GRUPO DE TRABALHO SOBRE
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PROCESS:	PI0406760-6
DATE OF DEPOSIT:	13/01/2004
TITLE:	Compositions and Methods for Combined Antiviral Therapy
APPLICANT:	GILEAD SCIENCES, INC.
STAKEHOLDERS:	ABIA, CONECTAS, GAPA/SP, GAPA/RS, GRAB, GESTOS, GIV, IDEC, FENAFAR, RNP+/SLS

Brazilian Interdisciplinary Association for AIDS - ABIA, nonprofit civil association, CNPJ/MF under No. 29.263.068/0001-45, with headquarters at Avenida Presidente Vargas, 446 - 13th floor, Centro, Rio de Janeiro, in this represented by its General Coordinator, pursuant to its Bylaws, Mr. Veriano de Souza Terto Júnior (DOC. 1);

CONECTAS Human Rights Association (Human Rights Network), a non-profit civil association, qualified as OSCIP - Civil Society Organization of Public Interest, CNPJ/MF under No. 04.706.954/0001-75, established Rua Barao de Itapetininga, 93, 5th floor, República, São Paulo / SP, herein represented by its Executive Director and legal representative in terms of its Bylaws, Mrs. Malak El Chichini Poppovic (DOC. 2);

SUPPORT GROUP FOR AIDS PREVENTION GAPA-SP, non-profit civil association, CNPJ under No. 54.530.886/0001-04, with headquarters at Rua Pedro Américo, 32, 13 floor, São Paulo / SP, in person its representative in accordance with its bylaws, Mr. José Carlos Veloso Pereira da Silva (DOC. 3);

SUPPORT GROUP FOR AIDS PREVENTION OF RIO GRANDE DO SUL -GAPA/RS, nonprofit civil association, registered under CNPJ No. 92.519.503/0001-96, with headquarters at Rua Luis Afonso, 234, Porto Alegre / RS in the person of its representative in accordance with its bylaws, Mrs. Carla Patrícia Gomes de Almeida (DOC. 4);

RESISTANCE GROUP ASA BRANCA - GRAB, non-profit civil association, registered under CNPJ No. 41302803/0001-88, with headquarters at Rua Teresa Cristina, 1050Fortaleza/CE in the person of its representative in terms of its Bylaws, Sr. Francisco Xavier Ramos Pedrosa Filho (DOC. 5);

GESTOS SEROPOSITIVITY COMMUNICATION AND GENDER, nonprofit civil association, duly qualified according to Law, CNPJ under No. 41.229.113/0001-40, with headquarters at Rua Medicis, 68, Recife / PE by its very representative legal under its Bylaws, Mrs. Alessandra Cabral dos Santos Nilo (DOC.6);

INCENTIVE TO LIFE GROUP - GIV - non-profit entity, incorporated under the law, registered under CNPJ n. 64.180.383/0001-00, headquartered at Rua Capitão Cavalcanti No. 145, in Vila Mariana, São

Paulo-Capital, in the person of its representative in accordance with its Bylaws, Mr. Cláudio Toledo Soares Pereira (DOC.7);

IDEC - BRAZILIAN INSTITUTE OF CONSUMER PROTECTION, nonprofit civil association, established pursuant to law, registered under CNPJ n. 58.120.387/0001-08, with headquarters at Rua Dr. Costa Júnior, no. 356, in the neighborhood Água Branca, São Paulo - Capital, in the person of its representative in terms of its Bylaws, Mrs. Lisa Gunn (DOC.8);

NATIONAL FEDERATION OF PHARMACEUTICAL - Fenafar, a union of the second degree, founded on October 25, 1974 and recognized by the Union Chart granted by the Ministry of Labor on October 1st, 1981 (Mtb - 11.448/75, Mtb - 318-408/80), an autonomous, civil, non-profit representative of all workers within the category of pharmacists, registered under CNPJ number 00.679.357/0001-48, with headquarters at Rua Barao de Itapetininga, 255, 11th floor, Set in 1105, Centro, São Paulo / SP, by its President and very representative in terms of its Bylaws, Mrs. Célia Machado Gervasio Chaves (DOC. 9);

NATIONAL NETWORK OF PEOPLE LIVING WITH HIV/AIDS SÃO LUIZ NUCLEUS - RNP+/SLS, nonprofit civil association, registered in the CNPJ. Under the no. 07.369.136/0001-12 headquartered at Rua São Gabriel, 200-Bairro Fé em Deus, São Luis / MA CEP 65035-660, by its legal representative Mr. José Ricardo Silva dos Santos (DOC. 10), signed by their attorneys undersigned, come respectfully to the presence of Your Honor, on the basis of Article 31 of Law No. 9.279/96, present

PRE GRANT OPPOSITION REVIEW

based on art. 31 of Law No. 9.279/96 (Industrial Property Law) in face of **GILEAD SCIENCES, INC**.. regarding the application for invention patent PI0406760-6, deposited with the National Institute of Industrial Property - INPI on 13/01/2004, which advocates the **DISMISSAL** of the application in question on the following facts and grounds:

SUMMARY OF ARGUMENTS

In this pre grant opposition are presented, at first, clarification on the timeliness and legitimacy of the stakeholders to present subsidy to the technical examination of patent application for invention PI0406760-6.

As will be demonstrated below, this patent application should not be granted in order that the matter claimed does not meet the patentability requirements of novelty, inventive activity and also lacks sufficient descriptive clarity and precision and is not supported by the Normative Act 127/97 and the Guidelines for the examination of patent applications in the biotechnology and pharmaceutical filed after 12/31/1994 at the INPI.

I-TIMELINESS AND THE LEGITIMACY OF THE STAKEHOLDERS

Law no. 9279, May 14th, 1996 (Law of Industrial Property - LPI), which regulates rights and obligations

regarding industrial property, in its article 31 provides for the possibility of interested parties to submit information to support the examination of applications for patents in the following terms:

> Art. 31. Published patent application until after the exam, interested parties shall be empowered to present documents and information to assist in the examination.

Normative Act 127/97, in turn, provides that for purposes of Article 31 of the LPI, it should be considered as final examination the date of conclusive technical opinion regarding the patentability, or the thirtieth day preceding the publication of approval, dismissal or definitive shelving.

> 7.5 END OF EXAMINATION
> For the purposes of articles 26 and 31 of the LPI, it is considered end of examination to date of the conclusive opinion regarding patentability, or the thirtieth day preceding the publication of the acceptance, dismissal or definitive shelving, whichever occurs last.

