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biopreneur

entrepreneur with biotech zeal

A Quarterly Magazine for Biopreneurs

Art: Sanjoy Rakshit

BIOPRENEUR

Goal

- To promote understanding of biosciences entrepreneurship; to encourage biopreneurs' participates in collaborative business development and to guide investors through the maze of opportunities in the biosciences industry.

- Develop a platform where freshmen and seasoned biopreneurs communicate and shares their knowledge and wisdom that they have learned hands-on.

- Develop means for the individual and institutional investors have access to true understanding of triple-bottom line return concept and opportunities that a biotech business can offer for their life and their grand children lives.

- Develop training, and mentoring programs by the biopreneurs for the biopreneurs

- Develop mechanism to work with economic development agencies for local and global economic-equity and human health

Biopreneur serves as a focal point for bringing together scientists, businesspeople and investors and plays a major role .in promoting the education and training of people with biotech zeal.

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Prologue:

*W*e know that every business is related to either inventive or innovative products or services and it must face some ups and downs throughout the phases of its development. Ultimately, and quite fortunately, a stage usually appears in typical development that can offer some comfort and satisfaction to participants of most business ventures. But purists in any field will advocate neither satisfaction, nor comfort alone, for its own sake. It is dedication, business zeal, will power to prove proficiency, and the unforgettable love of a product that entices most people involved to continue serving business goals. Our focus and our prime concern in this book is to explore *bioventure* and the journey of a *bioventurer*.

*B*ioventure represents a microcosm of the world at large concentrated into the small word of biological *venture capital*. As far as biopreneurs are concerned we have to define a scenario with a different kind of light—a light of a different color and temperature. It is an interesting and exciting a time for people wanting to appreciate the world of bioventure. And this is plainly because biotechnology, with emergent educational, governmental, and industrial support, is moving toward its wave crest.

*W*e can think of *bioventure* being a sleek aerodynamic car racing on three wheels—technology, management, and capital. Each wheel is extremely sophisticated, and must be taken care of appropriately to drive the car to an ultimate and optimal destination. After spending many years learning and teaching, when I joined the practiced field of authentic business, I realized the need for the proper understanding of those three driving *wheels*. As people from the field of research work, and management, we may be aware of the greater issues related to our own unique areas of interest, but to be a truly successful biopreneur we must have a commanding grasp on all three driving wheels in our bio-business.

*W*hen we look at the world of *bioventure* we find several cases where people intended to invest heavily, but due to a lack of suitable knowledge they decided to shy away. There are instances where companies having a potential to expand their horizons by meeting a mere few necessities—such as patenting their ideas, and technology. Simply having enough information and facts regarding selling intellectual property or research-based material to pharmaceutical establishments may help some budding bioventures to succeed. But insufficient information also causes comparable ventures to lag behind other more aggressive competitors.

*W*hen these realizations struck me, I felt there was a lack of one extraordinary item in our immediate area which could solve our collective problems. That extraordinary item was a quality study curriculum that might be of assistance to all people in the field of bioventure. My intent is that this study material must contain substantial information for all—upcoming entrepreneurs, people from the field of management, and suited investors. This would not only to serve getting people from various fields under the one roof—bioventure—but it would also create a feeling of unanimity within bioventure.

*W*orking together has always been a fun for people like us. Now we have the means to create that same fun—multiplied—by networking our talents, invented drugs, and various other biotechnological products. At the same time there could be an additional benefit waiting for each of us involved, in the form of earned capital. In all honesty, that is simply one future that I dream of for *bioventure*. The best possible future relies on greater understanding among the people associated with this business. This will be possible only if we can integrate our knowledge and experience, and operate within each other's respective fields of expertise. If we can appreciate the views that those among us want to share, and vice versa, then a treasure trove in bioventure is not far off.

~~ Biopreneur Editorial Board

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WHO ARE BIOPRENEURS?

Miyuki Shiratani and Ryan Baidya

Cupertino, California

Biopreneurs or *bioentrepreneurs* are normally adventurous, innovative, analytical, problem solvers. PhD training in any given field gives the primary skills and core knowledge of that field. However, there is another whole set of skills and understanding that is not covered in normal PhD training. That aspect is the understanding of entrepreneurship itself, which makes it easier to manage and administer the aspects of a specific business. With *bioventure* comes extreme complexity that requires business knowledge and understanding. To become an established and successful bioentrepreneur no one can avoid the business aspects of such a venture. A successful biopreneur must acquire and command the necessary basic knowledge of general business practices. Planning a business and the execution of that plan to achieve real success are two completely different aspects of bionventure, or of any business. A person may have to go through an intermediary phase, or phases—becoming a technical manager—and might also have to be a lead scientist or researcher as well.

The transition from technical contributor to technical manager is not easy. Globally, in biotechnology, scientists are often given the responsibility for projects and people without much thought or additional management training. This is especially true in the case of *biopreneurs* who want to establish a business without outside administrative help. If they transition perfectly—i.e. they understand the proper place and roles of administrative people and mold themselves in accord with that—they'll gain the same outcome as having outside managers brought into the team. The fact is that some biopreneurs make the transition rather well, though many experts agree that the industry has had a rough time in such transitional phases; it needs improvement. So, to reach the peak in your business, you cannot underestimate the need for efficient management styles.

Try to understand what happens within the minds of many biopreneurs. Failure in the transitional stage to manager occurs because most people with a PhD in biotechnology, while chalking out a business plan, focus on the scientific and technological aspects of the whole matter. As they consider their potential product and related incidentals, they see it only from a scientist's point of view. Thus when it comes to the administrative aspects of the venture, they believe that

implementing supervisory skills is simply a matter of time and gaining experience. They expect it to be a basic learning situation while they operate their new business.

Stan Sewitch, a human resources (HR) consultant in San Diego, contradicts that all too common belief saying, "Management is not an additional set of responsibilities requiring new skills to be added to one's professional repertoire," he continues, "Management is an entirely different career from that of the individual contributor in science." Sewitch, former director of human resources for Mycogen, San Diego, CA, USA, adds that technical professionals too often believe that managing people is a skill-set to be acquired. In most cases, they find out too late that this isn't the case. It's best to take Sewitch's advice seriously from the very outset of a project.

A researcher willing to set up a business based on his or her concept in biotechnology, known as a biopreneur in the industry, must achieve several useful qualities to reach the goal of becoming a successful businessman. Along with gaining managerial awareness it is also advantageous to know how they themselves are different from other businessmen. It surely helps them to smooth out any pertinent difficulties while adding indispensable qualities. It is essential to prospective *biopreneurs* to prepare for the future by learning and planning for their *bio*-venture. They must understand, along with other things, prior to commencing their business, their own drawbacks and weaknesses and how they may overcome them or at least be prepared to face them.

TRAITS OF A RESEARCHER AND A BUSINESSPERSON

RESEARCHER	BIOPRENEUR (Science+ Business)
Determinant & Stubborn	Determinant
Ambitious	Ambitious with realism
Problem solver	Problem solver & delegator
Unbound Explorer	Disciplined Exploration
Risk taker	Risk taker & hedger
Leadership (some cases)	Leadership & Team Player
Cheer leader (some cases)	Cheer leader
Sales person (some cases)	Sales person
Hard worker	Hard worker

Table 1: Characteristic differences between Researcher and Businessperson

From the above chart it is quite clear that researchers and *biopreneurs* are different in fundamental ways. You can recognize one thing clearly; if you are willing to become solely a researcher you may follow one path, inventing new things day in and day out. But if your goal is to become a successful businessman you will have a somewhat different pathway to take.

If fortune is inviting you to become a biopreneur you must choose a special lifestyle— one where you must play both roles—researcher and businessman. Along with the characteristics that a researcher exhibits a biopreneur carries additional attributes which demand particular attention. For example, a researcher's character-set insists on being ambitious. In contrast the character of a biopreneur requires ambition based on reality. That "reality" makes an ideal situation because in bioventure you must work to promote yourself along with your company's brand. There is no place for airy ambition as you are required to make a profit for your investors. In the case of bioventure, you will be forced into certain obligations such as: competitive intelligence, task-management, finding investors and funding, tax concerns and monetary returns for your investors, marketing strategies, concrete branding—the future of your brand, reworking corporate structure etc. These things will prevent you from exploring new product-lines without ample concern for profit in the venture. Thus, still retaining characteristics of a researcher, which you truly are, you will also think and execute things like a businessman. That means not to embellish, so that you will become an ideal biopreneur.

