effect as of the filing date of such earlier application: Provided further, That the applicant or the inventor identified in both applications are not one and the same.[19]

The Appellant's invention claims the priority date of 03 May 1995 and 18 November 1995 corresponding to its patent applications filed in the United Kingdom. Hence, the prior art documents in this case refer to publications issued before these priority dates. The Appellee presented documents which it claimed destroy the novelty of the Appellant's invention.

a) GB 2005 538 A — UK Patent Application published on 25 April 1979[20]

This patent application involves a pharmaceutical composition of amoxicillin trihydrate and potassium clavulanate with the proviso that the weight ratio of amoxicillin trihydrate to potassium clavulanate is from 6:1 to 1:1.

b) WO/1991/015197 Pharmaceutical Formulation — Publication Date: 17 October 1991[21]

The "Abstract" provides the following:

"A pharmaceutical formulation comprising an amoxicillin hydrate and an effervescent couple, for example citric acid plus sodium bicarbonate or sodium glycine carbonate, or tartaric acid or malic plus sodium carbonate. Potassium equivalents of these sodium salts may be used. The formulations may be free flowing powders or granules, or tablets."

In addition, the claims 1 to 3 and part of the description of this invention state the following:

(Claims)

“1. A pharmaceutical formulation comprising an amoxicillin hydrate and an effervescent couple, the couple comprising an acid component and an alkaline component, which generates carbon dioxide on contact with water, in which the alkaline component of the couple is present in excess of the stoichrometric equivalent of the acid component.

“2. A pharmaceutical formulation according to -claim 1 in which the amoxicillin hydrate is amoxicillin trihydrate and/or is in conjunction with a P-lactamase inhibitor.

“3. A pharmaceutical formulation according to claim 2 in which a Plactamase inhibitor is present and is clavulanic acid or a salt thereof, in a weight ratio of 12:1 to 1:1 amoxicillin hydrate : inhibitor"(Description)"The present invention relates to pharmaceutical compositions for oral administration in the treatment of bacterial infections.

"In some clinical situations, to improve patient compliance, it is desirable to administer medicaments orally in liquid form as suspensions or solutions."

c) US Patent No. 4,537,887 dated 27 August 1985.[22]

The "ABSTRACT" of this patent states that:

> "A unit dose pharmaceutical composition suitable for oral administration which composition comprises a pharmaceutically acceptable carrier, a desiccant, amoxicillin trihydrate equivalent to 20mg to 1500mg of amoxicillin and potassium clavulanate equivalent to 20 mg to 500 mg of clavulanic acid, with the proviso that the weight ration of amoxicillin to clavulanic acid is in the range 12:1 to 1:1; characterized in that the composition is in tablet form, wherein the desiccant is edible and incorporated within the tablets."

d) EUR. J PEDIATR., December 1986, Marchisio et. al.[23]

This document is a publication for the study of the efficacy of Amoxicillin twice daily in the treatment of acute otitis media in infants and children.

e) ANN PEDIATR., January 1989, LEBEAUT. COHEN R. AND NARCY P.[24]

A study on the treatment of acute otitis media in infants using an amoxicillin clavulanic acid formulation (in the form of an oral suspension for pediatric use).

f) PEDIATR MED. CHIR, January — February 1989, PECCO, P., ET. AL[25]

This document cites the use of amoxicillin and clavulanic acid in pediatric suspension of 312.5 mg/5ml (in the ratio of 4 to 1).

g) EUR. J. CLINICAL MICROBIOLOGY INFECT DIS., May 1993, JACOBSON, S., ET. AL.[26]

This is a clinical evaluation of study on the efficacy and safety of amoxicillin/clavulanate suspension given twice daily versus thrice daily in the treatment of otitis media in children. The dosage regimens evaluated were 50mg/ml amoxicillin + 12.5 mg/ml clavulanic acid given twice daily and 25mg/ml amoxicillin + 6.25 mg/ml clavulanic acid given thrice daily.