In this case none of the hypotheses that characterize the end of the examination of the patent application has happened yet. As noted in INPI[1] website, the application is in the national phase of international application filed through the Patent Cooperation Treaty or PCT, according to dispatch published in 1824 RPI, on 12/20/2005. Thus, the present petition for pre grant opposition is within the stipulated time for submission.

In addition, like any administrative proceeding, the patent examination procedure is bound by the rules of due legal process, which appears in Article 5th, LIV of the 1988 Federal Constitution, which requires full right of defense. In this sense, is the understanding Denis Borges Barbosa, related to procedures that move at the INPI:

> Therefore, knowing that the grant of a monopoly will lead to the restriction of freedom of initiative of others, the administrative procedure must respect the principles of publicity of administrative acts, the broad defense and the contradictory, all contained in the **larger principle of due legal process**. It is embodied, for example, to the extent that the deposit of the privilege is published in an official journal, so that interested parties may oppose it or **present subsidies to invention examination**[2].

As for accomplishing of the principle of due process, applies also to the process of examining a patent application, the norms contained in Law no. 9784, January 29th, 1999, which regulates the administrative procedure in the federal public administration. That law, that should be applied to any administrative procedure, provides a figure of the stakeholder throughout the course of his text, especially Article 9:

> Art. 9º. Are legitimized as stakeholders in the administrative process:

I - individuals or companies that begin it as holders of rights or individual interests or on the right of representation;
II - those who have not started the process, have rights or interests that might be affected by the decision to be adopted;
III - representative organizations and associations, with regard to collective rights and interests;
IV - people or associations legally established regarding diffuse interests or rights.

Thus, the administrative procedure law legitimizes the actions of third parties, expressly providing the legitimation of organizations to act in defense of rights or collective and diffuse interests, as is the case of organizations now proponents, who have extensive experience in the area of access to medicines, aiming, in the case, especially ensuring access for people living with HIV/AIDS to adequate resources for their treatment.

For this reason, the stakeholders are largely interested in the patent application under examination, since it refers primarily to the drug trade name Truvada ®, a combination of emtricitabine and tenofovir disoproxil fumarate, used to treat the Acquired Immunodeficiency Syndrome-AIDS.

ABIA - Brazilian Interdisciplinary AIDS Association was established in 1986 and since then carries out its activities aimed at ensuring access for people living with HIV/AIDS to adequate resources for treatment and care through monitoring of public health policies, education and prevention (www.abiaids.org.br).

Conectas Human Rights, established on September 11th, 2001; its mission is to promote and strengthen respect for human rights, among which the fundamental right to life and health, which are related to access to appropriate medical and pharmacological treatment (www.conectas.org).

GAPA SP - Support Group for AIDS Prevention, the first organization to work exclusively with AIDS in Latin America, was founded in April 1985 and has the mission of defending human rights and integration of people with AIDS in the society (www.gapabrsp.org.br).

The Support Group for AIDS Prevention in Rio Grande do Sul -GAPA/RS, founded in 1989, is a nongovernmental, independent, nonprofit organization, whose mission is to promote the reduction of HIV infection through prevention activities and strive for guaranteeing the rights of people affected by the AIDS epidemic (www.gapars.com.br).

The Resistance Group Asa Branca-GRAB, founded in 1989, is a nongovernmental, independent, nonprofit organization, whose mission is to contribute to improving the quality of life for lesbian, gay, bisexual and transgender people; people living with HIV/AIDS (www.grab.org.br).

GESTOS Seropositivity Communication and Gender's mission is to strengthen the human rights of positive people and people vulnerable to STD/HIV, producing knowledge and intervening in

Education, Communication and Public Policy from the perspective of Gender Equity, Sexual Citizenship and Social Justice (www.gestospe.org.br).

The GIV - Incentive Life Group, founded in 1990; its mission is providing better alternatives for quality of life, both in social and physical and mental health, to any person living with HIV/AIDS (www.giv.org.br).

IDEC - Brazilian Institute of Consumer Protection, founded in 1987; its mission is Brazilian consumer and citizen protection in consumer relations and also relations with the government, having worked strongly since its creation to ensure access to quality medicines for all who need them (www.idec.org.br).

The National Federation of Pharmacists - Fenafar is an entity representing the pharmaceutical category nationally. Founded on October 25th, 1974, currently has 17 affiliated Unions. In these 35 years Fenafar, through its leaders, has built a history of struggles, seeking always the respect to the class and the rescue of the important social role of the pharmacist in health care (www.fenafar.org.br).

THE NATIONAL NETWORK OF PEOPLE LIVING WITH HIV/AIDS SÃO LUIZ NUCLEUS - RNP+/SLS is an organization of people living with HIV/AIDS, with no party-political and religious links, which works to promote the empowerment of people who are seropositive for the virus HIV, regardless of gender, sexual orientation, creed, race or ethnicity and nationality (http://www.rnpvha.org.br).

These organizations are part of the Working Group on Intellectual Property (GTPI) of the Brazilian Network for the Integration of Peoples (REBRIP) that brings together diverse civil society organizations, social movements and experts related to the subject of intellectual property and access to health care in Brazil. The GTPI works from a public interest perspective, working to mitigate the negative impact of pharmaceutical patents in guaranteeing the population's access to medicines.

It is worth remembering that **society is the main stakeholder in the detailed analysis regarding the examination and grant of patent protection for new inventions**. That's because the Federal Constitution, to protect the inventor, does not make it with any other purpose but to stimulate technological and economic development of the Country, in view of the social interest and satisfaction of the needs of its members (art. 5º, XXIX, CF/88).

Therefore, it remains clear the timeliness of this subsidy to the examination and the legitimacy of the proposing organizations, as civil society organizations, to manifest themselves as stakeholders in this administrative procedure, since it examines, particularly, the patent application of Truvada® as well as other compounds used in AIDS treatment.

II - REASONS FOR DISMISSAL OF THIS APPLICATION FOR PATENT OF INVENTION

II.1 INITIAL CONSIDERATIONS

Through analysis of this patent application (filed on 1/13/2004) verifies that Gilead Sciences claims, especially, the combination of antiretroviral drug (ARV) emtricitabine (Emtriva®) with other ARV marketed under the name Viread ® (tenofovir disoproxil fumarate, TDF). This ARVs drug combination above is sold by Gilead under the name Truvada® (emtricitabine + tenofovir disoproxil fumarate).