Valuable opinions

Co-founder and Chairman of Responsys, Inc., Anand Jagannathan talked about the characteristics required to be an entrepreneur. Entrepreneurs need to have determination and drive, the ability to face rejection, and they need to be risk takers. They must know their "value proposition" with respect to customer "pain points." Most successful entrepreneurs, Jagannathan suggests, have a clear definition of their personal success that goes beyond reaching the IPO stage, an ability to listen and adapt to customer's requirements, and the ability to recognize and seize opportunity. Though it may be easy to read or listen to this, it's really very difficult to follow through. And, to materialize the whole concept is even harder.

Mr. Bipin Shah, a successful entrepreneur, now a *V.C.* in the *Silicon Valley*, once presented advice to the new entrepreneurs:

- Start only if you are committed for the long haul and prepared to go through the ups and downs.
- Start only if you have the deepest *passion* for what you are going to do.
- Start only if you are prepared to "*fail*" if things go "*wrong*" and they "*do*..."
- Start only if you are absolutely convinced that you are killing a *real pain* that exists in the *market today*.

Though an old familiar story but probably novel to new entrepreneurs—starting anything new always has risk factors, which could lead to failure. If you are inclined to stop at this point, or move on to other tangential visions, you may never return to your dream of establishing a real bio-venture and it will remain merely a fantasy. Whether it's a new, or an established venture, risk is always an innate part of the game. But you have to stick to your original choice of acquiring success. Gururaj "Desh" Deshpande rejected thoughts of returning to his life as a

professor and software engineer—Re: book titled *From Financial Flop to Billionaire*. After his first failure, Desphande stayed the course, always true to his original vision. Now a very successful entrepreneur, he relates: "A *manager* means doing things (the) 'right way' and a *leader* means doing the 'right things.'" If it's something you really believe in, he asserts, "…you're going to make it happen."

Here, before you decide which role fits you best, you have to know exactly what *right thing* and exactly which *right way*… Reading theories and building a business plan, based on theory alone, is not very hard, maybe even a little too easy. Your planning must be based first on *reality*. After that you have to be prepared to pursue essential intermediate goals in order to achieve success. First and foremost, you must consider possible risk factors that you or your company may need to face. Risks have to be faced; not succumbing to your fears will make you an ultimate winner.

Leadership—It's Expected

Outstanding leaders in business have the ability to convince others. You must have the ability to inspire your peers and to execute things at the right time. You have to motivate investors and partners to have faith in your abilities and concepts, so that they do not waver to invest or support your decisions.

It is particularly true that gaining something is frequently easier than retaining it. Leadership is that same sort of thing. As a leader you may have to make decisions without having all the information at hand, but your decisions will have to be a strong enough so that no one will want to oppose you afterward. Though only real experience helps true leaders to make decisions effectively, nonetheless, many times intuition, based on personal and concrete understanding, is also a great and positive assist.

You have to stick to your decisions until a time when you find significant flaws in them. Here you will have to mindful that as a leader you must not play the part of a dictator. Good and generous leaders have their goals focused on their team's goals. You have to be always ready to listen to your people because they may, in fact, have better ideas in mind than you. You must build a good team to execute what you think. Thus capable minds should surround you—their suggestions, comments and interpretations will always be helpful. You should try to remain the center-point of the team, and so your communicating skills will keep them in concert. You have to be strongly connected to your team-members, ready to listen to and talk to them as needed.

It may appear to be the job of managers but you also must learn how to separate your inner being—compartmentalizing yourself as required for a group venture. You must know how to gain the qualities needed to accomplish the duties of full leadership. You have to sanction yourself with powers like *ego*-power, *self*-power and *agency*-power. And it is your *soul*-power—the power of your spirit—that will keep you totally responsive to all appropriate feedback. That power will never lead you to feel-on-top of anyone, nor beneath anyone either. Also *ego*, if used positively, can make you self-aware; it can increase positive values in your life. But remember, your *ego*-power must not

become tactless egotism—self-centered selfishness—optimally it should lightly touch *egoism*, i.e. self-interest. That difference subtlety prevents you from losing your humanity.

As Deepak Chopra has shared, you as a leader have to have the ability to look and listen—not normal looking, and listening—you must not be blinded to observing reality. For the best possible future of your business, you must not be deaf to free-flowing ideas and advice from your partners and your subordinates.

Interestingly, this vision is not only for you, but also for the sake of social justice and environmental responsibility. After all you must be responsible for any harm caused to ambient surroundings if it's caused by your bioventure. So you ought to cultivate a sense of consciousness, and social-environmental awareness. Consciousness differentiates *tangled hierarchies.* Consciousness is necessary to virtually connect with reality. And so, it is a sense of consciousness, and awareness, that every human being, whether in business or any field or job, must possess, for the betterment of society and the environment in general.

A Simple Philosophy

Business is a service for the society and money is the by-product of that service. Every time, as you think of building a new venture, you ought to remind yourself of that statement. The by-product of the business is your profit and it is the living blood of your company, but the service you provide to society must not be any less than oxygen. That might be considered yet another responsibility, but as a leader you have to be prepared for such concepts.

Leadership is dependent on time and circumstances. You must be prepared to prove your abilities every time you are faced with requisite circumstances. You have to create a wholly positive environment for ongoing projects. As a leader you have to have understand synchronicity—a sense of co-ordination, and a sense of harmony within several jobs. A leader feels, visualizes, takes a risk, and accomplishes a commitment to pick up broken pieces, as he or she moves along to meet various goals. A leader never loses the winning spirit.

Nearing the end of this section, I would like to recap and philosophize. It's not wrong to say that leaders, and followers, co-create each other. Leaders, followers and environments co-arise within the same space and time. It is *rule* itself that differentiates the ruler from others. Although there are several points or characteristics that may help an entrepreneur to manage the role of *the ruler*, there is nothing that is fixed in any business. Rules work for business, but business is never for the sake of *rules*. Rules or basic guidelines to prepare your business are conceived from previous business experiences.

As a leader you will have to make your own rules. Time will allow such opportunities. Then why talk about not-making-rules or avoiding it? Why listen to other people? It is for a breakthrough or to invent new or better rules, when you will reach new vantage points of understanding—newer positions of understanding, thus modifying older rules.

Knowledge is only a stairway that leads you to a level of success—you have to become successful first, by

devising your own strategy. When your strategy is proven, you will establish your own rules in which to *rule* your business, as you see fit. This tipping point will be perceived as the birth of a real industry leader. …Hats off!

Inside the Minds of Biopreneurs

Now you know or at least have a vague notion of what a *biopreneur* is, a hint of the managerial aspects of the job, as well as the role and the ways of a leader. Now let's take a brief journey through the mind of a biopreneur. What they hold in their minds makes them different from other researchers, as it also makes them known to the world! What is the inspiring source of such strong will-power! According to Mr. Olaf Isachson, the author of *Joining the Entrepreneurial Elite*, the ten most traits of entrepreneurs, including biopreneurs possess, are:

- *They are in charge of their own destiny.* Contradicting this, anyone can say that every man is the master of his own destiny, it is true! But the winning drive is this: Like other people, entrepreneurs, when problems arise, do not leave their destiny in hands of an unforeseen circumstance.
- *They are non-conformists, able to be stand-alone or be with people.* It is their iron mettle that helps them to face any situation. They know how to mold themselves in accordance with a given situation.
- *They move beyond the local, the provincial, the familiar and the tried and true.* In short they are true risk-takers.
- *They avoid time-consuming trifles and are swift to make decisions.* True leadership is always a part of their character. Always, even in the roughest and hardest situations, they remain cool and calm—to make the right and best decisions.
- *There are no obstacles, only challenges and temporary setbacks.* The word *obstacle* does not exist in the vernacular of *biopreneurs*. It is a merely a *challenge*, as they love to call it, and obviously it is a challenge that makes them so excited and charged.
- *The harder they work the more energy they generate.* They generally possess nonstop energy to go on, and on, and on…
- *They love what they do, and their devotion and passion allows them to move beyond the confines of themselves.* The passion and love for what you are about to do will make its outcome much better, and of course generally positive.
- *They are visionaries and their biggest competitors are themselves.* It is ultimately their unique vision and decisions that make up responsibilities for the future of their ventures. Certainly, if they are wrong, they will reverse an imminent catastrophe.
- *They seldom give up. Failure is not in their vocabulary.* Just like the word *obstacle* they are not ready to think of *failure*. A small piece of advice here: it is better to have confidence, not thinking of failure or obstacles, but you have to keep your eyes open for anything of that sort

too, so that you find yourself and your people ready to face it, if it appears in the future.

