IP GUIDELINES

DATED AUGUST 7, 2006

PREAMBLE

The IP guidelines for TI Pharma sponsored Projects comply with the European State Aid Rules, the IOP-TTI Regulations and are in line with the Innovation Charter of NFU/VNO/NCW/VSNU. These IP Guidelines have been approved by *the Department of VWS* on [date].

The IP guidelines pertain to and must be applied at the level of individual Projects.

The IP guidelines contain the following sections:

- Preamble.
- Definitions.
- Ground Rules, i.e. the basic framework within which IP-related matters must reside, including the definitions set out below, and from which the Participants may not deviate unless on minor issues or points of interpretation and with the prior written approval of TI Pharma, which approval will not be withheld unreasonably. TI Pharma shall consult with SenterNovem in order to establish whether the applicable rules and regulations allow a proposed deviation.
- TI Pharma, in collaboration with its academic and industrial Partners, will prepare, as a service, a default technical annex to a Project Agreement based upon these Ground Rules. This default technical annex will be used if Participants do not reach an agreement as to specific IP rules as part of the Project Agreement or where they explicitly opt for this default technical annex.

DEFINITIONS

As used herein, the following terms will have the following meanings:

"**Access rights**" means licences and user rights to Foreground IP or Background IP.

"**Appendix**" means the appendix to these IP Guidelines.

"**Affiliate**" means a Person who directly, or indirectly through one or more intermediaries, Controls, or is controlled by, or is under common Control with, another Person.

"**Background IP**" means the intellectual property which is held by Participants prior to the execution of a Project Agreement, or acquired or generated in parallel with it.

"**Commercial Use**" means the direct or indirect utilisation of Foreground IP for developing, creating and marketing a product or process or for creating and providing a service.

"**Control**" means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract, or otherwise.

"**Dissemination**" means the disclosure of Foreground IP by any appropriate means other than publication through patenting of the Foreground IP.

"**Expert**" means an outside expert appointed by the executive board of TI Pharma, in agreement with the relevant parties, for advising on the value of any right to be transferred or granted.

"**Foreground IP**" means the intellectual property arising from a Project.

"Participant" means a Person having rights and obligations under the terms of a Project Agreement.

"**Partner**" means a Participant having rights and obligations under the terms of a partner agreement, made with TI Pharma in view of certain contributions to Projects to be accepted by TI Pharma, and under a Project Agreement.

"**Patent Co-ordinator**" means the Participant identified pursuant to these Guidelines or the Project Agreement who, in addition to its obligations as a Participant, is obliged to carry out the specific co-ordination tasks provided for in these Guidelines and/or the Project Agreement on behalf of TI Pharma and the other Participants.

"**Person**" means any individual, corporation, limited liability company, partnership, trust, joint stock company, business trust, unincorporated association, joint venture, governmental authority or other legal entity of any nature whatsoever.

"**Project**" means all the work referred to in Annex I of the relevant Project Agreement.

"**Project Agreement**" means an agreement, made between Participants of a Project and with TI Pharma in connection with the participation in, contribution to and execution of a Project.

"**Research Use**" means the direct or indirect utilisation of Foreground IP by a Participant, on a non-exclusive basis, in internal research activities.

"**Reasonable Efforts**" shall mean efforts and resources commonly used in the research-based pharmaceutical industry for the research, development and commercialization of a product at a similar stage in its product life taking into account the establishment of the product in the marketplace, the competitiveness of the marketplace, the proprietary position of the product, the regulatory structure involved, the profitability of the product and other relevant factors.

"**Third Party**" means a Person other than TI Pharma, the Participants, the Partners and their respective Affiliates.

"**TI Pharma**" means Stichting Top Institute Pharma, a foundation (*stichting*) established under the laws of The Netherlands, having its registered office in Leiden, The Netherlands, and having its principal place of business at Wassenaarseweg 72, 2333 AL Leiden, The Netherlands.

GROUND RULES

Scope

These Ground Rules shall be applicable between the parties to the Project Agreement. Participants may not deviate from these Ground Rules unless on minor issues or points of interpretation and with the prior written approval of TI Pharma, which approval will not be withheld unreasonably. TI Pharma shall consult with SenterNovem in order to establish whether the applicable rules and regulations allow a proposed deviation.

Ownership

Each Participant will remain the owner of its Background IP.

Foreground IP will be jointly owned by the Project Participants and TI Pharma in accordance with Title 7 of Book 3 of the Dutch Civil Code. TI Pharma owns 10%, the Participants own the remaining 90%, shared in accordance with the aggregate in-cash and in-kind contributions in the Project by each Participant, these contributions to be calculated in accordance with the accounting principles of TI Pharma and notified by TI Pharma in writing to the Participants prior to the execution of the Project Agreement. The inventive contribution of a Participant will be recognized in that any (employee(s) of a) Participant deemed to be an inventor according to United States patent laws will be mentioned on the relevant patent.

Participants can unanimously agree on a different allocation of their legal and beneficial ownership before they embark on a project, e.g. for reasons of protection or logistics, and must incorporate such agreement in the Project Agreement.

Such deviating allocation must be established on at arm’s length terms.

Proceeds of transfer of rights and/or licence are shared pro rato the ownership interest, unless agreed differently between the Participants and TI Pharma and laid down in the Project Agreement on at arm’s length terms.

