



Falco-Archer, Inc.

We Build Intellectual Properties...™

White Paper "Catalytic" Funding Organizations and Intellectual Property

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The relevance of intellectual property (IP) to many philanthropies has radically changed over the last 5-7 years. Some of this is due to shifts in funders' operating paradigms, especially where strategies and processes proven in the for-profit sector are adopted to accomplish funder's core missions. Examples of this type of philanthropy include the emergence (or popularization/acceptance) of "venture philanthropy"¹ and public-private partnerships (PPPs)² where in solving particularly intractable problems the emphasis is on close engagement between donors and recipients, building recipient's operating capabilities and capacity, clear performance expectations, and longer term investments. Grant-making is no longer the primary goal with these organizations. Catalyzing broad based change, collaboratively, efficiently, and strategically has become the primary mission.

When such "catalytic funding" is directed to product research, development, and commercialization, intellectual property will likely be a key consideration. In many cases, IP will become of larger strategic importance. This is because IP and its management are an integral part of product research, development, and commercialization. IP is also intrinsically important to the catalytic funding models being employed. Solving particularly challenging problems, e.g., low cost and appropriate HIV diagnostics for developing countries, often requires a multitude of technological inputs. Regardless of whether these are "off the shelf" or all new innovations, many will have associated with them exclusionary IP.

Catalytic funding also often includes an element to build the recipient's operational competencies in order to improve the chances for success. As in the for-profit sector, one of these core competencies is IP management. No company rationally embarks on

¹ See http://news.com.com/2030-1030_3-5206330.html?part=rss&tag=feed&subj=news

² See <http://www.who.int/intellectualproperty/topics/ppp/en/> and also the wide ranging work of Roy Widdus

developing and producing new products (or services) without considering the promise and peril of IP. No catalytic funding recipient should do so either.

The opportunities IP affords with respect to building (and exchanging) valuable exclusionary monopolies also cannot be overlooked. Similarly, the risk that product development or commercialization may be blocked by other’s IP monopolies cannot be ignored. The objective (in fact often the funder’s performance expectation) is to go to market and not waste money, other valuable resources, and time. Good IP management helps ensure this objective.

Because their investments are long term, catalytic funders are also commonly concerned with eventually ensuring access to funded products, especially by disadvantaged markets.³ One element of ensuring such access is to mitigate the risk of IP-based blocking. It’s important to note that such access may also be achieved by grantees building and utilizing IP monopolies, in particular by selectively out-licensing such rights and/or by using their IP as currency or a “bargaining chip” to obtain such access from other IP holders.

We recommend that catalytic funders in the product R&D and commercialization arena consider selectively using IP management approaches proven to work in the for-profit sector. These include:

1. Develop an IP strategy for funded projects and deploy it in concert with funding recipients. This strategy *must* be synchronized with both the funder’s mission *and* the grantee’s strategic and project plans. IP strategies should also complement (in fact often be driven by) sub strategies like technology and market strategies.
2. Because they are so closely tied to funder and grantee strategies, IP strategies will vary in scope. At a minimum, consideration should be given to meeting the following objectives:
 - a. Manage IP for opportunity. For example, can IP be created and used to improve chances of success? Can IP be used to access other’s IP or attract partners? Can other’s IP be limited? Can other’s IP be used to prompt innovation?
 - b. Manage risk. For example, can potential infringement risk be identified early and mitigated, if not avoided? One strategy is to “consolidate” access to IP which is potentially relevant to particular products (and/or

³ See, for example, the Malaria Vaccine Initiative’s mission: “...to *accelerate* the *development* of promising malaria vaccines and *ensure* their *availability and accessibility* for the developing world.”

- product categories), e.g., via patent pooling arrangements or sublicensing of collected license rights.
- c. Utilize IP information to develop actionable intelligence, e.g., for technical review and technology sourcing, identifying partners, targeting potential infringement risk, etc.
 - d. Integrate IP management with overall project management and key activities and *expect it to add value*. For example, involve IP managers in grant contracting, technical reviews, technology road mapping and the like. What they learn they will use to refine IP strategies and their execution.
 - e. Work with funding recipients to actively identify new, potential IP. Whether to seek protection of such IP should be the result of due consideration in accordance with mission/organizational and overall project strategic plans. Whenever possible, create *options* for IP generation and subsequent utilization, e.g., take advantage of the one-year timing window afforded by provisional patent filings. Bear in mind that IP may ultimately be used as a form of “currency” to attract partners and attain funder’s missions and project objectives.
3. IP management models should focus on demonstrating the value of IP to the project, developing an understanding of what IP is and what it can be used for, building project-appropriate IP and *utilizing it*, and mitigating IP related risk.

Catalytic funders may be interested in reviewing the materials on the Falco-Archer website (<http://www.falcoarcher.com>) regarding strategic IP management and the information at the web site for Falco-Archer’s [Intellectual Property Management Center](#) (IPMc), dedicated to providing IP management services to the global health sector..

We also recommend that catalytic funders in the product research, development, and commercialization arena seriously consider the following as a matter of grant making policy:

1. Secure paid-up, royalty-free IP rights from funding recipients in exchange for support. These should preferably take the form of acquired or license rights and not *options* to license rights. Such rights may be *conditional in their exercise* but not in their grant. Such rights may be constrained in their scope (e.g., territory and/or field of use), but only to the extent this matches with the funder’s mission. Such rights must be assignable or sublicensable to third parties capable of meeting the funder’s mission objectives.⁴

⁴ Note this is not dissimilar to the paid-up, non-exclusive, worldwide license the U.S. Government receives in exchange for funding R&D in the U.S. under 35 USC 18 §202(c)(4) (The Bayh-Dole Act).

2. Ensure funding applicants have *objectively* considered how IP rights held by others may impact the development and commercialization of their products (and/or services). A more thorough analysis (or progression of analyses) may be conducted as a part of funded work, but a preliminary assessment should be a grant application requirement.
3. Encourage funding recipients to manage the IP arising from funding in ways which complement the funder’s mission. There are two common focus areas here:
 - a. Selective patenting, i.e., being more selective in whether patents will be filed for particular inventions and if filed, *where* patent protection will be sought (often focusing on only developed countries, i.e., “advantaged” markets)
 - b. Out-licensing practices, in particular avoiding fully-exclusive licenses, setting aside license rights for disadvantaged markets, providing for “research use only” licenses, and retaining rights for funding recipient’s use.

See, for example, the patent filing and licensing practices recently proposed by the U.S. Public Health Service at <http://edocket.access.gpo.gov/2004/pdf/04-25671.pdf> or those drafted by OECD at <http://www.oecd.org/dataoecd/39/38/36198812.pdf>

4. Recognize that IP rights are, and will continue to be, controversial in how they may contribute to disparities in the distribution and availability of critically-needed products and services. Bear in mind IP rights and their inherently exclusionary nature will not “go away” anytime soon, despite calls to this effect. While some beneficial limitations to the adverse effects of IP may arise from pending changes in IP laws, the most productive solution to this conundrum may be to use the system on itself, i.e., to use IP rights to attain better “access”. One example is more reasoned, better targeted out-licensing practices by IP holders which segregate fields of use and/or markets in accordance with anticipated access issues. Another example is encouraging the development of IP to use as currency in gaining access to others IP rights.

Falco-Archer has extensive experience working with catalytic funders to develop IP aspects of grant making policy and IP sections of grant agreements.