- *They firmly believe there are no sins of commission—only those of omission.* That may differ depending on the individuals. However, it is also a particular *trait* that *biopreneurs* possess quite proudly.

Paths to success

We always like to know and teach, especially when we know a lot about business, leadership, etc., or about a formula that may bring success. I do not think there is any generalized formula or equation that can be used to define success. However, this does not prevent us from exploring and finding a cluster of formulas, or sets of characteristics, that may give us a foreseeable indication of a pathway to success. In *bioventure* this information is quite valuable. It is actually based on experience as well as the experiments of others who might inform us about possible, though not 100% flawless, paths to success. One thing might be applicable to X, though it may not equally be applicable to Z, and so on. A group of scholars at MIT's Sloan School of Management did research on this subject for five years. According to their studies here is their model for success:

- Success takes a balance of forces. Technology is not always necessary and is almost never sufficient.
- Due to the power of open communication by the virtue of the Internet revolution, the business model of future company might be a huge corporation or it might be a very small enterprise.
- Decentralization is key phrase of the future. In order to be successful one must make decisions based on ones proximity to the knowledge of his or her customers.
- True activities, not the corporate organization charts, will become the primary building blocks in a business. Out-sourcing and alliances will eliminate the need for huge personnel, and becomes the enabler of the small businessperson intent on staying lean but growing into a big business.
- Companies large and small will be both global and local. They will need the local touch and all will face global competition.
- The most impacting discovery of this research is regarding the coming golden era of *microenterprises*—a vision that is saturated in the power of Internet. Given the low cost of communications, everyone can be well informed and thus will make good decisions. The highly motivated, the creative and innovative, the biopreneur, will convert imparted data and knowledge into business wisdom, and build successful companies to compete with gorilla-corporations.

As I already have mentioned these are possible ways; it depends upon you, as you are the sole responsible agent for the future of your company. It is useful and a wise decision for the time being to read these ideas to comprehend the *right way* before you make any hasty decisions. No one and nothing in particular will bring success unless you understand and decide what is good for you. It is well said that success is the progressive realization of a worthy goal. Success

comes from the ability to feel compassion.

Success Redefined

Inderjit Singh, founder and CEO of Infiniti Solutions and also TIE Singapore, a member of parliament in Singapore, he has shared the story of his entrepreneurship. Acquiring a seat in government or joining a multinational company formerly defined success in Singapore. This might resonate with many of us who have known success in Japan, or have equated it to signing-up with a multinational organization, or gaining a government position. Singh climbed the ladder of success in Singapore through the same means. But then he attempted something a bit different; he was able to acquire venture funding from inside of Singapore, and from abroad. In doing this he ultimately realized his entrepreneurial dream by changing previously construed, or tacitly defined, limits.

He said, as a member of parliament he championed the cause of transforming Singapore from a corporate based economy into an entrepreneurial one by addressing all concerns, impediments, and challenges to entrepreneurship—his mission leaving: "no stone left unturned." According to him the key characteristics required to be a successful entrepreneur are as follows:

1) Determination
2) Risk-taking
3) Leadership
4) Number one sales person and number one cheerleader
5) Problem solver

So you see the basic traits required to be a successful entrepreneur stay same. It is only the method of utilizing these traits that change. Over the course, methods change with things such as the mind, time, and circumstances.

Though not directly connected to *bioventure* let us share another important success story. A well circulated story, if not well known, is one in which Ireland was looking to become a major center for Microsoft and wanted a major server hub. Unfortunately, Microsoft's investigation revealed that Ireland's electronic infrastructure could not support it because it did not have enough resident bandwidth. So everything stopped. What to do now! There was no looking back and no crying tears of woe. Ireland took on the enterprise, implementing the required bandwidth building it to the latest specifications in a very short span of time. The rest is history, thus establishing Ireland as a global center of excellence in Internet activity. And that is how one should be prepared for any forthcoming or unforeseen, unexpected, problem. Now then two questions arise:

How would another country have dealt with such a challenge?

How are other countries prepared to participate in similar dynamic and global marketplaces?

The problem and its solution will remain at their places we just have to find them out. Now that we have enjoyed a little bit of success kind a thing, let us explore some new ways to attend success:

Some Critical Success Factors In Biopreneurs

- Strong Will Power That Can Motivate Others.
- Early Contact With Successful Entrepreneurs.
- Exposure To Success Stories And Case Studies.
- Gain Practical, Real World Experience Before, During And After PhDs.
- Be Willing To Be Unusual/Unconventional.
- Agree To Embrace Risk, And Possibly Failure.
- Ready To Leave A Large Company.
- Great Idea To Start With.
- Excellent And Passionate Team - Near And Long Term Vision.
- Ability To Change Course Mid Stream.
- Execution, Execution And Execution!!
- Strategic And Marketing Brilliance.
- Frugality & Excellent Cash Management.
- Support Network - VCs, Board, Advisory Board And Other Value Add People.

Table 2: Success Factors in Bioventure

Though it may look like bringing the same old line in front again, I should like to remind you again that things are not to be followed strictly. Those are important yet very flexible rules. Those tools are for the sake of your business and your business is not there to prove their practicality. Every ruler creates his/her own rule but it's only after you be sure of calling yourself a ruler in business.

Sum up

As someone once said, the best of us is not what we do but what we inspire in others. Thus when we share our experience and knowledge it increases. Whatever the way we choose or wherever we move to work the basic knowledge and way will remain the same. We may face failure and obstacles only to remember, "Failure is one of the major milestones of an entrepreneur and each obstacle is an opportunity". It's not a theory, as a theory is also based on what we learn out of our failure and experiment, but our own flaw and failure will teach us the right way to success. It will make us winner one day. Everything is dependant on our mind as Silicon Valley is not a geographical location it is just a "state of mind". Think as a winner and you will find yourself as a winner. If you

loose the vigour of your mind you will be nowhere in near future.

If experiment is the only thing that you have in hand, do it sincerely, genuinely and with an inimitable passion for them. With the human life span longer and the business cycle shorter, the opportunities are immense for those with the motivation, the temperament, and the guts to do it their way. There was no one-way, there is no one-way and there will be no one-way. It was the biopreneur's way, it is the biopreneur's way and it will be the biopreneur's way.

(This artilce is taken from a book titled – Biopreneurs: the Molecular Millionaires)

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Bio-business – a new Gold Rush:

Bio- business comprises over 10 trillion dollars or 30 percent of the global economy. Countries throughout the world have identified new opportunities in the bio-business arena as the next hot technology area and are investing in training their scientists, setting up state-of-the-art life science and technology knowledge-clusters, establishing viable biotechnology industries to fuel growth in bio-business areas.

In the recent years, there is more willingness and push for cross-disciplinary work and ventures between high-tech and biotech. Professional and business investors may find biotech as a new Gold Rush of our time. Biotech offers infinite opportunities as long as human beings reside on this planet.

It is considered that the bio-business is going to be the fastest growing sector of the world economy during this century. Some even designate the 21st century as the *bio-century*. This workshop is designed to provide non-bio professionals a broader understanding of the field, and the opportunities lie within. Can you afford be simple a spectator?

Paradigm of Bio-business:

The biotech business is witnessed in everyday life from toothpaste to the medicine cabinet. It occupies more of our personal economics, and social relationships, from happiness to love than what we may realize. With the recent convergence of IT and nanotech with biotechnology, the Bio-field is growing and enabling more economic opportunities to be latched on to.