(h) CAN. MED. ASSOC. J., vol. 142, no. 2, January 15, 1990, pages 115 — 118, FELDMANN, W., ET AL.,[27]

This is a study on the twice-daily antibiotics in the treatment of acute otitis media: trimethoprim-sulfamethoxazole versus amoxicillin-clavulanate. Amoxicillin-clavulanate was given at a daily dosage of 50mg/kg (40 mg of amoxicillin and 10 mg of clavulanic acid) in two equal fractions every twelve (12) hours.

i.) INT. ME D. RES., vol 17, no.2 1989, pages 168 — 171, RUBERTO, U., ET. AL[28]

This is a study of Amoxicillin and Clavulanic Acid in the treatment of urinary tract infections in children.

A scrutiny of these documents showed that none of these publications illustrate a method for treatment similar to all the features of Claim Nos. 1 to 6 of the Letters Patent No. 1-1996-52993. None of these publications showed *method of treating bacterial infections in pediatric patients which method comprise administering to a patient in need thereof an antibacterially effective amount of a formulation comprising amoxicillin trihydrate and potassium clavulanate in combination, in a weight ratio 7:1 the weights being expressed as the free parent acids amoxicillin and clavulanic acid, the formulation being administered twice daily (bid).*

The patent documents GB 2005 538 A — UK Patent Application published on 25 April 1979, WO/1991/015197 Pharmaceutical Formulation — Publication Date: 17 October 1991 and US Patent No. 4,537,887 dated 27 August 1985 refers only to pharmaceutical formulations and not to the method of treatment being claimed by the Appellant's invention on Claim Nos. 1 to 6 of the Letters Patent No. 1-1996-52993. On the other hand, the printed publications cited by the Appellee illustrate only the formulation of Amoxicillin and Clavulanic Acid using a 4:1 ratio.

In determining whether novelty or newness is negatived by any prior art, only one item of the prior art may be used at a time. For anticipation to occur, the prior art must show that each element is found either expressly or described or under principles of inherency in a single prior art reference or that the claimed invention was probably known in a single prior art device or practice. 2' Thus, in this case, this Office finds Claim Nos. 1 to 6 of the Letters Patent No. 1-1996-52993 issued in favor of the Appellant as new or novel.

However, a further scrutiny of the international application WO/1991/015197 Pharmaceutical Formulation — Publication Date: 17 October 1991 showed that this document destroys the novelty of Claim Nos. 7 to 12 of the Appellant's invention.

The international application WO/1991/015197 refers to a pharmaceutical formulation comprising of amoxicillin trihydrate and potassium clavulanate in combination, in weight ratio of 12: 1 to 1:1 and thus, covers the weight ratio of 7:1 as claimed in the Appellant's invention. The abstract and description of W091/15197 provides for formulations of free flowing powders or granules, or tablets and that in some clinical situations, to improve patient compliance, it is desirable to administer medicaments orally in liquid form as suspensions or solutions. Thus, the statement of the Appellant that W091/15197 is directed to amoxicillin solution formulations, rather than suspension formulations is not entirely accurate.[30] Claim Nos. 7 to 12 of the subject invention are, therefore, not new and, hence, not patentable.

From the foregoing, the only question left is whether the finding of novelty of Claims Nos. 1 to 6 of the Appellant's invention is sufficient to uphold the validity of Letters Patent No. 1-1996-52993. This Office will now resolve the relevant issue of inventive step.

On the issue of inventive step

The Appellee maintains that the subject invention lacks inventive step and is obvious from the publications it submitted. The Appellant, however, claims inventive step of the subject invention because there is no single publication that disclose a pediatric pharmaceutical composition of 7:1 weight ratio for amoxicillin and clavulanate acid, in suspension form and administered twice daily.

Sec. 26 of the IP Code provides that:

> "SEC. 26. Inventive Step. - An invention involves an inventive step, if having regard to prior art, it is not obvious to a person skilled in the art at the time of the filing date or priority date of the application claiming the invention."

