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Master's Thesis of Intellectual Property Law

**IP Based Special Purpose Vehicle
model for Financing of Small
Biotechnology Companies**

소규모 생명 공학 기업 자금 조달을 위한 IP 기반

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Abstract

IP Based Special Purpose Vehicle model for Financing of Small Biotechnology Companies

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Biotechnology sector is attracting increasing amount of financing year by year. These investments are not only in existing products but also in new developmental and advance technologies like gene therapy, immune therapy, RNA interference etc. Most innovative companies are small, pre revenue companies in need of funding, where most of them are backed with IP and Know-how from these technologies. IP help investors to separate investment without commingling of other assets of investee, but risk diversification with ownership and returns are at the center of investment decisions. Historical evidences have proved that Special Purpose vehicles were effective in attracting financing for new technologies for big biotechnology companies, so the study focuses on effective use of such financial instruments to finance IP based small biotechnology companies.

The major objective of this study is to generate Special purpose Vehicle (SPV) structure which can fulfill the minimal needs of most IP financing transaction and facilitates efficient IP usage in small biotechnology firms. The research aims to understand and answer the major questions namely 1) what are the subject-specific needs of biotech industry, 2) what are their common IP monetization practices and their limitations 3) How SPVs can

be modified to benefit both investors and IP based small Biotechnology Firms. The resultant Proposed SPV model is not only helpful for small biotechnology companies but also can be useful to other IP centric companies with different technologies. A systematic approach of understanding development of modern IP monetization practices, their limitations and then using SPVs to minimize observed risk is the applied methodology of current research.

The research unwind the current research problem in six chapters, First chapter is Introduction, Second chapter is Biotechnology innovations and importance of IP, this chapter helps reader to understand the nature of biotechnology research, their types, protectable and non-protectable areas of research, its importance from all perspectives like from company, investor and country. This chapter latter precisely explains how the patents from biotechnology inventions deserves more importance than other industries and how can become helpful to design new models. The chapter three is Biotechnology Company financing, it gives an idea about the mechanism of financing that runs in biotechnology industry. It discusses those internal and external factors affecting the returns on investment, who are the dominant players, especially the role of Venture financiers. It provide the evidences that how historically special purpose corporations have helped big biotechnology companies in getting funding's from new investors for developing new products. It also talks about the recent scenario and how patent based approach is in process for financing biotechnology industry. Chapter four is Patent backed financial models, NPEs have played positive and important role in development of IP based financing market with their abundant funds and patent portfolio's. These

efforts resulted in generation of various specific NPE's and their concern financial models like in Litigation, management and operation's. This chapter explains the idea of utilizing firms IP for getting financed. It also discusses the general models and NPE based models like patent Loans, SLB, and Securitization etc. in detail which evolved over a time in this process. Chapter five is Biotech firms and suitable IP financing structures, this is not only a longest chapter in this research but also very crucial too. It starts with the explaining common practices that biotech firms use to monetize their IP. It mainly indicates the models in it and the pros & cons of current system. Latter it states about various approaches that can be used to minimize the risk in such transactions like by putting options or equity interests. The main concept of this whole research revolves around SPVs, so this chapter latter explains the concept of SPV in detail i.e. its structure, types, advantages, dis-advantages, its market reputation, its development etc. then chapter tries to explain, how this SPVs could be helpful for startups to attract financing, case studies, the possible modifications to make them compatible in modern times etc. and eventually this chapter explains the proposed model which talks about utilizing biotechnology firms IP as a collateral in SPVs and latter using these SPVs in tracking, monetization and financing. The sixth chapter is conclusion and Future Remarks

Proposed SPV model is comprised of series of contracts mainly regarding IP transfer, lease back, service and future technology control, which is supported with Options and transparency indicators. The practice of such model by small biotech companies is believed to benefit most of the IP transactions right from all types of licensing, securitization, litigation

financing, spin-out management etc. Use of proposed SPV model is supposed to minimize prosecution cost over patents (in case of technology transfer from parent company), can provide a ready-made infrastructure of intermediary in transactions like SLB and securitization, minimize parent companies risk in patent loan default, also beneficial in cross-licensing projects and Litigation financing programs. These SPVs are assumed effectively separating IP from firms other assets and avoid commingling of investors' funds with other projects and also facilitate the easy-simple tracking of funds and their returns through SPV. In this way, model benefits IP owners to attract secured financing, whereas for investors it allows IP specific safe form investment. Mentioned use of contracts not only allows the parent company to reuse IP, but also provide the future control over technology with "Call" option. Thesis further suggests that, enablement of such model in Securitization require alterations in concern statutory laws. The governments are suggested to figure out, whether is it possible and adjustable in current form of law or new special law is required to deal with this issue to facilitate the patent based securitization in country and promote the genesis of IP based financing.

Proposed Special purpose vehicle (SPV) structure fulfills the minimal needs of most IP financing transaction and also facilitates efficient IP usage and tracking to small biotechnology firms. Thesis promotes the idea of SPV usage by early stage companies by collateralizing patents from biotechnology industry which are considered as comparatively risky but still valuable too.

Keywords: Intellectual Property, Patent, Biotechnology, Finance, Commercialization, Special Purpose Vehicle

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Abbreviations

| Abbreviation | Long form |
|---------------------|--|
| CEO | Chief executive officer |
| EPO | European Patent Office |
| ETF | Exchange traded Funds |
| FDA | Food and Drug Administration |
| GMO | Genetically modified organisms |
| IP | Intellectual Property |
| IPB-SPV | Intellectual Property Based Special purpose |
| IPO | Initial Public Offering |
| JPO | Japan Patent Office |
| M&A | Mergers and acquisitions |
| NPE | Non-practicing entity |
| R&D | Research and Development |
| RNAi | RNA interference |
| SLB | Sale and License-Back |
| SME | Small and Medium Enterprises |
| SPARC | Special Purpose Accelerated Research |
| SPV | Special Purpose Vehicle |
| SWORD | Stock and Warrant Off-Balance |
| TRIPS | Trade-Related Aspects of Intellectual Property Rights (Agreement) |
| USPTO | United States Patent and Trademark Office |
| VC | Venture capital |
| WIPO | World Intellectual Property Organization |

Chapter 1. Introduction

1.1 Background

Biotechnology is an applied branch of science which exploits biological processes for industrial, medical and other purposes (1). Generally this branch of science has significant importance mainly because of its nature and commercial use. The Biotechnology industry is growing rapidly and covering more areas of applications e.g. most of the pharmaceutical companies are getting converted to biopharmaceutical (2). Importantly they also have a substantial contribution to countries economy by creating new jobs and business revenues. After realizing this considerable impact of the Biotechnology sector, various public as well as private institutions are getting attracted towards this sector and involved in designing various policies- structures to get maximum benefit from this industry (3, 4).

As Biotechnology is a heavily R&D and Innovation based industry, Startups and SME's with promising new technology based product pipelines are also impactful players in this area, concerning to new advances as well as future players in relevant areas. One of the big hurdles in the growth of these players is a lack of capital and professional management for the growing company. Traditional methods of financing like corporate alliances and venture financing provided funds to these small biotech companies but mostly they don't got equally treated and got dominated by big partners in administrative as well as monetary decisions (5, 6). Meanwhile, in a modern age of knowledge-based markets, importance of intangibles in company assets has been increased and Intellectual property assets got

importance in strategic decisions of a company. Nowadays various biotechnology funds have been getting generated. The business models and financial structures are getting applied to make these deals more safe and profitable. Studies showed that companies with patents are more likely to get chosen by financing institutions and in this way the recognition of IP (mostly Patents) starts in this financing process. Here In this Financing process, firms Intellectual property assets play two important role in leveraging their value. Firstly as quality indicator, as mentioned above they help to understand the quality, potential and technological capability of firm and secondly, as IP has commercial value it can be used for generating additional funding by generating various strategies as like other assets, so IP becomes a financing source too (7).

1.2 Trends

Historically SWORD and SPARC based Special purpose vehicles have played an important role in generating alternative funds for innovative projects by big biotech corporations and some of the important modern day blockbuster drugs are the result of such SPV based financing projects. The shares of such SPV's were traded on exchanges and then generated money from those investors was used to fund the R&D projects of these companies (6, 8).

Nowadays IP-based financing is growing fast and expanding widely. There are a variety of IP based business models such as IP transaction, IP license, IP investment for a joint venture, IP debt, IP-backed securitization, IP-based strategic alliances, M&A are the common practices taking place in the industry (9). Most of these practices

need intermediation of IP owners and investors at a certain point of transactions, of which they are part of some transactions (in the form of SPV) or have a potential to get used in other types too. As SPV has played a role for generating alternative finance and can act as intermediaries too, their use can become a beneficial standard of practice to minimize the risk of IP financing transactions. So it's been projected that the newly structured SPVs fulfilling the IP intermediation needs of Investor and IP owners can reignite the new way of financing Biotech firms through IP based SPVs(6).

So the hypothesis for this study is- If SPVs restructured according to modern needs of IP-based market then these SPVs can facilitate financing of small Biotechnology firms, because historically it's been observed that special purpose corporations have played important role in facilitating finance for new R&D projects of big Biotech firms.

1.3 Research Objective

Generate a SPV structure which can fulfill the minimal needs of any IP financing transaction and can also facilitate efficient IP usage and tracking to small biotechnology firms. So the thesis will try to understand and answer the subject-specific needs of biotech industry, their IP monetization practices, prior use of SPVs with their limitations and possible simplified approach over the way of financing for IP-based small Biotechnology Firms.

Chapter 2. Biotechnology innovations and importance of IP

2.2 What is Biotechnology?

Biotechnology is a modern branch of science; according to Convention on Biological Diversity (CBD) in 1992, it can be defined as “any technical application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use”

In fact, the related processes have been practiced from ancient times where people used the biological processes in their day-to-day life. The best example of such practices is the use of fermentation. The practice of using fermented products like wine, Idli, Yoghurt, Kimchi etc. have been observed in food habits of people from all around the world. After the discovery of DNA double helix model by Watson and crick in 1953, the research in this area got accelerated many folds and become the basis for modern Biotechnology, which primarily deals with the knowledge and applicability of genetic information from the living world (10).

2.2.1 Branches of Biotechnology

Biotechnology is also referred as an applied branch of science which deals with the study of application of basic sciences mostly for the commercial purposes. Therefore prime application areas of Biotechnology can be divided into four parts i.e. Industry, Healthcare, Agriculture and Non- food & environment. Some researchers prefer to categories above classification in following way too (11)

- 1) Red Biotechnology – branch of Biotechnology which deals with the application of related technics in a medical area e.g. ex-situ production of biochemical like hormones, antibiotics various gene-based therapies.
- 2) Green Biotechnology –The branch of Biotechnology which deals with the application of related technics in Agriculture and crop production area. Micro-propagation of plants, development of disease resistant and high yielding seeds and plant varieties, production of new environment-friendly bio-chemical's to use in agriculture field are some of the major areas of research in this field.
- 3) White Biotechnology-A branch of Biotechnology which deals with the application of related technics in Industrial processes, so also called as Industrial Biotechnology. This branch mainly uses biological organisms, bio-chemical's in a production of products either to reduce hazards or for value addition and increased yield.
- 4) Blue biotechnology – This branch has applications in marine and aquatic area but its uses are relatively lower than other types.
- 5) Bioinformatics- It's a use of computational techniques to solve biological problems so also called as “Computational Biology”. It has a crucial role in studies related to functional genomics, structural genomics, proteomics etc. which makes it a very important tool in the development of modern day biotechnology and pharmaceutical sector.

The possible applicability of biotechnology in various fields has opened many doors to human, to achieve there promised land for better future.

