



**CADILA HEALTHCARE LIMITED,**  
Petitioner,

**-versus-**

**ASTRAZENICA AB,**  
Respondent-Patentee.

x-----x

} **IPC No. 11-2011-00281**  
}  
} Petition for Cancellation:  
} Letters Patent No. 1-2000-002082  
} Date Issued: 16 April 2010  
} **Title: "Pharmaceutical**  
} **Composition"**

### NOTICE OF DECISION

**QUIAL GINEZ BELTRAN & YU**

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**GREETINGS:**

Please be informed that Decision No. 2013 - 07 dated January 16, 2013 (copy enclosed) was promulgated in the above entitled case.

Taguig City, January 16, 2013.

For the Director:

  
**Atty. EDWIN DANILO A. DATING**  
Director III  
Bureau of Legal Affairs



CADILA HEALTHCARE LIMITED ,	}	IPC No. 11-2011-00281
Petitioner,	}	Petition for Cancellation:
	}	
- versus -	}	Letters Patent No. 1-2000-002082
	}	Date Issued: 16 April 2010
ASTRAZENICA AB,	}	Title: <b>Pharmaceutical Composition</b>
Respondent-Patentee.	}	
x-----x		Decision No. 2013 - <u>07</u>

### DECISION BASED ON COMPROMISE AGREEMENT

CADILA HEALTHCARE LIMITED ("Petitioner") filed on 18 July 2011 a petition to cancel Letters Patent No. 1-2000-002082. The patent issued to ASTRAZENICA AB ("Respondent-Patentee") refers to an invention which relates to a *"Pharmaceutical composition and more particular to a Pharmaceutical Composition containing (E)-7-14-(4-fluorophenyl)-6-isopropyl-2(methyl(methylsulfonyl)aminolpyrimidin-5-yl]3R,5S)-3, 5 dihydroxyhept-6-enoic acid or a Pharmaceutically acceptable salt thereof as the active ingredients a an inorganic salt in which the cation is multivalent."*

This Bureau issued a Notice to Answer dated 05 September 2011 and served upon a copy thereof to Respondent-Registrant on 08 September 2011. The Respondent-Registrant filed its Answer on 07 December 2011.

In compliance to Office Order No. 154, s. 2010 (*"Rules of Procedure for IPO Mediation Proceedings"*) and Office Order No. 197, s. 2010 (*"Mechanics for IPO Mediation Settlement Period"*), this Bureau issued on 20 December 2011 Order No. 2011-335 referring the case to mediation.

On 16 March 2012, the ADR Services of this Bureau submitted a Mediator's Report indicating that the Respondent refused to undergo mediation proceedings and thus, is returning the case to the Bureau for further proceedings. On 13 May 2012, a Notice of Preliminary Conference was issued by this Bureau. During the preliminary conference on 14 August 2012, counsels of both parties moved for the resetting of the case to explore the possibility of a compromise agreement. During the continuation of the preliminary conference on 13 November 2012, the parties manifested that they already have the draft of the compromise agreement and moved for an additional time to submit the compromise agreement. On 12 December 2012, the parties filed a Joint Motion to Approve Compromise Agreement with Joint Motion to Dismiss attaching thereto a COMPROMISE AGREEMENT, the pertinent portions of which read, as follows:

"1. The SECOND PARTY shall NOT SUE the FIRST PARTY for the latter's use and distribution of the pharmaceutical compositions contained in Letters

Patent No. 1-2000-002082, a copy of which is integrally attached hereto as Annex "C" but for ready reference is reproduced hereunder, to wit:

### "PHARMACEUTICAL COMPOSITIONS"

#### Abstract:

The present invention relates to Pharmaceutical Composition and more particular to a Pharmaceutical Composition containing (E)-7-14-(4-fluorophenyl)-6-isopropyl)-2-methyl(methylsulfonyl)aminopyrimidin-5-yl]-3R,5S)-3,5 dihydroxyhept-6-enoic acid or a Pharmaceutically acceptable salt thereof as the active ingredients a an inorganic salt in which the cation is multivalent.

### PHARMACEUTICAL COMPOSITIONS

The present invention relates to pharmaceutical compositions and more particular to a pharmaceutical compositions containing (E)-7-[4-(4-fluorophenyl)-6-isopropyl)-2-[methyl (methylsulfonyl) amino]pyrimidin-5-yl]- (3R, 5S)-3, 5-dihydroxyhept-6-enoic acid or a pharmaceutically acceptable salt thereof (and referred to hereinafter as "the Agent"). In particular the sodium and calcium salts, and especially the calcium salt, bis [(E)-7-[4-fluorophenyl)-6-isopropyl)-2-methyl (methylsulfonyl)aminopyrimidin-5-yl]-3R, 5S)-3, 5 dihydroxyhept-6-enoic acid calcium salt (show as formula I below).

