

Comments on the Innovative Medicine Initiative (IMI)
IPR Policy Agreement
from the perspective of research organisations

Executive Summary:

The proposed IMI IPR Policy potentially puts the research organisation at a disadvantage with respect to the pharmaceutical industry regarding their IPR compared with the standard FP7 Grant Agreement (GA).

According to the IMI IPR Policy a pharmaceutical company participating in a project is able to use the Background and Foreground of the partners

- in any of its related companies (daughter, sister, mother) all over the world (far wider than the FP7 rules),
- for indirect exploitation – not restricted to the use of own Foreground as in FP7 GA.
- It may grant access to the partners' Background and Foreground to any third party of its choice if this is acting on its behalf,
- access is without any limit of time – the one year delay of the FP7 GA was left out

This far reaching access is potentially “for free” – a condition which is already spread by the pharmaceutical industry in presentations as the default (“royalty-free” instead of “fair and reasonable terms”).

In addition, the industry will have the chance to negotiate access to the Sideground of Participants thus potentially getting access to this as well.

Research organisations are in a vulnerable position as the specific procedures of IMI mean that they have to disclose their own ideas at an early stage of the process with insufficient possibility to protect them against exploitation of the pharmaceutical industry in case no agreement is signed later.

Research organisations are also vulnerable as they do not have the same possibility to commercialise results or the same legal support and experience as the pharmaceutical industry.

This is especially problematic as, once a Participant has signed the Project Agreement, it is no longer able to withdraw access to the IPR (Foreground or Background).

Considering the planned IMI selection process and the terms suggested by the IMI IPR Policy, the most innovative research organisations and SMEs will be deterred from a participation in IMI.

Differences between the IMI Intellectual Property Policy from August 2007 and the FP7 Grant Agreement

IMI Article II.2 Definition as compared to FP7 Annex II, Article II.1.2 – Affiliated Entities

The definition of an Affiliated Entity is wider than in FP7. It comprises not only “daughter” or “sister” companies but also the “mother” company (adding “directly or indirectly controlling a Participant” to the definition). This was deliberately avoided in FP7.

Consequences: Access rights for use of the results (Background as well as Foreground) will be far wider than in FP7.

This has even further reaching consequences as access rights for Affiliated Entities are not limited to those organisations based in the EU or in Associated Countries (see below for Article IV “Access Rights”).

Suggestion: Affiliated Entities should follow the definition of the FP7 GA.

IMI Articles II.5 & II.15 – Use

The IMI makes a difference between “Direct Exploitation” (= the development for commercialisation / commercialisation of Foreground) and “Research Use” (= “all purposes except direct exploitation”). The IMI IPR policy gives as an example of such Research Use “the application of Foreground as a tool for research and clinical research in the discovery, development or commercialisation of pharmaceutical products by for-profit institutions and organisations”. This concept is significantly wider than the common perception of “research purpose” and much closer to commercial use.

Consequences: “Research Use” disguises that it comprises (indirect) commercialisation. Research organisations bringing their IPR into the project will in all probability be faced with strong pressure to accept royalty-free conditions “for research Use” and the misleading terminology will facilitate this.

Suggestion: A more explicit labelling of this type of use as “Indirect Exploitation” would be important to allow negotiations of fair access conditions not only for institutions with very specialised legal support.

IMI Article II.16 & III.3 – “Sideground”

In Article II.16 Sideground (any results, data and information outside the project) is introduced. This was avoided in FP7 after experiences in FP6.

In Article III.3 it is suggested that within the Project Agreement ownership agreements could be made regarding Sideground.

Consequences: This draws in results and know-how outside the project and unnecessary for the results of the project. This can complicate negotiations for the Project Agreement and can put considerable pressure on the research partners to bring in additional know-how when the industry threatens to abandon the project. There is no need for bringing in Sideground.

Suggestion: Arrangements concerning Sideground should not be part of the IMI IPR Policy.