As it has applications in medical sector which is very near to our daily life. Commercial productions of various hormones are helping the doctors to eradicate and minimize the harsh effects of diseases. Human insulin is one of the gifts of this technology which is nowadays a common product in pharmacy shelves. In agriculture, it's helping the scientist to develop more disease resistant, high yielding, more nutritional, biotic- abiotic resistant and many more valuable varieties of plant to fulfill the growing demand of increasing world population, despite of actual agriculture area is constant or in some cases its decreasing . Scientists have produced various popular varieties of cotton, corn, soya, oilseeds and many other plants to fulfill the related demand too. So in this way biotechnology has created a good repute in modern day society and showed the way for promising results (10).

2.1.2 Biotechnology Innovation and Innovative firms

Prime focus of Biotechnology is always in medicine and then agriculture. Nowadays a lot of research is going in the healthcare sector as various pharmaceutical companies are entering in biopharma production too. Pace of innovation is much faster in these areas, compared to others. Some researchers have classified this innovation from biotech industry in following three categories (12) -

- 6) Innovation in medicinal products- the new biological products made by using r-DNA technology is considered as innovative products, if they are with new additional activity and use. New biological compounds and biosimilars are the popular examples of such products. But concerns are being raised over their safety, so the approach of safer approvals is being

practiced.

- 7) Innovation in manufacturing processes- Many of biomolecule of therapeutic and commercial use are being extracted from plants, animals from a long time. But the amount extracted is always not ideal or not in utilizable amount, and a process is tedious in nature. But the advances in biotechnology and various applications of cell culture has allowed the easy commercial production biological products. Research is continuing to improve the productivity per unit of culture and also in defining better hosts to produce such molecules i.e. from bacteria, yeast, animal-plant cells or even a whole organism body for production.
- 8) Innovation in regulatory science- It's not always possible to catch up a rate of innovation with the rate of approval in case of medicinal products. As current medicinal regulatory models have evolved by considering unknown moieties as risk, so the new innovative products always less known at their initial approval phases. Generally, lots of money and time of companies (especially biopharma) goes in such approvals and gathering of concerned required data. Sometimes it's sensible to reduce innovation to manage regulatory risk. In this way "regulatory" is also an area to consider in Biotechnology innovation.

Biotechnology innovations have become crucial mainly in two senses, first commercial importance- as producing billion dollar products and second social importance- as biotech research showed promising results over various harmful diseases like HIV-AIDS, Cancer etc. and saved

numerous lives by treating or vaccinating people. A similar case is in agriculture too where these innovations helping farmers to take the better production of crops and fulfilling the increasing agricultural demand.

In case of medicinal products, it's been found that 70% of the clinical pipeline is from small companies practicing in more advance areas like gene therapy, immune therapy and RNA interference (RNAi). This innovation has strong potential to transform the way of medication in coming years. Most of these biotechnology companies are small, pre-revenue companies which require funding for their research and operation. But this type of investment also results from the related returns, IP protection, availability of monetization systems, regulatory approvals etc. Any of it can affect the financing in this sector adversely, as biotechnology is already a risky type of investment concerned to required time and money (13).

2.1.3 Ethical Issues in Biotechnology

Biotechnology is the applied form of science especially revolving around life forms, so it has lot of direct or indirect effects on human life. The modern advents in molecular biology allowed scientists to easily interfere with the genetic content of an organism; this questions its originality and makes such innovation as prime topics for criticizing its authenticity and synthetic nature. These issues are considered crucial and serious, as they may have hazards and non-repairable effects on human species. Sometimes these researches also affect the religious beliefs too. Currently, some of the genetically modified plants varieties are prohibited in various countries due to strong public oppose

even despite of its market readiness which is a result of heavy research funding and quality time. Issues related to embryonic stem cell research were also got criticized as these are the early form of life, which means direct blocking of an infant in its early embryonic life. Therefore innovation in this area is also regulated by considering the concerns on environmental, religious and social issues. For example, European member states has been following the unified policies which concerns with issues related to,

- Genetic manipulation and related rights in such research;
- Biopharmaceutical (medicine) development, medical procedures and privacy – to secure the rights to personal genetic information to be used in related research.
- Bio-safety issues for disposing GMOs
- Innovations those are non-patentable.

In Project financing of the biotechnology industry, consideration of ethical issues is a very important factor at a company as well as national level. The main reason behind is its interconnection and resultant huge damage to all participants in the process (10).

2.2 Patentable and Non-patentable subject matter

Article 27 of TRIPS¹ agreement specifically talks about a patentable

¹ Article 27-Patentable Subject Matter of TRIPS

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.⁵ Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious

subject matter which creates a basic framework to develop country specific patent laws to protect relevant subject matter. Therefore country specific rules may vary from one jurisdiction to another, but mostly the core logic is almost same in all jurisdictions except the flexibility used by a particular country over a given subject matter by a treaty (e.g. like on plant sui-generis). where members may also exclude the inventions affecting public order, morality or the issues related to environmental hazards (14)

2.2.1 Patenting of Biological Materials and Biotechnology

Industrial applicability is a key feature of Biotechnology inventions, but issues related to protection of biological entities used in making of such products or processes are still in debate. Therefor interpreting same invention differently according to jurisdiction is a common approach followed by various inventors. Following are some of commonly patentable subject matters in the area (15).

- 1) Microorganisms- article 27.3b opens the way to member states to protect new organism and related processes within the boundary of national laws. But at the same time inventors has to deposit the

prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- (b) Plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement

newly developed bacterial strains in recognized international depositories. This treaty is known as Budapest treaty named after the signing place in 1973 which was later amended in 1980.

- 2) Plants-As provided by Article 27.3(b) of TRIPS, member states have freedom to adopt a PVP system of protection based on patents, or a sui generis system, or a combination of both for protection of new varieties of plant. Developed countries like the US, Japan have allowed the relevant patents in this area whereas the countries like India have adopted the way of protecting new varieties by making plant sue-generis made with the concerns of huge farmer community from a country. The general approach of patenting new varieties is by the claiming methods related to disease-free plants or adding additional value to it is being followed (16).
- 3) Animals- Not a direct animal species but some of its modified forms are patentable in some of the jurisdiction e.g. USA, South Korea, Japan, South Africa, EU etc. This mainly increased after the grant of “Harvard Mouse” patent, but despite of these patenting direct Human life forms is still restricted area in all jurisdictions.
- 4) Cloning- is a process of transferring nucleus of the mature multicellular organism to an unfertilized egg of same species. If the mature nucleuse has any additional gene then that type of cloning is considered as transgenic cloning. Dolly is the first transgenic animal created in 1997 made by cloning. Patenting of Animal cloning and related processes are comparatively easier than Human embryonic cloning which has strict restrictions in most of the jurisdictions while some countries like Japan, Korea allow its use in therapeutic research.
- 5) Biological Compounds- Patentability of biological compounds like

DNA, RNA, Plasmids, and Proteins is possible if they strictly follow all three patentability criteria's

I.e. novelty, Inventiveness and industrial applicability, as many times gene function is unknown even after the isolation of DNA. After the recent case of Myriad genetics, these criteria's become clearer and suggests patentability of cDNAs, new functional applications of naturally occurring nucleic acids, proteins, and small molecules of interest may possible, rather than protecting the compounds in their natural form.

- 6) Expressed sequence tag (EST's) - the issue of patenting EST's was the hot topic for major patent offices as they got millions of application over the relevant protections. But later the study from trilateral Patent Offices (USPTO, EPO, JPO) have emphasized on its industrial applicability or utility aspect. This allowed ESTs on only known and useful sequences under strict patentability rules.
- 7) Bioinformatics and Patenting- This is a new field within the borders of biology and computer which mainly deals with the related tools and programs. Some researchers have tried to classify the inventions from this field in following three categories i.e. a) Tools of Bioinformatics b) Methods of Bioinformatics c) Products of bioinformatics. It seems that first two types are mainly based on the software and abstract business related ideas, so such inventions are only can be protected in countries like the US as other most of the countries don't allow the protection of software's and Business methods.

So above was the summary of possible protection areas in biotechnology

innovation and its patentability.

2.3 IP Protection in Biotechnology

Studies showed that IP Protection is the crucial aspect of Biotech Business strategy. This protection is mainly obtained through Patents (17) and various country trends showing increased patent filings, in the area of life sciences and Biotechnology. This effect is a result of increased importance of these rights for inventors, companies and even for the nation. Following are some of the views on IP protection and its importance according to its assignees (18)

2.3.1 Importance of IP protection From a Companies Perspective

- Biotech is one of the most R&D intensive industries compared to similar research based industries like chemistry, as more amount of total revenues (40-50%) or budget is allocated to R&D activities.
- There is relatively high cost of developing new product or process, but at the same time the developed product is very easy to reverse engineer and get copied. Also, the research outcome is always with high uncertainty with regard to product, efficacy, marketability and regularity issues.
- Interlink in basic and applied research is getting continuously patented.
- Most of the activity is from small industries; where most of the research is collaborative between these companies and public/ academic research institutions.

2.3.2 Importance of IP protection From an Investors Perspective

- One of the main key issues that biotechnology industry investors care about is the ownership of the IP, followed by its value and applicability along with the issues like presence of strong in-house managing team and possible risk diversification
- A patent facilitates the investors in the identification of a potent company to invest. Further his challenge becomes to convert that patented invention in a profitable asset to which approaches could be numerous.
- Sometimes IP can serve as a source of finance even during a research period, as the gap in funding may occur due to long time in research pay off.

2.3.3 Importance of IP protection From a Countries Perspective

The main motto of IP protection is to incentivize innovation by promoting the protection of innovator rights, Technology Transfer and Public interest at the same time. Not all but some countries are getting benefitted directly and indirectly through the TRIPs and related laws.

Health Sector

In developed countries like the USA, IPR played a role as catalyst for innovation (19). According to a study from Association of University Technology Managers (AUTM) in 1997, after the introduction of Bayh–Dole Act there was an increase in research funding as well as patent filling from academic institutes have been found and also new spinoff have started through related activities. The survey reports that 70 percent of the licenses from these institutions were in life sciences,

diagnostics, reduced pain and sufferings which helped to improve National Health Issues (20). Whereas in developing countries like India a big pharmaceutical industry mainly based on generics have developed and helped countries Health as well as economic needs. In this way, the IP protection in Biotechnology can help to improve countries Health and Economic needs (19).

Food security

Most of the developing and underdeveloped economies are mostly based on agriculture and related products directly and indirectly. Most of the farmers in these countries hold a small piece of lands compared to their counterparts in developed country. So balancing approach of innovation protection and interest of smallholder farmers is the key issue to these countries. Patent, as well as Sui-generis, are the possible protection areas in this scenario. Most of the research in these countries goes on crop improvement by making them more resistant to biotic and abiotic factors, high yielding and nutritional. Successful outcomes of these efforts can result in promoting food security and alleviation of poverty in concern needful countries. But to promote such results, the main challenges in front of these countries are the designing of relevant policies to protect as well as promoting the innovation in all areas, especially in Biotechnology industry (19).

2.4 Varying Nature of Patents in Biotechnology and Other Industries

2.4.1 Why patents are more important in some industries than in others

Studies confirmed that the intrinsic properties of technology are crucial factors to decide the pattern and patent activity in related market (21). Broadly the impact of patents is primarily dependent on features of the technology, R&D process, features of the market, along with the competitor strategies. IP protection becomes highly crucial when R&D process is an integral part of product development, comparatively long, costly and more importantly uncertain. Also, the importance of patents is more, when the copying or reverse engineering is simple i.e. in industries related to machinery, chemicals, pharma; it's comparatively easy to copy the patented products due to the lower cost ratio between imitation and innovation. It becomes easier for imitators to copy the patented products when there are various alternatives available to patented ingredients, simplicity in codified data, and possibility of passing off. Mainly life sciences industry, machinery industries are soft targets in this sense as more alternatives to natural substances are available in both cases. So here, a concern is highly true about biopharma industry, as all mentioned factors perfectly match with biopharma industry. Whereas in the case of IT the technical changes are fast and therefore the effective life of technology is also short, so in these cases costly IP protection may not a good decision in most cases (21).