The Agent disclosed as an inhibit of 3-hydroxy-3methylglutaryl CoA reductase (HMG CoA reductase) in Europe Patent Application, Publication No. 0521471 and in Bioorganic and Medical Chemistry, (1997), 5(2), 437-444 and is useful in the treatment of hypercholesterolemia, hyperlipidproteinemia and atherosclerosis.

A Problem associated with the Agent is that it is particularly sensitive to degradation under certain conditions. The major degradation products formed are the corresponding (3R, 5S) lactone (hereinafter referred to as "the lactone") and an oxidation product (hereinafter referred to as "B2") in which the hydroxyl group adjacent to the carbon-carbon double bond is oxidized to a key functionality. The Potential for significant degradation of the Agent makes it difficult to formulate and provide a pharmaceutical composition with acceptable storage life for a marketed product.

Pharmaceutical formulations of certain 7-substituted-3, 5-dihydroxyhept-6-heptenoic acid salts, which are HMG CoA reductase inhibitors, are disclosed in UK Patent 2 262 229, and that they are sensitive to pH degradation. These formulations require the presence of an alkaline medium (such as a carbonate

or bicarbonate) capable of imparting a pH of at least 8 to an aqueous solution or dispersion of the composition.

However, we have found that for the Agent it is not sufficient to improve stability by solely controlling pH in the formulation. We have found that with the Agent stability is improved by selection of an inorganic salt to be added to the composition which contains one or more multivalent inorganic cations. Whilst not wishing to be bound by the theory we believe that the multivalent inorganic cation stabilizes the structure of the Agent and make it less susceptible to oxidation and/or lactonization.

We present as a feature of the invention

A pharmaceutical composition comprising the Agent as an active ingredient and an inorganic salt in which the cation is multivalent.

The use of an inorganic salt in which cation is multivalent as a stabilizing agent in a pharmaceutical composition comprising the Agent.

Preferred features of the invention are:

- (1) Wherein the Agent is present in the composition is more than 5mg, preferably more than 10mg. Excluded composition are those wherein the Agent is present at 1mg, 2mg, 5mg, and 10mg, Preferred composition are those where the amount of Agent is 20mg, 40mg, or 80mg.
- (2) Wherein the stabilizing compound is not synthetic hydrotalcite.
- (3) The pharmaceutical composition of the invention is a tablet or a powder.

Preferably the pharmaceutical composition of the invention is a tablet.

The multivalent cation found in the inorganic salt may be selected from the following, calcium, magnesium, zinc, aluminum, and iron or a mixture thereof. Preferred multivalent cations are calcium, aluminum and magnesium or a mixture thereof. Especially preferred multivalent cations are aluminum and magnesium or a mixture thereof.

The counter anion in the inorganic salt may be selected from a phosphate, a carbonate, a silicate, an oxide and a metasilicate. Preferred counter anions are selected from a carbonate a silicate, an oxide and a met silicate. Especially preferred counter anions are selected from a silicate, an oxide or metasilicate.

Individual aspects of the invention include an organic



salt comprising a multivalent cation selected from any of the above and a counter anion also selected from any of the above.

Preferred inorganic salts for use in the present invention are, aluminum magnesium metasilicate (Neusolin™, Fuji Chemical Industry Limited), Dibasic or tribasic calcium phosphate, tribasic magnesium phosphate and tribasic aluminum phosphate. Aluminum magnesium metasilicate and tribasic phosphate are especially preferred.

It is also preferable that such a composition has a good flow rate to assist processing into unit dosage forms for oral administration, for example into tablets, and good disintegration and dissolution characteristics when processed into tablets for oral administration, which tablets can be in different dosage strengths.

The ratio of inorganic salt to Agent in the pharmaceutical compositions is, for example, within the range of 1:80 to 50:1 by weight, for example 1:50 to 50:1 by weight, such as 1:10 to 10:1 by weight, and more particularly 1:5 to 10:1 by weight.

