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April 05th 2012

Third Party Opinion under Article 112 of the Law on Intellectual Property No. 50/2005/QH11 (as amended by Law No. 36/2009/QH12) against Viet Nam Application No. 1-2007-01909 in the name of Abbott Laboratories

Dear National Office of Intellectual Property of Vietnam,

The Vietnam National Network of People Living with HIV/AIDS (VNP+) is a non-profit patient group organisation that represents people living with HIV/AIDS individuals, groups and provincial networks in Vietnam. It is an organization run, by and for people living with HIV and AIDS. VNP+ works to advocate for the rights of HIV positive people including care and support, to fight stigma and discrimination, and are involved in prevention interventions to ensure they are able to have access to antiretroviral (ARVs) drugs. VNP+ was officially established in 2008. And it has been registered as name of the Action Center for People living with HIV/AIDS since 2009. Its network members have expanded to 128 groups and networks in all over the country. Currently VNP+ office is located in Hanoi and involved in many activities, with a diverse list of partners, to promote the health and well being of positive people. These include against PLHIV discrimination, treatment access and preparedness and increasing the involvement of PLHIV in all facets of the HIV/AIDS response towards the epidemic. VNP+ brings together PLHIV self-help groups, alliances and networks at provincial/city level currently engaged in HIV/AIDS prevention and control in Viet Nam. Within this mandate, one of the key roles of VNP+ is to ensure that unmerited patents that could harm affordable access to key ARVs are not granted.

One such patent application of concern is Vietnamese Application No. 1-2007-01909 (‘01909), which derives from International Application No. PCT/US2006/005944 ((Published as WO2006/091529). Accordingly, as permitted under Article 112 of the Law on Intellectual Property No. 50/2005/QH11, as amended by Law No. 36/2009/QH12 (Law No. 50/2005/QH11 and 36/2009/QH12), we set out below our written opinion as to why ‘01909 should not be granted a patent.

Before setting out our opinion, we would like to provide a brief background as to the subject matter claimed in '01909.

Background to '01909

The HIV/AIDS epidemic poses one of the greatest challenges to global public health. Roughly over 40 million people worldwide are living with HIV/AIDS, with approximately 67,000 (and increasing) adults in Viet Nam currently in need of ARV treatment.[1] As more and more patients develop drug resistance to their first-line regimen, they will require newer second-line medication.

Lopinavir and ritonavir are classified as protease inhibitors and form a key part of second-line HIV medication as recommended by the World Health Organization. The patent application of concern here, '01909, claims a new solid dosage pharmaceutical formulation comprising lopinavir and/or ritonavir. Both lopinavir and ritonavir are previously patented compounds. The first patent filed for the compound lopinavir dates back to 1995 (U.S Provisional application No. 08/572, 226) and 1989 for ritonavir (US Application No. 355,945). Since these dates, the Applicant of '01909, Abbott Laboratories, has patented several versions of formulations covering lopinavir and/or ritonavir, including the same dosage formulation claimed in '01909. Through its patenting practices, Abbott Laboratories seeks to extend the patent life and its exclusive control over the soon to be expiring patents covering the compounds lopinavir and ritonavir. By doing so, Abbott Laboratories is aiming to prevent legitimate and significantly more affordable generic versions of lopinavir/ritonavir, which currently costs in the region of $1092 to $2767 per patient per year in Vietnam.

While the above facts are not the grounds for our opinion under Article 112, we respectfully ask that they are taking into full consideration when examining '01909.

Opinion against the Grant of Protection for Application No. 1-2007-01909

It is the opinion of VNP+ that application '01909 should not be granted patent protection based on the following grounds:

1. In light of prior art and common general knowledge, '01909 lacks novelty and inventive step as required under Article 58 of Law No. 50/2005/QH11 and 36/2009/QH12.

2. The claimed subject matter of '01909 is merely a method for treating humans and, therefore, does qualify as an invention under Article 59 Law No. 50/2005/QH11 and 36/2009/QH12.

Each of the above grounds are addressed in detail below.

'1909 lacks novelty and inventive step

[1] UNAIDS Viet Nam 2010 Progress Report at page 27 available at http://www.unaids.org/en/dataanalysis/monitoringcountryprogress/2010progressreportssubmittedbycountries/vietnam_2010_country_progress_report_en.pdf

The techniques for the pharmaceutical dosage form claimed in '01909 have already been claimed and disclosed in the following earlier patents:

a) WO2005/039551 ('551) attached as **Exhibit 1** (Granted as Viet Nam Patent No. VN 1-0009900 (Application No. 1-2006-00476)): which has an earlier priority date of 28 August 2003, filing date of 23 August 2004 and was published on 6 May 2005.

The subject matter covered by '551 virtually claims the very same solid pharmaceutical dosage form claimed in '01909. For example, '551 covers a solid dispersion of at least one protease inhibitor (including ritonavir and/or lopinavir) with at least one pharmaceutical acceptable water-soluble polymer (the said water-soluble polymer having Tg of at least 50c) and at least one pharmaceutically acceptable surfactant (the said surfactant having an HLB value of from about 4 to 10). The dosage form claimed in '551 comprises a glassy solution or solid solution of the said protease inhibitor and has the same ratio of about 5 to 30% of the total dosage form as claimed in '01909. Moreover, like '01909, '551 claims better bioavailability based on a fed and fasted state (see Protocol for Oral Bioavailability Studies on page 15, lines 11-25 of '551).

