

PRE-GRANT REPRESENTATION BY WAY OF OPPOSITION  
UNDER SECTION 25(1) OF THE PATENTS ACT  
1970(39 OF 1970) AND RULE 55 (1) OF THE RULES  
AS AMENDED BY THE PATENTS (AMENDMENT) ACT, 2005

The Patent Controller,  
Chennai

**Re: Patent Application No. 805/MAS/1997 filed on 21 April 1997 titled “Antivirally Active Heterocyclic Azahexane Derivatives”**

**STATEMENT OF FACTS/ EVIDENCE**

1. The address of the Opponents for service of all notices and processes is as shown below. The Opponents may also be served notices and processes on its counsel at First Floor, No. 4A, M.A.H. Road, Tasker Town, Shivajinagar, Bangalore, 560 051.
2. The Indian Network for People Living with HIV/AIDS (“INP+”), a community-based, non-profit organisation, registered as a society under the Tamil Nadu Societies Registration Act in May 1997, having its main office at Flat No. 6, Kash Towers, No. 93, South West Boag Road, T. Nagar, Chennai, 600017, and the Karnataka Network of People Living with HIV/AIDS (“KNP+”), a community-based, non-profit organisation, registered as a society under the Karnataka Societies Registration Act 1960, having its main office at 142, 15<sup>th</sup> Main, 8<sup>th</sup> Cross, Wilson Garden, Bangalore, 560030 (collectively, the “Opponents”) hereby make a representation by way of opposition under § 25(1) of the Patent Act 1970, as amended by the Patents (Amendment) Act, 2005 (the “Act”) against the grant of patent application, titled: “Antivirally Active Heterocyclic Azahexane

Derivatives,” made by Applicant Novartis AG (the “Applicant”), bearing Indian patent application No. 805/MAS/1997 filed on 21 April 1997 (the “Application”).

This representation is proper under § 25(1) of the Act as the application has been published but a patent has not been granted. Specifically, this representation is brought under the grounds as stated in § 25(1)(b), (e), (f) and (h) of the Act.

3. INP+ is a national-level community-based organization representing the needs of people living with HIV/AIDS (“PLHAs”). INP+ has under its umbrella many organizations at the State level. KNP+ is the Karnataka state-level member network of INP+. The essence of both INP+ and KNP+ is to provide a voice for PLHAs at the local, regional and national levels in order to facilitate systemic change in critical areas such as care and support, access to treatments and addressing issues of discrimination facing PLHAs in Indian society. Of particular concern to Opponents is the impact of the new product patent regime on PLHAs’ access to safe, effective and affordable HIV/AIDS treatments. The Opponents are opposing the above-mentioned application for a patent under section 25(1) of the Patents Act.
4. The patent application was filed at the Patent Office in Chennai, therefore, the Patent Controller has the jurisdiction to hear and decide this pre-grant opposition in Chennai. Opponents hereby request a hearing as per provisions under Rule 55(1) of the Patent Rules, 2005.

**THE PATENT, IF GRANTED, WILL CAUSE SIGNIFICANT PUBLIC HARM**

5. The present Application relates to a treatment for AIDS, a disease that is causing untold harm and misery in India and throughout much of the developing world. While AIDS, in part through the availability of treatments like the one at issue

here, has become a chronic but manageable lifelong condition for many in the developed world, it remains a death sentence for the millions who cannot afford or otherwise access treatment. Patent protections granted to treatments for AIDS only exacerbate this problem. Patents grant the patent owner a 20-year monopoly, during which the owner is free to set prices at levels impossibly beyond reach for the vast majority of those who are in desperate need of treatment.