Preferably the pharmaceutical composition of the invention is formulated into an oral dosage form, such as a tablet. Accordingly a further aspect of the invention comprises a pharmaceutical composition comprising the Agent, an inorganic salt in which the cation is multivalent, and one or more fillers, binders, disintegrants or lubricants. A still further aspect of the invention relates to a pharmaceutical composition for oral administration comprising of the Agent, one or more fillers, one or more binders, one or more disintegrants, one or more lubricants, and an inorganic salt in which the cation is multivalent.

Suitable fillers include, for example lactose, sugar, starches, modified starches, mannitol, sorbitol, inorganic salt, cellulose derivatives (e.g. microcrystalline cellulose, cellulose), calcium sulfate, xylitol, and lactitol.

Suitable binders include, for example polyvinylpyrrolidone, lactose, starches, modified starches, sugar, gum acacia, gum tragacanth, guar gum, pectin, wax binders, microcrystalline cellulose, methylcellulose, carboxymethylcellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, copolyvidone, gelatin and sodium alginate.

Suitable disintegrants include, for example, croscarmellose sodium, crospovidone, polyvinylpyrrolidone, sodium starch glycolate, corn starch, microcrystalline cellulose, hydroxypropyl methylcellulose, and hydroxypropyl cellulose.

Suitable lubricants include, for example, magnesium stearate, stearic acid, palmitic acid, calcium stearate, talc, carnauba wax, hydrogenated vegetable oils, mineral oil, polyethylene glycols, and sodium stearyl fumarate.

Additional conventional excipients which may be added include preservatives, stabilisers, anti-oxidants, silica, flow, conditioners, antiadherents or glidants.

Other suitable fillers, binders, disintegrants, lubricants and additional excipients which may be used are described in *Handbook of pharmaceutical Excipients*, 2<sup>nd</sup> Edition, American Pharmaceutical Associations; *The Theory of Industrial Pharmacy*, 2<sup>nd</sup> Edition, Lachman, Leon, 1976; *Pharmaceutical Dosage Forms: Tablets Volume 1*, 2<sup>nd</sup> Edition, Lieberman, Herbert A., *et al*, 1989; *Modern Pharmaceutics*, Bankers, Gilbert and Rhodes, Christopher T, 1979; and *Remington's Pharmaceutical Sciences*, 15<sup>th</sup> Edition, 1975.

Typically the Agent will be present in an amount within the range of 1 to 50%, for example 1 to 25%, such as 1 to 20%, and particularly 5 to 18% by weight.

Typically the inorganic salt, such as tribasic calcium phosphate, will be present in an amount within the range of 1 to 25%, for example 1 to 20%, such as 5 to 18% by weight.

Typically one or more fillers will be present in an amount 30-90% by weight.

Typically one or more binders will be present in an amount 2- 90% by weight.

Typically one or more disintegrates will be present in an amount 2-10% and especially 4 to 6% by weight.

It will be appreciated that a particular excipient may act as both a binder and filler or as binder filler and a disintegrant. Typically the combined amount of filler, binder and disintegrant comprises, for example, 70 to 90% by weight of the composition.

Typically one or more lubricant will be present in an amount 0.5-3%, and specially 1 to 2% by weight.

The pharmaceutical composition of the invention may be prepared, using standard techniques and manufacturing processes generally known in the art, for example by dry blending the components. For example, the Agent and an inorganic salt in which the cation is multivalent, one or more fillers, one or more binders and one more disintegrants, as well as other additional excipients if desired are blended together.

The components of the blend prior to blending, or the blend itself, may be passed through a mesh screen, for example a 400-700 pm mesh screen. A lubricant, which may also be screened is then added to the blend and blending continued until a homogenous mixture is obtained. The mixture is then compressed into tablets. Alternatively, a wet granulation technique can be employed. For example, the Agent and an inorganic salt in which the cation is multivalent, one or more fillers, one or more binders, and a portion of a disintegrant, for example by using a granulator, and the powder blend is granulated with a small volume of purified water. The granulation is dried and passed through a mill. The remainder of the disintegrant and a lubricant are added to the milled granulation and after blending the resultant homogeneous mixture is compressed into tablets. It will be appreciated that modifications of the dry blending and wet granulation techniques, including the order of addition of the components and their screening and blending prior to compression into tablets, may be carried out according to principles well known in the art.

A Tablet coating may then be applied, for example by spray-coating with a water-based film coating formulation. The coating may comprise, for example, lactose, hydroxypropyl methylcellulose, triacetin, titanium dioxide and ferric oxides. Coating ingredient combinations are commercially available, such as those described in the examples hereinafter. The coating may comprise, for example, 0.5 to 10% by weight of the tablet composition, particularly 1 to 6%, and preferably 2 to 3%. Coatings containing ferric oxides are especially preferred as they reduce the rate of formation of photodegradation products of the Agent.