The novelty and inventive step characteristics of a patentable invention are different criteria. The expression inventive step conveys the idea that it is not enough that the claimed invention is new, that is, different from what exists in the state of the art, but that this difference must have two characteristics.

Firstly, it must be inventive, that is, the result of a creative idea and it must be a step, that is, it must be noticeable. There must be a clearly identifiable difference between the state of the art and the claimed invention. Secondly, it is required that this advance or progress be significant and essential to the invention. In order to assess the nature of the differences which are relied

upon as constituting an inventive step, account has to be taken of the prior art as a whole. Thus, as distinct from the assessment of novelty, the subject matter of the claim under examination is compared not with each publication or other disclosure separately, but with the combinations thereof, insofar as each such combination is obvious to the person having ordinary skill in the art.[31]

Considering that Claim Nos. 7 to 12 of the subject invention is not novel and not patentable because of the international application WO/1991/015197, published in 1991, it is only Claim Nos. 1 to 6 that remains to be examined on the issue of inventive step. Besides, the Appellant's Claim Nos. 7 to 12 of the pharmaceutical formulation comprising amoxicillin trihydrate and potassium clavulanate in combination, in a weight ratio of 7:1 are widely known. This is even affirmed by the Appellant in its patent application:

> The combination of the antibiotic amoxicillin, as amoxycilhn trihydrate, and potassium clavulanate, is a well-known and widely used oral medicament for bacterial infections, marketed by SmithKline Beecham in many countries under the trademark Augmentin.
>
> Regulatory approval has been obtained, for instance in the UK and US, for tablets containing amoxicillin (250mg) and potassium clavulanate (125mg) (ratio 2:1), in a three times daily dosing schedule (rid), so that that daily dose of amoxycilun and potassium clavulanate is 750mg and 375mg respectively (the weights being expressed as the free parent acids amoxicillin and clavulanic acid, this manner of expression being used throughout). In severe infections, the ratio is changed to 4:1, so that the daily doses of amoxicillin and potassium clavulanate are 1500mg and 375mg respectively. In other countries such as Italy and Spain, tablets containing amoxicillin (875) and potassium clavulanate (125mg) (ratio 7:1) are approved for twice daily dosing (bid). In France, sachets comprising amoxicillin (1000mg) and potassium clavulanate (125 mg) (ratio 8:1) are marketed, for reconstitution with water prior to use, as an individual dosage for adults.

Moreover, US Patent No. 4,537,887 dated 27 August 1985 has already disclosed "a pharmaceutical composition suitable for oral administration which composition comprises a pharmaceutically acceptable carrier, a desiccant, amoxycillin trihydrate equivalent to 20mg to 1500mg of amoxycillin and potassium clavulanate equivalent to 20 mg to 500 mg of clavulanic acid", with the proviso that the weight ration of amoxicillin to clavulanic acid is in the range 12:1 to 1:1.

Accordingly, the pharmaceutical composition having a weight ratio of 7:1 being claimed by the Appellant, aside from being not new, is also obvious among the persons skilled in this art. A person skilled in the art is defined in Rule 207 of the Rules and Regulations on Inventions:

> Rule 207. Person Skilled in the Art. - 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. He is presumed to have knowledge of all references that are sufficiently related to one another and to the pertinent art and to have knowledge of all arts reasonably pertinent to the particular problems with which the inventor was involved. He is presumed also to have had at his disposal the normal means and capacity for routine work and experimentation.

In this case, the persons skilled in the art of dosage formulation for bacterial infections knew the existence of such weight combinations of amoxicillin and potassium clavulanate ranging from 12:1 to 1: 1 combination ratio. In addition, inventions on suspension form of the pertinent pharmaceutical formulation are also obvious to these persons considering the availability of this formulation in tablet form. Mere change of form of medicines is within the reach of a pharmacist. As testified by the Appellee's witness Agnes S. Heruela-Casiding:

7. Based on my knowledge and profession experience as pharmacist, dosage formulation of a drug refers to the formulation of the active ingredients of a drug into different forms, such as tablets, capsules, suspensions, injections and the like, with the different weights of active ingredients being considered. For instance, the active ingredient — amoxicillin, an antibiotic is readily available in the market in the form of capsules, suspensions and injections. In the case of capsules, it also available in different weights and dosage formulations namely: amoxicillin 250 and amoxicillin 500; [32]

Returning now to the issue of whether there is inventive step on Claim Nos. 1 to 6 of Letters Patent No. 1-1996-52993, the pieces of evidence presented by the Appellee, including the patent documents and printed publications have convinced this Office of the lack of inventiveness of these claims.