2.4.2 Difference between Complex and Discrete technologies

Complex technologies are difficult to replicate and also can be called as hi-tech technologies, whereas, discrete technologies are prone to imitate easily with cheaper cost. Following table highlights the need and importance of patent protection for certain areas of technology, with the focus of biotechnology innovations (21, 22).

Protecting manufacturing processes is much harder than protecting products; as processes are also harder to keep as the trade secret. The use and effectivity of patents differs across the various industries and such trend is almost similar across various countries too (21).

| Complex Technology | Discrete Technology |
|--|--|
| Typically electronics, software and semiconductors | Typically biotechnology, drugs, chemicals, steel and metal products |
| These technologies are more difficult to replicate | Easy to replicate |
| Low patent value | High patent value |
| Generally requires many patents to protect the technology | Comparatively fewer patents are required to protect the technology |
| Provides great bargaining power to technology owner to exploit the value from the patents (in case of mass licensing programs-FRAND) | Generally here technology is in few hands |
| Lower chances of having comparative advantage through patenting | Higher chances of having comparative advantage through patenting |
| Freedom to operate is a big problem | Comparatively freedom to operate is not a big problem |
| Threat of high number of licensing and settlement demands from trolls | Comparatively less number of licensing and settlement demands from trolls |
| Patenting is mostly for incremental innovations | Patenting is mostly for disruptive innovations |
| Generally high-tech products mostly consist of many components with related dependent patent's | Nature of patenting innovation is comparatively simple. |
| These results in many patents related to a single product | Mostly a final (especially biotech, pharma) product is consisting of couple of patents |
| High possibility of patent thickets | Less possibility of patent thicket |
| Makes cross-licensing a necessary activity for manufacturing as well as for commercialization purpose. | Cross-licensing is not a general practice |
| Short shelf life in terms of technical applicability and monetization potency | Longer shelf life with similar monetization potency |

Table 1 - Difference between Complex and Discrete technologies

Chapter 3 Biotechnology Company financing

3.1 Biotechnology Company financing

Finance is nothing but the science of money management required to support operations, product development and for market entry. As like other forms of finance, Biotechnology finance is also dependent on the interrelation of risk and return. In general practice, it's understood as, if the risk is more that means on such investment returns will be also more. Market entry, technology competitiveness, regulatory, market acceptance, interest rate, currency, economic structure and type of finance (debt or equity) are the subject-specific risks to this market.

3.1.1 Variable affecting Biotechnology Finance

The biotechnology industry has some of its subject specific critical success factors that decide the fate of research, product development and company operations. Following are some of the factors that are more likely to affect the biotechnology company financing activity (23). So the study of these factors is crucial to develop any decision or financing structure in this field. Relative risk-balancing approach of these factors can help in the increased success of related decisions and structures.

a) Lengthy Developmental Period and Effect of FDA

Development of Any drug, Biologic or medical device concerned to living organisms, especially humans, is lengthy and resource consuming process. The expenditure may go up to several million dollars. According to some reports finding, a new drug molecule starts from

reviewing 10,000s of substances and then a systematic screening of these molecules ultimately can pass only single or a couple of molecules for final production through a number of clinical trials. This process also takes 10 to 15 years, and finally approval from Food and Drug Administration (“FDA”) to enter into the market. In the case of therapeutic products, molecule goes for FDA approval at the end (Could be at 10 to 15 years of work) of a very long and expensive research. So it's considered as very crucial aspect in medicinal product life cycle and decisions related to financing those entities in clinical pipeline.

b) Ethical Issues

As discussed in chapter 2, biotechnological research is directly related to human life and environment with long term effects. There are so many ethical issues with this industry. Currently, genetically modified food and Stem cells related issues are on high. The regulatory approvals are costly, lengthy and sometimes uncertain. So many times the value of firm immediately increases after the approval from FDA for their product but at the same time, sociopolitical and ethical issues may restrict the market entry of certain products.

c) International Law and Import-Export Issues

Companies always want to launch their products in an international market to get benefited more from their research and expenditure. But various treaties, concern country-specific rules, standards, policies make this inter-country trade complex. As issues related to health and environments allows country specific examinations, which result in extra expenditure on testing, regulating and modifying the product accordingly. This extra expected or unexpected process requires more

amounts of funds and so financing.

d) Intellectual Property

IP is the most valuable technology of modern age industries, as increasing ratio of intangibles to tangibles is being observed. Studies showed that IP is playing important role in company selection to financers, as it's a sign of company potential and security over protected market product. At the same time, this asset can generate finance on short and long term basis. Investor concerns over IP can go around its ownership, its applicability and possible application area in technology and territory. They are also concerned with the possible risk-sharing mechanism related to assets. In investments or transactions related to bankruptcy matters, the issues regarding IP licenses and related contracts are the major concerns of investors in such kind of vulture financing.

e) Tax and Tax credits

Tax issues to Biotechnology industry vary with company life cycle, because of its subject specificity. Most of the companies in their early stage are R&D specific and works towards the development of product, so most of the expenses are on R&D. So in this stage, the company can exploit the available tax deduction and tax credits applied to R&D expenditure. Also, afterword's developing a technology/ patent, commercializing such technology/ patents may get categories in different taxation matters and exemptions.

f) Appropriate business structure and Lifecycle of Company Choice of Business structure

This decision will determine how the organization and its owners will get taxed, there related liabilities and ability to raise finance. Therefore specifying short term and long term goals of a firm by business owners is a very important task for deciding the proper business structure.

Ownership options

Company ownership is dependent upon the developmental stage of company as well as on the risk factor related to owners, so there are various options available to deal with it. Each option has its merits and demerits accordingly. Sole proprietorship, general partnership, limited partnership, limited liability partnership, Limited Liability Company and corporation (C and S type) are the types of ownership that an organization can have. At an early stage of business, mostly an individual and sole proprietorship occurs, whereas gradually depending on company growth and needs it can be changed accordingly.

Effect on Funding

Business ownership decision not only affects the administrative and taxation applications but also it affects the view of investor for his future financing. Generally Venture capitalist chose C type of corporations to invest as they can go for their Initial Public Offering (IPO), can get a tax free identity and ease in transferring shareholders rights.

g) Life cycle of Company

Generally, company life can be categories depending on its growth and size. The startup, developmental, early commercialization, growth, maturity and (sometimes) bankruptcy are the stages of companies. As

financiers look for risk as well as returns on their investment, generally they look to invest in first three types of companies i.e. Startup, developmental, early commercialization stage companies (but it's situation specific also). But In a case of new IP-based companies, they can raise event specific finance from their IP assets at any stage of their life cycle.

3.2 Financing through R&D limited partnership or Special Purpose Corporation (SPC)

Since early 1980's big biotechnology companies started alternative finance strategies to apply in their new innovative R&D projects by introducing a new method of project financing, through Special Purpose vehicles (SPV). These SPVs have played a major role in the development of several blockbuster drugs of that time. So the success of these structures has a lead generation of various collaborative ventures in the form of R&D limited partnership or Special purpose Corporation (SPC). The main aim of these SPE's was to generate funds for new R&D projects by providing a collaborative structure of SPV having equity stakes of parent Biotech Company and investors. Here the parent company generally provided the part of their technology and investors provided monetary funds. Special Purpose Accelerated Research Corporation (SPARC) and Stock and Warrant Off-Balance-Sheet Research and Development (SWORD) are two popular brand names of these SPE's (24).

Special Purpose Accelerated Research Corporation (SPARC) - Are the corporations who issues unit interest through public offerings to individual and institutional investors. These corporations handle the

research projects, by signing contracts with biotech R&Ds for developing a technology for SPARC.

Warrant off-Balance-Sheet Research and Development (SWORD) - it's just an alternative term of SPARC used by different industry practitioners. Any single unit has two shares, one of them is ventures common stock (with sponsoring parents "call" option rights) and other is warrant to purchase the shares of common stock of the parent for investor's interest.

Off Balance sheet- Notably, all these transactions of SPARC and SWORD were out of balance sheets of investors and here parent company were generating funds through public offerings of units of these SPV's.

Interestingly, after the disclosures of SPV mediated scams of several big companies like Enron the financial and accounting standards made these transactions harder and the relative use of these SPVs decreased surprisingly from big biotech corporations (6).

3.3 Current scenario of Biotech financing

Similar with other booming industries like software; Biotech is also continuing to attract huge amount of investments regularly. To this, some industry experts consider a stage between a "Booms and Busts". Still, with this risk financial institutions are continuing to invest in the area by expecting relatively high returns to their risk. In last two years, the investment in industry has been found increasing. In the year 2015, biotech companies were able to raise around US\$71 billion which is around 12.6 % more than previous year. This financing has been seen

through different sources and types i.e. by debt, rounds of public finance and venture capital. At the same, funding to pre-IPO companies also a famous option where these kinds of investments were able to attract around US\$5.2 billion. These observations are very important to our study, as this research is mainly concern with the issues of startup or SME financing through their IP. Although the big picture looks stable of this financing, the quarterly analysis shows variability in financing towards the last one. Inevitably this large amount of funds questions towards the possibilities of a big slowdown. Quarterly averages were increased due to some big deals with companies like Celgene, Biogene and Gilead Sciences (25).

3.3.1 Teachings from recent activities

Increased investments and national policies may certainly affect each other. The key regulators in such investments in case of US were more friendly policies towards these industries. Concerns to environmental regulations, public policies, incentives to research and acquisition of such research have made ease to such investments in area. During the year 2015 number of biotech (mainly therapeutic) companies were able to attract financing, some of those companies are - Intercept Therapeutics, Bio-marine pharmaceutical, Alnylam Pharmaceuticals, Bluebird Bios, Horizon pharma etc. In case of Alnylam Pharmaceuticals, it's a company primarily based on a technology called RNA interference which has high therapeutic potential. But still company doesn't have any product in market; this company has able to secure a deal of \$517 million alone. Currently, it's mainly based on research and development of products and has one of the largest portfolios of patents in RNAi technology. Similar industry

examples show that such funding's mostly in companies at their developmental stage, but still with the high advanced technologies in their hand with know-how as well as required intellectual protection. This means instead of market fluctuations and forecasts, investors are still willing to invest in commercially unproven technologies. Similarly, IPO events from companies like BeiGene and Editas pointed out that companies with good technology research and expert management teams can also get funded in a similar way. If we observe these events keenly it shows that most of these companies can be categories as startup or SME with strong technologies at the base and the way of protecting such technologies is nothing but the way of IP protection (25). These are the primary attractions of investors, so this observation indirectly points out the potential of IP-based financing in Biotechnology area in coming era.

| Top US Venture Financing (US\$150m +), 2015 | | | Top US Biotech IPOs (US\$150m +), 2015 | | |
|---|-----------------------|----------------|--|-------------------|-------------------------|
| Company | Therapeutic Focus | Amount (US\$m) | Company | Therapeutic Focus | Relevant raised (US\$m) |
| Boston Pharmaceuticals* | Multiple | 600 | NantKwest | Oncology | 238 |
| ModeRNA Therapeutics | Multiple | 450 | Spark Therapeutics | Ophthalmology | 185 |
| Intarcia Therapeutics | Diabetes | 300 | Aimmune Therapeutics | Allergy | 184 |
| Stemcentrx | Oncology | 250 | Natera | Multiple | 180 |
| Denali Therapeutics* | Neurology | 217 | Blueprint Medicines | Oncology | 169 |
| Adaptive Biotechnologies | Oncology | 195 | RegenXBio | Hematology | 159 |
| Humacyte | Regenerative medicine | 150 | Seres Health | Gastrointestinal | 154 |

Table 2- Top US VC financing and IPOs in 2015

3.3.2 Role of VC Financing

The trend of venture financing is found increasing over the other types of financing, and also becoming the prime source to new biotechnology companies. In the year 2015 VC's invested around \$11.8 billion, wherein 2014 the number was \$8.2 billion. VC's investing in companies based on cutting age technologies mainly in gene and cell therapy and becoming more trustworthy in such risky matters.

| Top European venture financing (US\$100m+), 2015 | | | Top European Biotech IPOs (US\$100m+), 2015 | | |
|--|--------------------|----------------|---|-------------------------|-------------------------|
| Company | Therapeutic Focus | Amount (US\$M) | Company | Therapeutic Focus | Relevant raised (US\$M) |
| Immunocore* | Oncology | 313 | Adaptimmune | Oncology | 191 |
| Nabriva Therapeutics | Infectious disease | 120 | Cassiopea | Dermatology | 172 |
| Mereo BioPharma* | Multiple | 117 | Ascendis Pharma | Metabolic/Endocrinology | 124 |
| CureVac | Oncology | 111 | Biocartis | Diagnostic | 109 |
| *First venture round | | | Nabriva Therapeutics | Infectious disease | 106 |

Table 3- Top European VC financing and IPOs in 2015

Similarly, these investments by VC's are also demanding a VC centric Business models, strategies, asset-centric and tax efficient business structures (25). These business structures are intended to be more specific to biotech industry needs, efficient in handling of such investments and more preferably should allow using resources effectively and profitably.