The first patent of emtricitabine, one of the products used in the combination object of this patent application, dates back to the 90s (US5210085 -1991), filed by Emory University (USA) and is protected by several patents, after the license agreement, are currently owned by Gilead. Patents relating to emtricitabine were not deposited in Brazil, so this product is nationally in the public domain.

The other product of the combination and subject of this patent application is tenofovir disoproxil fumarate (TDF), which was the subject of a patent application PI 9811045-4 (priority 7/23/1998) filed by Gilead. That application was rejected on 30 June 2009 by the INPI, to be in violation of Articles 8 and 13 of the LPI[3]. This request was disputed, through pre grant oppositions by the Office of Drug Technology (Farmanguinhos) in December 2005, in January 2007 by the Oswaldo Cruz Foundation (FIOCRUZ) and by organizations GTPI/REBRIP[4] in December 2006. Both oppositions submitted requested the dismissal of the patent application of TDF in Brazil, based on non-compliance with the requirement of inventive activity. The organizations and the public laboratory claimed that there was no inventive activity to justify patent protection, since obtaining the compound is trivial for one skilled in the art (TDF is in fact a salt of tenofovir). These arguments were accepted by the INPI to dismiss the application for patent on TDF.

Importantly, the rejection of the patent application of TDF led, according to data from the Health Surveillance Secretariat of the Ministry of Health, the actual reduction in the unit price of the product in 31.1%[5]. In addition, as announced by the Department of Science, Technology and Strategic Inputs of the Ministry of Health, national generic version of this product is being developed - through public-private partnerships and under the Common Industrial Complex Health - with estimates of release in the second half of 2010[6].

Although the original patent application for TDF was rejected (PI9811045-4), on March 31st, 2009 was published by the INPI divisional patent application for TDF (PI9816239-0) filed by Gilead. Rebelling against the divisional application of TDF, organizations from GTPI/REBRIP[7] presented on November 6, 2009 a pre grant opposition the to technical examination supporting that the application violates a patent LPI, either because the applicant has included new claims not provided in the original

application, or because such claims do not meet the requirements of novelty and inventiveness.

Thus, the patent application currently under examination has as chief claim the combination of a product that is in the public domain in Brazil with a product whose patent application was rejected by the INPI because it did not meet the requirements of patentability. Therefore, as will be demonstrated below, this application for a patent should not be granted in order that their claims do not meet the patentability requirements, are not supported in Normative Act 127/97 and in the guidelines for the examination, nor constitute patentable subject matter.

I.2 ANALYSIS OF CLAIMS CONTAINED IN PATENT APPLICATION AND ARGUMENTS FOR ITS DISMISSAL

By analyzing the set of claims of this patent application it is apparent that five different types of claims were included for essentially the same object, namely:

- a) Claims number 1-24 - "Method for the treatment or prevention of symptoms or effects of HIV infection in an infected animal which comprises administering to this animal a therapeutically effective amount of a composition comprising ...";
- b) Claims number 25-41 - "Pharmaceutical formulation ...";
- c) Claims number 42-46 - "Packaging for the consumer ...";
- d) Claims number 47-54 - "Combination chemically stable ...";
- e) Claims number 55-58 - "Oral pharmaceutical dosage form of chemically stable ...".

As will be demonstrated below, none of the claims must be granted by this INPI by being at odds with the relevant legislation. Consider:

a) Claim No. 1-24 - Method of Treatment

In the claims number 1 (main) to 24, method claims are presented for the treatment or prevention of symptoms or effects of an HIV infection. Claim number 1 provides as follows:

> 1. Method for the treatment or prevention of symptoms or effects of HIV infection in an infected animal which comprises administering to this animal a therapeutically effective amount of a composition comprising fumarate ester diisopropoxycarbonyloxymethyl acid [2-(6-aminopurine-9-il)-1-methyl-etoximethyl-phosphonic acid (tenofovir disoproxil fumarate) or a physiologically functional derivative of this and (2R, 5S, cis)-4amino-5-fluoro-1-(2-hydroxymethyl-1 ,3-oxatiolan- 5-yl) - (1H)-pyrimidine-2-one (emtricitabine) or a physiologically functional derivative of emtricitabine.

As this is a method of treatment, claims number 1-24 cannot be granted, as it will be seen below,

either because they are not considered an invention, or by not fulfilling the requirement of industrial application. Moreover, these claims also lack descriptive sufficiency, indispensable for the granting of a patent.

a.1) Breach of Article 10, VIII of the LPI-treatment method is not considered an invention

It should be noted, however, that method of treatment is not considered an invention by our legislation and cannot be protected by a patent. Let's see Article 10, clause VIII of the LPI, verbatim:

> Art. 10, LPI - Are not considered inventions or utility models:
> (...)
> VIII - surgical techniques and surgical and therapeutic methods or diagnostic methods, for use on human or animal body;

This restriction is in perfect conformity with the TRIPS Agreement and was predicted precisely to protect public health:

> Art. 27, TRIPS. **Patentable Subject Matter**
> (...)
> 2 - **Members may exclude from patentability inventions**, the prevention within their territory of the **commercial exploitation of which is necessary to protect** order public or morality, including to **protect human**, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law
> 3 - Members may also exclude from patentability: a) diagnostic, **therapeutic** and surgical **methods** for the **treatment of humans** or animals (emphasis added)

Also, items 2.36.2, 2.36.4, 2.36.5 of the "Guidelines for the examination of patent applications in the biotechnology and pharmaceutical filed after 12/31/1994," adopted by this INPI provide that type of claims "Method for treating X disease characterized by compound Y to a patient suffering from disease X" are interpreted as therapeutic methods and, therefore, are not considered inventions according to Art. 10,VIII of the LPI.

Furthermore Article 42 of the LPI states that patents are granted only for **products and processes and not for methods**:

> Article 42, LPI. The patent gives the holder the right to prevent third parties not having his consent from making, using, offering for sale, selling or importing for these purposes:
> I - a **product** under patent;
> II - a **process** or **product** directly obtained by patented process.

Likewise, the subheading "c" of item 15.1.3.1 of Normative Act 127/97 of the INPI does not make provision for an invention patent for methods of treatment:

> c) the claims may be of one or more categories (such as product and process, process and apparatus, product, process and apparatus, etc.), since they are linked by a single inventive concept being arranged in the most practical way possible.