From the references presented by the Appellee, all the elements of the Appellant's letters patents comprising pediatrical pharmaceutical composition of 7:1 to be given twice daily in suspension form are already obvious to a person skilled in the art. The Appellee presented references which contain clinical studies showing the use of the pharmaceutical composition of amoxicillin/clavulanate acid in treating bacterial infections on children. For example, the document EUR. J. CLINICAL MICROBIOLOGY INFECT DIS., May 1993, JACOBSON, S., ET. AL[33] discloses a study on the efficacy and safety of amoxicillin/clavulanate suspension given twice daily versus thrice daily in the treatment of otitis media in children. In addition, the document ANN PEDIATR., January 1989, LEBEAUT. COHEN R. AND NARCY P.[34] cited a study on the treatment of acute otitis media in infants using an amoxicillin-clavulanic acid formulation (in the form of an oral suspension for pediatric use).

While the pharmaceutical formulation given in these studies may have used the weight ratio of 4:1 of amoxicillin/clavulanate acid, a formulation of 7:1 weight ratio of amoxicillin/clavulanate acid is already widely known as shown in US Patent No. 4,537,887 and the international application WO/1991/015197. The claim of increasing the dosage to a weight ratio of 7:1 is, therefore, an obvious improvement well within the ordinary skills of a person skilled in this art. What would have been achieved by this claimed improvement is substantially the same as that of the prior art.

The Appellant contends that a pharmacist is not a person skilled in the art and submitted the testimony of its own witness Mr. Nikko P. Quevada [35] to show that its invention is novel and has inventive step. The Appellant posits that a pharmacist cannot claim that the subject invention lacks inventive step.

Section 23 of the Pharmacy Law[36] states that:

"Section 23. Definition of Practice of Pharmacy.- A person shall be deemed to be practicing pharmacy within the meaning of this Article, who shall, for fee, salary, percentage, or other reward paid or given directly to himself or indirectly through another, prepare or manufacture, analyze, assay, preserve, store, distribute or sell any medicine, drug, chemicals, cosmetics, pharmaceuticals, devices or contrivances used in pursuance thereof; or render pharmaceutical service in any office or drug and cosmetic establishment where scientific, technological, or professional knowledge of pharmacy is applied; or engage in teaching scientific, technological or professional pharmacy subject in a college of pharmacy; or conduct or undertake scientific pharmaceutical research for biological and bacteriological testings and examination."

It is, therefore, evident that the Appellee's witness, Ms. Agnes S. Heruela-Casiding, as a pharmacist, can be considered a person skilled in the art in the area of dosage formulation of pharmaceutical products. Even the "Australian Decision"[37] that was submitted by the Appellant stated that there is no dispute a doctor or a pharmaceutical formulator is to be considered a person skilled in the art, to wit:

Who is the person skilled in the art?

52. The person skilled in the art is a person, or team of people, who is a skilled but non-inventive worker in the relevant field of technology in Australia. According to Nis Howard, the team in this case would include:

- the notional medical practitioner working in Australia before 3 May 1995 in the treatment of infectious diseases, and
- a pharmaceutical formulator working in Australia before 3 May 1995

53. Dr. Pypstra also suggests that the team would include a pharmacologist. There appeared to be no argument on the issue of the person skilled in the art.[38]

Furthermore, in the cross-examination proceedings of Ms. Agnes S. Heruela-Casiding which was cited by the Appellant, she was categorical in her assertions concerning the dosage formulation for adults and children of amoxicillin and potassium clavulanate.