Accordingly we present as a feature of the invention a pharmaceutical composition comprising the Agent, the composition having a ferric oxide light protective coating.

A further aspect of the present invention comprises a method of preparing a stabilized pharmaceutical composition which comprises admixing the Agent with an inorganic salt in which the cation is multivalent. A further aspect of the present invention comprises a method of producing a stabilized pharmaceutical composition which comprises incorporating an inorganic salt in which the cation is multivalent in a pharmaceutical composition containing the Agent.

#### Example 1

The Agent	2.50mg
Tribasic calcium phosphate	20.0mg
Microcrystalline cellulose	47.0mg
Lactose monohydrate	47.0mg
Sodium starch glycolate	3.00mg

Butyrate hydroxyloluene	0.05mg
Magnesium stearate	1.00mg

The Agent, microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, tribasic calcium phosphate and butyrate hydroxyloluene were blended together for 10 minutes. Magnesium stearate was screened through a # 40 mesh (425 p.m) screen and added to the blend and blending continued for a further three minutes. The resulting homogenous mixture was compressed into tablets.

The Tablets were stored at 70°C/80% relative humidity for one week. After one week there was found to be only 0.11% w/w of the oxidation product B2 formed and only 0.50% w/w of the lactone.

#### Example 2

The Agent	2.50mg
Providone	2.50mg
Tribasic calcium phosphate	20.0mg
Microcrystalline cellulose	47.0mg
Mannitol	47.0mg
Sodium starch glycolate	3.00mg
Butyrate hydroxyloluene	0.05mg
Magnesium stearate	1.00mg

The Agent, providone, mannitol, microcrystalline cellulose, butylated hydroxyloluene, tribasic calcium phosphate and sodium starch glycolate (in the amounts given below) were blended for 5 to 60 minutes. Magnesium stearate was screened through a # 40 mesh (425 µm) screen and added to the blend and blending continued for a further three minutes. The resulting homogenous mixture was compressed into tablets. The compressed tablets were then coated by spraying with a mixture of hydroxypropyl methylcellulose, polyethylene glycol 400, titanium dioxide and ferric oxide (sold as Spectrablend™ by Warner-Jenkinson) and water in coating pan. The weight gain provided by the coating was 1 to 6% w/w, and preferably 2 to 3% w/w.

The Tablets were stored at 70°C/80% relative humidity for one week. After one week there was found to be only 0.06% w/w of the oxidation product B2 formed and only 2.22% w/w of the lactone.

#### Example 3

The Agent	2.60 mg
Crospovidone	3.75 mg
Tribasic calcium phosphate	5.66 mg
Microcrystalline cellulose	15.5 mg



Lactose monohydrate	46.5 mg
Magnesium stearate	0.94 mg

The Agent and crospovidone were blended together for 5 minutes and the blend then passed through 400- 700  $\mu$ m screen. A small portion of microcrystalline cellulose was passed through the screen afterwards. The screened materials were blended with other ingredients, exclusively the lubricant, for 10 minutes. Magnesium stearate was passed through a #40 mesh (425)  $\mu$ m screen and added and added to the blend and mixture was blended for a further 3 minutes. The resulting homogenous mixture was compressed into tablets. The compressed tablets were coated by spraying with a mixture of lactose monohydrate, hydroxypropyl methylcellulose, triacetin and ferric oxide (sold as Opadry II™ by Colorcon) and water in a coating pan. The weight gain provided by the coating is 1 to 6% w/w, and preferably 2 to 3%w/w.

The Tablets were stored at 70°C/80% relative humidity for one week. After this time only 0.19% w/w of the oxidation product B2 had formed and 2.71% w/w of the lactone.

