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### **1. Introduction**

Pharmaceuticals is a strategic area for the European Union to comply with the commitments of the Lisbon Agenda.

In this context, intensifying the link between the public sector and private initiatives to improve research and innovation in the field is key. This is the *raison d'être* of the Joint Technology Initiative on Innovative Medicines and its implementing instrument, the IMI Joint Undertaking (hereafter IMI JU), set up by [Council Regulation \(EC\) No. 73/2008](#) of 20 December 2007 (the IMI Regulation) on the basis of article 171 of the EC Treaty.

The IMI JU is set up for a period up to 31 December 2017 with the clear objective of improving drug research and development in Europe and ensuring a rapid integration of the results by the related industry and regulatory practice. Founding members and financial contributors are the European Federation of Pharmaceutical Industries and Associations ([EFPIA](#)) and the European Community, represented by the European Commission, although it is open to new members. By means of competitive calls for project proposals, this initiative is expected to foster research and innovation in the field.

### **2. The IP policy of the IMI JU Research Actions**

[IMI JU Research Actions](#) have distinct rules for participation and intellectual property (IP) policy. This is due to the fact that the [Rules for participation under the Seventh Framework Programme](#) (FP7) (which contain the IP regime applicable to FP7 projects) do not apply to Community contributions to joint undertakings or any other structures set up under article 171 of the EC Treaty<sup>1</sup>. That said, the IMI IP policy is based on that of FP7, with certain differences derived from the concrete purposes of the IMI JU and actions, as required by the IMI Regulation<sup>2</sup>. For this reason (and because potential participants in the IMI JU actions may already be familiar with the FP7 rules) we are to explain the policy basics by referencing the FP7 IP-related rules.

The general objectives of the IMI IP policy are established in article 22 of the IMI JU Statutes, integral part of the IMI Regulation, and developed in the [IMI IP rules](#), which are to be incorporated into the Grant Agreement and Project Agreements (the latter being those agreements among project partners –the consortium agreement in FP7 projects).

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## IP policy in IMI actions

A quick look at the rules suggests that we are in front of research & development-focused actions with a clear aim of a swift dissemination and sharing of the results, which has a direct impact on the IP regime, notably on the licensing scheme.

### 2.1. IP-related definitions (Section II, IMI IP policy)

“Affiliated Entity”. The scope of this term is wider than under the FP7 rules since it includes parent companies and it is not limited to entities established in EU Member States or countries associated to FP7. However, many consortia under FP6 and FP7 have implemented a similar approach, which reflects the multinational profile of the sector.

“Background” is, like in FP7, project-related information and IP rights held by participants before the project. However, contrary to FP7, IP rights applied after the project starts but related to prior information are also included. There is also a provision (in section III.1.2) stating the participants’ right (not obligation) to bring into the project, as Background, IP-related resources acquired after the project starts.

“Sideground” (discharged by the FP7 rules though not necessarily by consortia in practice) is defined as results generated in the project but unrelated to the Project Objectives<sup>3</sup> and unnecessary for the project or the Research Use of Foreground.

The FP7 “use” is divided into:

1. “Direct Exploitation”, which means development for commercialisation or commercialisation of the Foreground itself;
2. “Research Use”, which means use of Foreground or Background necessary to use Foreground for purposes other than for completing the project or for Direct Exploitation (it goes further than academic research and includes application of Foreground in research for the development of pharmaceutical products by for-profit institutions; see note on p.3 of the IMI IP policy)

It is relevant to note that the use of Foreground “in general” is foreseen (not necessarily one’s own Foreground as in FP7).

### 2.2. Ownership of Background, Sideground and Foreground (Section III, IMI IP policy)

Contrary to FP7, the IMI IP rules refer to the ownership of Background to avoid any doubts that participation in IMI actions does not affect the ownership regime of any Background brought into the project, which has to be identified in the Project Agreement.

Ensuring smooth implementation of the project and further application of the results is key in IMI actions, which illustrates some of the differences with FP7. For instance, there is more control of limitations that affect the access or use of Background. Indeed, any “legal restrictions” (which include not only restrictions from the law but also from prior contractual commitments) that may affect the use of Background for the project or for Research Use shall be communicated

to the Executive Office (managing office of the IMI JU) before signature of the Grant Agreement.

Owners of Sideground are the participants that generate it, though it may be otherwise agreed in the Project Agreement.

Foreground belongs to the participant that generates it, though it may be decided differently in the Project Agreement. Personnel rights and joint ownership have the same regulation as in FP7.

The fact that the rules expressly recognise the autonomy of the parties to agree on ownership regimes different from the default ones does not mean that this autonomy does not exist in FP7 (on the contrary, while not expressly foreseen, as in SME actions, project partners always have the option to transfer their ownership). In any case, due attention should be paid by participants should they wish to negotiate this issue in their Project Agreements.