As every discipline goes through its roller-coaster of highs and lows, bio has gone through its own high and lows in the mid 80s, while the IT-*dot.com* had its day in the late 90s. During this roller coaster ride many fared well in the game while considerable others lost a big chunk of their portfolio net worth; however, the fundamentals remained the same and those who maneuvered with sound understanding of the field fared the best.

Common Senses not common traits:

Common sense of fundamental doctrines in most businesses is universal and applicable all of the time—either in a depressed or vibrant economy. What chiefly differ are the business and the intrinsic model that follows the business. Knowing the specifics and understanding the unique-nature of the field gives one professional tools, skills, and wit to win a race of apparent ambiguity. People fail in their endeavors not just because they do not know, but moreover because of confusion and lack of confidence which arises from the weak understanding of the interlinking of the many 'bio-parts'. Biotech, by virtue, has its own specific and unique distinction. Having spherical knowledge and understanding of the field would help one to make prudent decisions either for business investment or for career development within the field.

Ryan Baidya

Patent Protection for Life Science Inventions: Unique Challenges for Applicants

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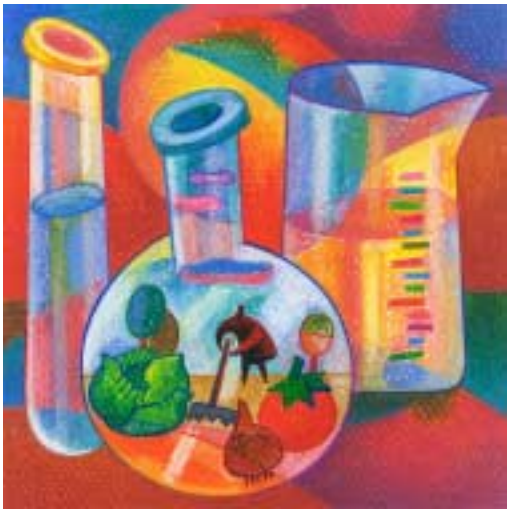
Synopsis- Life sciences inventors face a rigorous standard for the written disclosure in patent applications. Each patent application must provide an extensive, highly detailed amount of teaching that enables a hypothetical person of ordinary skill in the art to practice a claimed invention with even a moderate amount of breadth. The United States Patent and Trademark Office is also very careful about the scope of any invention that is claimed in the patent application. For example, if there is any potential for over-reaching of invention scope or a claimed application in gene therapy (which the Patent Office does not yet recognize), the patent applicant will face rejections requiring that the claim scope be appropriately narrowed. The application can be strengthened by the appropriate use of deposits and a claim strategy focused on the invention rather than the invention's potential

In the United States, patent protection can be obtained for any novel, non-obvious and useful invention that is a process, machine, manufacture, or composition of matter. Generally, patent protection provides an inventor with a right to a monopoly on his or her invention for a limited number of years (or if the inventor is not practicing the invention, a right to a reasonable royalty for others' use of the patented invention). In exchange for this limited monopoly, the inventor must provide the public (via the patent disclosure) with a clear description of the invention and the process of making and using the invention so that the public can make and use the invention when the monopoly expires. This is the fundamental trade-off in the patent policy – the public, through the inventor's detailed disclosure of the invention in the patent, obtains knowledge of the technology, while the inventor obtains a limited monopoly to the technology.



An inventor obtains patent protection by submitting a patent application that distinctly claims and describes his or her novel, non-obvious, and useful invention. The application undergoes examination by a Patent and Trademark Office Examiner who determines if the invention is novel, non-obvious, and possesses a clear utility. In addition the Patent Examiner determines if the patent application's detailed disclosure, known as the specification,

"contain[s] a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains…to make and use the same" (35 U.S.C. §112, 1st paragraph). In other words, the application must provide a clear written description of the invention so that a hypothetical person "skilled in the art" would be able to make and use the invention (i.e., would be "enabled"). Inventions in rapidly developing technologies such as the life sciences face particular challenges with regard to these written description and enablement requirements.

The "claims" of any issued patent are the numbered paragraphs at the end that describe in detail the exact scope of the subject matter covered by, or protected by the patent. They are analogous to the boundary descriptions in a property deed, describing in detail the boundaries of the patent protection. The claims of a patent application are compared by the Patent and Trademark Office Examiner against the present state-of-the-art in the present technological field (known as "prior art" and including prior patents, publications, articles, literature, and other technologies in the public domain). Often times, the majority of the patent examination process involve a formal negotiation between the patent applicant and the Examiner regarding the precise language of the patent claims. Not only do the inventions covered by these claims need to be novel and non-obvious over the prior art, but the claims must also be fully supported by the written description of the patent specification. In other words, a patent application cannot claim an "anti-gravity" machine if the patent specification fails to describe how to make and use such a machine.

Often biotech inventions occur at the nexus of human ingenuity and highly complex natural compositions of matter. The Applicant is faced with the challenge of describing a viral strain, hybridoma cell line, transgenic animal, or a newly isolated gene in such a way that it could be made or used. Scientists routinely write protocols that detail the way something was made or isolated but would be the first to acknowledge natural variation in biological materials. Where words alone are insufficient to describe the invented biological material, the Patent Office allows deposits of many types of biological materials with a Patent Depository such as the American Type Culture Collection (ATCC). Reference to and identification of the deposited materials in a patent application fulfills the written description requirement for the deposited materials. The benefits of depositing material must be weighed against the cost and inconvenience of depositing the material.

In addition to depositing any claimed biological materials, patent applications for life science materials should teach possible alterations extensively. The Patent and Trademark Office considers the art of biotechnology new and highly unpredictable, thus general teachings of how to design variants are usually not considered sufficiently described to provide the scope of coverage most patentees desire. Suppose an inventor has isolated a novel nucleotide sequence encoding a high fidelity, thermostable polymerase and has created a mutant form with extremely

high fidelity and wishes to obtain patent protection on the original sequence and the improved sequence. The inventor claims his sequences and variants that have at least 95% identity and are capable of synthesizing DNA. In the application the inventor should describe any variants that he made, any variants that he planned to make, any residues that are particularly crucial, and any residues that he predicts could be altered without impacting the protein's function. Describe all the variants that were made, even the less successful ones.

These less successful variants indicate changes that can be made without significantly impacting activity and provide direct teaching of variants within the scope of the invention. If there is a region of the protein that will have less impact on activity, the inventor should indicate that she recognizes that variations in that region are covered. If there are regions that are crucial for activity, the inventor should describe the subset of variations that might be acceptable. Altering a glycine residue to alanine, for example, might be tolerated better than altering glycine to tryptophan. If multiple variations might yield different results, the inventor should describe the potential combinations. Provide at least one specific functional assay for the protein and provide a broad range of results indicative of function.

Deposit, describe, and don't stretch. Suppose an inventor has discovered an assay system that allows him to rapidly screen numerous compounds for a particular activity that he hopes will yield a multi-million dollar medication. The inventor should claim: the assay system; any novel components of the assay system; methods of using the assay system; methods for performing the assay to identify compounds with a specific measurable activity; and novel compounds that are in hand. If the identified compounds share well-defined structural similarities, the inventor should try to claim the genus of structurally similar compounds with the activity. Avoid "reach-through" claims that attempt to cover compounds that could be discovered using the novel assay.

In another example, suppose an inventor has developed a novel method of assaying a biomarker for which an abnormal level correlates with a particular disease state. The inventor claims methods of using the biomarker assay, comparing the results to a standard, and characterizing the biomarker level as abnormal.

In the current Patent and Trademark Office environment such broad claims are likely to face written description rejections (a rejection based upon the examiner's argument that the claims are not supported by the written description of the patent application). Such broad claims will cause the examiner to question whether the invention is sufficiently described to indicate that the Applicant was in possession of the invention. At the very least the application should include narrow claims that indicate whether an increased or decreased biomarker level correlates with the particular disease state. The specification should describe data correlating the altered biomarker level with the disease thus demonstrating that the Applicant was in possession of the invention.

In a similar scenario, the inventor, a well-known eyebrow specialist, has identified a set of genes expressed differently in diseased eyebrow samples than healthy eyebrow samples. Recognizing the importance of early diagnosis in eyebrow disease, the specialist invents a method of detecting eyebrow disease based on this differential expression. The specification provides clear evidence that differential expression of the gene set occurs in each of the top five eyebrow diseases.

