Schaner & Lubitz, PLLC

Venture Philanthropy Legal Report Spring 2009 #1:

<u>The Importance of An Interruption License</u>

This report is one in a series on legal issues of interest to non-profit organizations engaged in or thinking about Venture Philanthropy work. We serve as outside general counsel to a number of such entities. Feel free to contact us. We would be happy to further discuss how we can help make your work successful.

The Beginnings Of Venture Philanthropy In Drug Development

In 1999, our client, the Cystic Fibrosis Foundation (CFF), asked us to assist it in negotiating and drafting a collaboration agreement with a company called Aurora Bio-Sciences, which took the form of a grant award from CFF to Aurora. The collaboration was novel, because CFF had never before made a grant to a for profit company.

Unbeknownst to us at the time, that award launched an activity that would become known as "Venture Philanthropy." Aurora subsequently merged with Vertex Pharmaceuticals and, as the resulting initial research indicated promise, that first award to Aurora spawned subsequent CFF awards to Vertex and 40 or 50 CFF awards to other biotechnology companies.

Foundations aimed at other diseases have joined the Venture Philanthropy effort. Other of our clients, including the Juvenile Diabetes Research Foundation, the Stanley Medical Research Foundation, the Michael J. Fox Foundation for Parkinson's Research, and the Multiple Myeloma Research Foundation, have completed approximately 50 more venture philanthropy transactions.

Each of these 100 or so transactions have had unique characteristics and qualities. But they share one thing in common: each is important in its own right, because if successfully completed the resulting collaboration brings hope for a new drug or diagnostic leading to a better quality of life and a longer life span for those at which the drug or diagnostic is aimed.

What Is An Interruption License?

Over the course of these transactions, we have developed a checklist of important issues to consider before and during a Venture Philanthropy deal. Interruption is an issue that has been on the list from the very beginning.

Before Venture Philanthropy, it was not common for foundations making grants to reserve for themselves any remedy if an awardee decided to cease research related to development of a drug or diagnostic. Foundations made awards, mostly to academic institutions, and hoped that they would bear fruit in the form of scientific advancement.

Starting with the Aurora award, we have pushed to include a remedy for the interruption problem. We have done so for a number of reasons, which can be summarized by the following: (1) the dollars involved in Venture Philanthropy awards generally are sufficiently large that waste can be devastating; but, (2) once awards are made, a charity cannot require awardees to continue their research after the term of the award, and it is simply unrealistic to try to dictate priorities to an awardee.

Our solution to this interruption problem has been to include in the initial award an Interruption License, an exclusive license to intellectual property created with award funds that is granted at the time of the award, but is dormant unless there is an Interruption, at which time it springs to life. An Interruption is generally defined as a cessation of reasonable efforts to develop a commercial product from the intellectual property over an extended period. We have successfully included an Interruption License in many of the 100 or so Venture Philanthropy transactions with which we have been involved.

If an Interruption occurs, the awarding charity with an Interruption License obtains the right to develop the intellectual property, usually through another Venture Philanthropy partner, into a potential drug or diagnostic.

How An Interruption License Helps Our Clients: A Case Study

Toward the end of 2008, an awardee ("A") of one of our clients ("C") notified C that because of its financial predicament and difficult economic times generally, A could no longer support the development efforts of a drug (the "Drug") considered by C to be a very important new weapon in the fight against the disease C seeks to eradicate. A notified C, because, with our help, C had an Interruption License pursuant to the initial grant award from C to A.

When we began drafting Interruption Licenses for our clients, we anticipated that they would be triggered either because of a publicly recorded bankruptcy filing or because an awardee (not necessarily with notice to our client) terminated or slowed research for a continuous period below levels that would constitute commercially reasonable efforts. In the latter circumstance, we expected that upon an assertion by C or another awarding charity that an Interruption had occurred, the awardee would challenge such an assertion. Though proof of an Interruption in such circumstances could be difficult, we nevertheless expected that such an assertion could trigger reinvigoration of commercially reasonable efforts by A to develop a product — a result that is actually more desirable than taking the intellectual property itself.