Access

Access to Background IP must be limited to the extent needed to enable the execution of the Project. Such Access is on request only, subject to the execution of a confidentiality agreement and at no cost. Access rights to

Background IP shall be granted provided that the Participant concerned is free to grant them. Pre-identified Background IP may be excluded by its owner from Access Rights.
The owner of Background IP is not obliged to grant Access Rights needed to commercialize Foreground IP.
Access will be granted to Foreground IP to enable Research Use at no cost.

Protection

Any patents (including patent applications) on Foreground IP shall be prosecuted following a mutual decision of TI Pharma and the Participants to that effect. Participants in the Project will designate one amongst them as Patent Co-ordinator. Any patents on Foreground IP shall be prosecuted and maintained by the Patent Co-ordinator in accordance with the instructions of the joint Participants. Each Participant must notify the other Participants within twenty-four (24) months from the first filing date of the patent whether it wishes to exploit the patent by putting it to Commercial Use, either within its own company or through licensing to Third Parties. The Participants will, upon such notification, negotiate a transfer of ownership or the grant of an exclusive or semi-exclusive license to the Participant taking up exploitation in good faith on at arm's length terms and conditions, taking into account the aggregate in-cash and in-kind contributions in the Project of such Participant, these contributions to be calculated in accordance with the accounting principles of TI Pharma and notified by TI Pharma in writing to the Participants prior to the execution of the Project Agreement. Any such agreement will include the obligation of the Participant taking up exploitation of the patent to reimburse TI Pharma and the other Participants for the out-of-pocket costs incurred in the prosecution (or filing) and maintenance of the patent.

Any action against infringement shall be initiated by the Patent Co-ordinator but only after the prior approval of a majority (in accordance with ownership interest) of the Participants owning the Foreground IP.

Costs related to these actions and to the filing and maintenance of the patent on the Foreground IP are borne in accordance with ownership interest, unless agreed otherwise and laid down in the Project Agreement.

Where a Participant does not wish to join with TI Pharma and the other Participants in the prosecution of a patent or to continue any filing or to join in any further filings, it shall inform TI Pharma and the other Participants. In such a case the ownership interest of that Participant in the Foreground IP shall adhere to TI Pharma and the other Participants in accordance with their ownership interest in the Foreground IP and the relevant Participant shall co-operate in the execution of any formalities to effect such assignment.

Such assignment shall be without prejudice to any Access Rights for Research Use of the Foreground IP.

Where the joint Participants do not wish to exploit any patent on Foreground IP, they shall endeavour to identify a Person willing and able to exploit that patent on Foreground IP by putting it to Commercial Use, either within its own company or through licensing to Third Parties. In that case, the Participants will negotiate a transfer of ownership or the grant of an exclusive or semi-exclusive license to the Third Party taking up exploitation.

Commercial Use, Transfer of ownership

Without prejudice to the third paragraph of this clause, (a) Participant(s) wishing to obtain a licence for the Commercial Use of Foreground IP, or to obtain full ownership of the Foreground IP held by the other Participants in the Project and by TI Pharma, will notify the other Participants and TI Pharma, who will negotiate on price and the other material terms and conditions of the proposed transfer in good faith on at arm's length terms and conditions, taking into account the aggregate in-cash and in-kind contributions in the Project of such Participant, these contributions to be calculated in accordance with the accounting principles of TI Pharma and notified by TI Pharma in writing to the Participants prior to the execution of the Project Agreement.

Without prejudice to the third paragraph of this clause, before any ownership interest in Foreground IP, in whole or in part, held by TI Pharma or a Participant may be sold or otherwise transferred (including transfer by gift or operation of law) to a Third Party, the other Participants and TI Pharma shall have a right of first refusal to purchase the ownership interest in the Foreground IP on to be negotiated commercial terms and conditions. Upon refusal by all Participants, the ownership interest may then be offered under no more favourable terms and conditions to others.

In deviation from the first and second paragraph of this clause, if Foreground IP is considered an improvement of specific Background IP used in the execution of the Project and identified in an attachment to the Project Agreement, the Participant owning said specific Background IP will have a right of first refusal which right shall have precedent over the right of first refusal described in the previous paragraph.

If Participants and TI Pharma cannot successfully conclude their negotiations within 90 days, price and terms will be determined by the Expert.

Neither a transfer of ownership in Foreground IP nor a grant of exclusive or semi-exclusive rights to Foreground IP will in any way obstruct or be used to obstruct Research Use by any of the Participants. A Participant acquiring ownership rights and/or an exclusive or semi-exclusive licence will ensure that any Third Party in turn acquiring ownership rights and/or a sublicense will respect this obligation not to obstruct Research Use.

Due Diligence

The Participants shall actively seek opportunities to commercialize the Foreground IP. In case one of the Participants in the Project acquires the full ownership of Foreground IP or an exclusive licence for Commercial Use of Foreground IP, this Participant must make Reasonable Efforts to develop and commercialize the Foreground IP and demonstrate that it is proceeding with the commercialization, unless agreed otherwise and laid down in the Project Agreement.

Failing due diligence the rights will revert to TI Pharma and the other Participants in accordance with their original ownership interest on appropriate commercial terms, unless agreed otherwise and laid down in the Project Agreement.

Dissemination

Publications are encouraged provided that they are reviewed from a point of view of patentability and publications may be suspended for a reasonable period of time, to be specified in the Project Agreement, to allow a patent application to be filed. Foreground IP must be disseminated as soon as possible but within two years after the end of the Project, either through Participants or through the Top Institute Pharma, if Participants do not disseminate.

No guarantees

Unless expressly agreed by such Participant, no Participant shall be deemed to have made any warranties of merchantability or fitness for any particular purpose of the Foreground IP.