6. Due in large part to the availability of safe, effective and affordable generic AIDS medications manufactured by Indian companies, lifesaving treatment has only recently become a realistic option for millions of AIDS-sufferers in India and throughout the developing world. Over the past five years, the prices of first-line antiretroviral drugs has plummeted nearly 100-fold, from around USD 10,000 (Rs. 4,50,000) per person per year to USD 150 (Rs. 6750) per person per year. This dramatic decrease in prices was made possible by the ability of India's generic pharmaceutical industry to manufacture these lifesaving drugs at a fraction of the cost of western pharmaceutical companies.
7. Although the availability of low-cost first generation drugs from India has extended the lives of millions in India and throughout the developing world, the global battle against AIDS is far from over. There is no cure for AIDS, and eventually, even the most effective of first-line regimens loses its efficacy due to the emergence of drug-resistant strains of HIV within the body. Increasingly, in India and throughout the developing world, there is an urgent need to secure an affordable source of second-line AIDS treatments in order to deal with the growing problem of drug-resistance. At the current prices for many of these

second-line treatments, however, the goal of providing continued lifesaving treatment to millions of those in need remains far out of reach.

8. The most effective way to lower the cost of these essential medicines is to promote competition, particularly within India's vibrant pharmaceutical industry. However, in order for there to be any effective generic competition, it is imperative that patents not be granted in India for uninventive, incremental improvements to already-known drugs. Although India was compelled by its WTO obligations to introduce product patent protection for pharmaceutical products through the Patents (Amendment) Act of 2005, India retains full sovereignty in determining the standards that must be met with respect to patentability. As such, India is under no obligation to follow the perilous path that many developed nations have taken in setting loose standards for novelty and inventive step that result in patent protection for incremental innovations, all too often at the cost of public health.
9. The Opponents firmly believe that a proper application of the basic standards for novelty and inventive step in the context of the Indian Patents Act will result in the invalidation of the current Application. The Opponents, therefore, humbly request that this Patent Office scrutinise the Application with special care, as it is this Office's decision that will determine whether millions of people will have affordable access to lifesaving treatment.

#### **TECHNICAL BACKGROUND OF THE APPLICATION**

10. The current Application relates to a class of antiretroviral medicines called protease inhibitors. Prior to the development of protease inhibitors, most

treatments for AIDS focused on inhibiting the reverse transcriptase enzyme, which is responsible for replicating the viral code within the host cell. However, as a result of research funded by the United States government's National Institute of Allergy and Infectious Diseases ("NIAID"), the protease enzyme was discovered and identified as a promising potential therapeutic target. *See* NIAID AIDS Agenda, (1996), attached hereto as **Exhibit A**.

11. Among the general class of retroviruses, of which HIV is a member, viral replication takes place whereby the infected cell mechanisms are 'hijacked' for the manufacture of viral polyproteins. These polyproteins are long, unbroken protein chains that must then be broken down by the protease enzyme into its component parts to yield the viral structural proteins. Without these polyproteins being cleaved by the protease enzyme into functional proteins, only immature, non-infective virions are produced. The HIV protease enzyme was identified through NIAID-supported research as responsible for this critical step in viral reproduction, and consequently became a key target for further publicly funded research. *See* *Id.*, *see also* Tomasselli, A., et al., "The Complexities of AIDS: An Assessment of the HIV Protease as a Therapeutic Target," *Chimica Oggi*, (1991), p. 10, attached hereto as **Exhibit B**.

12. Through further publicly funded research, other important discoveries were made that facilitated in the development of effective inhibitors of the protease enzyme, including the discovery of the structure of the protease enzyme, as well as assays designed to measure the inhibition of the protease enzyme. *See* **Ex. A**. Additionally, the development of effective HIV protease-specific inhibitors was

expedited by the discovery that the HIV protease is a member of the aspartic proteinase family, which includes well-known aspartic enzymes such as renin, for which effective inhibitors had already been developed. *See* Debouck, C. and Metcalf, B., “Human Immunodeficiency Virus Protease: A Target for AIDS Therapy,” *Drug Development Research* 21:1-7, (1990) at p. 6, attached hereto as **Exhibit C** and references cited therein; *see also* Norbeck, D. and Kempf, D., “HIV Protease Inhibitors,” *Annu. Rep. Med. Chem.*, 26:141-150 (1991) at pp. 143-144, attached hereto as **Exhibit D** and references cited therein; Navia, M. et al., “Three-dimensional Structure of Aspartyl Protease from Human Immunodeficiency Virus HIV-1,” *Nature*, 337:615-620 (1989), at 620, attached hereto as **Exhibit E**, and references cited therein.