IMI Article III.2.1 – Ownership of Foreground

In Article III.2.1 it is decreed that the allocation of an ownership of Foreground different than to the Participant generating it can be agreed in the Project Agreement. In FP7 the ownership of Foreground is always with the generating party. Transfers of ownership are possible, with associated conditions allowing sufficient opportunity for the other Participants to protect their rights.

Consequences: It destabilises the basic right of the party to protect its own results. The FP7 procedure of ownership handling preserves the interests of all Participants in an equal measure while in the IMI procedure certain Participants can be put at a disadvantage. Again, the FP7 procedure is not totally excluded but potentially bypassed and left to the negotiations of the Project Agreement during which the research partners are at a clear disadvantage.

Suggestion: The ownership should be with the generating Participant by default as in FP7. For a transfer of ownership the same rules as in FP7 should apply. (Articles II.26 and II.27 of the Annex II to the FP7 GA)

IMI Article IV.3 – Limitation of Access Rights in case of withdrawal

In Article IV.32 it is stated that the termination of participation of a Participant does not affect its obligation to give access to both its Foreground and Background. This is contrary to FP7 GA Annex II Art. II.34.2 where after terminating a participation in the project Access Rights are limited to 1 year unless otherwise agreed.

Consequences: If a research partner agrees to unfavourable access conditions to his own Foreground and Background which is very likely as the current IMI IPR Policy allows the industry to have far reaching and free Access Rights there is no way for him to withdraw from these commitments.

Suggestion: Even though under FP7 it would in principle be possible to agree Access Rights for an indeterminate period to the other partners, it should not be made the default under the IMI IPR Policy. In particular, Access Rights to Background should be limited in case of withdrawal of a Participant from the consortium.

IMI Article IV.4 – “Sub-licences”

In Art. IV.4 and also in FP7 GA Annex II Art. II.32.5, it is stated that Access Rights do not entitle a right to grant sub-licences unless otherwise agreed by the owner. In addition to this, though, IMI Article IV.4 states that any party who has Access Rights for completing the project or for Research Use can authorise other (third) parties to exercise these rights on behalf of the party.

Consequences: This extension undermines the restriction to grant sub-licences, as all parties acting on behalf of the holder of the Access Rights will not require sub-licences.

Suggestion: The right to grant sub-licences with the agreement of the owner is seen as sufficient and guarantees the ability of the owner to commercialise its Foreground. Therefore the FP7 rules should be followed. The right to grant sub-licenses should also not be part of the Project Agreement as this can be negotiated later.

IMI Article IV.3 “Access Rights to Participants and Affiliated Entities to Foreground / Background for Research Use”

Article IV.3 gives Access Rights to the Foreground / Background of other Participants for “Research Use”, i.e. for all indirect exploitation; in the FP7 GA Annex II Art. II.34.1 and II.34.3, however, only Access Rights for use of own Foreground are foreseen. This right is seemingly not at all limited in time, other than FP7 GA Annex II Art. II.34.2.

Consequence: The rights for access are much wider, covering any use of Foreground apart from a direct exploitation of Foreground, and for an indefinite time. In addition, in FP7 the possibility of Affiliated Entities to exercise Access Rights of Foreground / Background is limited to the purpose of their exploitation of their own Foreground from the project. Usually this is very limited.

A wide use of the project results as such is certainly not bad. However, this can limit the owner’s chance of direct exploitation of results, especially if this access is negotiated to be royalty-free.

In addition, the obligation of a Participant to grant access to its Background not only for the other Participants to commercially exploit their own Foreground, but also for any other use of the Foreground seems unacceptable if it had to be granted for free.

Suggestion:

1. Access to Background for Use have to be on fair and reasonable conditions only – any other terms would make the participation of publicly funded research organisations practically impossible. This should be clearly stated in the rules, thus avoiding very lengthy negotiations. Under the circumstances of use (indirect exploitation) the option to get access royalty-free should not be negotiable. Royalty-free access as an option compared to fair and reasonable terms might still be considered for use of own Foreground.
2. There should be a possibility for Participants to grant Access Rights to Background only for the project purpose. As Background might e.g. comprise biobanks which frequent use will consume, access to Background has to be very limited to the project purposes and cannot be widely granted for any possible purpose.
3. The exercise of Access Rights has to be limited in time.