3.3.2.1 Key Financing Insights

The trend of financing based on innovation capital in US, has been found increasing; share of such innovation based financing reached 58% in year 2015, the highest till date in US and Europe. The companies got chose not only based on development but also with new models implemented in development of products. Preference of financing to early stage biotech companies by venture funds is at the top compared to previous year's preferences; sharing 30% of venture funds (25).

3.3.2.2 Scenario around the world

In the year 2015 the investment through Venture capitalist were on high compared to previous years, in various sense like the sum of amount of money got funded in US and Europe both. In these cases, the average funding size was also got increased comparatively and indirectly points that's increasing interest of VC's in Biotechnology sector (25). In case of Biomedicine companies funding raised from VC rounds, US is at top with the amount of >\$6 billion. Whereas at the same time, companies from countries like China (\$640 million), Canada (\$84 million) and Europe (\$500 million) were also able to generate considerable funding from VC rounds in 2014 (26).

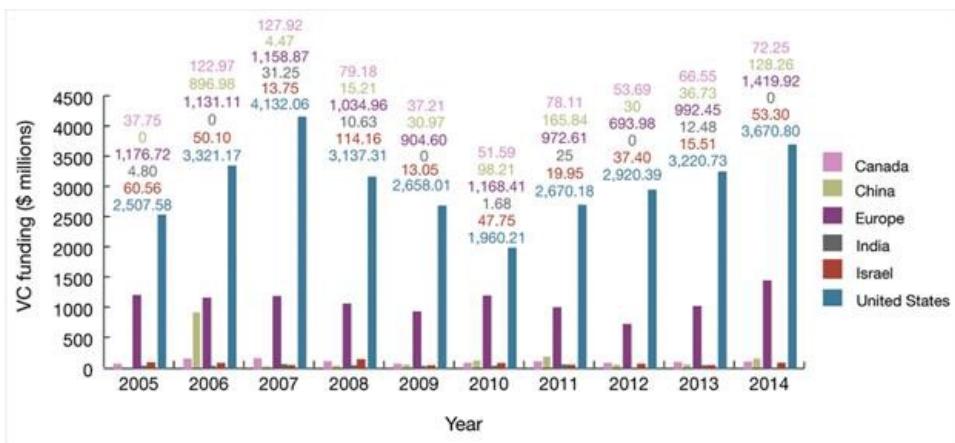


Fig.1- VC investment for Biotech (Medicine) innovative companies by region (26)

3.4 Patent based approach in process

Above discussed all financing in Biotech companies, happening though traditional ways (in case of VC's it's by equity sharing and IPOs). Every time these ways of financing are not convenient for small companies and sometimes, even for financing firms as they have to invest in whole company operation. So recently financing by collateralization of patents, securitization of revenues, sales and leaseback financing models have been observed in industry. These models separate whole company assets and IP assets differently and then they invest in such models. So it's found that the use of such models could be useful for both participating parties giving a win-win strategy.

Chapter 4 Patent backed financial models

4.1 The Concept of Intellectual Property and Finance

Intellectual property Finance is the emerging field, which deals with study efficient use of company IP portfolio to access investments in equity or by debt (9). Generally, Venture capital firms are interested in Equity finance of potentially promising companies (in this typical case, it's based on IP). Whereas in case of, debt financing various financing firms along with Banks showed interest in collateralizing IP, from IP-centric innovative firms (7, 27).

4.2 Scope and types of Intellectual Property Rights

4.2.1 The Concept of Intellectual Property

According to an explanation provided by WIPO in their introductory material to common public, in broad Sense Intellectual Property is a legal right resulted from intellectual activity in the industrial, scientific, literary and artistic fields. Countries protect such IP rights with two major intentions, first for protecting the moral and economic rights of the creator, making its access to public and secondly to promote such activities to encourage socioeconomic development. Traditionally IP is divided into two parts i.e. “industrial property” and “copyright.”

According to WIPO convention² IP should include rights related to following (28)

- Literary, artistic and scientific works,

² Provided by the Convention Establishing the World Intellectual Property Organization (WIPO), concluded in Stockholm on July 14, 1967 (Article 2(viii))

- Performances of performing artists, phonograms and broadcasts,
- Inventions in all fields of human endeavor,
- Scientific discoveries,
- Industrial designs,
- Trademarks, service marks and commercial names and designations,
- Protection against unfair competition,

Following are some important forms of intellectual property along with their brief intro (28)-

- a) Patent- It is a right granted by a state, to a patent owner to exclude others from commercially exploiting (i.e. making, using, selling, importing) the patented invention in return for complete disclosure of an invention and such rights are granted to the owner for a limited time period. The main criteria's for granting the patent rights are the novelty, Inventiveness (Non-Obvious) and industrial applicability. In some particular cases, states have rights to exclude some inventions from patenting on the basis of security and moral aspects.
- b) Copyright and Related Rights- copyright law only protects the expression of ideas and not the idea itself. In other words, it protects the creativity in choice and arrangement of words, musical notes, colors, shapes etc. the protection period varies from country to country but most of them give at list a protection up to the entire life of a creator from the date of its creation. Whereas related rights mean rights related to or “neighboring on” copyright i.e. performances of performing artists, phonograms and broadcasts and considered an

important aspect of copyright law.

- c) Trademarks- “A trademark is any sign that individualizes the goods of a given enterprise and distinguishes them from the goods of its competitors. Generally, it’s an indicator of a source of a good or service (e.g. Service mark).
- d) Industrial Designs and Integrated Circuits-In general sense industrial design is the activity of achieving formal or ornamental appearance of a mass produced items within the same cost constraints resulting in either a more applicability to consumer or in increased efficiency of a product. whereas in legal sense, it’s a protection of ornamental and non-functional features of an industrial article resulting from a design activity. The second important thing from above title is Integrated circuits, which means a protection of layout-designs (topographies) of integrated circuits.
- e) Others Related Rights- Nowadays some new channels in IP are getting generated, with the evolving of new technologies e.g. Software is one of such area where there can be a requirement of various protections like copyright, patent, Business method protection etc. Secondly the other important, but not generalized area of protection is Sui generis system specific to particular territory e.g. plant sui generis system for protection of new plant varieties, topography of semiconductor chips and integrated circuits, sui generis for protecting semiconductor chip innovations, sui generis on Vessel Hull Design to protect original designs of watercraft hulls and decks.

In this new era of knowledge-based economy as in companies (especially startups and SME's) comparative share of Intangible assets increasing, they are lacking in valuable tangible assets e.g. Machinery, livestock, land etc. which they had been using as a mortgage for financing in critical conditions. But as intellectual property is considered as a property (although intangible), it can be used as another form of property to generate funds by making various financial instruments based on specific nature of this assets.

4.2.2 Scope and types of Finance

According to Oxford dictionary, the word finance means management of money and can be defined as art and science of managing money, which includes financial services and financial instruments. The activity of Finance provides funds when it needed to the company, hence concerned as a very important aspect of any business (29). Similarly, the term Business Finance deals with the activity concerned with planning, raising, controlling, administering of the funds used in the business (Guthumann and Dougall).The main objectives of financial management are profit maximization and wealth maximization of a firm.

Finance can be divided into two parts short term finance and long-term finance if required. Short term financial requirements are generally known as working capital which is require for normal working of a company e.g. procurement of raw materials, payment of wages, day-to-day expenditures whereas, long-term financing is also called as capital expenditure because it's mainly used for investment in fixed assets land, building, plant and machinery and other fixed

expenditure.

Sources of finance-

Financing can be achieved from various sources and these sources can be divided into following 3 major categories (29)

- 1) Security Finance- If finance is done by issuing securities such as shares and debenture, it is called as security finance, it plays important role in deciding the capital structure of the company.
- 2) Internal Finance- It uses profits as a source of capital for new investment in company, rather than distributing it to owners or shareholder. It's one of the less expensive modes of finance as there are very less or no any transaction charges involved
- 3) Loans Finance- it's a lending of money from financer to a borrower, majorly the banks and specialized institutes are involved in this kind of transactions.

Companies can obtain finance through internal as well as external sources. As seen above in a second type of financing i.e. Internal Financing, company can obtain the finance from internal sources too, but it can be possible only if a company is considerably big with generous profits. In a case of new company sometimes (Specifically here startups or SMEs) it may not possible to raise finance through internal sources and they have to depend on external sources such as shares, debentures and loans. So in our thesis, we will be talking about the possible best options for financing startups from external sources based on IP assets.

Use of IP to raise financing-

As per the evidences patent can be used as the indicator of

technology competitiveness, and at the same time they can be used as the source of finance for the companies. It's also been found, there are several financial instruments based on IP are being used by these companies and financing firms (9)

4.3 Intellectual property financing

4.3.1 Role of IP as a financial asset

As mentioned previously Intellectual Property Finance (IP Finance) is a concept mainly based on the development of financial activities by using firms IP portfolio. This activity intended to results in increased value and commercialization potential of Firms IP with the increased returns on investment for the investors, at the same time.

The main factor in this type of financing is the determination of an exact value of an IP. Although it's not possible to decide the exact value of patent yet, but there is a promising research going in this way to evaluate IP more precisely. So, somebody can use such calculations to claim proper amount of funds to support the company's needs³.

4.3.2 NPE based IP Financing

In 2001 Peter Detkin who was working with Intel's IP counsel used the term "patent troll" to describe "TechSearchs" CEO and lawyers, when Intel was defending a patent suit against them. In a simple way, we can describe patent troll as a person or entity who acquires

³ As Valuation is one of the critical point in the area of Intellectual Property and specifically in IP Financing, this thesis is only limited to work on the development of related financial instruments and concern strategies and not on Patent Valuation

ownership of a patent without the intention of actually using it to produce a product. Rather main intention of acquiring patent is, either for licensing or for suing some manufacturer or user who is suspected of using such patented technology in a product without permission (30). There are some synonyms used for Patent trolls are like Non Practicing entities, Patent assertion entities etc.