13. Thus, well before the priority date of the present Application, the HIV protease enzyme had been identified as a key therapeutic target, the three-dimensional structure of the protease enzyme, including a detailed mapping of the active site, had been disclosed, and various assays to determine the inhibitory effect of candidate substances had been developed. Additionally, given the HIV protease enzyme’s structural similarity with other aspartic proteases for which inhibitors had already been developed, researchers could draw upon a wealth of pre-existing technical knowledge in developing effective inhibitors of the HIV protease. This knowledge, combined with modern computational three-dimensional quantitative structure-activity relationship (“3D-QSAR”) techniques, allowed researchers to identify with relative ease several powerful inhibitors of the HIV protease enzyme for further testing and analysis. *See, e.g.*, **Ex. D** at 144; Oprea, T. et al, “Three-

Dimensional Quantitative Structure-Activity Relationship of Human Immunodeficiency Virus (I) Protease Inhibitors,” J. Med. Chem., 37:2206-2215 (1994), attached hereto as **Exhibit F**.

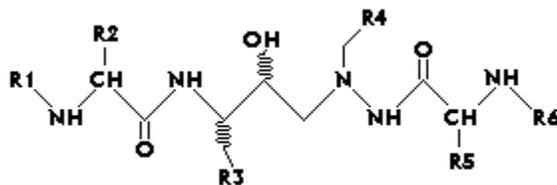
14. As a result of these and other advancements, several protease-inhibiting compounds had already been patented prior to the priority date of the present Application. Among these patents, one in particular: WO9419332 (the “‘332 patent” (attached hereto as **Exhibit G**) discloses compounds that overlap considerably with the compound disclosed in the present Application. Indeed, as will be demonstrated in detail below, the ‘332 patent effectively discloses the compound that is the subject of the present Application.

15. Tellingly, the Application’s discussion of the relevant prior art makes no mention of the ‘332 patent, nor does it disclose the considerable body of pre-existing technical knowledge that led to the development of protease inhibitors. It is, however, in this context that the present Application must be evaluated. When the Application is evaluated in light of all of the relevant prior art, it becomes clear that whatever technical advancement is embodied in the present Application is, at most, the result of a non-inventive process of trial and error. The Opponents humbly submit that a meaningful application of the standards of novelty and inventive step provide ample basis for rejecting the present Application.

#### **GROUND**

16. This Opposition is based upon the following grounds under § 25(1) of the Act, each of which is without prejudice to any other:

- a. § 25(1)(b)(ii) - that the invention so far as claimed in any claim of the complete specification has been published before the priority date of the claim elsewhere in any other document.
- b. §25(1)(e) – that the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the applicant’s claim.
- c. § 25(1)(f) – that the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act, in particular under § 3(d).
- d. § 25(1)(h) – that the applicant has failed to disclose to the Controller the information required by § 8 or has furnished the information which in any material particular was false to his knowledge.
17. The Applicant has failed to meet its burden of showing that the alleged invention described in the Application is entitled to a patent under the Act. Essentially, all of the claims in the Application relate to a compound of the following formula:



wherein the functional groups R<sub>1</sub> through R<sub>6</sub> are as defined in the claims. The claims may be summarised as follows:

- (a) Claim 1 relates to a compound of the formula expressed above, with R<sub>1</sub> through R<sub>6</sub> are as defined in the claim.
- (b) Claims 2-9 are dependent on claim 1, and identify preferred expressions of the functional groups.
- (c) Claims 10-13 are dependent on claims 1-9, and relate to the use of the claimed compounds in pharmaceutical compositions.
- (d) Claim 14 is a process claim for the preparation of the compound of claim 1.

