

IP Policy Forum: Intellectual Property Rights (IPR) In Collaborative Drug Development in the EU: Helping a European Public-Private Partnership Deliver - The Need for a Flexible Approach to IPR

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INTELLECTUAL PROPERTY RIGHTS (IPR) IN COLLABORATIVE DRUG
DEVELOPMENT IN THE EU: HELPING A EUROPEAN PUBLIC-PRIVATE
PARTNERSHIP DELIVER – THE NEED FOR A FLEXIBLE APPROACH TO IPR

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The integrated R&D model historically employed by pharmaceutical companies, in which every step of drug development is conducted in-house, is no longer efficient in delivering the new therapies that are needed to address the major health challenges that society faces. Over the past decade we have seen companies externalize many of their once core activities in order to regain operational efficiency and feed their dwindling pipelines. These efforts have also been complemented by the establishment of open innovation models leading to the leveraging of external sources of knowledge and know-how, especially in universities and biotechnology companies. The recognition that a single entity is unable to overcome the challenges faced and deliver the new treatments needed by society has also resulted in the proliferation of public-private partnerships (PPP) in which large companies, Small and Medium Enterprises (SMEs), academic researchers and patients' organizations collaborate. An example of such a PPP is the Innovative Medicines Initiative (IMI), a PPP between the European Commission and the European Federation of Pharmaceutical Industries and Associations. Consortia supported by IMI face many challenges, one of which is the need to operate in a balanced manner in terms of IPR. IMI facilitates consortium agreements by providing a flexible IP policy and by playing the role of an impartial third party.

In general, IMI's IP policy aims to promote and reward knowledge creation, innovation, disclosure, and exploitation, through fair rewards and allocation of

rights. Given the diversity of projects supported by IMI and the complexities associated to IP management in public-private partnerships, a flexible approach is a key element for success. Accordingly, the overall IP policy has been designed to best serve the specific situation of each consortium considering basic and mandatory components. As a general provision, each participant remains the exclusive owner of all the know-how and IP rights it holds before becoming a partner in an IMI project. Information and IP that are necessary for the completion of the project are identified by each owner prior to the start of the project and defined as ‘Background.’ The results that are generated during the course of the project as part of its objectives are defined as ‘Foreground.’ Ownership rights to Foreground can be negotiated and be adapted to the project needs—and here lies one of the key flexibilities in IMI’s IP policy. ‘Background’ and ‘Foreground’ are then accessible on a royalty-free basis to project participants to the extent necessary for undertaking the project.

As we see the continued proliferation of PPPs and open-collaborative networks ensuring openness and fairness in relation to IPR will remain a challenge. Our experience demonstrates that projects benefit from this flexible IPR policy. A strength of which is in ensuring that IPR agreements are agreed before the project starts providing consortia with less legal uncertainty and useless *a posteriori* discussions. In this way IMI is able to support projects across a wide range of topics from drug discovery platforms such as the European Lead Factory to education and training topics such as SafeSciMet.