IMI Article IV.3. – Additional aspect: Access Rights to Affiliated Entities

As in the FP7 GA Annex II, any Affiliated Entity to a Participant has the same Access Rights as a Participant. In FP7 these Access Rights are limited to Affiliated Entities based in the EU or the Associated Countries, in the IMI rules all Affiliated Entities **worldwide** can request Access Rights – and Affiliated Entities, contrary to FP7 rules, also comprise mother companies (see definitions).

Consequence: The benefit of the projects will not favour the European market but support international companies all over the world. It cannot be in the interest of the Member States and Associated Countries to support industry outside their own market. If the community contributes 1 billion euros to the IMI, as a result it is to be expected that there will be an advantage for Europe as a site. However, this does not bar companies worldwide to use the research results if they pay the due license fees.

Suggestion: Following the rules of FP7, Access Rights of Affiliated Entities must be limited to those established in a Member State or Associated Country. Under no circumstances royalty-free access rights should be envisaged for non-EU-members.

IMI Article IV.4 – Access Rights to Third Parties for Research Use

In Article IV.4 it is decreed that Third Parties will have Access Rights to Foreground and Background of the project for use other than Direct Exploitation. Sufficient justification is required in order to exclude some parts of the Background from these Access Rights. Some additional details for Access Rights are different to those defined for Participants and Affiliated Entities. This comprises, for example, the access to Background: “Third Parties have the right to request and receive under licence Access Rights to the Background of the Participants, but only to the extent reasonable required for and only for the purpose of the Research Use of Foreground.” – a very useful condition we would wish to see in IMI Art. IV.3 regarding the Access Rights of Participants and Affiliated Entities.

Also, the terms for providing Access Rights must be included in the proposal and are subject to the evaluation.

In FP7, no such rights for Third Parties are defined.

Consequence: This Article aims at ensuring the wider use of project results beyond the Participants in the consortium. There are differences made between the modalities of access for Research Use for Participants and Third Parties which we regret – the condition of “access reasonably required” should apply to both.

Suggestion: It should be considered to limit the Access Rights of Third Parties to organisations established in the Member States or Associated Countries. The differences in the treatment of Participants and Third Parties seem unnecessary, or rather they should not differ for Research Use (as long as it does not involve the use of own Foreground) unless reasonable. This would reflect the nature of the IMI as a Public-Private Partnership for research rather than a subsidy for industry.

Additional points of concern:

In FP7, partners are able to make pre-proposal agreements before they contribute to a proposal. In the case of IMI, the research organisations and SMEs will have to submit Expressions of Interest to be reviewed by the review panel together with pharmaceutical companies which want to become later a partner in the project.

In addition, when negotiating and executing Access Rights the research organisations are not equal to the industrial partners as they do not have the same means of commercialisation of results nor the same legal support to defend their interests.

Consequence: The research partners have to disclose the basic ideas for research at a very early stage. This will put them in a much more vulnerable position to protect their interests. Together with the lack of legal support and experience they are at a clear disadvantage during negotiation of the Project Agreement. This makes participating in IMI calls unattractive to research organisations, which have to fear that the efforts spent in preparing the proposal and the disclosure of ideas will be followed by lengthy negotiations not reaching a result they are able to accept. The more innovative their ideas, the less attractive participation will be. This is a danger IMI has to avoid.

Suggestion: Considering the procedures of the IMI and the unequal distribution of advantages between parties in the project, the negotiation of the Project Agreement must not leave so many unknown parameters regarding the rights of the Participants. More legal certainty has to be ensured in order to protect the interests of the research organisations and spare all concerned the time-consuming negotiations which might lead to failure in the end. Therefore the suggestions as made above should be considered.