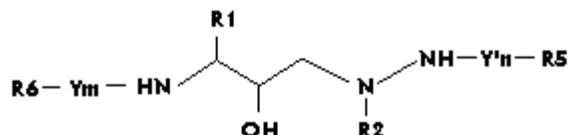
However, as will be demonstrated in further detail below, such a compound was disclosed and thus made part of the state of the art by the disclosures contained within the '332 patent. Furthermore, the claimed compound was obvious to one skilled in the art in light of the relevant prior art. Additionally, the claimed compound is, at most, a new form of a known substance, and is thus not patentable under § 3(d) of the Act. Finally, the Applicant has failed to provide the Patent Controller with the information required under § 8, and thus should be denied a patent on this ground. Each of these separate and independent grounds are discussed in further detail below.

***The Alleged Invention Is Anticipated by a Prior Publication under § 2(j) and Should Be Denied under § 25(1)(b) of the Act.***

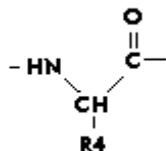
18. Claim 1 and dependent claims 2-13 of the present Application fail for lack of novelty. Under Section 2(j), an invention is defined as a new product or process involving an inventive step and capable of industrial application. Section 25(1)(b) provides a basis for denying an application if the invention has been published before the priority date of the claim, in India or elsewhere, in any other document.

Thus, if a publication published prior to the present Application discloses the claimed invention, then the Application lacks novelty and must be rejected.

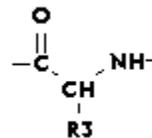
19. In the present case, the compound described in '332 patent encompasses and discloses the compound that is the subject of the present Application. The '332 patent discloses a protease inhibiting compound of the following formula:



This patent states that Y can be:

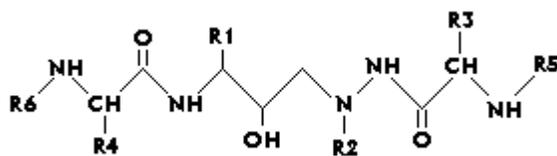


and that Y' can be:

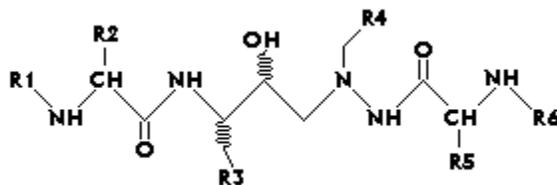


and further, that the values for  $m$  and  $n$  can be either 0 or 1. *See Ex. G*, pp. 3-5.

Thus, assuming that the values for  $m$  and  $n$  are both 1, and substituting in Y and Y' as defined above, the '332 patent discloses a compound of the following formula:



The structure of the above molecule disclosed in the '332 patent is identical to that disclosed in the present Application:



- Thus, if R<sub>6</sub>, R<sub>4</sub>, R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub> and R<sub>5</sub> of the '332 patent correspond, respectively, to R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, CH<sub>2</sub>R<sub>4</sub>, R<sub>5</sub> and R<sub>6</sub> of the present Application, then the '332 patent will have disclosed the molecule that is the subject of the present Application and thus destroy its novelty.
20. The present Application defines R<sub>1</sub> and R<sub>6</sub>, independently, as a lower alkoxy carbonyl (i.e., group of the general formula, COOR, with R being an alkyl group. *See* Application, p. 129. Similarly, the '332 patent describes R<sub>5</sub> and R<sub>6</sub>, independently as: “-C(T)-G-R<sub>7</sub>” wherein T and G can be O, and R<sub>7</sub> can be a lower alkyl. *See Ex. G*, p. 7. Thus, the '332 patent discloses R<sub>5</sub> and R<sub>6</sub> as a lower alkoxy carbonyl.
21. R<sub>2</sub> and R<sub>5</sub> are independently defined in the Application as a “secondary or tertiary lower alkyl or lower alkylthio-lower alkyl.” *See* Application, p. 129. Correspondingly, the '332 patent specifically discloses lower alkyl for R<sub>4</sub> and R<sub>3</sub>. *See Ex. G*, p. 5.
22. R<sub>3</sub> is defined in the Application as a “phenyl that is unsubstituted or substituted by one or more lower alkoxy radicals, or C<sub>4</sub> - C<sub>8</sub> cycloalkyl.” *See* Application, p. 129. In the formula presented in the Application, R<sub>3</sub> is bonded by way of an alkyl group (CH<sub>2</sub>) to the molecule. Correspondingly, R<sub>1</sub> of the '332 patent can be an (aryl)alkyl, where “aryl” is defined as a “C<sub>6</sub> monocyclic aromatic ring” (i.e., phenyl) that can also be unsubstituted or substituted with, among other things alkoxy radicals. *See Ex. G*, pp. 3, 24.
23. R<sub>4</sub> is defined in the Application as a “phenyl or cyclohexyl each substituted in the 4-position by unsaturated heterocyclyl that is bonded by way of a ring of carbon