#### Transfer of ownership

Contrary to FP7, transfer of Background is also dealt with in the rules and is regulated in the same manner as transfer of Foreground. Rules follow the FP7 path (e.g. passing on the obligations under the project to the assignee is compulsory) but clarify that participants do not need authorisation from each other when intending to transfer their Background or Foreground to certain third parties (namely, affiliates, purchasers of assets, successors resulting from a merger). However, participants have to be informed and these third parties shall commit in writing to be bound by the Grant Agreement.

### **2.3. Access rights (Section IV, IMI IP policy)**

As under FP7, requests shall be made in writing, although there is a possibility to agree otherwise in the Project Agreement (something implemented in practice by many consortia in FP7); the granting can be conditioned upon safeguards involving confidentiality or use for the intended purpose; and no automatic sub-licensing is provided for (however there is a sort of a "have-made rights" provision, as an Access Rights-holder may authorise another party to exercise the rights granted, provided that the former responds for the latter). It should also be noted that Third Parties (any entity which is not a participant) are taken into account for the granting of Access Rights.

As regards economic conditions, Access Rights to both Background and Foreground for the completion of the project shall be granted on a royalty-free basis (the same approach followed in frontier research actions and SME actions, as regards the RTD performers, under FP7).

As regards use of the Foreground, the IMI IP policy distinguishes between:

#### **1. Access rights for participants and Affiliated Entities for Research Use**

Access rights to Background and Foreground are to be granted under fair and reasonable terms or royalty-free (same economic terms applicable to project participants for use of own foreground under FP7);

## IP policy in IMI actions

### 2. Access rights for Third Parties for Research Use

After the completion of the project, Third Parties have the right to request Access Rights to Foreground for Research Use and also to Background if necessary to the Research Use of Foreground. These access rights are to be granted under fair and reasonable terms (thus, fair return is guaranteed);

Exclusion of specific elements of Background is foreseen only as regards Third Party access, but the partners wishing to exclude have to ask permission from the Executive Office before the project starts and detail these exceptions in the Grant Agreement. Therefore, the issue of Third Party access rights to participants' Background shall be carefully considered before the signature of the Grant Agreement and negotiated accordingly.

### 3. Direct Exploitation

Having due regard for their general obligations under the Grant Agreement, participants may use their Foreground, Background and Sideground as they wish. If access to other participants' Background and/or Foreground is necessary for the Direct Exploitation of Foreground, the parties involved will have to negotiate such access on a case-by-case basis, though participants may agree on these Access Rights in the Project Agreement.

Finally, please note that, contrary to FP7, there is no time-limit for requesting Access Rights. Broad licensing on a non-exclusive basis is quite a general practice in research, as it helps to have the licensed solutions further tested and validated. In any case, participants shall be aware of the rule, and attentively identify the Background they will make available to the project and negotiate the Access Rights-related provisions of the Project Agreement.

#### 2.4. Confidentiality and Dissemination of Foreground (Sections V and VI, IMI IP policy)

Unlike in FP7, protection of Foreground does not have a particular section but is dealt with summarily in the references to confidentiality, where it is stated that participants, when reviewing dissemination plans, may either require a delay or make modifications for patentability reasons, or even require that Confidential Information be kept as a trade secret.

Although references are limited to patents and trade secrets, a practical interpretation would lead to the conclusion that more than excluding the possibility to take into account or consider other IP rights in a protection plan and strategy, what the policy wants to ensure is that any time IP protection can be an issue due care is taken in dissemination activities (the golden rule "protect first, publish later"). It is worth noting that delays related to protection have been kept to a reasonable length (3 months maximum to decide, unless otherwise agreed in the Project Agreement).

Finally, it is expected that participants disseminate Foreground no later than one year after the project's termination. Should they fail to do so, the Executive Office may do it.

### 3. Final remarks

The IMI IP policy is based on the principles and practice from FP7 and FP6 but responds to the particular profile of the IMI actions (drug research & development projects) and purposes (seeking mainly to ensure a quick, easy and enduring sharing of the solutions achieved in the projects). The entities involved in IMI projects have even greater autonomy to implement their IP management-related decisions than under FP7. Therefore, responsible and committed partnering, as well as a careful negotiation of the Project Agreement, are key to achieving the objectives that the IMI actions pursue.

1. See recital 26 of the FP7 Rules for participation.
2. Article 15 of the IMI Regulation asks the IMI JU to adopt distinct IP-related rules based on the principles of the FP7 rules.
3. "Project Objectives" are those set up in the Grant Agreement, which do not include direct development and/or commercialisation of marketable pharmaceutical or diagnostic products (see section II.14).

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