

***PRESENTATION:***

**BIOTECHNOLOGY  
AND MEDICAL TECHNOLOGY  
IN SEATTLE:  
I.P. AND VENTURE CAPITAL PERSPECTIVES**

**Steve Rosenman\***

As some of you know, I am a late inning relief pitcher for Dave Maki, who is unable to attend today. Dave spent many years with our firm, the Seed IP Law Group, but has moved on to Perennial Ventures. We continue to maintain a close relationship with Perennial and I will be sharing with you some of the information that Perennial has provided us regarding biotech investment and biomedical investment in Seattle. I will also talk about some of the needs that are unique to biotechnology and biomedical device clients from an intellectual property perspective. Afterward, I will run through a few examples of some Seattle biotech industry stories that are developing now, success stories that continue to be quite interesting.

The Seattle biotech and high-tech landscape has attracted a lot of attention. Many biotech companies are the result of spin-off technology developed at research institutions that have long traditions here in Seattle. Over \$5 billion in venture cap funds have been invested under local control.

Nationally, by most typically investors' perspectives, there is generally an emphasis on a long-term investment and a long-term goal. In the venture capital world, turnarounds are much shorter. Venture capitalists will usually be interested in quarterly evaluations of performance, and will look to get a company up and running and off the ground and hopefully take it public. The venture capitalist investment levels in the United States over the last five years made a slow but steady rise; then in 1999, a much more dramatic rise was seen in venture capital invested in U.S. companies. In 2000, there was a fairly steep drop-off in the investment level. There was somewhat of a paralleling of the trend in the Northwest. Here, in the late 1990s there was slow but steady growth; then a lot of activity in 1999; and then somewhat of a fall-off in 2000, although not as severe.

Software and telecom are the sectors that have attracted the most attention. Although they have been able to maintain their market percentage of total venture capital dollars invested, the actual amount invested has fallen by over 35%. During the same period, life

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\* Seed Intellectual Property Law Group.

sciences, including pharmaceutical, biotechnology, and biomedical devices and services, have made an increase from just under 10% to almost 12% of the venture capital market. Granted, there is still an overall decline in the total amount of dollars invested, but the life science industry was hit incrementally less severely than the software and telecom sectors.

What are venture capitalists looking for? In certain cases, there are issues that are unique to a biotechnology/biomedical perspective. Management is very important from the venture capitalist perspective. There are a number of second-generation biotech companies here in the Seattle area, many with fairly prominent scientists and chief executive officers culled from the first generation of successful biotechnology launches.

Venture capitalists look for unique and proprietary technologies, which are often very critical in biotechnology, biomedical and pharmaceutical industries.

Venture capitalists are also going to look at market opportunity. This is where there are some cruel realities in the biotech industry. Venture capitalists will typically be interested in those disease areas for which there is a large market. This means, for instance, that a particular university research that has ingeniously found the answer to some fairly rare disease may not be particularly attractive to venture capitalists. Attractive types of research are those that target what are perceived to be much more widespread needs, for better or worse. Areas such as cancer, diabetes, degenerative disease and infection are the areas in which venture capitalists are most interested. Additionally, sometimes research on what may not have been initially regarded as a large market sector may serendipitously produce experimental findings that wind up being useful. In other cases, the FDA has assigned orphan status to certain types of products and technology, for which there may also be opportunities of commercialization.

Finally, venture capitalists will look for a well-defined value proposition. Are prospective companies seeking venture capital funding able to produce a plan showing that the ratio of funding necessary to achieve their end-point goal is feasible?

An evaluation of U.S. patent applications shows that there has been a steady increase in the amount of biotech filings. Earlier this year, a lot of attention attached to the release of the human genome sequence; a number in the biotech industry have prepared for that. We certainly do not feel that that is the end of patent application filing activity; in many regards, it is just the beginning. The human genome sequence has been provided for a handful of individuals, but not all of the genes have been fully characterized, and certainly many of their functions remain uncharacterized. In this huge array of human genes many will be targeted to develop actual therapeutics for a number of disease indications.

We encourage clients to build their intellectual property estate, or patent portfolio. We advise clients that it is important to maximize the proceeds value and to quantify their technology in a way that makes it easier for someone about to invest in their technology to determine whether it is a worthwhile investment. We work with our companies' executive boards and boards of directors to be sure that we are creating consistency between the intellectual property strategy and the business plan of the company. As a result, we project and develop what are mutually responsive R&D and IP strategies – because these things do tend to mutate and evolve over time.

Finally, we are firm believers in crisis avoidance. This is easily accomplished when you have a good in-house program for protecting your intellectual property. This appeals to venture capitalists, knowing that a company is protecting its assets from the get-go.

Similarly, we encourage what we would regard as a fairly aggressive patent filing strategy. The book, *Rembrandts in the Attic*,<sup>1</sup> is one that we endorse whole-heartedly. It describes the value of building an intellectual property estate by filing patent applications early and often. Of course, those of you coming from the biomedical/biotech areas will know that there is strong pressure, even among industry scientists, to publish in peer-reviewed journals. There must be communication between the intellectual property attorney and the inventors to ensure that patent protection is in place before there is a publication of research findings. This attention to detail is certainly something that venture capitalists appreciate.

In the course of our advising clients, and also in the course of conducting their due diligence, venture capitalists will want to see that the technology is being protected in a way that is commercially relevant. Over the last five years, we have certainly seen changes in the way that patent protection is sought, particularly from non-profit research institutions. Early on, patent protection would be sought without a clear sense of what types of products might eventually arise; applicants would simply hope to be protected by that patent. Now, industry, working hand in hand with universities and other non-profits, is tending to guide the preparation and drafting of patent applications and the prosecution of the patent applications, to obtain claims that will protect commercially viable embodiments of inventions.

