Marquette Intellectual Property Law Review

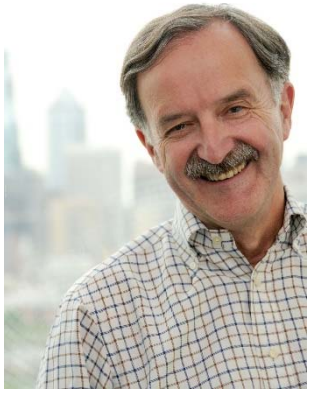
Volume 18 | Issue 1 Article 14

IP Policy Forum: Need for New IP Approaches to Facilitate Collaborative (Academic-Industrial) Drug Development

Garret A. Fitzgerald

NEED FOR NEW IP APPROACHES TO FACILITATE COLLABORATIVE (ACADEMIC-INDUSTRIAL) DRUG DEVELOPMENT

GARRET A. FITZGERALD, M.D., FRS
PROFESSOR OF MEDICINE & PHARAMCOLOGY CHAIR
DEPT. OF PHARMACOLOGY
DIRECTOR, INSTITUTE FOR TRANSLATIONAL MEDICINE & THERAPEUTICS
UNIVERSITY OF PENNSYLVANIA



The relative strengths and weakness of academia and industry in the skills necessary to bring a molecule forward to an approved drug are widely appreciated. Indeed, the efficiency of moving to a modular approach to drug discovery and development—with modules drawn at different stages from diverse sectors and geographies—has been realized in the altruistic sector. However, conversion of this approach to the for–profit sector requires a revision of our thinking on intellectual property (IP).

The potential value of too many molecules remains locked in company freezers, while exploitation of biological insights in academia is classically limited by the lack of tool compounds and of translational infrastructure to convert such leads into approved drugs. Segregating these opportunities from each other are unrealistic expectations of IP rewards by both academia and industry, and an outmoded and inefficient approach to IP by both parties. While some progress has been made with respect to academic infrastructure via clinical and translational science awards; and, industry has begun to make widespread but essentially limited deals with universities, it is worth considering the fundamentals of IP.

Despite the odds of a new molecular entity becoming an approved drug being extremely long, the dominant IP is vested in chemical composition of

matter. In the era of large vertically integrated companies—now on the wane—this did not really matter. The chemist, the expert in model systems and the clinical trialist all worked for the sponsoring company and all would profit via its stock shares if the drug was approved. In an era of modular drug discovery and development, the trick will be to engage the best investigators at various stages in the process, despite them working in a different public or private entity than the originator of the chemical matter in question. Provision of the funds to do their bit of the research will be insufficient; if they are best in brand they will have plenty of resources to conduct the research that is their own priority. Rather, they need to be incentivized by a piece of the action—some of the profit derived from an approved drug.

As suggested recently,[6] one approach would be to model prospectively the hurdles in the process and to apportion value—in terms of a share in the profits—to overcoming them on the way to drug approval. This has the attraction of postponing the statement of value until it is actually realized. It shifts the dominant IP from an entity with perhaps a 1:40,000 chance of having commercial value to something that actually has value. Of course, real life will depart from the prospective model, but the model can be adjusted in Bayesian fashion as the process proceeds, so that at its conclusion, the model will recapitulate the relative challenge of the hurdles along the way and apportion value appropriately to their being overcome. This approach requires an initial pot of money—potentially from diverse funders who may set the "grand challenge"—and prospective agreement on the part of contributions to their reward being subject to the modeling exercise.

We are used to modeling—3d structures, pharmacokinetics, and market value—at many stages of drug development; perhaps we should extend it to the domain of IP.

(Photo provided by Sabina Louise Pierce)

6. Garret A. FitzGerald, *Can Intellectual Property Save Drug Development?*, 338 SCIENCE 483–84 (2012).