It is of note that the European Patent Office-EPO (International Search Authority) when issuing its written opinion regarding patent application PCT correspondent (PCT/US2004/000832) to the request on screen expressed that it would not examine the claims number 1-24. This has occurred because the claims mentioned presented methods of treatment and, therefore, occurred on Article 67.1 (iv) of the Cooperation Treaty Patent Law which provides that no international preliminary examination will be carried out in patent applications claiming methods for treatment, in verbatim:

> 67.1 No International Preliminary Examining Authority shall be required to carry out an international preliminary examination on an international application if, and to the extent to which, its subject matter is any of the following:
> (iv) **methods for treatment of the human** or animal body by surgery or therapy, as well as diagnostic methods, (emphasis added).

For these reasons mentioned above the claims number 1 to 24 cannot be provided for they concern a therapeutic method in accordance with Article 10, paragraph VIII of the LPI.

a.2) Breach of Articles 8 and 15 of the LPI-the absence of the requirement of industrial application

Moreover, claims of treatment method, by definition, do not meet the requirement of industrial application established by Article 8 of the LPI. In fact, Article 15 of the LPI thus defines industrial application:

> Art. 15 - Inventions and utility models are considered susceptible of industrial application if they can be made or used in any industry.

Nor the descriptive report does not explain how it is given to industrial application for the above method of treatment present in claims number 1 to 24. So also the subheading "k" of item 15.1.2, the Normative Act 127/97 of the INPI is not observed, which provides that the applicant must "indicate explicitly, the industrial use when it is not obvious from the description of the invention."

Moreover, there is no way a treatment method be used or produced in an industry, since this type of claim is tantamount to required instructions to physicians about how to use a certain drug to treat a disease in particular.

This is the understanding Shabalala and Correa[8], that treatment methods **have no industrial application, because the effect occurs in the body of the patient, not qualifying as a feature of the pharmaceutical or manufacturing method to be used in the industry**.

Thus, even in a broader interpretation of that requirement, **there is no possibility that a claim of treatment method can fulfill the requirement for patentability of industrial application.**

a.3) Breach of Articles 24 and 25 of the LPI-lack of descriptive sufficiency and clarity and precision

Moreover, it appears that the claims lack descriptive sufficiency (art. 24 of the LPI) as well as clarity and precision (art. 25 of the LPI) since most of the claims (in particular the "1" - on which depend almost all the others) contains vague and too broad expressions to be patentable as "*physiologically functional derivative of this*," *about* "and "*acceptable physiological derivative*".

In view of all of the above, claims No. 1 to 24 do not deserve to be upheld, since they claim therapeutic method, not having industrial application and do not have descriptive sufficiency and violate, among others, the articles 8, 10, VIII, 15, 24, and 25 of LPI.

b) Claims number 25-41 - formulation claims

In the claims number 25 (main) to number 41 (dependents) is sought patent protection for a formulation with the mere combination of already existing products.
The main claim is as follows:

> 25. Pharmaceutical formulation comprising fumarate diisopropoxycarbonyloxymethyl ester acid [2-6 (6-amino-purin-9-yl)-1methyl-ethoxy-methyl]-phosphonic acid (tenofovir disoproxil fumarate) or a physiologically functional derivative of this and (2R, 5S , cis)-4-amino-5fluor-1-(2-hydroxymethyl-1 ,3-oxatiolan-5-yl) - (1H)-pyrimidine-2-one (emtricitabine) or a physiologically functional derivative thereof.

As will be demonstrated below, the claims of formulation (no. 25-41) show no novelty or inventive step, and must be dismissed. Moreover, in this block of claims are still included stipulations of dosage/concentration, which can be equated to treatment methods, and therefore cannot be considered an invention. Finally, are included Markush type claims, which do not reveal the technology they seek to protect in this patent application.

b.1) Breach of Articles 8 and 11 of the LPI-the lack of novelty requirement

The main claim and all other dependent claims do not meet the novelty requirement provided for in Articles 8 and 11 of the LPI. This is due to the fact that existent anteriorities already reveal the combination of tenofovir with emtricitabine. Such information was also presented at the preliminary examination of the international patent application PCT/US2004/000832 (corresponding to the

request on screen).

They are:

D1: RISTIG MARIA B ET AL: "Tenofovir disoproxil fumarate therapy for chronic hepatitis B in human immunodeficiency virus/hepatitis B virus-coinfected individual for whom interferon-alpha and lamivudine therapy have failed." Journal of Infectious Diseases, 2002, 186:1844-7.

D2: MURRY, JEFFREY P ET AL: "Reversion of the MI84V mutation in simian immunodeficiency virus reverse transcriptase is selected by tenofovir, even in the presence of lamivudine" Journal of Virology, 12 Jan 2003, 77:1120-30.

D3: "Anti-HIV drug updates-three drugs on the near horizon" Project Inform Perspective, Jan 2003, 35:4-7.

D4: FUNG HORATIOBE TAL "Tenofovir disoproxil fumarate: A nucleotide reverse transcriptase inhibitor for the treatment of HIV infection" Clinical Therapeutics, 2002, 24:1515-1548.

D5: MULATO ASETAL "Anti-HIV Activity of Adefovir (PMEA) and PMPA in combination with Antiretroviral Compounds: in vitro analyses" Antiviral Research, 1997, 36:91-97.

D6: WO00/25797 A (BARRY DAVID; ROUSSEAU FRANCK (US); FURMAN PHILLIPA (US); PAINTER GEO), 11 May 2000.

D1 discloses the use of disoproxil fumarate tenofovir (TDF) in patients receiving lamivudine (3TC) or emtricitabine (FTC) (page 1844, second column, penultimate paragraph). Although this document is mainly related to the treatment of hepatitis B in patients co-infected with HIV/HBV, it also reports that there is an anti-HIV activity (page 1845, second column, last paragraph before "Discussion").

D2 reveal studies on the appearance of resistance in SIV when using tenofovir (PMPA) with 3TC or PMPA with FTC.

D3 reveals that there is intent to combine PMPA (tenofovir) and FTC (emtricitabine) in a single pill (page 7, column 2, last paragraph).

D4 discloses the use of TDF in combination with 3TC for the treatment of HIV contamination.

D5 teaches that the combination of PMPA or adefovir (PMEA) with 3TC induces an active inhibition of HIV replication *in vitro*.

D6 shows the combination of FTC with PMEA for the treatment of hepatitis B. PMEA (adefovir) is mentioned in the description of this patent application as a functional derivative of tenofovir.