atom, has from 5 to 8 ring atoms, contains from 1 to 4 hetero atoms selected from nitrogen, oxygen, sulfur, sulfinyl (-SO-) and sulfonyl (-SO<sub>2</sub>-) and is unsubstituted or substituted by lower alkyl or by phenyl-lower alkyl.” See Application, p. 129. In the formula presented in the Application, R<sub>4</sub> is bonded by way of an alkyl group (CH<sub>2</sub>) to the molecule. The -CH<sub>2</sub>R<sub>4</sub> is equivalent to the ‘332 patent’s definition of R<sub>2</sub>, which states that it can be (aryl)alkyl. Again, aryl is defined in the ‘332 patent as able to be substituted with a heterocyclic moiety. See **Ex. G**, pp. 3, 24.

24. Thus, in addition to disclosing the identical molecular structure, the ‘332 patent encompasses and discloses all of the corresponding functional groups as claimed in the present Application, as illustrated in the table below:

805/MAS/1997	WO 9419332
R <sub>1</sub> – lower alkoxy carbonyl [-COOR, with R being alkoxy]	R <sub>6</sub> - -C(T)-G- R <sub>7</sub> ; T and G can be O, R <sub>7</sub> can be lower alkoxy.
R <sub>2</sub> – secondary or tertiary lower alkyl or lower alkylthio-lower alkyl	R <sub>4</sub> - loweralkyl
R <sub>3</sub> – unsubstituted or substituted phenyl, bonded via alkyl (CH <sub>2</sub> )	R <sub>1</sub> – (aryl)alkyl
CH <sub>2</sub> R <sub>4</sub> – phenyl or cyclohexyl substituted by heterocyclyl, bonded via alkyl (CH <sub>2</sub> )	R <sub>3</sub> – (aryl)alkyl; aryl can be substituted by heterocyclyl.
R <sub>5</sub> – secondary or tertiary lower alkyl or lower alkylthio-lower alkyl	R <sub>2</sub> - loweralkyl
R <sub>6</sub> – “lower alkoxy carbonyl” [-COOR, with R being alkyl]	R <sub>5</sub> - “-C(T)-G- R <sub>7</sub> ,” T and G can be O, R <sub>7</sub> can be lower alkyl.

25. Although it is true that the ‘332 patent discloses a larger class of compounds than those covered by the present Application, this alone is insufficient to render the claimed compound novel. As this Patent Office has previously held, novelty is destroyed where a prior reference makes a disclosure sufficient to enable a person skilled in the art to practice the claimed invention. See Decision in the Matter of

Application No. 1602/MAS/1998, 25 January 2006, at p. 3, attached hereto as **Exhibit H**. In that matter, this Patent Office held that a prior disclosure of a base compound and “any pharmaceutically acceptable salt thereof,” along with a generic list of several candidate acids with which to form such a salt, was sufficient to destroy the novelty of a subsequent application that attempted to claim the beneficial properties of one specific salt form of the compound. *Id.* This was because the disclosure of a base compound and any number of candidate acids was a sufficient disclosure to enable someone of ordinary skill in the art to create the corresponding salts without any further instruction or guidance. *Id.*

26. Likewise, here, it is indisputable that among the compounds disclosed in the ‘332 patent, one of them corresponds to the precise compound that is claimed in the present Application. Given this fact, and the Applicant’s own admission that the subject compound can be prepared according to processes known *per se* (see Application, p. 18), the disclosures contained in the ‘332 patent are sufficient to anticipate the alleged invention. As such, claim 1, along with dependent claims 2-13, fail for lack of novelty, and should be rejected on this basis.

