PRE-GRANT REPRESENTATION BY WAY OF OPPOSITION UNDER SECTION 25(1) OF THE PATENTS ACT 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 959/MAS/95, "2-(2-Amino-1, 6-Dihydro-6-oxo-purin-9-yl)-methoxy-1, 3-propanediol Derivative", filed 27 July 1995.

STATEMENT OF FACTS

1. The Tamil Nadu Networking People with HIV/AIDS (TNNP+), a community – based non-profit organization , Society Registration Number 14/2005, registered under the Societies Registration Act of 1989 in February 2005, and 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, hereby makes a representation by way of opposition under section 25(1) of the Patent Act 1970, as amended by the Patents (Amendment) Act, 2005 (the "Act") against the grant of patent application, titled: "2-(2-Amino-1, 6-Dihydro-6-oxo-purin-9-yl)-methoxy-1, 3-propanediol Derivative," made by Applicant F Hoffmann-La Roche (the "Applicant"), bearing Indian patent application No. 959/MAS/95, filed on 27 July 1995 (the "Application"). This representation is proper under section 25(1) of the Act as the Application has been published but a patent has not been granted.

2. INP+ is a national community-based organization representing the needs of people living with HIV/AIDS ("PLHAs"). INP+ is the national level organization and has under its umbrella many organizations at the State level. TNNP+ is the Tamil Nadu state-level member network of INP+. The essence of INP+ 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 the Opponent is the impact of the new product patent regime on PLHAs' access to safe, effective and affordable HIV/AIDS treatments. The Opponents therefore have a direct interest in wether patent is granted in this Application.

3. The present Application was filed at the Patent Office in Chennai, and therefore the Patent Controller has jurisdiction to hear this pre-grant opposition in Chennai. The Opponents hereby request a hearing under Rule 55(1) of the Patent Rules, 2005.

4. The Indian Patents (Amendment) Act, 2005 was passed to bring India into compliance with its obligations under TRIPS. Accession to TRIPS, signed in 1995, required India to effect a product patent regime after ten years. Thus, from 1995, it became clear that India would adopt a product patent regime by 2005. Prior to India incurring any obligations under TRIPS, the Patents Act, 1970 only granted patents for processes but not for products. As such, all inventions relating to products that were disclosed prior to 1995 were deemed to form part of the public domain, and remain so today even with the passage of the Act. Thus, any product patent application claiming priority from an application prior to 1995 must be rejected on the grounds that the subject matter of the invention lacks novelty.

5. The Opponents strongly believe that the Application is not eligible for patent under the Patents Act. In particular, we oppose under:
    a. section 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; or

b. section 25(1)(h) – that the applicant has failed to disclose to the Controller the information required by section 8 or has furnished the information which in any material particular is false to his knowledge.

6. Accordingly, under section 25(1) of the Act and Rule 55(1) of the Rules, the Opponent seeks to oppose this Application for patent for the reasons set out below.

7. The present Application relates to valganciclovir, a pharmaceutical compound that is a pro-drug of another known compound, ganciclovir. The claims can be summarized as follows:

   a. Claim 1 is for ganciclovir or any of its salts in the pro-drug form.
   b. Claims 2 to 8 are dependent on Claim 1 and describe different salt components of Claim 1.
   c. Claims 9 and 10 are dependent on Claims 1-8 and describe the addition of an excipient or carrier, and the intravenous use of the compound.
   d. Claim 11 claims a specific formula of the compound.
   e. Claim 12 claims the process for preparing valganciclovir.

GROUNDS

8. The Application is not eligible for patent under the Act because:
   a. The entire application and all its claims were already in the public domain at the time of filing;
   b. The Applicant has failed to provide sufficient information or has provided incorrect information on other applications for patents made in other countries for the same invention.

a. The entire application and all its claims were already in the public domain

9. Patents may only be granted to new inventions. Section 2(j) defines an "invention" as "a *new* product or process involving an inventive step and capable of industrial application" (emphasis added). Thus, to be eligible for patent, a product must be novel and must not have been known. Anything in the public domain cannot be new.