Therefore, the claimed subject matter cannot meet the requirement of novelty in view of the previous publication of the documents listed above.

b.2) Breach of Articles 8 and 13 of the LPI-the absence of the requirement of inventive activity

In addition, the dependent claims **26 and 27** require the association of the claimed subject matter under paragraph 25 added to vehicles or excipients. Such claims also must be rejected in view that formulations and processes for their preparation already ingrained in the public domain combined with excipients or vehicles not discriminated in any way cannot meet the requirements of novelty and inventive step, since it is obvious to someone skilled in the art.

Thus, Correa[9] alert:

> *"las formulaciones y composiciones nuevas, como también los procesos para su preparación, se deberían considerar obvias teniendo en cuenta el arte previo, en particular, cuando se reivindica un único principio activo junto con vehículos o excipientes conocidos o no especificados.* ***Como excepción, las reivindicaciones de este tipo podrían ser patentables si se obtiene un efecto realmente inesperado o sorpresivo; por ejemplo, cuando se resuelve, de manera no obvia, un problema verdaderamente difícil o una necesidad de larga data, tal como una disminución considerable de los efectos colaterales, o cuando la solución que se encuentra al problema origina una enorme ventaja en comparación con el estado de la técnica.*** **(emphasis added)****

As noted above, formulations and compositions could only be patentable if they have really new or differentiated effects, which depart them from the field of obviousness. However this is not the case of the claims presented herein, since there is no coverage associated with these effects in the descriptive report.

b.3) Breach of Article 10, VIII of the LPI - dose/concentration are comparable to treatment method and are not considered invention

Claims 28 to 33, in turn, refer to the dosage/concentration. Claims involving the stipulation of doses of existing products have to be repelled in the sense that they are equivalent to method claims for treatment, since the dose of a product is ultimately the way in which the product is used therapeutically. Moreover, according Correa[10], dosages claims do not meet the requirement of industrial applicability as the effects of such product occur only in the body of the individual who ingests it.

b.4) Breach of Article 2.9.1 of the Guidelines for Examination - compounds defined by its physical form

Claim 35 asks for patenting of formulation in question as a tablet or capsule. Such a claim should not succeed under the "guidelines for the examination of patent applications in the biotechnology and pharmaceutical filed after 12/31/1994" adopted by the INPI. Consider:

> 2.9 Compositions defined by their physical form
>
> 2.9.1 Compositions, particularly pharmaceuticals, are often defined by their physical form. Thus, a composition can be claimed in the form of a pill, tablet, injectable solution, suppository, etc. In these cases, depending on what was perceived (by the study of the descriptive report) as the invention, it may be indispensable presence in the text of the claim of the constructive characteristics (e.g., shape, thickness, coating type, etc.). of the product, in addition to defining the components of the composition itself. Here adjust all the various considerations made above with respect to other compositions. **Thus, for example, a claim such as "pharmaceutical composition characterized by being in capsule form" should be rejected because it does not define precisely the protected object,** it is noted that in this case, protection would be on any composition in capsule form. However, if the capsule is set in a more specific and detailed definition (as to its construction features, for example) the claim could be granted. (Emphasis added)

The policy of the INPI is clear in this regard by stating categorically that claims based on "composition in the form of (...)", as in this case should be promptly rejected.

b.5) Breach of Articles 24 and 25 of the LPI - Markush type claims

Claims 38-41 are Markush-type. Claims of this type decharacterize the patent system maculating one of its most basic assumptions: disclosure in exchange for the monopoly. In fact, one of the main arguments for the existing patent protection is the clear and adequate disclosure of technology so that after the period of protection, the society can reproduce the invention freely and easily.

Markush-type claims are common in the pharmaceutical area. The claims are worded broadly and not specifically reveal no invention, but are intended to protect a series of compounds. In other words, they refer to a chemical structure that has multiple chemical substitutes allowed, functionally equivalent in one or more parts of the compound. However, this large number of compounds has not proven, disclosed, researched or tested their properties.

According to Correa[11], acceptance of Markush type claims raises several problems of the patentability requirements, since they aim to cover in a single patent application variables and different molecules that were not revealed and/or tested, making it difficult or even impossible to search the state of the art. Thus, this type of claim should be rejected for violating the provisions of Articles 24 and 25 of the LPI, which require descriptive sufficiency, clarity and accuracy of the claims in the grounds of the application object of protection.

c) Claims 42 to 46: packaging for the consumer and information on product usage

Claim 42 (main) and its dependents (43 to 46) relate to the protection of consumer packaging and instructions for using the drug:

> *42. Packaging for consumer comprising at least one active ingredient selected fumarate acid ester diisopropoxycarbonyloxymethyl 2-(6-amino-purin-9-yl)-1methyl-etoximethyl.-phosphonic (tenofovir disoproxil fumarate) and (2R, 5S , cis)-4-amino-5-fluoro-1-(2-hidromethyl-1 ,3-oxatiolan-5-yl) - (1H)-pyrimidine-2-ona (emtricitabine), and an information insert containing directions on the use of tenofovir and emtricitabine together in combination.*

Claims 43 to 46 differ from claim 42 only in relation to dosage of the drug tenofovir disoproxil fumarate and emtricitabine.

These claims should be dismissed because they are not considered invention, and they lack descriptive sufficiency.

c.1) Breach of Article 10 of the LPI - are not considered invention

Claims number 42 to 46 are not patentable according to the article 10 of the LPI for representing only "information reporting" (Article 10, VI), "educational and advertising schemes" (Article 10, III) and "therapeutic method" (Article 10, VIII).

> *Art. 10.* ***It is not considered inventions*** *or utility models:*
> *I-discoveries, scientific theories and mathematical methods;*
> *II-purely abstract concepts;*
> *III-**schemes**, plans, principles or commercial methods, accounting, financial, **educational, advertising**, lottery and supervision;*
> *IV-literary, architectural, artistic and scientific work or any aesthetic creation;*
> *V-computer programs* per se*;*
> *VI-**information reporting**;*
> *VII-game rules;*
> *VIII - **technical and operative methods, as well as diagnostic or therapeutic methods**, for use on human or animal body; and*
> *IX-all or part of natural living beings and biological materials found in nature, or even if isolated, including the genome or germplasm of any natural living being and natural biological processes.*

Thus, it may not be granted for this INPI.

c.2) Breach of Article 25 of the LPI - descriptive insufficiency

Moreover, in the descriptive report (pages 37 and 38) the element is insufficiently detailed with respect to this claim, as the applicant submits, **is already in the state of the art**:

> *Use of Composition*
> *"... Any one of several methods known to people versed in the technique for packaging of tablets, pills, or other solid dosage forms suitable for oral administration, which does not degrade the components of the present invention are suitable for use in packaging .... " (page 37)*

The applicant cannot, therefore, apply patent protection for a package which will be manufactured by a method already known in the state of the art.