Q: There are no broadly applicable principles or formulas for converting doses of drug used in adults to doses that are safe and effective in children? Did you consider this when you did product development of C-Amoxiclav by converting 4:1 to 7:1?

A: Yes I consider that but as I've told you I did several research, several journals, several books and that is a general statement. The conversion is depend upon the active pharmaceutical ingredient, for example, amlo... I forgot the pharmatological.., because there are product listed by the WHO wherein this product you have to conduct a study if you have to convert it to pediatric from adult or from adult to pediatric, but regarding Co-Amoxiclav it is very... the Coamoxicillin.

Q: I'm sorry?

A: The Pharmacokenetics, the distribution of source of elimination excretion of this product is the same for both adult and children.

Q. Do you have basis for your statement?

A: I can bring it.

Q: I'll bring your attention to page 126 column 2, last paragraph line 1 to 8. Do you agree with the statement of Goodman and Gillman and I quote, 'the date from the association of drug levels with efficacy and toxicity must be interpreted in the context of the pharmacodynamic variability and the tabulation. The plasma concentration of Phenobarbital required control... for example is higher in children than in adults. Variability in pharmacodynamic response can result from any of the factors responsible for authoring drug effect that include genetics, age, disease and other drug. Do you agree with this statement?

A: Yes sir because it's a general statement, example Phenobarbital, other cardio... drug for heart diseases, and-psychotic drugs, that is a general statement sir."

Q: So on the basis of your other references you were able to make a mathematical computation of converting the dosage for Co-Amoxiclav to children at 7:1 at 400 and 200 mg of Amoxicillin for twice daily dosing is that correct?

A: Yes sir.

x x x

Q: What is your basis for saying that the conversion for adult and children is the same?

A: Safe only for certain products.

Q: And for other products?

A: No.

Q: What are these certain products and these other products?

A: Like what I mentioned the anti-psychotic drugs, the medicines for heart diseases, for...

Q: Amoxicilin that falls under the other drugs that are safe to convert is that your testimony?

A: Yes, sir, because there's already listing issued by the WHO wherein they required clinical trials if you convert an adult dosing to pediatric and CoAmoxiclay. Amoxicillin clavulanate they are not included in the list.[39]

Aptly, in the Comment by the Appellee, it contended the following:

16. This is confirmed in the 1990 publication entitled Amoxicillin/Clavulanic Acid: An Update of its Antibacterial Activity, Pharmacokinetic Properties and Therapeutic Use by Peter A. Todd and Paul Benfield[40] which also revealed that coamoxyclav is a compound that has seen countless clinical studies and testing, and has been in existence in various weight ratio, dosage frequency and form. It has been explored, experimented upon and made subject of various medical publications and lectures...

17. Scientists thus were able to confirm that the 'pharmacokinetic profile of amoxicillin and clavulanic acid in children paralleled that in adults' such that in order to compute for the dosage for children based on the adult formation, the process is simply to make adjustment for weight.[41]

While admitting that all the basic elements of its invention are already known and available, although not in one prior art reference, but in a combination of these references, the Appellant is advocating that it is an inventive step for its part to combine all these existing and known elements of the invention and come up with a method of treatment using a pharmaceutical composition in a given weight ratio of amoxicillin and clavulanate acid. This position may still have some merit if we are not talking of a method of treatment but solely of a pharmaceutical product that is not widely known and which have not been subjected to numerous clinical trials, dosage formulations and forms. It is, however, not disputed that the pharmaceutical formulation of the subject invention is already widely known.

As a privilege granted by the State that amounts to a grant of monopoly, patents should be strictly construed and given only to those inventions that have significantly contributed to existing arts. Innovations that would be obvious or which are within the presumed knowledge of those skilled in the art relevant to the field should not be accorded patent protection. An innovation to be entitled to protection should be more than an obvious thing and should be genuinely useful in achieving the benefits being claimed.