NPE's are criticized for their aggressive nature and claimed that, they do not promote innovation and are causing excessive baseless litigations. But contrary to popular belief, patent trolls also act to benefit society by playing a role of market intermediary in the patent market. They allow liquidity, market clearing, and increased efficiency to the patent markets. In fact, these intermediaries are prime initiators who started patent monetization programs and developed various strategies to finance innovation, through IP (31). So it's very necessary and helpful to understand the types and financial models applied by NPEs in IP-based financing area. Typically NPEs can be categorized depending on their working area i.e. NPEs active in IP Management Support, IP Trading Mechanism, Aggressive NPE (IP Portfolio Building & Licensing), defensive NPE (Defensive Patent Aggregation), Platform Based (by providing a framework for Patent Sharing), IP-Based Financing NPE's (32) etc.

| Type | Features |
|--|---|
| Aggressive NPE | Licensing of intellectual property rights (IP Acquisition and Licensing) |
| | IP / Technology Development and Licensing |
| | Patent Pool Administration |
| | University Technology Transfer |
| Defensive NPE | Defensive patents acquisition |
| | Sharing of patents/ patent portfolio |
| Intellectual property trading | Intellectual Property Broker (IP License / Transfer Brokerage) |
| | Online intellectual property trading markets (Online IP Marketplace) |
| | Intellectual Property Auction (IP Auction) |
| Intellectual Property Management Support | Support in various crucial activities like Company's patent portfolio analysis, licensing, litigation, Patent infringement analysis, Invalidity analysis. |
| Intellectual Property Funding | Using Intellectual property as a collateral (IP-Backed Lending) |
| | Invention Investment Fund (Innovation Investment Fund) |
| | Patents event-based funding |
| | Patent investments (Investment In IP-centric Companies) |

Table 4- Various NPE based Financing Models

(1) Aggressive NPE

These kinds of NPEs exploit the IP market imperfection and loopholes, from patent law to make money out of IP. Generally, they aggregate patents with quite broad claims, mainly for litigation and licensing purposes. Their main source of income is infringement claims, from companies who infringe the rights mistakenly. Generally, they also target the manufacturing companies to whom, any issues to production process may heavily harm company's economic condition. Typical examples are Acacia Research, Rates Technology Inc. etc.

Licensing enforcing NPE's e.g. are InterDigital, Conversant IP, IP Create, etc. IP / Technology Development and Licensing based NPE's are MPEG LA, Sisvel, and Patent Pool Administrators acting through licensing programs are technology licensing office of Stanford University. It can further classify as university technology transfer NPE's.

(2) Defensive NPE

Are those kinds of NPEs who aggregate, those important patents which might get infringed by a company from a defendant side and can be used by aggressive NPEs for litigation. So Defensive NPEs mainly assert patents to protect a company from future litigation, if that patent gets asserted by aggressive NPE in future.

Some of the patent management companies provide professional services to customers (or member companies) to protect their product and act like defensive NPE. They aggressively engage in finding potentially problematic patent and their claims for a particular technology and then acquire the rights of that patent. In that way, these NPEs prevent litigation of member companies and also avoid the

future damage to them. Also these NPEs resolve the disputes of member companies through licensing and sub-licensing agreements. Generally, such NPEs charge annual fees for members and generate a fund to operate current portfolio and for new acquisition. Suitable examples of these NPE's are AST (Allied Security Trust), RPX (Rational Patent Exchange) (33)

(3) Intellectual Property Trading

It's a selling or licensing of IP/patents through a platform where consumer, as well as IP owners can take part. The host can perform the role of intermediary to facilitate the easy monetization process. As discussed in table these platforms mainly work as IP brokers, as online IP marketplace, as IP auction platforms etc.

(4) Intellectual property management support (IP Management Support)

These kinds of firms provide capability generating services to IP-focused firms by giving strategic support in activities like Company's patent portfolio analysis, licensing, litigation, Patent infringement analysis, IP valuation, IP monetization.

(5) Intellectual property-based financing (IP-Based Financing)

The use of intellectual property to finance the firm is one of the famous NPE business model used in this space. NPEs invest in potentially promising IP, by which IP holding firms as well as financer's get benefited. The financing firms generally apply models like IP-backed lending (where IP is used as collateral), financing new innovative projects by securing some IP rights from it, financing patent-related events like litigation, are some of the common strategies used by such NPEs. NPE's create specialized Funds to support such programs, so this kind of monetization practices has great influence

throughout intellectual property ecosystem.

Such Firms got further specialized for working in particular models and evolved as “IP specialized financial companies” e.g. companies for IP Litigation Financing, Private Investment Fund, Regional Development Funds, and for IP M & A (34-36) . These companies play important role in IP monetization process and therefor the main focus of this research is to work for strengthening this system further.

| Type | Active players |
|--|---|
| IP Litigation Financing | Arca Capital, Burford, Calunius, Committed Capital, Fulbrook, Harbour, Hudson Bay Capital, IMF/Bentham, Iriquois, Juridica, Vannin, 1624 Capital, Pragmatus |
| Private Investment Funds | Alpha Funds, Altitude Capital, Coller Capital, Fortress, ,Panoptis, Inv. Capital Partners, Northwater Capital, NW Patent Funding, Paradox Capital, Rembrandt, Techquity |
| Regional Development Funds | Intellectual Discovery, France Brevets, Hamburg IP Fund, IP Gest, ITRI/ Taiwan, China SOEs, Japan IP Bridge |
| IP M&A Services and IP Capital Placement Agents | Barclays (RPX, ACTG, IDCC), Evercore (AOL, IDCC), Houlihan Lokey (PWAV), KPMG (Qimonda), Lazard (Nortel, Motorola,Kodak), 3LP Advisors, Pluritas |

Table 5– Various IP financing models and relative players

The dot-com bubble burst, in Silicon Valley has allowed acquiring so many valuable patents from bankrupt companies with possible promising returns and that's how the investment started towards this business models. Financing of Intellectual property is possible through various investment models and under various financial instruments.

4.4 Different Forms of Financial instruments and their characteristics

As financing has two main types i.e. Equity based finance and debt based finance. Companies can use any of these models to monetize their IP accordingly. Financial Instruments based on patent are highly customizable and used by various players like banks, NPEs, VC financer's etc. But actual model diffusion is quite low so didn't developing as require. Following are some of the most common forms of financial instruments used (9)

- patent loans,
- patent sale and lease back
- Patent securitizations

Nowadays along with these traditional instruments, IP assets are also being offered on trading platforms by offering the share interest in their value (37).

4.4.1 Patent Loans

The practice of using the patent as collateral is century backed practice as once Einstein used his patents as collateral. After 1980s such practices got generalized as some of the companies approached these models to get funding, they used their Intangible assets like patent, trademark etc. as collateral and borrowed money from financial institutions. These financing institutions value the IP on their quality, market potential and on the basis of various other factors, and then offer the loan amount to the IP holding company. Banks had offered such services initially. Banks from US, Japan, Germany had started such programs, to which latter the banks from other developing countries also joined e.g. banks from China, Singapore and Malaysia. Actual development barriers in this system are a lack of proper valuation techniques and in-house

protocol's to process such kind of collateralization (9). Along with the banks, there are also some private players has entered in this market to finance IP-based firms through a loan (38).

| Institution | Activity |
|---|--|
| GIK Worldwide | Has obtained loan of 17 million in loan on the basis of its patent portfolio based on Video Conference technology. |
| Dow Chemical | In 1994 has obtained loan of 100 million, On the basis of 50% value of related entire patent portfolio. |
| Development Bank of Japan (1995) | After starting initiative in 1995, next decade bank provided loan to 260 SMEs based on their IP(16 billion Yen) |
| China Bank of Communications (Beijing Branch) | Started offering IP backed loans in 2006 and immediately after 2 years registered 300 cases (on 700 patents valued 6 billion Yuan) |
| Initiative Finanzstandort Deutschland (IFD) | Started the program to promote SME financing based on IP as collateral. |

Table 6- Institutional activities in regard with IP collateralization

4.4.1.2 Venture debt

It's a kind of mixed model of equity and debt financing in which company can get a loan over its IP on a particular interest rate. But at the same time, the financing company secures equity in company and there is a threat of seizing IP assets as well as other company assets in case of default (7).

4.4.2 Sale and License-Back (SLB)

In 1993 Aberlyn Capital Management a venture capital company financed a biotechnology firm called RhoMed \$1 million on its single patent through a sale and leaseback model, and this was the first recorded case of this transaction. In this type of financing IP holding company sells its IP assets to a finance company in return for the funding, but at the same time after purchasing the ownership of IP assets the new IP holding company (Financer company) again leaseback the same set of that IP assets to the original owner company to facilitate them to continue with existing operations and products based on that IP. By using this model firm can generate money through their IP and at the same time can utilize the legal rights of sold IP too.

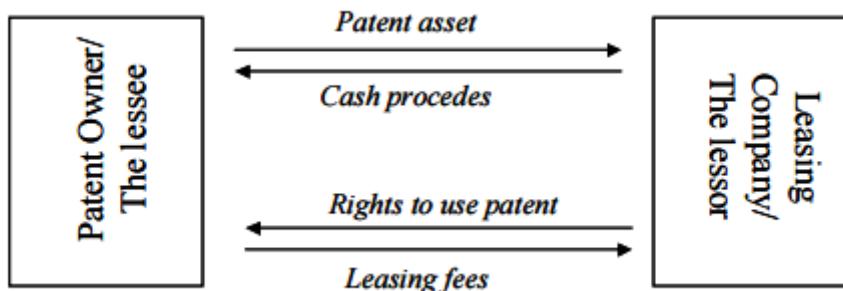


Figure 2– Patent sale and leaseback process (Adapted from Frank, 2005)

In such kind of agreements, involving parties use various options to minimize the risk of transaction and gives flexibility to the agreement. The options could be in issues related with repurchase/ sell of patent to

ownership; royalty and IP use related issues etc. Although the deal related to RhoMed further got failed to secure projected benefits. The SLB model has been found lots of potential in this IP financing area as patents are suitable to get financed based on the ownership rights(9).

South Korean company Intellectual Discovery (established in 2010) is one of the best examples of such initiatives in this area. This is a collaborative initiative of Korean government (Ministry of Industry) and Private companies (like Samsung, Hyundai Motors, LG Electronics, SK, KT etc.) which has the special focus on SLB models and working actively in this area (39)⁴.

4.4.3 IP Securitization

In this type of financing, income (royalty) from an IP-based product are securitized in special purpose vehicle to issue these securities in a capital market. This kind of financing is considered as some safe type of financing as the securities are issued by SPV are legally considered as separate from the IP holding company.

The basic structure of SPV is consist of following players - originator or an IP holding company which sells its IP to a separate SPV to secure it from affect of company's status like bankruptcy. Then further these SPVs issues securities over such IP income stream in the capital market. Here related cash flow is managed by Trusts. Along with this main players, there are also other actors are present which handles the activities related to the transaction, credit merit

⁴ Intellectual Discovery Group Performance Report- 2014 (<http://www.ipdiscovery.com/site/kr/contents/gnr/view.jsp?lang=kr&bbsCd=pr&bbsSeq=2230>)

assignment, selling security and supply of external credit enhancement (9, 41).

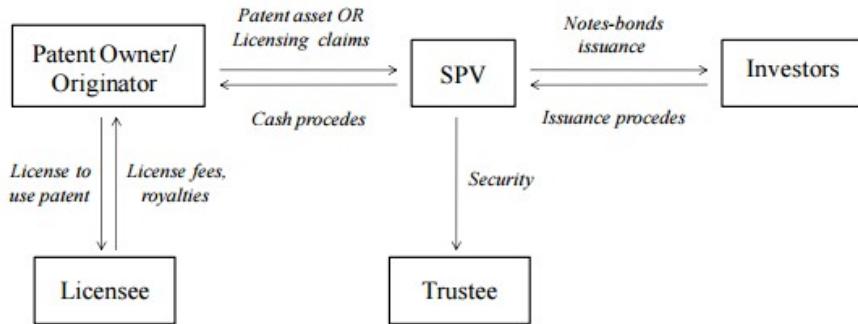


Figure 3– Patent securitization process (40)

Securitization of such royalties can be possible for existing as well as future revenue stream, so this model could be applied to big company product stream to small company future product stream too. In this way this model is beneficial for smaller companies which can get early and immediate funding based on future royalty stream and mainly by without losing a control on company management. As like other models, this model is also in its initial developmental stage and most evidences are from the US. The famous case in this area is from Royalty Pharma AG, which has used IP securitization in its IP financing program. Main cause for underdevelopment of such models is the complex nature of IP assets and high upfront costs to generate these infrastructures. Therefore such models can be useful for those institutions with consistent portfolios like Universities. In absence of this, there is a very important role of IP financing intermediaries comes in picture for the further development of this models.