The application claims methods of detecting eyebrow disease that include the steps of assaying the eyebrow disease related gene set in a subject, comparing the results to a predetermined standard, and characterizing a subject with the appropriate increases or decreases in gene expression levels as a subject with eyebrow disease or without eyebrow disease. Such claims are likely to face a "non-enablement" rejection based on the examiner's argument that the method could identify armpit diseases or bigtoe diseases as well as eyebrow disease, thus the claims are not enabled for methods of detecting eyebrow disease.

To reduce the likelihood of these types of non-enablement rejections, include claims that indicate the novel method is tissue preferred. For example, provide claims with the step of providing an eyebrow tissue sample from the subject.

Additionally, methods that rely on differential expression of a gene set face increased scrutiny by the Patent and Trademark Office. While not as firmly rejected as gene therapy claims, there is an increasing concern about the variability and reproducibility of the available differential gene expression assays, particularly microarray based methods and the impact that alterations in the microarray analysis software's underlying assumptions could have on the analysis of microarray data.

It is not clear to what extreme the Patent Office will take this concern; however, it is advisable to teach suitable software programs and a range of parameters that could be used in the microarray data analysis. If the Patent and Trademark Office regards microarray data analysis programs as analogous to sequence homology programs, it may become necessary to specify a preferred microarray data analysis program to be used with the invention.

Finally, provide claims that distinguish the invention from gene therapy. The Patent and Trademark Office does not consider gene therapy a viable technology; therefore, any claim that could be construed to cover gene therapy is considered not enabled for the full breadth of the claim.

There are numerous acceptable ways to delineate the claims and the appropriate way of doing this depends on the actual invention. For instance, the Patent Office routinely accepts use of the term "isolated" transformed cells or tissue to distinguish the claimed material or methods from gene therapy.

In summary, life sciences inventors face a rigorous standard for written description and enablement in patent applications. Each patent application must provide an extensive, highly detailed amount of teaching to

provide a written description that enables a claim with even a moderate amount of breadth. The application can be strengthened by the appropriate use of deposits and a claim strategy focused on the invention rather than the invention's potential.

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Why do many cancer patients relapse even after removal of their tumor?

The promise of targeted therapy against cancer stem cells

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Why do many cancer patients relapse even after removal of their tumor? How do these aggressive tumors spread and metastasize to other parts of the body? Why has the current treatment regimen of surgery, chemotherapy and radiation therapy failed to provide long-term survival for many cancer patients? These are difficult questions. As a potential answer, the cancer stem cell theory that is now at the forefront of cancer research offers an intriguing explanation.

Cells that make up a patient's tumor may be organized in a hierarchical manner. At the top of this hierarchy are malignant cells that behave like stem cells, being able to divide and give rise to themselves and to other tumor cells. This small subset of cells may initiate and maintain tumor growth. Some studies have shown that injecting as few as a 100 of these cells can grow an aggressive brain tumor (glioblastoma multiforme) in the brain of an immunocompromised mouse. The implications of such a finding are enormous. These cancer stem cells (CSC) can give rise to a heterogeneous mix of cells as seen in the morphology of many aggressive tumors. If these cancer stem cells survive the current treatment regimen, then they may cause the re-growth of a tumor in a patient. These cells may invade surrounding normal tissue or move to another location in the body and form a metastatic tumor. Current treatment modalities treat the tumor as a bulk entity and try to eliminate as many tumor cells as possible. However, targeted therapy against these cancer stem cells can provide a better means of eliminating a tumor completely. Can we isolate and eliminate them? How? How do we spare the normal stem cells in the body while trying to eliminate the cancerous ones? Researchers in academia and industry are finding creative approaches in the pursuit of such a targeted therapy.

It is certainly not easy to isolate these cells from solid tumors (brain, breast, prostate tumors, etc.) and maintain them in culture. However, it is possible to isolate them with the use of distinct cell-surface markers or modified culture methods that favor stem cell maintenance. Recently, isolation and characterization of these cells from many solid tumors have revealed many interesting findings: they constitute only a rare population of cells (between <1-5%) within the tumor and they utilize inherent molecular mechanisms that promote resistance to radiation therapy or drug treatments. These findings suggest that CSC are a hard target to go after. At the same time, they also provide clues that can be exploited to develop therapies based on eliminating them. Elucidating the molecular mechanisms through which these cells

maintain their stem cell state, give rise to tumor cells, resist standard therapy, and metastasize will give us a handle on how to target them specifically. Researchers have identified approaches that can specifically target CSC or their microenvironment. For example, Duke university researchers recently demonstrated that CSC recruit their own vasculature for nutrient support. They also showed that preventing the growth of new blood vessels effectively reduced CSC numbers. Researchers in Italy have suggested another approach relying on the signaling molecule bone morphogenetic protein's (BMP) ability to terminally differentiate CSC into tumor cells. This type of "differentiation therapy" could render differentiated CSC more susceptible to existing treatment modalities.

The biopharma industry is exploring opportunities to quickly bring to market therapies based on CSC elimination. The pace of industrial development in this area is picking up as companies are generating more exciting results related to the effectiveness of this approach. Some of the key players in this field are Genentech, Oncomed Pharmaceuticals, GlaxoSmithKline, and Stemline Therapeutics. It may be a matter of time before such targeted therapies are on the market.

Just as normal stem cells rely on developmental cues and molecular signaling pathways during the growth of an organism, CSC may utilize some of these same pathways in an unregulated manner to support tumor growth. Genentech's approach relies on characterizing and interfering with these pathways to promote tumor regression. In collaboration with Curis, Genentech is developing compounds that inhibit the Hedgehog signaling pathway that is known to play a role in CSC maintenance, tumor growth and metastasis in skin, brain, pancreatic, prostate and gastrointestinal cancers, among others. Phase I clinical trials of a Hedgehog antagonist are currently underway along with plans of starting a Phase II trial by this year.

Oncomed Pharmaceuticals is employing a screening approach to identify and develop monoclonal antibodies that may specifically target CSC populations. They isolate CSC from primary human tumors, create xenograft models of these tumors by injecting these cells into mice, and test a panel of antibodies against these animal models to determine promising candidates for further testing. This type of approach may identify a wider range of potential therapeutic candidates that can be employed against specific tumor types. Initiation of clinical trials of their lead candidate is expected to start this year.

Some of the currently available drugs may also eliminate CSC. GlaxoSmithKline's Tykerb is currently approved for patients with advanced breast cancer that has spread to other parts of the body. Recently, in two independent Phase I clinical trials, Tykerb was found to reduce CSC numbers by as much as 50% in some breast cancer patients when administered along with Genentech's Herceptin and slow the spread of the tumor to the brain in combination with Roche's Xeloda. These encouraging results have prompted GSK to re-position Tykerb for detailed studies related to its effect on CSC.

SL-401 from Stemline Therapeutics is also a biologic compound in Phase I clinical trials currently that has demonstrated the ability to inhibit tumor growth by targeting CSC. SL-

401 targets Interleukin-3 receptor, overexpressed in Acute Myeloid Leukaemia stem cells, and delivers a toxin to the cells thus eliminating them. On a very encouraging note, one of the patients in the study, who had been refractory to standard chemotherapy, achieved a complete response with SL-401 treatment demonstrating the compound's potent anti-tumor activity.

As the cancer stem cell field matures, we are likely to see more therapies that are designed specifically against these malignant cells within cancers. Many technical challenges remain in the quest towards targeted therapy against CSC. But it is now increasingly clear that surpassing these hurdles will open up a promising new and effective approach to cancer treatment

Anuraag Sarangi is currently pursuing a Ph.D. in the Neuroscience program at Vanderbilt University. His research focuses on the role of the Hedgehog signaling pathway in brain tumor stem cells. Prior to joining Vanderbilt, he completed a M.Sc. in Computer Science from Indiana University in 2004. Anuraag also serves as the Co-Director of the Tennessee Biotechnology Association Student Chapter.

Business Plan Tips For The Entrepreneur or Intrapreneur

Sherri Dohemann

Ortho-McNeil Neurologics, Inc.

The bottom line - Are you an entrepreneur or Intrapreneur? Innovation and customer knowledge should go hand in hand:

If you are an entrepreneur, then your customers are many and varied and include patients, payers, doctors/clinicians, regulators, and investors.