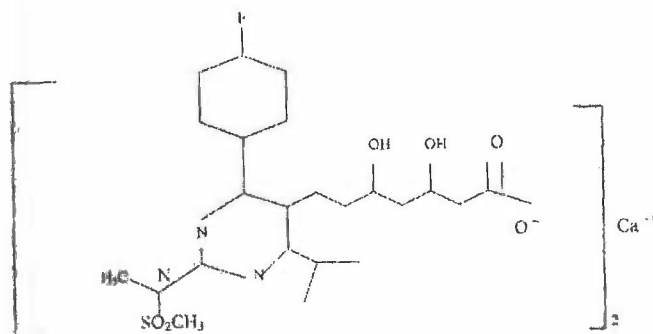
#### Example 4

The Agent	2.50 mg
Providone	2.50 mg
Tribasic calcium phosphate	20.0 mg
Microcrystalline cellulose	34.5 mg
Lactose monohydrate	34.0 mg
Sodium starch glycolate	6.00 mg
Magnesium stearate	1.00 mg
Butylated hydroxytoluene	0.05 mg

A Portion of the tribasic calcium phosphate and butylated hydroxytoluene were blended for 30 seconds in a bag. The Agent, providone, remainder of the tribasic calcium phosphate, microcrystalline cellulose, lactose monohydrate, tribasic calcium phosphate/ butylated hydroxytoluene mixture and a mixture and a portion of a sodium starch glycolate were blended in a granulator for 30 seconds. The powder blend was granulated with purified water for 1 minute at the addition rate of 70 mg/ tablet/minute. The granulation is dried in a fluidized bed drier at 50°C until the loss on drying is less than 2% w/w. The dried granulation is passed through a mill (e.g. Comil™). The milled granulation and the remainder of the sodium starch glycolate was blended for approximately 5 minutes. Magnesium stearate was screened through a #40 mesh (245  $\mu$ m) screen and added to the blend and blending continued for a further three minutes. The resulting homogeneous mixture was compressed into tablets.

The tablets were stored at 70°C/80% relative humidity

for one week. After this time only 0.23% w/w of the oxidation product B2 had formed and only 0.28% of the lactone.



Formula 1

Formula 1

#### AMENDED CLAIMS

1. A pharmaceutical composition comprising (E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methylsulfonyl]amino]pyrimidin-5-yl]-(3R, 5S)-3,5-dihydroxyhept-6-enoic acid or a pharmaceutically acceptable salt thereof as the active ingredients and an inorganic salt in which the cation is multivalent provided that the inorganic salt is not synthetic hydrotalcite or hydroptalcite.
2. A pharmaceutical tablet composition comprising (E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl (methylsulfonyl) amino]pyrimidin-5-yl]-(3R, 5S)-3,5-dihydroxyhept-6-enoic acid or a pharmaceutically acceptable salt thereof as the active ingredient and an inorganic salt in which the cation is multivalent.
3. A pharmaceutical composition as claimed in claim 1 or 2 wherein the cation of the inorganic salt is selected from calcium, magnesium, zinc, aluminum, and iron or a mixture thereof.
4. A pharmaceutical composition as claimed in claim 1 or 2 wherein the counter anion in the inorganic salt is selected from a carbonate, a silicate, an oxide and a metasilicate.
5. A pharmaceutical composition as claimed in claim 1 or 2 wherein the counter anion in the inorganic salt is selected from a silicate, an oxide and a metasilicate.
6. A pharmaceutical composition as claimed in claim 1 or 2 wherein the inorganic salt is aluminum, magnesium, metasilicate.

7. A pharmaceutical composition as claimed in claim 1 which is a tablet or powder.
8. A pharmaceutical composition as claimed in claim 1 or 2 in which more than 5mg of active ingredient is present.
9. A pharmaceutical composition as claimed in claim 1 or 2 which more than 10mg of active ingredients is present.
10. A pharmaceutical composition as claimed on claim 1 or 2 wherein the counter ratio of the inorganic salt to the active ingredients is in the range of 1:80 to 50:1 by weight.
11. A pharmaceutical composition as claimed in claim 1 or 2 additionally comprising one or more fillers, binders, disintegrants or lubricants
12. A pharmaceutical composition as claimed in claim 1 or 2 wherein the active ingredients is present in an amount 1 to 50% by weight of the composition.
13. A pharmaceutical composition as claimed in claim 1 or 2 wherein the inorganic salt is present in an amount 1 to 50% by weight of the composition.
14. A pharmaceutical composition as claimed in claim 11 wherein the fillers is present in an amount 30 to 90% by weight of the composition.
15. A pharmaceutical composition as claimed in claim 11 wherein the binders is present in an amount 2 to 90% by weight of the composition.
16. A pharmaceutical composition as claimed in claim 11 wherein the disintegrant is present in an amount 2 to 10% by weight of the composition.
17. A pharmaceutical composition as claimed in claim 11 wherein the lubricant is present in an amount 0.5% to 3% by weight.
18. A pharmaceutical composition as claimed in claim 1 or 2 wherein the active ingredient is the calcium salt of (E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl (methylsulfony) amino]pyrimidin-5-yl]-(3R, 5S)-3, 5-dihydroxyhept-6-enoic acid.
19. A pharmaceutical composition as claimed in claim 1 or 2 wherein: (i) the active ingredient is the calcium salt of (E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidin-5-yl]-(3R, 5S)-3-5-dihydroxyhept-6-enoic acid; (ii) the cation of the inorganic salt is selected from calcium, magnesium, zinc, aluminum and iron or a