In addition, the applicant conceptualized in the descriptive report what is meant by "information inserted" or "package insert":

> *"... The packaging material can also have label and information related to the pharmaceutical composition printed on it. Additionally, an article of manufacture may contain brochure, report, notice, pamphlet or leaflet containing product information.*
> *This form of pharmaceutical information is referred to in the pharmaceutical industry as a "package insert". A package insert can be attached or included with a pharmaceutical article of manufacture. The package insert and any article of manufacture labeling provides information relating to pharmaceutical composition. The information and labeling provide various forms of information used by health professionals and patients, describing the composition, its dosage, and various other parameters required by regulatory agencies such as the United States Food and Drug Agency. " (page 38)*

By reading the narrative report is clear that the applicant did not reveal the contents of "information inserted" which claims to protect, nor any information relating to the use of the combination itself, thus setting descriptive insufficiency.

Although the description of use was also not patentable according to article 10 of the LPI, this claim is supported by a vast emptiness and the effort to protect a blank paper. Well, there is no invention to claim a package containing descriptive information already known or method of treatment product that is indeed the object of the patent application.

Thus, the claims 42 to 46 must be dismissed for they do not constitute subject matter of patent protection and do not meet legal requirements.

d) Claims number 47-54 - drug combinations without revealing any way to accomplish this mixture

Before presenting the arguments for supporting the dismissal of claims 47 to 54, it is also important to highlight the negative impact of patent protection for improper combinations can have on public health and access to medicines.

From the therapeutic point of view the Expert Committee World Health Organization (WHO) for Selection and Use of Essential Medicines recommends and endorses the use of fixed-dose combinations and the development of new versions[12] to facilitate compliance (administration) of drug treatment. Worth noting, however, that innovation in therapeutic terms as the combination of existing drugs in a single dose has no necessary relation to scientific innovation technology, as discussed below.

Because of this fact, is vital that the patent applications claiming combinations are reviewed carefully so as not to unduly grant patents which do not comply with the requirements of patentability.

<u>d.1) Breach of Articles 8 and 13 of the LPI - combinations do not meet the requirement of inventive activity</u>

As already mentioned the present patent application claims patent protection intended primarily for the mere combination of two existing products of tenofovir disoproxil fumarate (Viread) and emtricitabine (Emtriva).

As can be seen through analysis of claims number 3, 33, 44 and 46, together with the illustrations below[13], one may note that even within the claimed dosage of the combination of the two products it is the same for each one of ARV drugs used alone, *i.e.*, 200 mg emtricitabine and 300 mg of TDF.

FTC, emtricitabine	*Emtriva*		*200mg capsule*	200mg once a day	**Common:**	Nausea, vomiting, diarrhoea, abdominal pain, headache, dizziness, weakness, rash
Nucleotide reverse transcriptase inhibitors (NtRTIs)						
Tenofovir	*Viread*		*300mg tablet*	300mg once a day	**Common:** **Rare:**	Nausea, vomiting, diarrhoea, dizziness, low blood phosphate levels Kidney problems
FTC / tenofovir	*Truvada*		*Tablet comprising 200mg FTC and 300mg tenofovir*		One tablet once a day	See FTC and tenofovir

Now, claim the combination of two known pharmaceuticals (emtricitabine US 5,210,085+ TDF, U.S. Provisional Patent Application Serial No. 60/022, 708) and disclosed in the prior state of the art including the same dosage is obvious to one skilled in the art, therefore violates the requirement of inventive activity in Article 13 of the LPI.

Correa recommends[14], in press corroborated by the World Health Organization-WHO, the combinations of active ingredients should be considered without inventive activity. Moreover, according to Correa[15], often the claims of combination, in practice, can be treated as applications for patents for methods of treatment, also forbidden by law, when claiming solely a method for

administering a known drug combination.

Still, this patent application also violates the "Guidelines for the examination of patent applications in the biotechnology and pharmaceutical filed after 12/31/1994" on item 2.8:

> *2.8 Compositions showing separate components*
>
> *In these compositions, often called combinations, the components (or groups of components) are physically separated, and packaged or administered (in the case of medicine) together or separately. In these cases, one must observe carefully how the claim is defined:*
>
> *a) are defined only the component groups, even if it is mentioned that can be packaged together or separately, are granted and, if precautionary caveat regarding the provisions of Article 10 (VIII) in the case of a pharmaceutical composition;*
>
> *b) are defined component groups and the specific way of administration (e.g., at intervals determined by parenteral, oral administration); here it is necessary to decide, by the study of the descriptive report and the technique, if the withdrawal of form of application is possible, ie, without entailing an unjustified mutilation or extension of protection, but if it is required in this regard and it is emphasized on the Art 10 (VIII), where no one must reject the claim as a whole, as it would also protect the therapeutic method.*

As if the lack of inventive step were insufficient, it is important to note that the requesting company tries to add protection from new combinations - involving other antiretrovirals such as efavirenz, atazanavir and lopinavir/ritonavir (claims 56, 57, 58) - in addition to the combination of this application - the TDF+FTC.

Thus, therefore the claims 47 to 54 must be dismissed for violating the requirement for patentability of an invention, as exposed in articles 8 and 13 of the LPI.

<u>d.2) Breach of Articles 24 and 25 of the LPI - the lack of clarity and precision and descriptive adequacy</u>

As already mentioned, the main claim of the patent application now under consideration is the combination of tenofovir disoproxil fumarate with emtricitabine. Besides the fact that both products are already known and their combination has already been disclosed in the state of the art and lack of inventive step, which alone would require rejection of the application in question, the applicant still fails to reveal how such a combination would be performed. So, it does not bring absolutely no additional knowledge to society.

As is known, the system of intellectual property protection is designed to enable an exchange

between public and private. This system is established by the granting of a temporary privilege of marketing (patent) issued to the inventor in exchange for this obligation to disclose and describe the best constructive way to develop the invention, this knowledge will be immediately available to the general public representing a additional knowledge to society. It is the goal of protection through patents - broad access to technology, innovation, in exchange for the monopoly granted to the inventor. Without the descriptive sufficiency, the very institution of the patent is jeopardized.