The solid pharmaceutical dosage form claimed in '551 is essentially the same patent now being claimed by the in '01909.

b) WO2004/032903 (see US 7846477 ('477) for English translation) attached as **Exhibit 2**: which has an earlier priority date of 9 October 2002, filing date of 9 October 2003 and publication date of 22 April 2004.

The '477 patent is relevant prior art because it discloses solid dosage forms for use in the treatment of HIV comprising solid solutions or solid dispersions of lopinavir in a water-soluble polymer (with a Tg of at least 50c) and a surfactant. As '477 does not specify how the said dosage forms are to be administered i.e. it does not disclose that they are administered to the patient "without regard to food", it can be said to capture the benefits for the dosage form claimed in '01909.

c) US6599528 ('528) attached as **Exhibit 3**: which has an earlier filing date of 17 March 2000 and publication date of 29 July 2003.

'The '528 patent is relevant prior art as it teaches the composition of protease inhibitors (which would include the subject matter of '01909 i.e. lopinavir and ritonavir) with water-soluble polymers such as copovidone and at least one surfactant. '528 also discloses that suitable and preferred surfactants have an HLB (hydrophilic lipophilic balance) value of 2-18, which captures the HLB range of 4-10 described in '01909.

d) WO2001/34119 ('119) attached as **Exhibit 4**: which has an earlier priority date of 12 November 1999, filing date of 10 November 2000 and publication date of 17 May 2001.

The '119 patent is relevant as it discloses a solid dispersion form comprising ritonavir and/or lopinavir, a water-soluble carrier such as polyethylene glycol (PEG), a crystalline inhibitor such as polyvinylpyrrolidone (PVP) and a surfactent. Although

this patent incorporates PVP in a PEG matrix, it is common general knowledge in the field that PVP could be used as a matrix itself. As such this patent makes it obvious for a person skilled in the art to make a solid dispersion using a PVP matrix as claimed for the solid dosage formulation in '01909.

e) US2002/0198160 ('160) attached as **Exhibit 5**: which has and earlier priority date of 1 May 2001, filing date of 29 April 2002 and publication date of 26 December 2002.

The '160 patent discloses that lopinavir and or the pharmaceutically active agent may be administered as part of one or more pharmaceutical compositions, which may also contain ritonavir. '160 describe how a surfactant such as sorbitan monlaurate may be added to the pharmaceutical composition of ritonavir and lopinavir.

f) US2001/0051721 ('721) attached as **Exhibit 6**: which has an earlier priority date of 30 March 2000, filing date of 27 February 2001 and publication date of 13 December 2001.

The '721 patent is relevant as it discloses that when administered for treatment of an HIV infection, lopinavir is preferably administered in combination with ritonavir in a ratio of 4:1 (lopinavir:ritonavir). This disclosure clearly destroys the novelty of claim 3 in '01909.

Based on the prior art above, it is plainly obvious that the solid pharmaceutical dosage form claimed in '01909 lacks novelty.

Even assuming that some of the claims in '01909 are novel, which we do not believe is the case, the above prior art shows that there has been no inventive step. The technical solutions claimed in 01909 were already disclosed and signposted by the above prior art. As such, the techniques claimed in '01909 would have been obvious to a person skilled in the art of formulation.

'01909 is not an invention under Article 59

Article 59 of Law No. 50/2005/QH11 and 36/2009/QH12 provides that 'human and animal disease prevention, diagnostic and treatment methods shall not be protected as inventions.

The subject matter forming the invention in '01909 is nothing more than a method for treating humans disguised as a solid pharmaceutical dosage formulation. While the Applicant is claiming a solid dosage formulation that increases the bioavailability of lopinavir and/or ritonavir, this outcome is entirely dependent on whether the said patient taking the dosage form is in a fed or fasted state. The 'discovery' that administration of the claimed dosage forms under fasted or fed conditions, is nothing more than an additional item of knowledge about the dosage forms therapeutic application but which does not warrant patent protection. That the earlier patent '551 already discloses this knowledge already shows that the Applicant is merely seeking to incrementally extend its protection over the compounds ritonavir and lopinavir.

Therefore, what the Applicant is requesting patent protection for is a method of

administration (depending on a fed or fasted state) of the dosage form and the clinical data that it claims, in particularly in claims 6-14. Such claims are merely treatment methods and should be rejected as such.

The opinion above clearly sets out why ‘01909 should be refused in its entirety. The granting of patent protection to ‘01909 would amount to double–patenting by the Applicant and only further delay legitimate generic competition and affordable access to the many Vietnamese patients seeking access to this medicine.

Sincerely

Do Dang Dong - Chairman
On behalf of Vietnam National Network of People Living with HIV/AIDS