However, the circumstance faced by C involved no such challenge. A had taken the Drug to Phase 3 trials, but did not have sufficient funds to take it to market and so notified C. Because of the same adverse economic conditions currently affecting many sectors of the economy, A had been unsuccessful in licensing the Drug to third parties. A's announcement to C gave C an opportunity to contemplate how it might help successfully bring the Drug to market.

Closing The Deal To Consummate The Goals Of The Interruption License

When it became known in the industry that A had decided to give up on the Drug, C began receiving expressions of interest from third parties to license the Drug (possibly because third parties considered C a more desirable partner than A due to its vast experience with the disease), so C hoped that it could immediately sublicense it to a company that had the resources to complete ongoing clinical trials and take the Drug to market.

One of the interested third parties ("I"), a well funded start-up, had a prior history with the Drug (two of its officers had previously worked for A) and was familiar with the Drug and its potential. Accordingly, I became the favored candidate, and discussions between C and I commenced at the same time as the details were being worked out with A for transfer of the Drug to C.

The terms of the Agreement between C and A did not require C to pay A anything if the Interruption License was activated. However, as C (with our assistance) began to discuss the details of the turnover of the intellectual property, C concluded that it would be best to offer A an incentive to cooperate in the turnover and thereafter. Many of A's employees would soon be terminated, and, if A cooperated, C and I might secure the help of these employees either in the short run, as the Drug and associated agreements were transferred, or in the longer run, to continue to work on Drug development efforts. In the end, C decided to offer A a percentage of any royalty C might earn if the Drug is commercialized. The royalty incentive to A has worked as anticipated, and A continues to cooperate with C and I to help in the transfer.

C has completed a sublicense agreement with I pursuant to which C will contribute some additional funds to the completion of ongoing clinical trials. Because I is well funded and experienced with the Drug, because A continues to cooperate, and because C recognized the importance of the Drug -- by funding the initial research, reserving for itself an Interruption License, and providing incentives to both A and I to make the transfer happen -- there is hope that in 2-3 years the patients with the disease that C seeks to eradicate will have a Drug that could be life-enhancing, indeed life-saving. A potentially helpful by-product to all of this is that if the Drug is commercialized, C also could earn additional royalties, which it then can use to further its mission in helping people with the disease.

How An Interruption License Can Help Everyone Involved, Most Importantly The Patients Who May Benefit From A Resulting Product

If the original agreement between C and A had not contained an Interruption License, the Drug likely would have been shelved after A concluded that it did not have sufficient funds to continue developing it. Although it is possible that A eventually could have found I or another willing buyer for the Drug, having participated in the negotiation process, we can definitively say that C's excellent reputation in the field and C's active efforts to find a partner with whom it could work were critical.

Had A shelved the Drug, the patients of this particular dread disease would have been deprived of the Drug's potential. C would have expended considerable funds in its award to A in the hope that the Drug would be developed, but only to lament that its investment would be gathering dust on the shelves of A for economic, not scientific reasons. And C's hope for royalties (another issue on our client checklist and another likely subject for a subsequent Legal Report), which have the potential to be reinvested by C in its fight against the disease, would have been dashed.

Although it also is possible that C could have expressed interest in purchasing the Drug after A decided to shelve it (assuming, of course, that A would have notified C even though it would have had no legal obligation to do so), it is highly unlikely that C would have been in a position to offer A anything for the Drug; C, like everyone else in these difficult economic times, does not have excess unallocated funds to make spot purchases.

Conclusion: Have Your Checklist Before Entering Into The Venture Philanthropy Field

The Interruption License is one of many important considerations for a charity to contemplate before giving a Venture Philanthropy award. Such considerations should not be lost in the rush to complete the award.

The importance of a well drafted award agreement must not be discounted. If you make Venture Philanthropy awards or are contemplating doing so, we would be happy to assist you.

About the authors

Ken Schaner has practiced law for more than 42 years. He began his legal career at the Internal Revenue Service, where helped draft the 1969 amendments to the tax code pertaining to exempt organizations. He was a founding partner of Swidler & Berlin, where he also served as managing partner and head of the corporate practice, and then a partner at Bingham McCutchen before founding Schaner & Lubitz, PLLC.

David Lubitz has practiced law for more than 17 years. He has represented or worked for non-profit organizations for almost all of that time. He was a partner at Swidler Berlin and Bingham McCutchen before founding Schaner & Lubitz, PLLC.