The descriptive sufficiency and clarity are of great importance especially for the pharmaceutical field, since the rapid reproduction of the invention during the term of the patent (in case of compulsory license or use of the Bolar exception) or soon after the expiration of the patent has vital relevance to public health policies.

However, the applicant does not reveal the way in which shall be performed the combination of the products described in claims 47 to 54, limiting the claim to request protection for the mix without even giving indications of how this combination would be made. In fact, at no time did the applicant explains how technically would be held the distinct combinations (either the combination of TDF/FTC, and their combination with other drugs that were included in the schedule of claims).

Claims 47 to 54 do not meet, thus the requirement of descriptive sufficiency and clarity and precision, in addition to not meeting the requirement of inventive activity. Must therefore be denied by this INPI.

e) Claims number 55-58 - pharmaceutical dosage form

Claims 55-58 relate to pharmaceutical dosage forms, as said earlier claims that involve the stipulation of doses of existing products must be rejected in view that they are equivalent to claims of a method of treatment since the dose of a product is ultimately the way in which the product is used therapeutically. Moreover, as already mentioned, according Correa[16], claims dosages do not meet the requirement of industrial applicability as the effects of such product occur only in the body of the individual who ingests it.

Another point that deserves to be highlighted in claims 56, 57 and 58 is the attempt by the applicant to include within the dosage form of claims of disoproxil fumarate tenofovir with emtricitabine and other antiretrovirals alien to the application, such as atazanavir (Reyataz), lopinavir/ritonavir (Kaletra) and efavirenz (Sustiva). Such associations are not supported in the specification and are not the subject of the application in question, so they must not be accepted.

II.3 THE LACK OF NOVELTY OF THE ISOLATED/SEPARATE USE OF THE PRODUCT COMBINATION

In addition to the above blocks of claims and the combination of TDF/FTC, the applicant would also, quite opportunistically, protect the isolated use of each product, although the use of isolated/separated from both ARVs (emtricitabine and tenofovir disoproxil fumarate) for the treatment of HIV is already known and used before the filing of this patent application.

In fact, in claims number 15, 16, 43, 44, 45, and 46 the applicant will again intend to protect this use as verified by analysis of the claims below:

> 15. "Method for the treatment or prevention of symptoms or effects of HIV infection in an infected animal **which comprises administering** to this animal in **combination or alternation** a therapeutically effective amount of ester fumarate ...";
>
> 16. "Method according to claim 15, when tenofovir disoproxil fumarate or a physiologically functional derivative thereof, and emtricitabine or a physiologically functional derivative thereof, are administered **in alternation**."
>
> 43. "Packaging for consumer according to claim 42, including a pill, tablet, capsule or tablet coformulated of 100 to 1000 mg of tenofovir disoproxil fumarate and 100 to 1000 mg of emtricitabine."
>
> 44. "Packaging for consumer according to claim 43, comprising a pill, tablet, capsule or tablet coformulated of 300 mg tenofovir disoproxil fumarate and 200 mg emtricitabine."
>
> 45. "Packaging for consumer according to claim 42, including a pill, tablet, tablet or capsule **separated** from 100 to 1000 mg of tenofovir disoproxil fumarate and 100 to 1000 mg of emtricitabine."
>
> 46. "Packaging for consumer according to claim 45, comprising a pill, tablet, tablet or capsule **separated** of 300 mg tenofovir disoproxil fumarate and 200 mg emtricitabine."

Considering the inexistence of patent protection for emtricitabine in Brazil and having been refused the application for patent of tenofovir disoproxil fumarate, the applicant insidiously attempt by the claims outlined above to obtain the monopoly of existing drugs in clear violation of the requirement novelty provisions of Article 8 and Article 11 of the LPI. Aggravating this further, it attempts to gain monopoly of isolated drugs, both sold by the own applicant.

II.4 - SUMMARY TABLE

In conclusion, the present patent application must be dismissed. As explained above, all claims violate, for one reason or another, the conditions and requirements stipulated by the LPI, and regulatory acts and guidelines for proper examination of this INPI.

The table below resumes, briefly, the arguments developed earlier in this pre grant opposition, highlighting the reasons that compel the refusal of the application.

Protection	Claim	Compounds	Details	Violated Article
Method of treatment	1, 2, 3	Tenofovir disoproxil Emtricitabine	Combined	Art. 8, LPI Art. 10, VIII, LPI Art. 15, LPI Art. 24, LPI Art. 25, LPI
	4, 5, 6, 7	Tenofovir disoproxil fumarate Emtricitabine	Derivative	
	8 and 11	Tenofovir disoproxil fumarate	Derivative	
	9	Tenofovir disoproxil Emtricitabine Method according to claim 1, wherein a component of the composition is (2R, 5S, cis)-4-amino-1-(2hydroxymethyl-1 ,3-oxatiolan-5-yl) (1H)-primidin-2- one (3TC)	Derivative	
	10	Emtricitabine	Derivative	
	12	Tenofovir disoproxil fumarate Method according to claim 11, wherein at least one of R1 and R2 is-CH2OC(=O)C(CH3)3		
	13	Tenofovir disoproxil fumarate Method according to claim 11, wherein at least one of R1 and R2 is -CH2OC(=O)OCH(CH3)3.		
	14	Tenofovir disoproxil fumarate Method according to claim 11, wherein at least one of R1 and R2 is -CH2OC(=O)OCH(CH3)2.		
	15 and 17	Tenofovir disoproxil fumarate Emtricitabine	and/or derivatives combined	
	16	Tenofovir disoproxil fumarate Emtricitabine	and/or derivatives alternated	
	18	Tenofovir disoproxil fumarate Emtricitabine	and/or derivatives combined to take once a day	
	19	Tenofovir disoproxil Emtricitabine	for use in humans	
	20	Tenofovir disoproxil fumarate Emtricitabine With PI, NRTI, NNRTI, and II.	and/or derivatives combined	
	21	Tenofovir disoproxil fumarate Emtricitabine Method according to claim 20, in which the third active ingredient is 9-[R-2 [[(s)-[[(s)-1(isopropoxycarbonyl)ethyl]amino]fenoxyfosfini]	Combination	