The good news is that you'll always be learning; a solid handle on innovating and knowing your customers and their needs will put you ahead of your competitors.

The following 4 items are some business plan sections required to approach any investor and help you understand your customers, including large companies for exit strategy options.

The days of winning on thinking up of just a hot technology innovation are over. There is still funding to be had, mergers to be made, and IPO's, however answer those questions before they stop you in your tracks.

1) Detailed and accurate assessment of customer or pipeline need fulfillment/complement with technology based on current treatment trends.

2) Accurate assessment of any current organization's either competitors or potential buyers capability measured against disruptive market changes- Cartesian method.

3) Understand governance of large organizations that may be your corporate investor: who assesses, who signs off decides, and why etc.

4) Innovation, why it's now survival, not just growth and why it's easier for small companies to innovate and perhaps for large companies to buy.

Looking at your company and any partner large companies:

When looking at a company partner or assessing your own company, World-Class Operations and finance-ceteris paribus-is there the vision to see where your science/ technology innovation fits with the customer? Do you and your partner company know how you'll gain customer community support for the innovation?

However, you need to know how it fits their practice reality in physiological, patient profile, financial, and practice detail-to win funding from investors; that's what they'll ask to see. Have a reimbursement plan based on a market assessment knowing what payer will see what value in your product and why.

My perspective is that the creation of a plan to win in the marketplace starts by being able to accurately assess your organization's capability to move this innovation forward. Also, you'd need to see what has to be done to increase that capability and propose appropriate governance changes supportive of the vision. This requires the necessary commitment from the needed levels for the changes and the right resources. The communication to reinforce the agreements enables the changes in roles and responsibilities to support the vision.

It seems critical that the correct current capabilities and business environment be accurately perceived for your business and your partner investor or co-promoter. This would be combined with horizon scanning capability for where the trends of the market are going.

Days where large firms can capitalize on- ways of doing things and technologies to scales up of the masses for extended periods are said to be over in technology markets because of disruptive innovation. That is why innovation seems necessary for survival, not just growth now.

Where are some places where entrepreneurs or intrapreneurs can learn more and network?

http://www.FountainBlue.biz Lessons in Funding
From the Fountain Incubators' Panel:

Tips on Working with Incubators

- Incubators could be virtual or brick and mortar, and will work with you to suit your needs.
- Incubators can support you in building your strategy, developing your technology, connecting you with funding sources, connecting you with quality service providers, providing a shared infrastructure, creating a community of entrepreneurs, etc.,
- Understand the options for incubating companies and the value each one provides. Also understand what your objectives are to ensure that they are in alignment with the opportunities presented.

Thoughts on Securing Funding for Early Stage Life Science Start-Ups

- Bootstrap for as long as possible, while still making progress.

- Understand when and why you should take money and research how you
- can connect with the right investors (private? Angel? VC? Foundation) at the right time.
- Understand the value of the funder beyond the money - will they provide expertise, connections, operational support, coaching, etc.

- When considering funding, ensure that it will position your company well for additional and future funding.

- SBIR grants are a good option for early stage drug development, however phase one funding is relatively small and grant findings in general are episodic rather than continual. In addition, there are restrictions on how the grant monies can be applied, although there is no equity loss for the findings.

* Research STTR NIH grants
http://grants.nih.gov/grants/funding/sbir.htm,

DARPA grants
http://www.darpa.mil/body/off_programs.html,

RAID NIH grants
http://dtp.nci.nih.gov/docs/raid/raid_pp.html,

and other government grant options
http://www.grants.gov/search/search.do?oppId=15474&flag2006=true&mode=VIEW

* Research funding opportunities from private foundations on specific diseases if it is relevant to your start-up.

Other Thoughts on Building Your Life Science Company

* Consider opportunities for new ways to deliver, package, and apply etc., known drugs or deliver platforms or devices in other ways.

* The business model may evolve as you go, with the development of your technology, clinical trials, needs in the market, etc., Structure your funding, partnership and other strategies accordingly.

*Consider corporate development partners, investors, or grants (primarily for institutions-research).

* Outsourcing development may be an efficient option, but choose to retain development of the core technologies.

* Perform drug/product development and business development in parallel.

* Protect your IP when working with potential partners, funders, etc.,

* Select your co-founders carefully, and understand the role each will play in the success of the company.

* Roles of the co-founders will evolve as the company grows. A funding event will likely impact the roles of the founders.

information from the Venture Capital Industry: www.nvca.org

Partnering conference information: www.biowindhover.com.

news, info, learn about large company partners : www.windhover.com

news, events, and partnering information: http://www.devicelink.com/mx/

Check out the week's activities at http://eweek.stanford.edu venture speed rounds, Biomedical technology showcase, and more

Sherri Dohemann *is a Senior Sales professional at Ortho-McNeil Neurologics, with eight years of experience representing 13 molecular entities to #11 different specialists for a range of 6 disease states. She is a volunteer organizer for the Fountain Blue Life Sciences Forum, an organization that offers education and networking to life science entrepreneurs & their teams such as staff members, advisers, board members, and investors. Sherri completed a BS degree in Combined Sciences, an interdisciplinary natural sciences degree from Santa Clara University and attended Stanford Biodesign's Emerging Entrepreneurs in Biomedical Technology in 2007. .*

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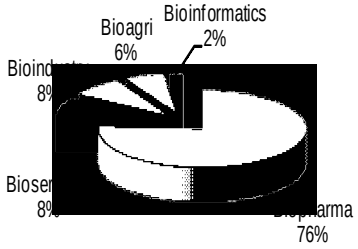
BioIndia™

India has been providing the developing world comprise of 2/3 of the world's population with the necessary medicines from common cold to HIV, from antibiotics to anti-diabetics for the past several decades. Over these periods India has developed a well-developed drug manufacturing industry that now poised to compete with multinational pharmaceuticals companies such as, Pfizer, Roche, Merck and GSK globally. Initial model of the Bio-industry was to provide medicine to the bottom of the pyramids emerging as the model to provide cost saving options to the top of the pyramid (CK Prahalad).

Composition of Indian Biotech Industry



Indian pharma and biotech corporations have obtained clearance from FDA to launch several generics drug in USA and many are in the pipelines. More and more biotech and pharma companies in India are partnering with their counter parts in USA for pre-clinical and clinical studies – an emerging bio-outsourcing economy.

India has developed a solid infrastructure for pre-clinical and clinical studies that is approved and recognized by FDA. Recently FDA expressed its intend to house inspectors and agents in India to assist Indian and USA bio-companies in their drug development, manufacturing and regulatory processes and compliance protocols – A step forward for BioIndia.

- Clinical trials in India is growing at a 60% AAGR
- Crossed USD 100 million in 2004.
- By 2010, the industry will spend USD 300M+ on clinical trials in India.
- 240 international studies recruiting subjects = 1.2% of the total studies worldwide
- 66% of international clinical trials are Phase III
- 207 sites FDA registered
- 40,000 subjects participated in clinical trials to date (<0.02% of population)

- India companies have approximate share of 35% in DMFs and 25% in ANDAs filing globally
- Second and third tier companies have aggressively scaled up ANDA/DMF filing in the US market over the last 2-3 years

In this section we will bring forth what's been happening in the biobuiness in India.

BIO-BUSINESSES IN INDIA

Q1-2008

The Ex-President of India, Mr A.P.J. Abdul Kalam asked Bio-industry to produce 40% of world's generic drugs.

In March at Vadodara, while addressing a gathering here to celebrate the centenary function of Alembic Ltd, the former President of India, Mr A.P.J. Abdul Kalam said the global production of pharmaceuticals, branded and generics put together is nearly $550 billion.

The domestic pharmaceuticals industry, at present, has a turnover of $12.5 billion of generics for domestic and export markets against the production of $78 billion worth of generics in the world. He called attention to the need for India to contribute 40 per cent of the world's generic drug production and focus on eradication of diseases such as malaria and tuberculosis.

Reddy's Laboratories is to acquire part of Dow Chemical's business in UK.