mixture thereof; and (iii) the counter anion in the inorganic salt is selected from a carbonate, a silicate, an oxide and metasilicate.

20. The use of inorganic salt in which the cation is multivalent to stabilize the compound (E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methyl sulfonyl)amino] pyrimidin-5-yl]-(3R, 5S)-3,5-dihydroxyhept-6-enoic acid or a pharmaceutically acceptable thereof, provided that the inorganic salt is not synthetic hydrotalcite or hydrotalcite.

21. The use according to claim 20 wherein the counter anion in the inorganic salt is selected from a carbonate, a silicate, an oxide and a metasilicate.

22. The use according to claim 20 wherein the counter anion in the inorganic salt is selected from a silicate, an oxide or a metasilicate.

23. Use as claimed in claim 20 wherein the inorganic salt in which the cation is multivalent is aluminum magnesium metasilicate.

24. A method of producing a stabilized pharmaceutical composition which comprises incorporating an inorganic salt in which the cation is multivalent in a pharmaceutical composition containing the compound (E)-7-[4-(4-fluorophenyl)-6-isopropyl-2[methyl] (methylsulfonyl)amino]pyrimidin-5-yl]-3R,5S)-3,5-dihydroxyhept-6-enoic acid or a pharmaceutically acceptable salt thereof, provided that the inorganic salt is not synthetic hydrotalcite or hydrotalcite.

25. The method according to claim 24 wherein the counter anion in the inorganic salt is selected from a silicate, an oxide or a metasilicate.

26. The method as claimed in claim 24 wherein the inorganic salt in which the cation is multivalent is aluminum magnesium metasilicate.

2. That the SECOND PARTY shall hereby forever release, remise and/or discharge the FIRST PARTY, whether civilly, criminally or administratively, from any and all liabilities, claims, demands and/or such causes of action which could be raised by the SECOND PARTY in the use and distribution by the FIRST PARTY of the pharmaceutical compositions contained in Letters Patent No.1-2000-002082 as well as those which it may now or later have against the FIRST PARTY arising from relating to or in connection with the said use and distribution of the pharmaceutical compositions contained in Letters patent No. 1-200-002082.

3. That the FIRST PARTY shall also forever release, remise and/or discharge the SECOND PARTY, whether civilly, criminally or administratively, from any and all liabilities, claims, demands and/or such causes of action



which could be raised by the FIRST PARTY and/or THIRD PARTIES with respect to the use and distribution by the FIRST PARTY of the pharmaceutical compositions contained in Letters Patent No. 1-2000-002082 as well as those with the FIRST PARTY and/or THIRD PARTIES may now or later have against the SECOND PARTY arising from, relating to or in connection with the said use and distribution of the pharmaceutical compositions contained in Letters patent No. 1-200-002082.

4. That the use and distribution by the SECOND PARTY of the pharmaceutical compositions contained in Letters Patent No. 1-2000-002082 shall be limited only in the Philippines.

5. That in consideration of the foregoing, the FIRST PARTY and the SECOND PARTY shall cause the dismissal of their claims and counterclaims in the Inter Partes Case.

6. The parties hereby agree that the terms and conditions of this Agreement are absolutely confidential between them and shall not be disclosed to any pharmaceutical company and/or any third party. Any disclosure in violation of this section shall be deemed a material breach of this Agreement."

WHEREFORE, premises considered, the parties' COMPROMISE AGREEMENT is hereby **APPROVED**. Accordingly, the Compromise Agreement having the force and effect of a decision or judgment, the parties are hereby enjoined to comply with the terms and conditions set forth therein. Let the filewrapper of Letters Patent No. 1-2000-002082 be returned, together with a copy of this Decision, to the Bureau of Patents for information and appropriate action.

**SO ORDERED.**

Taguig City, 16 January 2013.



Atty. NATHANIEL S. AREVALO  
Director IV, Bureau of Legal Affairs