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Protection	Claim	Compounds	Details	Violated Article	
		methoxy]propyl] adenine (GS-7340).			
	22	Tenofovir disoproxil Emtricitabine With *glidant* (lubricant?)	Combined		
	23	Tenofovir disoproxil Emtricitabine With *glidant* (lubricant?) that is derived from... and any combination with each other.	Combined		
	24	Tenofovir disoproxil Emtricitabine With *glidant* (lubricant?) and that is derived from any combination among themselves, in which metallic stearates are selected from...	Combined		
Pharmaceutical formulation	25	Tenofovir disoproxil fumarate Emtricitabine	and/or isolated derivatives	Art. 8, LPI	Art. 11, LPI
	26	Tenofovir disoproxil fumarate Emtricitabine With one or more acceptable carriers or excipients		Art. 13, LPI	
	27	Tenofovir disoproxil fumarate Emtricitabine With one or more acceptable carriers or excipients that are… or combinations among them.			
	28	Tenofovir disoproxil fumarate Emtricitabine present in a ratio of 1:50 to 50:1 by weight	and /or derivatives		
	29	Tenofovir disoproxil fumarate Emtricitabine present in a ratio of 1:10 to 10:1 by weight	and /or derivatives		
	30	Tenofovir disoproxil fumarate Emtricitabine In unitary dosage form	and/or isolated derivatives Art. 10, VIII, LPI	Art. 10, VIII, LPI	
	31	Tenofovir disoproxil fumarate Emtricitabine In unitary dosage form with amounts from 100 mg to 1000 mg	and/or isolated derivatives		
	32	Tenofovir disoproxil fumarate Emtricitabine Formula Claim 31: 'in unit dosage form with an amount from 100 mg to 1000 mg regarding disoproxil fumarate tenofovir and emtricitabine	and/or isolated derivatives		

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Protection	Claim	Compounds	Details	Violated Article
	33	Tenofovir disoproxil fumarate Emtricitabine		
	34	Tenofovir disoproxil fumarate Emtricitabine and/or isolated derivatives for oral consumption		
	35	Tenofovir disoproxil fumarate Emtricitabine	and /or derivatives isolated in form of capsule/pill	Art. 2.9.1, Guid elines
	36	Tenofovir disoproxil fumarate Emtricitabine	and /or derivatives isolated to take once a day	
	37	Tenofovir disoproxil fumarate Derived from Emtricitabine	isolated	
	38	Derivative of tenofovir disoproxil fumarate Emtricitabine	isolated	Art. 24, LPI Art. 25, LPI
	39	Derivative of tenofovir disoproxil fumarate Emtricitabine Pharmaceutical formulation according to claim 38, wherein at least one of R1 and R2 is-CH2OC(=O)C(CH3)3		
	40	Derivative of tenofovir disoproxil fumarate Emtricitabine Pharmaceutical formulation according to claim 38, wherein at least one of R1 and R2 is-CH2OC(=O)OC(CH3)3		
	41	Derivative of tenofovir disoproxil fumarate Emtricitabine Pharmaceutical formulation according to claim 38, wherein at least one of R1 and R2 is -CH2OC(=O)C(CH3)2.		
Package	42	Tenofovir disoproxil fumarate Emtricitabine AND package insert	Combined	Art. 10, III, VI e VIII, LPI Art. 25, LPI
	43	Tenofovir disoproxil fumarate Emtricitabine AND package insert	Combined	
	44	Tenofovir disoproxil fumarate Emtricitabine AND package insert	Combined	
	45	Tenofovir disoproxil fumarate Emtricitabine AND package insert	isolated	
	46	Tenofovir disoproxil fumarate Emtricitabine AND package insert	isolated	
Chemical	47	Tenofovir disoproxil fumarate	C.C. stable	Art. 8, LPI Art.

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Protection	Claim	Compounds	Details	Violated Article
combination (C.C.)		Emtricitabine		13, LPI Art. 24, LPI Art. 25, LPI
	48	Tenofovir disoproxil fumarate Emtricitabine	C.C. stable in pharmaceutical dosage	
	49	Tenofovir disoproxil fumarate Emtricitabine	C.C. stable in oral pharmaceutical dosage	
	50	Tenofovir disoproxil fumarate Emtricitabine With a third antiretroviral agent	C.C. stable w/wo pharmaceutical dosage Whether or not oral	
	51	Tenofovir disoproxil fumarate Emtricitabine With a third viral agent that is a NNRTI or PI.	C.C. stable w/wo pharmaceutical dosage Whether or not oral	
	52	Tenofovir disoproxil fumarate Emtricitabine With a third viral agent that is a PI.	C.C. stable w/wo pharmaceutical dosage Whether or not oral	
	53	Tenofovir disoproxil fumarate Emtricitabine With a third viral agent that is a NNRTI.	C.C. stable w/wo pharmaceutical dosage Whether or not oral	
	54	Tenofovir disoproxil fumarate Emtricitabine With a third viral agent that is Reyataz, Kaletra or Sustiva.	C.C. stable w/wo pharmaceutical dosage Whether or not oral	
Pharmaceutical dosage form	55	Tenofovir disoproxil fumarate Emtricitabine	C.C. stable oral	Article 10
	56	Tenofovir disoproxil fumarate Emtricitabine Reyataz	C.C. stable oral	
	57	Tenofovir disoproxil fumarate Emtricitabine Kaletra	C.C. stable oral	

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Protection	Claim	Compounds	Details	Violated Article
	58	Tenofovir disoproxil fumarate Emtricitabine Sustiva	C.C. stable oral	

III-APPLICATION

With all of the above, the organizations require the **DISMISSAL** of patent claim PI0406760-6 entitled "**Compositions and Methods for Antiviral Therapy Combination**," since it contradicts directly the requirements for patentability and other requirements stipulated by the Law of Industrial Property.

Accordingly,
we request the granting of the above.

Rio de Janeiro, August 20th, 2010.

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List of Attached Documents:

- DOC 1 - ABIA documents;
- DOC 2 - CONECTAS documents;
- DOC 3 - GAPA-SP documents;
- DOC 4 - GAPA-RS documents;
- DOC 5 - GRAB documents;
- DOC 6 - GESTOS documents;
- DOC 7 - GIV documents;
- DOC 8 - IDEC documents;
- DOC 9 - FENAFAR documents;
- DOC 10 - RNP+/SLS documents.

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** formulations and new compositions, as well as processes for their preparation, should be considered obvious given the prior art, in particular, when only one active ingredient is claimed with carriers or excipients known or not specified. **As an exception, the claims of this type could be patentable if it produces a really unexpected or surprising effect, for example, when it resolves, not obviously or a problem really difficult or a long-standing need, as a considerable decrease in side effects, or when the solution to the problem is placing an enormous advantage compared to the state of the art. (Emphasis added.)**