Our development of these strategies will involve examining the prior art, consulting with the inventors regarding their knowledge of the prior art, and on-line searching. Additionally, we ask the kinds of questions regarding the market that venture capitalists would want to know, such as: What kind of third party activities are known? Are there blocking positions? Might there be reasons to enter a particular field with greater gusto than may have been initially contemplated? Or, should they shy away from an area, or seek some kind of a licensing opportunity, so that the company knows that they have freedom to operate in a particular technology area?

The ability of a start-up company to show its technology and market potential to the venture cap community goes hand-in-hand with maintaining and building its intellectual property portfolio. We look at companies' business plans, mission statements, and technical achievements or accomplishments that need to be attained to permit them to navigate a path through development of their patent portfolio. The venture cap community will be interested in what type and degree of exclusivity a given company's intellectual property position will provide. I have been speaking primarily about patents, but there will be counseling which may involve advising a client to instead protect certain technology as trade secret.

Thinking globally – part of our client counseling, and something that is important from a venture capitalist perspective – is to look at markets outside the United States.

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<sup>1</sup> Kevin G. Rivette and David Kline, *REMBRANDTS IN THE ATTIC*; Harvard Business School Press, 2000; 240 pp.; ISBN: 0-87584-899-0.

Comparative analysis of patent provisions of the United States, Europe, and Japan shows a number of similarities and important differences that enter into how a biotechnology company builds its patent portfolio. Novelty and priority factors are important. The disclosure requirements vary among the different patent jurisdictions, as do filing procedures. Until passage of the recently implemented American Inventors Protection Act, publication of the application did not take place in the United States. Also, processing costs are not insubstantial, especially in some foreign countries where translation costs and other filing requirements may enter into a company's calculation of how to allocate its assets, including the assets it needs to use for protecting its intellectual property position. Any time asset allocation is important, venture capital people will be interested.

Now I'd like to give you a picture of a number of Seattle area biotech and biomed companies, and a sense of some of the technology these companies have developed. I will follow the approaches I have just described, including: (1) working initially from venture capital money; (2) working closely with patent counsel to develop a patent estate; and (3) having a clear vision of what specific sector of technology the company seeks to pursue.

The first example is Xcyte Therapies, which is a Seattle company located in the old Fred Hutchinson Building. Its technology derives mostly from manipulations of the human immune system, and in particular, human t-lymphocytes, which are specialized white blood cells that circulate throughout the body and are involved in orchestrating the immune system's response and regulation. There are a number of the larger disease indications that may be targeted by this technology, including cancer and immuno-suppression. Immuno-suppression has been known to accompany HIV, chemotherapy and other cancer treatments, organ transplants, and chronic illnesses such as hepatitis, diabetes, and kidney failure. In all of these areas, the immune system plays an important regulatory role. In many of these situations, patients present with decreased t-cell function or decreased absolute numbers of t-cells. Xcyte's clear target, therefore, is ways to remedy this deficit in actual or functional t-cell presence. Xcyte's core technology, the Xccelerate system, involves taking a patient sample of blood or bone marrow and treating it in-vitro with Xcyte's proprietary beads, which are designed to specifically activate t-cells to produce desirable enhancement of an immune response. Those beads are then removed and the cell sample is returned to the clinic where it can be re-infused into the patient to promote desirable immune responses. Xcyte has been having good success with this technology.

Another example of a Seattle-area company that has focused its energies on a clear segment of the biotechnology landscape is Molecumetics. Molecumetics is involved in synthetic-organic chemistry to screen for prospective new drugs. They identify compounds that can become candidates for investigative new drug applications and entry into FDA clinical trials. The company's specialties and expertise include high-throughput synthesis, small molecules, medicinal chemistry, analytical and screening support, infomatics (processing of data), and pre-clinical development. Molecumetics' strategy involves interfacing chemistry and structural biology to find candidate drugs that mimic relevant biological shapes found in nature. Molecumetics has exhibited a focus that appealed to the investment community – it decided not to assume sole responsibility for clinical trials or for certain components of product development. Rather, over the last several years Molecumetics has established partnership arrangements with a number of large pharmaceutical

companies whose strengths may be better suited to some of the later phases of developing a clinical product.

Another Seattle company is ZymoGenetics – a perfect example of the industry and executive collaborations that I've been talking about. George Rathman, recently named CEO of ZymoGenetics, has a proven track record. Previously he took the Icos company from a start-up to a public corporation. Prior to that, he developed a very good reputation for having launched Amgen. So, ZymoGenetics, already well-positioned, has somewhat of an unusual life cycle. They started out as an independent for a number of years, then became largely held by Norvo Nordisk of Denmark, and then more recently they became independent again. How did they do this? By focusing on a specific mandate in their business plan and accompanying that mission with intellectual property protection of the technology they chose to pursue. ZymoGenetics' niche has been in what they would call "therapeutic proteins," and they have targeted number of disease indications. Projects such as the human genome project will identify a whole host of proteins in the human genome, some of which ZymoGenetics has designated as plausible therapeutics. So a protein in full-length or slightly truncated form, or fairly modestly modified form, may itself be the biopharmaceutical composition that can be usefully administered. Between mid-1996 and mid-1998, ZymoGenetics became the leader in filing in this area. ZymoGenetics is maintaining a clear focus.

One last example is a medical imaging company called Advanced Diagnostic, Inc. Advanced Diagnostic brings new technology to medical imaging to provide improvements over existing types of ultrasound imaging in medical applications. Advanced Diagnostic has been developing optical sonography. Once again, they're focusing on a specific technology and a specific market sector, in this case, medical imaging in soft tissue. This strategy has proven very successful for this company.

Thank you very much.