In summary, Claim Nos. 1 to 6 of Letters Patent No. 1-1996-52993 are not patentable for being obvious to persons skilled in the art, hence, lacking in inventive step. Claim Nos. 7 to 12 of

Letters Patent No. 1-1996-52993 which refers to a pediatric pharmaceutical formulation are not new and lacks inventive step.

Wherefore, premises considered, the appeal is hereby DISMISSED. Let a copy of this Decision as well as the records be furnished and returned to the Director of Bureau of Legal Affairs for appropriate action. Further, let also the Director of the Bureau of Patents and the library of the Documentation, Information and Technology Transfer Bureau be furnished a copy of this Decision for information, guidance, and records purposes.

SO ORDERED.

16 September 2010, Makati City

RICARDO R. BLANCAFLOR
Director General

FOOTNOTES:

1 Subsequently, the Appellee filed on 08 June 2006 an "AMENDED VERIFIED PETITION FOR CANCELLATION" which reiterated its allegations in the VERIFIED PETITION FOR CANCELLATION and incorporated the affidavits of the Appellee's witnesses supporting the conclusion that the subject patent lacks inventive step.
2 AN ACT CREATING A PATENT OFFICE, PRESCRIBING ITS POWERS AND DUTIES, REGULATING THE ISSUANCE OF PATENTS, AND APPROPRIATING FUNDS THEREFOR.
3 Exhibit "A".
4 Exhibit "B".
5 Exhibit "A" attached to the Reply, dated 20 October 2006.
6 Exhibit "B" attached to the Reply.
7 Exhibit "C" attached to the Reply.
8 Exhibits "D" to "I" attached to the Reply.
9 Exhibit "J" attached to the Reply.
10 Annex "A".
11 Annex "B".
12 Annex "C".
13 Annex "D".
14 Annex "A" of the Rejoinder (to the Reply dated October 10, 2006), dated 30 October 2006.
15 Annex "B" of the Rejoinder.
16 The Appellee filed its Comment on 28 August 2007.
17 See Section 36 of the IP Code.
18 See APPEAL, dated 04 July 2007, page 12.
19 Sections 23 and 24 of the IP Code are taken from Section 9 of RA 165 which states that:
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 others in the Philippines before 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 ifit 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.
20 See Exhibit "A" attached to the Reply.
21 See Exhibit "B" attached to the Reply.
22 See Exhibit "C" attached to the Reply.
23 See Exhibit "D"as attached to the Reply.
24 See Exhibit "E" as attached to the Reply.
25 See Exhibit "F" as attached to the Reply.
26 See Exhibit "G" as attached to the Reply.
27 See Exhibit "H".
28 See Exhibit "I".
29 Angelita Manzano vs. Court of Appeals, R. No. 113388, 05 September 1997.
30 APPEAL, page 12, paragraph 34.1.
31 See WIPO Intellectual Property Handbook: Policy, Law and Use. Chapter 2. Fields of Intellectual Property Protection, paragraphs 2.27 to 2.29.
32 AFFIDAVIT-TESTIMONY of Ms. Agnes S. Heruela-Casiding, page 4, attached as Exhibit "B" in the amended verified petition for cancellation.
33 See Exhibit "G".
34 See Exhibit "E" as attached to the Reply.
35 Annex "A" to the Appellant's Verified Answer. Mr. Quevada is a holder of Ph.D degree in chemistry and is a professor in De La Salle University.
36 Rep. Act No. 5921.

37 DECISION OF A DELEGATE OF THE COMMISSIONER OF PATENTS, 14 May 2004. See Exhibit B of the Rejoinder (to the Reply dated October 10, 2006), dated 30 October 2006.
38 See Page 11 of the Australian Decision.
39 See APPEAL, pages 23-25 citing TSN dated 26 June 2006, pp. 40-52, in Civil Case No. 06-373, entitled "SmithKline Beecham P. L. C. et al v. Natrapharm et al before RTC Makati Branch 138.
40 As attachment to a Counter-Manifestation, submitted by the Appellee to the Bureau of Legal Affairs on 12 April 2007
41 COMMENT, page 9, paragraphs 16 —17.