4.4.4 ETF model

Commonly Exchange-traded Funds (ETF) own the underlying assets like shares of stock, bonds, oil futures, gold bars, foreign currency, etc. and divides ownership of those assets into shares. IP- based ETF models are based on the shares made on the value of intellectual property and traded on the index. So accordingly, it's also possible to buy shares of IP assets from various kinds of companies. Presently this type of approach is considered as potential approach, as day by day value of companies intangible assets are increasing compared to its tangible assets.

One of the best examples of such model is Ocean Tomo 300® Patent Index (OT300), platform based upon IP assets of a company and represents a diversified portfolio of 300 companies that own the most valuable patents relative to their book value⁵.

4.5 Developmental Barriers

Although, IP-based financing has a lot of promising aspects like bringing liquidity in the firm, still it's been found this sector is not getting much utilized by IP holding firms and specifically by SME's.

Following are some of the market-related barriers found, to be affecting the progress of IP financing sector (7). But one should have must consider that, as IP is not a traditional form of asset, there could be some subject- specific barriers which cannot be eliminated fully, but can be minimized up to some extent.

- a) In SME/ Startups IP is not only at center

Several times at innovation-based firms IP is always not at center

⁵ Ocean Tomo 300® Patent Index (<http://www.oceantomo.com/ocean-tomo-300/>)

because, the other factors also have a considerable impact on firm's productivity like skills of the workers, their dedication, know-how etc. Therefore sometimes IP is combined with these other factors and becomes hard to separate, but at the same time it can be at the core of company strategy.

b) Fewer options in Exit from IP-based investments-

Traditional Assets have already developed and has a mature market for the resell in a case of exits from those. But because of lacking in proper valuation technics and underdeveloped secondary market, IP is not prone to give immediate returns in those cases. So along with other private investors banks are also reluctant to finance in such matters.

c) High Assessment cost and High risk

Although financing can be possible on the basis of potential IP value (still the requirement of proper valuation techniques) but it's difficult and costly matter even to assess IP and importantly the trustiness on the firm to invest. Assessing the potential of a firm in administration, production and related issues is also important. Despite of this all assessment value of IP is always subject to change on time and other factors.

d) Awareness about IP

Still in this era of knowledge-based economy, SME have not fully understood the importance of IP and their protection. The reasons could primly the unawareness and sometimes high maintenance cost. Various surveys have denoted that SMEs tries to keep secrecy about their inventions than patenting it. ((42) For the United Kingdom)

e) IP records on Balance sheet

As IP is an asset it can be entered on the company balance sheet which comes with the features of credit and liability. This kind of approach first initiates practices of IP assessment and after, it helps financial institutions to recognize IP as collateral and its value to that firm. So more work in IP related accounting practice and corporate reporting of IP, is required to develop and exploit its benefits.

f) Underdeveloped Banking system

Although some countries and banks have started the initiatives in this area, but still the banks do not fully accept IP as assets for collateralization and seems reluctant in such matters. The reasons could be the valuation methods, required expertise to handle the matter and related processes in the system to accommodate it in existing framework (42).

4.6 Effective use

Patent Backed Financing could be a great opportunity for those companies with potential technologies and strong portfolios, which are in need of more funds but reluctant to share equity in venture capital market (43, 44).

These instruments help to separate and evaluate overall company repute on one side, and IP assets on other. This helps the innovative firms to attract finance effectively, because the financing sometimes will be evaluated on future cash flows (45).

The current scenario consists of fewer deals, lack of transparency and high level of secrecy in such kind of deals. Effective ways towards

minimizing these factors could boost up this market.

In a case of IP securitization, the future cash flow is the only characteristics that make IP as the securizable asset. Other than these characteristics there are considerable structural impediments in the development of these models (46).

There is a complexity in value and risk assessment of a patent portfolio. There are some risk factors that can affect the future cash flow also. Therefore in current situation only those patents generating cash flow are more suitable for utilizing in IP financing program. The immature secondary market of sell is also a reason for difficulties in a disposal of patents acquired through collateral defaults.

Unavailability of standard processes, even for a bank loan and high designing cost of these processes to make the customized IP backed financial instruments is another challenge to develop this market (9) so such processes are assumed to ease IP backed financing further.

Chapter 5 Biotech firms and suitable IP financing structures

5.1 Leveraging IP in Biotech

As most of startups and SME's in biotech industry are mainly R&D based and many times product release takes several years to come into a market even after the initial proper legal protection. Also in the case of successful commercial product release, they mostly have a single product to commercialize in the market. These companies use their IP mainly to protect, regulate investments and for competitive advantage. Following are some relevant strategies that IP centric biotech companies have been practicing to monetize their patent portfolio (47).

5.1.1 Out-Licensing

Simply it's a license grant by one company to another, and traditionally known. A normal licensing can be done by structuring the contracts in various ways i.e. giving exclusive or non- exclusive rights to a licensee, or by putting territorial / technology specific restricting rights. Upon licensing of rights, companies can get money through an upfront payment, royalties, milestone payments etc. As product research period is very long in Biotech industry, the available IP can be used for various financing as well as strategic purposes in such period e.g. collaborations and cross-licensing. Companies can use received funds and royalty revenues to build their existing technology more inclusive; or to focus on other more specific areas in technology by narrowing the current research focus.

At the same time as out-licensing is a good source of financing company in short term basis, sometimes it may affect company strategy in a long-term. Because initially protected technology may get under evaluated and sometimes may licensee's activities can affect the reputation of technology in public. So balancing approach of short-term and the long-term basis, on precise technological analysis can allow a licensor a good deal⁶.

5.1.2 Cross-licensing

Bio companies can use their existing portfolio to minimize the problem of blocking patents from another company making a hurdle in the development of new technology further. Generally, cross-licensing helps in collaborative research which allows companies to make collaborative products or technologies based on their shared IP rights. Sometimes the generated portfolio of sharing of a technology can be applicable in another field of technology, and in this way the both companies can leverage this cross-licensing project together.

But this kind of deals can affect the company exclusivity on particular technology, which results in shared royalty rates⁷.

⁶ In first case, a company called CyDex pharmaceuticals used their technology related to drug delivery system to out license to other big pharma companies then used money from generated revenues to make their existing system more inclusive by including more off patent drugs on that platform which made the company to generate \$50million at their IPO ; Where as in other case, a company called ThromboGenics has out licensed their technology related to specific target related antibodies to D. Collen Research Foundation in return of lump sum payment of research expenditure of that program and additional 25% share of future revenues from that program, interestingly later the company ThromboGenics has used this money to focus on more specific area of that technology.

⁷ The cross-licensing deal between AVI bioPharma and Eleos on technology based on antisense molecules and p53 protein allowed them Not only to develop a p53 based treatment for cancer but also deal has allowed the protection of p53 based targeting technology applications in other area of health too so both companies together can benefit

5.1.3 Selling IP or royalties owed on it

In this type of IP leverage, the IP owner can entirely sell the rights to IP or he can sell the royalty rights arising from an IP protected product or process. When company technology focus changes in other area of research that time companies might discover some IP portfolios, of less importance to the company in such particular situations. But at same time, the same IP portfolio can be of high value to other players in the field. In such situations companies can sell that IP rights and can generate funds to finance current technology focus. In another case, if IP is already making some revenues or in the phase of getting potential promising returns, in such conditions it's possible to sell the related rights on that royalty to make money.

This kind of deals are possible only in case of specified diverted focus of companies from existing valuable IP; whereas in royalty-based deals it can only be possible in case of immediate demonstrable financial returns from the product⁸.

5.1.4 Lending secured by IP

As IP is an asset, it can be treated as other tangible assets and can be used as collateral for a loan. The interest rate is generally based on market size of products and company reputation so this kind of investment options are good for company stakeholders, but might be

from that new avenue also

⁸ A company called Cytori Therapeutics has generated funds by selling their one product line related to surgical Implants and related IP to focus and develop the technology related to adipose tissue derived stem cell therapy which was their interested research area latter. A company called Dyax has generated funds from a deal based on their royalties of their product and used that money to advance their other product stream related to hereditary angioedema.

worst in a case of default where IP can get seized by lender⁹.

5.1.5 Litigation

One of the most important areas in patent monetization is litigation. One of the main issues related to startup/SMEs related patents is the ownership as well as infringement. As the inventors and initial owners are not always aware of related laws, such conditions always happen. The big issue in these kinds of litigations is money. Startup companies' can't afford such kind of activities at their nascent stage, as average patent litigation case takes \$4-\$5 million as overall expenditure. External sources at this time can be very much helpful at this stage and can save companies from breaking. But the important thing is, startup company owners has to negotiate this kind of deals very wisely to minimize future risks to company ownership that might arise out of such deals (48-50).

5.1.6 Securitization

It's another more crucial and well-practiced form of patent monetization. Patent securitization is a specialized form of IP-based securitization which has used to securitize earnings from copyright protection earlier in 1970's in the United States. Biotech patents are assets that can be securitized for royalties and future cash flow, if followed some accounting and financing standers properly¹⁰. It

⁹ a company called Entrée got loan of \$20 million from a lenders to support their future operations, in this case the collateral included the royalty payments received from their sublicensing program

¹⁰ First case of patent securitization is recorded in year 2000 from "Royalty Pharma" which were able to securitize assets on a anti HIV medicine called "Zerit" from Yale University and raised US\$115 million over it

provides the new source of funding to IP owners by giving cash offset and protection over funding. IP owners' don't lose patent rights (as like in IP secured loans) or even don't have to sign contracts with non-adjustable conditions to seek finance. Patent securitization is seen as, a new financial product with the features of clear, simplified assets provided by risk management mechanism i.e. SPV (41).

5.2 Biotech IP monetization related risks and risk minimization approaches

5.2.1 Advantages and disadvantages of current Biotech IP models

As all of above, are the potential monetization ways of available IP assets from Biotechnology companies. These companies can use any of these ways if they have really strong and valuable IP and can choose a proper monetization way depending on company condition and situation. But as each method has its own advantages, it also has it's some method specific disadvantages too. This may become very critical to a company future. Like in a case of out-licensing company may get less money because of early undervaluation of technology and may affect company reputation if Licensees wrong practices and public behavior which affects to its associated companies too. In a case of cross- licensing you lose your exclusivity on technology and then a company has to share assumed royalty. Patent loans can cease the patent itself in the case of default, whereas litigation costs too much for a company which can result in the make or break the company future.so it's very important to make such financial models for biotech startup or SME's that can give the same benefits as like now to both parties but at the same time, it should also minimize the disadvantages predicted from this kind of deals.

| Method | Advantages | Disadvantages |
|---|--|---|
| Out-licensing | Raises capital | Engenders fear of out-licensing too early |
| | Is suitable for early-stage technology | Cedes some control over reputation and valuation of technology |
| | Narrows company focus | |
| Cross-licensing | Removes blocking of patents | Requires giving up exclusive rights |
| | | |
| | Can allow collaboration | Can allow competition |
| Selling intellectual property or royalties owed on it | Raises short-term capital | Requires demonstrable financial returns |
| | Narrows company focus | Discounts value of IP |
| Lending secured by IP | Makes use of IP, which may be company's most valuable asset | Interest rates obtained do not generally reflect IP value |
| | Raises non-dilutive capital risks | losing IP upon default |
| Litigation Finance | Allows proper enforcement or litigation of IP | company future depends on negotiation |
| | Can help a company to generate extra revenue from its infringing market products to their IP | lender may ask for too much stakes at the difficult times |
| | Helps to solve legal issues of startups and SMEs professionally. | |
| Securitization | Enable financing on future profits | High uncertainty on future approvals and market conditions (41) |
| | No risk to IP ownership and parent company financial status | |

Table-7 Comparative features of Each IP monetization model

5.2.2 Options

An OPTION contract is an agreement in which a seller (writer) conveys to a buyer (holder) of a contract the right, but not the obligation, to buy or sell a specific quantity of something at a specified price on or before a specified date. So these types of contracts in licensing agreements have been used for generating more belief in deal and to minimize risks. Options can be exercised by a seller and buyer in call or put way (51).