Dr Reddy's Laboratories (Hyderabad, India) entered into a definitive agreement with Dow Chemical Company (USA) to acquire a portion of Dowpharma Small Molecules business associated with its operation in Mirfield and Cambridge, UK. Through this acquisition Dr. Reddy's Laboratories will acquire the associated product-portfolio, technologies, intellectual property, trademarks, and the customers. Dr. Reddy's will also receive a non-exclusive license to Dow's Pfenex Expression Technology for biocatalysis development. The transaction is expected to close by the end of April, 2008 pending regulatory approval.

Suven and Eli Lily signed Second Drug discovery Collaboration in CNS therapeutics

Suven Life Sciences Limited, (Hyderabad, India) announced in March 2008 that it signed a second collaborative pre-clinical R&D agreement with Eli Lilly in the therapeutic area of central nervous system disorders (CNS).

Under the terms of this agreement Suven will be responsible for identifing and selecting durg candidates for CNS. Suven will receive up-front payment for the R&D works and in addition to that Suven will receive milestone payments for potential drug candidates in the range of $19 million to $23 million per candidate molecule. The company is also entitled to future royalties on net sales of any products that may be successfully commercialized from the collaboration.

US pharmaceuticals industry to adopt Indian Pharmacopoeia standards

As the US standard has no monographs for antiretroviral drugs, the US drug makers would follow the Indian Pharmacopoeia Commission's standards manual for HIV/AIDS drugs. By expanding the scope of a cooperation deal signed in 2006 between the US Pharmacopoeia and the Indian Pharmacopeia commission, the US will be now publishing monographs, or a set of referral standards, developed by the Indian Pharmacopeia Commission for about 51 anti-AIDS drugs.

Pharmacopoeia is the drug standards manual for the pharmaceuticals industry published periodically by different countries to help drug manufacturers as well as the regulators to follow the parameters for making a standard drug. Currently, the US Pharmacopoeia and British Pharmacopoeia are the two widely referred pharmacopoeias in the world.

FDA Approved Natco's API facilities in India

In March 2008, the US Food and Drug Administration has approved Natco Pharma's Active Pharmaceutical Ingredients (APIs) facility at Mekaguda in Mahaboobnagar district, Andhra Pradesh for production of some additional products. The approved products include Imatinib Mesylate (medicine for blood cancer), Anastrazole (breast cancer), Granisetron (nausea) and Rizatripan (migraine).

Accenture is expanding its life-sciences operation in India

Accenture envision high growth in the life-sciences down-stream processes outsourcing primarily because of uncontrollable cost and need to expedite lab-to-market process. More and more pharma companies are looking to places where stable, reliable and regulatory comparable infrastructures are in place.

Accenture's life science R&D centre in Bangalore is its largest in the world with 2,500 employees comprising domain experts such as clinicians, nurses, scientists and bio-statisticians apart from technology professionals. Accenture is , therefore, looking at expanding the scope and scale of its lifescience operations in India . Accenture may double the number of employees in its R&D centre and also spread to more cities in India to attract talent.

StemCyte, Apollo-hospital and Cadila created a joint venture for stem-cell products

StemCyte Inc.(Arcadia, California) announced the formation of a joint venture, StemCyte India Therapeutics Pvt. Ltd., in India with Apollo Hospitals and Cadila Pharmaceuticals. The joint-venture company will provide stem cell therapies derived from umbilical cord blood to treat patients with certain malignant blood disorders, such as leukemia, lymphoma and myeloma; sickle cell anemia and thalassemia; and immune deficiency diseases. The StemCyte India Therapeutics will contribute to the clinical studies to develop cell therapies for potential diseases with no possible cure available at present.

"The joint venture enables us to combine StemCyte's proven cell therapy products with Apollo and Cadila's expertise in the Indian healthcare arena for the benefit of one of the world largest patient populations," said Kenneth J. Giacin, chairman and the chief executive officer of StemCyte. He added, "Moreover, StemCyte India Therapeutics is an important part of our global expansion strategy."

Creation of New Venture, StemCyte India, Continues StemCyte's International Expansion and Utilizes the Strengths and Regional Expertise of Apollo Hospitals and Cadila Pharmaceuticals

The US is seeking additional scientific, regulatory and technical collaboration with India as a means to improve healthcare outcomes for patients in USA and around the world.

On March 18 in Washington DC, the U.S.-India Business Council (USIBC) hosted the Mr. Michael O. Leavitt, Secretary, U.S. Department of Health and Human Services. Secretary Leavitt highlighted the need collaboration as a means to improve healthcare outcomes for patients around the world. Secretary Leavitt shared about his desires for greater scientific, regulatory and technical collaboration between the U.S. and India. A central goal of the Coalition for Healthy India is to foster greater regulatory harmonization between the U.S. and India, resulting in decreased costs and increased patient safety.

BIO-BUSINESSES IN ASIA

Q1-2008

BIO-BUSINESSES IN & AROUND
JAPAN, S. KOREA, SINGAPORE & CHINA

Q1-2008

NSB Postech, Inc and Fred Hutchinson Cancer Research Center to Collaborate on Development of New Class of Proteomic Microarrays

In March NSB Postech (South Korea) announced that it has entered into a collaboration agreement with Fred Hutchinson Cancer Research Center (FHCRC) to coordinate their efforts and to determine the efficacy of the NSB's NanoCones surface technology in creating high quality proteomic microarrays to be used in the study of human diseases.

NSB is a South Korean biotech company which possesses a proprietary microarray technology and a great deal of expertise in nano-scale controlled surface chemistry. NSB has agreed to fund the collaboration.

Antibody or protein microarrays are glass microscope slides onto which very small amounts of thousands of different antibodies or proteins have been affixed at distinct locations. Antibody microarrays can be used to simultaneously determine the level of each antibody's specific binding partner in complex mixtures such as blood so thousands of different assays can be performed with small amounts of sample.

RAVEN BIOTECHNOLOGIES AND BIOPROCESSING TECHNOLOGY INSTITUTE ANNOUNCE COLLABORATION TO ADVANCE DISCOVERY OF STEM CELL ANTIBODIES

In April Raven biotechnologies, inc.(Singapore), a privately held company focused on the discovery and development of monoclonal antibody therapeutics (MAbs) for cancer, and the Bioprocessing Technology Institute (BTI) (San Francisco, CA), announced a R&D collaborative agreement for the discovery of novel cancer stem cell antibodies.

Under the terms of this R&D agreement, Raven biotechnologies, Inc will license its proprietary whole cell immunization technology to BTI for use with BTI's stem cells. Raven will screen the resulting antibodies against its collection of cancer lines, and cancer stem cell lines. Raven will retain the rights to the antibodies BTI generates using Raven's immunization technology for use in cancer therapeutics and diagnostics; and BTI will have the rights to the antibodies it generates for all other stem cell therapies.

Masimo PVI(TM) Cleared for Market in Japan

PVI could help clinicians assess a patient's fluid responsiveness noninvasively, according to a new study published in 'Anesthesia & Analgesia'

In April, Japanese Ministry of Health, Labor and Welfare (MHLW) approved Masimo's (Irvine, CA) PVI measurement. PVI is an index automatically derived from the Masimo plethysmographic waveform, which has been demonstrated to noninvasively assess fluid responsiveness in mechanically ventilated patients and can help clinicians assess if a patient's cardiac function is compromised.

PVI may help clinicians and emergency professionals to determine if a patient is dehydrated or over-hydrated-enabling more accurate fluid administration decisions-all by simply referring to the numerical Masimo PVI value that is continuously displayed on Masimo Rainbow SET Pulse CO-Oximeters.

PVI is a dynamic new indicator of fluid responsiveness that does not require an invasive procedure or manual calculation, yet has been demonstrated to be sensitive to changes in preload and to be an accurate predictor of fluid responsiveness in mechanically ventilated patients

Naglazyme Approved by Japanese Ministry of Health

In March, BioMarin Pharmaceutical Inc. (Nasdaq: BMRN) (Novato, CA) announced that AnGes MG, Inc. (Osaka, Japan), BioMarin's marketing and distribution partner granted approval for its Marketing Application for Naglazyme(R) (galsulfase) from the Japanese Ministry of Health, Labor and Welfare (MHLW) for the treatment of patients with Mucopolysaccharidosis VI (MPS VI). Naglazyme was approved by the U.S. Food and Drug Administration (FDA) in May 2005 and by the European Commission (EC) in January 2006.