***The Alleged Invention Is Obvious to a Person Skilled in the Art under § 2(ja) and Should Be Denied under §25(1)(e) of the Act.***

27. Assuming without admitting that the disclosures in the ‘332 patent did not fully disclose the compound claimed in the present Application, the ‘332 patent was nevertheless sufficient to render the present Application obvious to one skilled in the art. This is particularly true in light of all of the pre-existing knowledge about the HIV protease enzyme that was available at the time of the present Application. As discussed above, government supported research was responsible for the

discovery of the HIV protease enzyme as a therapeutic target. *See Ex. A.* Moreover, NIAID supported research revealed the three-dimensional structure of the protease enzyme and developed assays to determine the efficacy of protease-inhibiting compounds. *Id.* Additionally, recent advancements in 3D-QSAR techniques allowed researchers to use computational models to suggest functional groups, the geometry of structural features, and regions of electrostatic and steric interactions essential for activity or fit to the receptor binding/active site. *See Ex. F* and references cited therein.

28. For all of the reasons stated above, claim 1 and its dependent claims 2-13 of the present Application also fail because they lack the inventive step required for patentability. Under § 2(ja) of the Act, “inventive step” is defined as “a feature of an invention that involves technical advance as compared to the existing knowledge...that makes the invention not obvious to a person skilled in the art.”
29. The inventive step requirement exists to ensure that only genuine inventions, and not routine or incremental improvements to existing technologies, are granted patent protection. The ultimate touchstone of this requirement is thus genuine *inventiveness* – the fact that an applicant may have expended time and money developing an improvement is insufficient to satisfy this requirement. Likewise, the fact that an application represents a significant improvement over the state of the art is insufficient if the improvement was obvious or merely the result of routine trial and error. Patents granted on obvious improvements to existing technologies impede rather than encourage innovation, as they confer private ownership over ideas that would otherwise be in the public domain. As such, it is

imperative that the Patent Controller vigorously apply the inventive step requirement in the examination process.

30. As we have seen, the disclosures in the '332 patent overlap with and encompass the compound claimed in the present Application. Furthermore, the Applicant has admitted that the compound at issue can be prepared with processes known *per se*. See Application, p. 18. Given these facts, and the pre-existing knowledge and techniques available to Applicant at the time of the alleged invention, it is clear that whatever technical advance that is embodied in the present Application is nothing more than the product of, at most, a routine, uninventive trial and error process. As this Patent Office has already held, compounds obtained in a “customary manner” from generic prior disclosures fail to satisfy the inventive step requirement. See **Ex. H** at p. 3. As such, claim 1 and its dependent claims 2-13 fail because they lack the inventive step required for patentability.

***The Alleged Invention Is Not an Invention under § 3(d) Because It Is the Mere “Discovery” Of a New Form of a Known Substance, and Should Be Denied Under § 25(1)(f) of the Act.***

31. Without prejudice to the grounds of opposition already stated, the alleged invention is not patentable under the Act because it is, at most, the mere “discovery” of a new form of a known substance. Under § 3(d) of the Act, the “mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance” is not an invention within the meaning of the Act. For all of the reasons already stated, the compound that is the subject of the Application is, at most, a new form of the compounds covered under the '332 patent. Because of this, the Applicant is required under § 3(d) to

show that there is an enhancement of the known efficacy of this new form. The Applicant has failed to do so.