- Call options give the buyer the right to BUY the underlying asset by certain date at a certain price
- Put options give the buyer the right to SELL the underlying asset by a certain date at a certain price

In Patent licensing Options have been used as a simple but effective tool for minimizing risks from a contract. The parties can use Put and call options effectively according to their needs. Some of the models like SLB are using these options effectively in their IP deals.

5.2.3 Equity interest

Equity is the difference between the value of assets and the cost of liability over an ownership. Whereas in lay man's terms a practice of investing in company intending to have equity share, can be called as equity- based investments. In terms of IP licensing agreements, this type of approach is sometimes preferred by investors (especially VCs) to secure a part in whole company stakes. Generally, in case of VC investments, this approach helps VC to gain their profits by selling their equity ownership after an exit through merger and acquisition or majorly after an investee company goes for an Initial public offering.

Studies and practices showed that success of these approaches in patent licensing deals and especially in licensing based on sales and lease back type approaches (52).

5.3 Concept of Special purpose vehicle (SPV)

An SPV or a special purpose entity (SPE), is a legal entity created by a firm (known as the sponsor or originator) by transferring assets to the SPV, to carry out some specific purpose, or circumscribed activity, or a series of such transactions (53). SPVs can be made for purposes like Financing, managing subsidiaries, holding, financial assets and liabilities, securitization, cash management; managing Royalty's and film rights and other asset management activities. SPVs have been observed as risky entities because of its improper use by some corporation, but they are not all risky and can become highly useful if governed properly. They have been utilized by big companies for fulfilling specific demands like investments and for risk minimization. The SPVs can be beneficial, if it's able to maintain its transparency to financer's and able to manage risk at some time. Following is the simple background and structural properties that will help to understand the basic concept behind SPV (54).

5.3.1 Market Background

SPV can become beneficial to banks, financer's and companies if operated under good guidance and management. If SPVs structured in view of such factors to minimize risk associated, then these can become a useful instrument of Company financing. As there are more advantages with SPV use than the disadvantages, possibly they will

be continued to play a important role of intermediaries in future.

5.3.2 Characteristics of SPV

SPV's are risk minimizing tool and generally created for a specific purpose and time. A SPV structure mainly allows the incentives on risky investments and opens a new door to investors, to utilize those risks in future incomes. Following are some of the uses of SPVs

- 1) Securitization- Main player in securitization process and generally used for securitizing Loans and other receivables.
- 2) Raising Capital- Here, based on collateral quality SPVs can get finance and not on the company repute or history. So this type of feature is useful to raise funding for new spinoffs too.
- 3) Financing- It can be used to fund new projects without hindering current one, and also this feature allows extra borrowings in limiting situations.
- 4) Asset Transfer- Transferring of many asset rights is a lengthy and complex matter. In a case of SPV, it's a bundle of many related assets. Therefore transferring the rights of direct SPV ownership (single time) is easy than the individual transfer of those assets.
- 5) Risk Sharing- As SPV is a separate legal structure; its parent company can't get affected in case of bankruptcy related events of SPV.
- 6) Financial engineering- Sometimes it can get exploited negatively by manipulating investments, to pretend pseudo situation and generate false reports e.g. Enron case

5.3.3 Structure of a SPV

SPV structure varies depending on the purpose and geography like limited liability company (US), charitable trust (Canada), corporation, trust, partnership etc. typically there are three players - SPV, parent company or originator and an Investor.

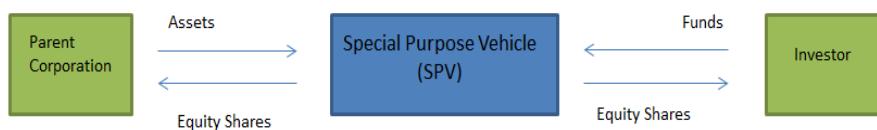


Fig 4- General Structure of SPV

Parent company creates SPV and transfers its assets (from the balance sheet) to it, in return of funds. Equity investors buy the assets by debt financing to create funds to transfer to a parent company. In this way the parent company gets financing whereas investors get equity shares in a SPV. The investors value assets depending on its quality and not on the basis of parent companies repute. For example, in the case of patent securitization, the investors will evaluate the value depending upon the future market of patented product or revenues. So he can securities those earnings and then he can invest the compensatory money in the form of funds to a parent company. The Loans or accounts receivables are purchased by SPV and categories depending on risks (called as tranches), and then these tranches will be offered to investors to buy and get benefited on the risk involved.

5.3.4 Advantages and Disadvantages of SPV

| Advantages of SPV | Disadvantages of SPV |
|---|--|
| It can provides the ownership of assets to more than two partners | Less clarity in operations in case of multi- level securitization |
| Cheap and easy setup | Closing inefficient SPV can harm parent companies credit in market |
| Easy to limit the internal transaction depending on purpose | Bad results from SPV assets, can point out to other similar assets from parent company and affect adversely |
| Exemption of choice of Jurisdiction | Undesired effect from a SPV may block or affect future investment decisions from investors to the parent company |
| Availability of SPV based tax benefit offerings | Combinatory negative effect of SPV may also block the other capital market finance to parent company |
| Limited liability to can be possible | Any suspicious activity to SPV assets can result in negative impression on similar assets from parent company |
| Its isolated legal structure, helps to separate it from parent companies adverse situations like bankruptcy | |
| As here assets are off balance, it's possible to use it to maintain standards expected by institutions | |

Table 8- Advantages and Disadvantages of SPV

If observe keenly to the disadvantages section, one can conclude that firstly the multi-layer securitization requires high management and administrative capabilities to avoid such situations. Secondly, as most of the other factors are related to underperformance of SPV and parent company repute, the help of subject matter experts and good screening practices can help to avoid this kind of situations from the investor point of view.

5.3.5 Major SPV failures and preventive regulations

Usage of any tool, depends on the hands those are handling it and their intentions; interestingly SPV is also a tool, which is prone to get misuse. Financial engineering of SPV structure can allow the controllers to abuse the use of this tool to manipulate numbers and create pseudo situations. In last two decades, some of these incidents happened from very big corporations which surprised the world. In 2001, a big corporation called Enron has used the SPVs to hide their debts and finally went bankrupt; this misconduct resulted in falling of share price of Enron from \$90 to less than a dollar which made huge losses to their shareholders. A similar case has been found from Tower financial (1994), Bear Stearns and Lehman Bros. (2008). All these were big corporations and misused the facility of off-balance sheet benefit of SPV entity. Therefore major finance related legal bodies have decided to tighten the related rules by limiting this factor further. Enron has used hundreds of SPVs to conceal their billion dollars debt resulted from unsuccessful programs; while in a case of Lehman brother's insolvency, major reason was with structural weakness in documentation and partly happened similarly with Tower financial and Bear Stearns. The major tactic used in these frauds was misusing the feature of SPV which allows it to act as a Bankruptcy remote by putting it on off-balance sheet on record. In simple terms, as SPV's were off balance sheet tools, they were prone to get misuse. So Integration of SPVs with originator could be the simple and effective solution to above discussed problem. This Consolidation enables SPVs not to get exploited as bankruptcy remote and would reduce moral hazard risk which can be interpreted by off-balance sheet SPVs and minimizes the risk of being utilized as a financial tool for hiding inappropriate

conditions.

The Consolidation of SPVs depends upon which accounting standards are used. According to International Financing Reporting Standards (IFRS), it requires the SPV asset has to record in in the balance sheet of controlling entity. Further, they also specified (SIC 12) basic criteria to get considered as a Controlling entity. This criterion considers the factors like resultant benefits, control and risk. In such cases, SPV assets and dependent funding's has to show as assets and liabilities accordingly. While in the case of US, which follows Generally Accepted Accounting

Principles (GAAP) standards from the year 2010 it also restricts the records of SPV assets in controlling bodies and tried to imitate same effects like IFRS. It also forces to bring SPV on records of controlling entities. Also new Global standards on bank capital adequacy and liquidity called BASEL III, has been made after a financial crisis to address the identified deficiencies in bank system. Under which for Capital standards and new capital buffers (mandatory capital that required to hold financial institution) banks required to have increased capital and higher quality of capital than the previous rules of BASEL II.

In short after the bankruptcy of Lehman Brothers in 2008 considerable regulatory changes have been taken place especially for SPVs. Mainly for documentation lending, application of Legal risk management practices, restructuring and valuation. So, all these efforts together are supposed to prohibit further misuse of SPVs at least by known loopholes.

5.3.6 Reasons for failures of SPVs

Success of SPV's depends on a couple of internal as well as external factors. Following are some of the situations in which SPV may fail to its purpose-

Failing of SPVs may occur in the case of an exit of one of participating entity or in case of conflict of interest between them (55).

In a case of exit, from originators reputational perspective its neither in their favor nor in investors favor (under certain conditions of fulfilling pro-rata rights). At the same time factor of reputation also assures investors and banks to invest even in a case of availability of inefficient data. Therefore in such cases, SPV could become inefficient from risk and regulatory perspective. Whereas in case of conflict of interest proper detailed agreements may solve such improper conditions effectively.

In the case of Securitization, if concern statutory laws are not clear enough on assets to collateralize (In this case, it's about Intellectual property and especially the patents) possibility of failing with use of SPV may occur (56).

As the trend of using patent's future royalties for securitization, is a comparatively newer approach in the finance field; still, the related country laws are not clear enough about patents use in securitization as such activities often comingle with multiple concern laws at the same time. Similarly, issue of IP valuation is also a crucial factor to this kind of approach as a science of IP Valuation is still in its developmental phase.

5.3.6 Risk Management

The risk with the SPV structure can be managed by applying good practices with a clear motivation. These effective practices can be applied in Governance, reporting, routine cross- checks, regulation, simplification in structuring etc. to minimize the risk effectively. Following are some of the effective practices that may help to prevent misuse of SPVs if applied in related SPV transactions (54).

- Governance of SPV should be proportioned with active players and structural complexity.
- There should be regular access to reports explaining comparative dependent risk to firms SPVs along with other institution-wide risks, which could also increase transaction capability.
- The regular supervision of qualitative, developmental factors of on-balance sheet components and SPV activities.
- The special purpose of the vehicle should always be strictly followed to fulfill the intended purpose properly.
- Higher standards on accounting requirements, rating institutions, document disclosures with simplified SPV structures could also serve the purpose.
- Enabling SPV consolidation with originator and providing retention flexibility with dependent risks for an investor.

It's been observed that risky and illiquid nature of SPV investment often owned with insufficient structural and related data. In the case of banks, they also reluctant to evaluate the credit quality of collateralized assets in such loans. So therefore majorly the SPVs

were not under strict supervision previously, but the application of above measures is expected to prevent the exploitation of this financial tool effectively. SPVs have been used for risk minimization and also in the financing of highly risky assets traditionally but its structural gaps have allowed its abuse by some corporations. Use of SPV is not controllable as there are benefits with its use, but in future more safe practices needed with more transparency, high standards and support from sponsoring institution.