As the first drug approved for MPS VI treatment, the FDA and EC both gave Naglazyme an orphan drug status, conferring seven years of market exclusivity in the United States and 10 years of market exclusivity in the European Union. Naglazyme also obtained orphan drug status in June 2007 from the MHLW in Japan.

BioMarin established a marketing and distribution agreement with AnGes in December 2006, through which AnGes obtained exclusive rights to market Naglazyme in the Japanese market. AnGes submitted a marketing application to the MHLW in August 2007.

Oncolys BioPharma and Tacere Therapeutics to Develop Hepatitis C cure using RNAi technology

In March, Oncolys BioPharma, Inc. (Tokyo, Japan) and Tacere Therapeutics, Inc. (San Jose, CA,) announced that they have entered into a strategic alliance and license agreement to develop and commercialize throughout Asia, Tacere's RNA interference (RNAi)-based Hepatitis C virus (HCV) compound. This agreement resulted from the strategic alliance entered into by Tacere and Oncolys in June 2007, whereby Oncolys was granted an option to acquire the Asian rights for TT-033.

Under the terms of the agreement, Oncolys and Tacere will form a joint steering committee that will work with the Tacere and Pfizer steering committee to oversee preclinical research and development efforts for TT-033/OBP-701.

In addition to an up-front payment, Tacere will be eligible to receive milestone payments through successful achievement of development, approval, and commercialization milestones resulting in total potential payments to Tacere of up to $60 million. Upon commercialization of TT-033/OBP-701, Tacere would be entitled to receive royalties on net sales by Oncolys. Further, if Oncolys sublicenses its rights under the strategic alliance to any major pharmaceutical company, the milestone payments and sales royalties Oncolys receives will be shared with Tacere at predetermined rates based upon the stage of development at which the milestones occur.

Corgenix licensed cardio-inflammation bio-marker from Japan

Corgenix Medical Corporation (BB: CONX) (Denver, Colorado) , a developer of diagnostic test kits, licensed a diagnostic technology for serum amyloid protein (SAP), an important serum bio-marker for cardiovascular inflammation from with the Okayama Prefecture Industrial Promotion Foundation, Japan.

This exclusive licensing agreement provides corgenix worldwide rights to diagnostic technology measuring serum bio-marker for cardiovascular inflammation detection.

Professor Eiji Matsuura at the University of Okayama Graduate School of Medicine, Dentistry and Pharmaceutical Sciences invented the technology. Corgenix has had strategic alliances with the scientists and academic institutions in Okayama, Japan, since 2001. The Company's earlier product AtherOx(TM) was also developed in collaboration with University of Okayama scientists. Present agreement strengthens the collaborative relationship with the Okayama Prefecture aimed at developing innovative and important diagnostic products in the future.

China Medical Technologies Completed the Development of Prostate Cancer FISH Reagent

In April, China Medical Technologies, Inc. (Beijing, China) (NASDAQ:CMED) , announced the completion of development of the Prostate Cancer FISH Detection Kit, a prostate cancer-specific molecular diagnostic test based on the Fluorescent in situ Hybridization ("FISH") technology.

The Kit is designed to detect TMPRSS2 and ETS gene fusions in prostate pathological tissues. Dysregulation of ETS family members through fusions with TMPRSS2 are implicated as cancer-causing gene rearrangements in prostate cancer,

CMED, a leading China-based medical device company, develops, manufactures and markets advanced in-vitro diagnostic products and high intensity focused ultrasound tumor therapy systems.

Gastric Cancer Drug Market to Triple by 2012 in China

Decision Resources, one of the world's leading research and advisory firms focusing on pharmaceutical and healthcare issues, forecasts in April 2008, that the Chinese gastric cancer drug market will nearly triple between 2007 and 2012. According to the new Emerging Markets report entitled Gastric Cancer in China; this growth will be fueled by increased access to health insurance and greater patient spending power, leading to increased usage of targeted therapies. Additionally, the prevalence of gastric cancer in China is among the highest in the world. In 2007, approximately 392,000 cases were diagnosed in China, and it is forecasted that the indication population will grow 2.3 percent per year between 2007 and 2012.

The report also finds that Jiangsu Simcere's Endostar and Merck KGaA's Erbitux are the targeted therapies prescribed most often by Chinese physicians for the treatment of gastric cancer. These new targeted therapies will be prescribed to a greater percentage of the eligible population in China than in the past, benefiting from increased physician familiarity and better efficacy and toxicity profiles than conventional chemotherapy agents. More importantly, surveyed physicians anticipate that some targeted therapies will be included in the National Reimbursement Drug List (NRDL) by 2012, significantly increasing patient accessibility to these drugs.

Pandemic Influenza H5N1 Vaccine to be launched in China

Sinovac Biotech Ltd. (Beijing/China)(AMEX:SVA) , a leading biotech company developing human vaccines, announced in April 2008, that Panflu, its pandemic influenza H5N1 whole viron inactivated vaccine, received clearance to produce and

market in China by the China State Food and Drug Administration (SFDA). Panflu is the first and only approved vaccine available in China against the H5N1 influenza virus.

Per the production license for Panflu granted by SFDA, the vaccine is approved for production solely to be supplied to the Chinese national vaccine stockpiling program and will not be sold directly to the market. The license also indicates that the Chinese government has the exclusive right to initiate Panflu vaccinations in an emergency or in the event of an influenza pandemic.

Sinovac previously announced positive top-line results of a randomized, double-blind, Phase II clinical trial of its pandemic influenza (H5N1) vaccine at the end of 2007. The Phase II clinical trial results were submitted in February 2008 to the SFDA. Sinovac commenced the development of a pandemic influenza vaccine in 2004. In June 2006, the Phase I clinical trial results indicated good immunogenicity and safety.

AMDL Signs Exclusive Licensing Agreement with Mygene for Human Papilloma Virus Diagnostic Kit

AMDL, Inc. (AMEX:ADL) , headquartered in Tustin, California, with operations in Shenzhen, Jiangxi, and Jilin, China, is a vertically integrated specialty pharmaceutical company. In April, AMDL announced that it entered into an exclusive sublicensing (subject to certain terms and conditions) agreement with MyGene International, Inc. ("MGI," USA) for the MyGene HPV Chip Kit for in-vitro genotype testing of Human Papilloma Virus (HPV).

The agreement between MGI and AMDL is an exclusive sublicense to use the patents, trademark, and technology in manufacturing, promoting, marketing, distributing, and selling the MyGene HPV Test Kit in China (including Hong Kong), Taiwan, Singapore, Malaysia, Thailand, Cambodia, and Vietnam.

HPV is the most common sexually transmitted infection. Globally there are approximately 330 million women presently infected with HPV, with 70% of existing infections in Asian populations.

ProGenTech received $21 Million Series C Financing

April 2, 2008 /PRNewswire/ -- ProGenTech, biotech company based in Shanghai, China and Emeryville, CA developing a contamination free, cassette based automated nucleic acid purification system, announced in April 2008 that it has closed a $21 million Series C financing led by Bay City Capital (San Francisco) and DT Capital (Shanghai).

Company also announced its management changes. Trevor Hawkins, PhD joined the company as Chairman and Chief Executive Officer. Dr. Hawkins was previously the CEO of Philips Molecular Healthcare business and held senior executive roles at GE and MDS. He was also the Director of the US DOE Joint Genome Institute, and led the DOE's efforts to sequence the Human genome. ProGenTech's founder Steve Yu become COO and president while founder Jesus Ching will serve as Chief Scientific officer.

The key advantage of ProGenTech's automated system is that it eliminates the possibilities of user exposure and cross-contamination by virtue of its unique cassette-based approach. The company's initial products have applications in both research and medical diagnostics.

Have passion to write on business, sciences and economics topics that might relate to and benefited by the biotech/life sciences/investment professionals – express it, and not hold it long to avoid high BP.

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ACKNOWLEDGEMENTS

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Medzym – www.medzym.com

Medzym, Inc. is a privately held biotechnology company focused on building molecular therapeutics based on effective platform technologies. Company's current focus is on Age-related eye disorders- (1) eye-diseases, (2) Anti-Inflammatory/Allergy, and (2) Cardio-vascular.