32. The extent of Applicant's demonstration of efficacy is limited to showing the alleged inhibitory activity of the various examples described in the specification. See Application, pp. 126-127. However, the fact that the claimed compounds have an inhibitory effect on HIV protease is insufficient to satisfy the requirements of § 3(d). The Applicant was required under the law to show not only that the claimed compounds are effective, but that they represent a significant improvement in properties with regard to efficacy over the other compounds disclosed in the '332 patent. Because Applicant has failed to do so, the Application should be denied under § 3(d) of the Act.

***The Applicant has failed to disclose the information required by § 8 or has furnished information that was false to his knowledge, and thus the Application should be denied under § 25(1)(h) of the Act.***

33. Further without prejudice to the grounds of opposition already stated, the Applicant has, at a minimum, failed to disclose information relating to foreign applications as required under § 8 of the Act. This fact alone is sufficient grounds for denying the present Application under § 25(1)(h) of the Act. Section 8 requires an applicant to provide the Patent Controller with information relating to foreign applications covering the "same or substantially the same invention." Section 8 further requires an applicant to undertake to keep the Controller informed, from time to time, as to the status of foreign applications covering the same or substantially the same invention. Under Rule 12(1A), the statement and undertaking under § 8 must be made within three months of filing. Rule 12(2) requires the Applicant to inform the Patent Controller of additional particulars

within three months of the additional filing. The details required by § 8 are clear from Form 3, which include status of the application. Under § 25(1)(h), a failure to comply with § 8 is grounds for opposition and is therefore sufficient to reject an application in its entirety.

**34.** The Applicant, as of the date of filing of the current Application on 21 April, 1997, had already filed an application for a patent in at least two foreign patent offices – the United States and Europe – for substantially the same alleged invention as the one at issue here. *See* EP 0900210 (filed 14 April, 1997) and US 5849911 (filed 9 April, 1997), attached hereto as **Exhibit I** and **Exhibit J**, respectively. Both of these patents have the identical title as the current Application – “Antivirally Active Heterocyclic Azahexane Derivatives,” and both patents claim priority from the same Swiss patent applications as the current Application. *Id.* A cursory review of both these patents shows that they both concern the same compound as the one at issue in the present Application. Because both of these patent applications concerned the “same or substantially the same” alleged invention as the one at issue here, the Applicant was obligated under § 8 of the Act to inform the Patent Controller of this information in Form 3 at the time of filing. Since the Applicant has failed to do so, § 25(1)(h) provides a basis for rejecting the entire Application.

**35.** Further, in the European patent, the Applicant discloses the ‘332 patent, along with other patents covering similar compounds, as relevant prior art. *See Ex. I*, p. 2, lines 44-58 – p. 3, lines 1-3. However, such a discussion of directly relevant prior art is absent in the present Application. Given the disclosure of this directly

relevant prior art in the European application, it is indisputable that the Applicant had knowledge of its existence, and yet failed to notify this Patent Office of this fact. The Opponents submit that this amounts to inequitable behaviour on the part of Applicant, and that the failure to disclose such directly pertinent information amounts to furnishing information that was false to the Applicant's knowledge in direct contravention to § 25(1)(h) of the Act. On this basis, the entire Application should be denied.

### **CONCLUSION**

36. Given all of the foregoing, Opponents hereby humbly request that the Patent Office reject the Application on the following grounds:
- (a) Claim 1 and its dependent claims 2-13 of the present Application fail for lack of novelty;
  - (b) Claim 1 and its dependent claims 2-13 of the present Application fail for lack of inventiveness;
  - (c) Claim 1 and its dependent claims 2-13 of the present Application is not an invention under § 3(d) of the Act;
  - (d) The entire Application is defective as Applicant has failed to provide the Controller with information as required under § 8 of the Act.
37. Opponents further request that the Office grant a hearing as per Rule 55(1) of the Patent Rules.

**Respectfully submitted,**

On Behalf of the Indian Network for People Living with HIV/AIDS,

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K.K. Abraham

Date

On Behalf of the Karnataka Network of People Living with HIV/AIDS,

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Date