10. Any product invented before 1995 falls in the public domain by virtue of the fact that it was not eligible for patent in India. The present Application was filed in the Chennai Patent Office on 27 July 1995. By the Applicant's own admission, an application for patent for the same invention was filed in the United States on 28 July 1994 (*see* Application, Form 2 at (ii)). Further, the Applicant's own press release states that valganciclovir was discovered in 1994 (*see* "Seven Years after Discovery in Palo Alto, Valcyte™ Receives FDA Approval for Treatment of AIDS-Related CMV Retinitis", press release by Hoffman-La Roche, April 2, 2001, attached as Exhibit 1). The alleged invention was therefore known at least by July 1994. Since the compound was known before 1995, it is in the public domain and forms part of the state of the art.

11. The US application is, by the Applicant's own admission, for the same invention. This is confirmed by studying the description of each application; they are virtually identical. Therefore the entire invention claimed in the Application was already in the public domain and is not new. The Applicant humbly submits that the Application and all its claims are not patentable and should be rejected under section 25(1)(f).

b. The Applicant has failed to provide sufficient information or has provided incorrect information under section 8

12. Section 8 of the Patents Act requires an applicant for patent to furnish the Patent Office with detailed particulars of any patent applications for the same or similar inventions made in any other country, and to undertake to update the Patent Controller of detailed particulars of every other application made subsequent to

filing within the prescribed time. Under Rule 12(1A), the statement and undertaking under section 8 must be made within 3 months of filing. Rule 12(2) requires the Applicant to inform the Patent Controller of additional particulars within 3 months of the additional filing. The details required by section 8 are clear from Form 3, and include status of the application. Under section 25(1)(h), a failure to comply with section 8 is a ground for opposition and is therefore sufficient to reject an application in its entirety.

13. It has come to the Opponent's attention that the Applicant has provided insufficient information under section 8. On the 19 July 1995, the Applicant filed an application for a substantially similar invention in the European patent office (*see* "2-(2-amino-1,6-dihydro-6-oxo-purin-9-yl)methoxy-1,3-propanediol derivative", EP0694547, published 31 January 1996, attached as Exhibit 2, and European Patent Register for EP0694547, attached as Exhibit 3). This claimed priority from the same 28 July 1994 US patent application – application number 281,893 – as the present Application. The European Application was made prior to the present Indian Application and was pending at the time of filing the Indian Application, and details of it should have been disclosed under section 8. This is, of itself, a sufficient ground for rejecting the Application.

14. Furthermore, US application 281,893 was later abandoned, and re-filed as application 453,223 on 30 May 1995 – again, prior to the date of filing in India – and was pending when the Application was filed here (*see* "2-(2-amino-1,6-dihydro-6-oxo-purin-9-yl) methoxy-1,3- propanediol derivative", US6,083,953, July 4, 2000 at "Parent Case Text", attached as Exhibit 4). Since both the present Application and application 453,223 are made by the Applicant, it must be imputed that the Applicant had knowledge of both and knowingly submitted false information to the Patent Controller. This is a sufficient ground under section 25(1)(h) to reject the application in its entirety.

15. Application 453,223 was also subsequently abandoned, and continued in an application of 4 March 1997 (*see* US6,083,9523 above). This last application was granted patent on 4 July 2000 as US6,083,9523. It is interesting to note that both the US patent and the European patent EP0694547 make far narrower claims than the present Application, although the description is almost identical.

16. On the basis of the above, it is submitted that the Application in its entirety should be rejected under section 25(1)(h).

CONCLUSION

17. Given the foregoing, the Opponent humbly requests the Patent Office to reject the Application on both or either of the following grounds:
    a. The alleged invention is in the public domain and is therefore not new;
    b. The Application fails to meet the formal disclosure requirements under section 8

    Both of these grounds relate to material flaws that go to the heart of the Application and either is sufficient to for it to be rejected in its entirety, rather than requiring a claim-by-claim assessment.

18. The Opponent further requests that the Patent 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 (INP+)

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K.K. Abraham ***Date***

On Behalf of the Tamil Nadu Networking with HIV/AIDS (TNNP+)

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Daisy David ***Date***