5.4 Startups and SPVs

5.4.1 Importance of SPVs to startups

The ability to accept minimum investment in SPV, if complemented with the pattern of financing institutions like VCs, seed financer's etc. could become a good option for startup financing (57). These SPVs not only can have multiple two digit investors (In an LLC structure) for a single project funding but also its handling and administration is easy, because of a ultimate single point of contact (In the form of SPV) representing the investors, is possible to simplify managerial decisions. Single point contact is always been considered as beneficial way for new startups e.g. in a case of VC funding. But in another side in case of multiple investors, it may become difficult to handle issues related to general queries to individual interest separately. So SPVs option of collecting them in a single entity and then contacting them through a view of a single individual entity makes this complex process easier for both sides. Collateralizing IP for securitization or having loans may decrease the interest rate and provide the opportunity to startups to attract investment on future

royalties of especially patents. The major benefit of such securitization is, the startup can have loan or financing (through SPV) and at the same time, it doesn't need to offer the stakes in a main company. So in this way by Securitizing patents in SPV company can lower the interest rate on the loan or fund and at the same time strongly can avoid the threat over the company ownership by incoming investor interest. Additionally, registration of this SPV in low tax jurisdictions like Cayman Island, Bahamas etc. can benefit the startup with related tax benefits on their income whereas, the investors can have better investment returns on their investment. Even the efforts have been started to facilitate administration and marketing of such SPVs to raise additional funding by existing companies (57).

As we can see, SPV offer investors a critical liquidity as well as pro-rata rights to concur the current problem of decreasing investment returns. These kinds of innovative strategies enable VCs to attract long-term high-risk investments and convince their investors over the other high-risk investments like Hedge Funds (58). The SPVs are alternate creative options to increase returns on investments. Specifically, it allows pooling capital without the restrictions of primary goals, design and structural limits defined by limited partners initially. Also, it allows accepting investments from outside investors of limited partners and then investing in companies rather than being a partner in syndicate by direct investment. SPVs can be created very fast and also it protects the investor in situations like, reduced value over investment. Typical SPV fund structure is based on an advisory board and agreed governing rights.

Funding startups at seed stage enabled investors to perform their pro-rata rights by approaching companies at an early stage and also at comparatively lower investments in their later investment rounds (59). This is one of the major reasons that VCs are trying to make SPVs for their investments. Successful, VC operated SPVs are putting a way forward for funding's in similar situations e.g. SPV used by Birchmere Ventures. These SPVs are typically 3-8 million in size, which is able to give 20%, carry on the exit time. Generally, Investment banks use SPVs to generate liquidity to fulfill the market requirement. Recently these SPV are in the form of secondary fund vehicles which have been used to fund late stage startups. These late stage startups are mainly the tech-unicorn companies with the valuation (based on addressable market and exits) of more than a billion dollars. Here SPVs can be presented in the size of 300 million easily. Late stage financing enables startups to maintain their private stage for a longer period before going for an IPO or M&A. It also presumed that longer a company stays private; it may also increases its value on later market exit. Late stage financing enables startups to maintain their private stage for longer period before going for an IPO or M&A. So, It also presumed that longer a company stays private; it may also increase its value on later market exit (60).

5.4.2 SPV based pattern of Tech Startup Financing in Silicon Valley

Silicon Valley is a home to high technology startups and the financer's (mostly VCs and angels) interested in such startups. These investments are from sole investors or sometimes involve multiple partners in a single startup. These combinatorial funds facilitate institutional investors, acquaintances, business executives a special

opportunity to invest in high potential startups which otherwise impossible at the individual level with such big investment (61). Even big funds don't invest directly majority of their funds in a single firm, rather they diversify their investment at the same time in various startups.

5.4.2.1 Syndicate SPVs

Due to the high valuation of Tech companies, VCs become unable to invest in hot financing rounds of such hi-tech startups and keep their pro rata investment rights in those rounds. So VCs now turned to follow a new strategy of using SPV, under a single purpose of capital pooling and accessing direct stakes in a startup by taking part in particular financing at a specific point of time. These SPVs allows the VCs to collect funds from other investors also at the same time. The specific risks to this approach is mainly with its structuring, taxation clarity along with legal (securities law, investment laws, trust etc.) and administrative compliance

In the case of Pinterest, a bookmarking site company financing whose market valuation was set 8 billion at that time. Still, with such high market value, most companies were interested in investing in Pinterest but not with all of their funds rather they were interested in investing part of their investments. But to mitigate these problems, these firms used a novel way to fix it i.e. by using SPV. Here in case of Pinterest, managing director of First Mark (a Venture capital company) was involved in creating a special fund to pool all interested investors with their investments, where the created special fund can further claim direct stakes in Pinterest (61). In the Pinterest deal, the strategic approach used by investors to fund the new startups i.e. they are

choosing SPV structures to defend their most trustworthy investments. Here SPV based investment represents a stake in a single firm at a specific developmental stage and time. In this way, these SPVs helps the dependent VCs to compete with big Funds like mutual and hedge funds and banks who can easily invest billions of dollars single handed in most promising latter stage startups, which otherwise could have impossible . Also, another reality is, the venture funds can't always have the funds required to take percentage stakes in the startups as the valuation of these firms may rise quickly. The other examples of this strategy are startups like Instacart Inc. (grocery delivery service) and Coinbase Inc. (Bitcoin processor), Lyft Inc., Palantir Technologies Inc. The specialty of these newly formed SPV investments was that, these deals happened comparatively quickly to get access to prime targets. So automatically the general due diligence time was also less and the investing firms were just able to catch the speculations over potential growth, instead of detailed analysis on revenue, cost and financial projections of a startup firm. But at the same time, it's very important for an entrepreneur to get some value addition through an investment. Purely SPV enabled investments are not always useful for startups.

Earlier SPV's buying and pooling of existing shares from early investors, employees etc. so these SPVs were structured to enable secondary trading of shares. Whereas newer form of SPVs has primary shares of the company and then they are now offering these SPVs for investments.

5.4.3 The Mainstreaming of SPVs

Generally, SPVs were exploited by big corporations and high valued startups. They have been used by later stage startups like Facebook, Twitter prior to their IPO. But the SPVs for early stage companies are novel to VC investments market and also can be called as mainstream SPVs. As these SPVs are in their early growth period their success can be boosted by designing proper SPV structure (distribution waterfalls, carry calculations, dilution, governance etc.) and process. Future planning regarding investing company funding rounds will be a useful strategy to avoid future ambiguity. Enablement of accommodating multiple partners in single SPV is general need of startups, so structuring accordingly could be the key to success (62).

As we know SPVs are not new to the market, recently being used by VC for fund pooling as a co-investment fund. So it's a need of an hour to modify these structures according to next generation, technology based innovative companies.

5.5 Need of Biotech-Based SPVs

The first use of SPV by a biotech firm is from current industry major player Genentech. In 1982 a brokerage and asset management firm called PaineWebber (Now owned by UBS AG) introduced the concept of SPV to Genentech to generate alternative finance. The concept was a common practice in oil and real estate sector which was enabled to attract and facilitate investment for biotech projects. Generally, R&D limited partnership (LP) and special purpose corporations (SPCs) later become normal models to use in industry. SPC are also known by other modified forms like Special purpose accelerated

research corporation (SPARCs) or Stock and warrants off-balance sheet R&D corporation (SWORD), designed specifically to invest in Biotech SPVs. These intermediaries allowed the project-specific investment through an offer of warrants and parent company stocks. The companies used generated income to finance, related R&D projects. The contracts also provided the right to parent Biotech companies to buy the rights from SPV again. Here governing of such entities was regulated by a number of legal contracts. The investment option facilitates investors to invest as well as it provides liquidity to companies, as the unit interests were registered on exchanges like NASDAQ and AMEX (6, 8).

5.5.1 Advantages

- Diversification of risk in new R&D projects by outside investments and call back option for reacquisition of all rights on SPV.
- Possibility of Investments on highly Risky projects
- Better option than financing through corporate alliance

5.5.2 How the Biotech SPVs differ from other ones

- Provided funding from outside investors¹¹
- SPVs were according to financial and accounting standards with considerable importance reflected in company annual report

It's been found that SPVs used by biotech companies were having legitimate funding from external investors. The accounting practices

¹¹ As in Enron case it was partly from internal sources too

were always been in accordance with standards with its detailed report in company's annual report (6). Interestingly Biotech SPVs have already practiced by consolidating SPVs in annual statements by sponsors, so they deserve more trust than SPVs of other industry market players.

5.5.3 Use of SPVs in Biotech

Previously it was suited for more mature firms to get invested (and now we are proposing for startups and SMEs). Many major institutions have used SPVs to raise finance e.g. Genentech (Genentech clinical partners, I, III and IV, LP) Amgen (Amgen clinical partners LP) Dura pharm. (Dura Delivery Systems, Inc.), cytogen (CytoRed) etc. most of these firms have a significant impact on the development of Biotech industry today. Whereas Activase (Tissue plasminogen activator), Protopin (Human Growth Hormone), Neupogen (granulocyte colony stimulating factor, p75 (tumor necrosis factor receptor) etc. are some of the important molecules got developed under SPV type of funding. Products from hormones, Enzymes to antibody therapies and drug delivery technologies were got developmental funding through these projects (6).

Traditionally VCs mostly relied on IPO and M&A as an exit strategy but recently, some VCs in the biotech arena like Clarus Venture are experimenting with traditional strategies (63). They are trying to formulate new ways to become less dependent on traditional exit strategies to minimize the risk in such investments and searching preliminary opportunities in the area of R&D financing. Because of various reasons, the biopharma companies reduce their expenditure on

their R&D; the reasons could be an early expiration of patents etc. Such affected projects with reduced funding can be the good targets from an investors point of view as well as the parent companies point of view, as they just have to share the payments on products and not the ownership share (if it's included in the contract). Funding various clinical trial stages of already approved products and enjoying milestone payments on its success is newly approached way of investing through generating a special purpose vehicle. This way is quite a mutually beneficial way as it reduces the time of returns on investment as compared to startup financing, product potential is well-known, expenditure on such trials is predictable and returns are negotiable. EDV, OxOnc are some of the examples of SPVs used by Clarus to finance the R&D programs of related companies (63).

5.5.4 Immediate Needs-

- Increased operating and developmental expenditure demanding more financing to projects.
- Changed market conditions are mostly based on Intangible assets of biotech firms (Especially with Startups and SMEs) and therefore SPVs can be restructured depending on the changed market structure.
- Banks are also in search of finding new solutions at current situation with concern to SPVs
- The requirement of more decisive and financing and accounting standard compatible models are needed in the new era.

There are strong ties of modern biotech market development and the role of SPV. SPV has been used by the market leader in

Biotechnology to fund their new projects without hindering their existing investors. SPV based investments helped the companies to fund their nascent research projects, increase subject expertise, management and resources to increase the possibility of success from the project.

5.6 Proposed model

The new model can be considered as a partial combination of R&D LP's and SPC's, as its providing a biotech company a fund and attracting the investors through equity shares (8). At the same time the model doesn't talk about the public offerings of such SPVs for financing, instead, its primary goal (as of now), is to offer equity shares of SPV to various kind of investors like VCs, Banks, crowd funding platforms etc. interested in IP-based financing.

5.6.1 Proposed model structure

The thesis proposes an organizational structure of IP-based SPV (IPB-SPV) intended to facilitate management and financing of Biotech firms. The proposed IPB-SPV can be generated through a series of contracts which primarily involves following agreements¹²

(i) The IP transfer and Leaseback agreement-

- a) In this contract, parent company first transfers its Nascent Technology /patent rights to SPV and then SPV can license back the required rights to the parent company to carry out its ongoing practices if there are any, otherwise SPV can have all the rights of the patent. (Generally, SLB type contact is expected)
- b) In return of License back, the parent company has to deposit royalties or milestone payments to SPV.

¹² Based on SWORD organizational contracts, since modern patent system have all the relative characteristics and also evidenced from the common protected practices in the field.

- c) Further SPV can have full rights of sublicensing in the case of non-exclusive license.

(ii) The services agreement,-

The parent is intended to provide, the management and administrative services throughout the developmental process (In fact, it's minimal, as it's a mere a legal entity) and the funds are managed and distributed to equity holders accordingly.

(iii) The Equity and Future control arrangement-

- a) The parent company will have all equity shares in a company and then can sell its equity to future Investors.
- b) The parent company has the right to perform the Options (Call and Put).
- c) The IP maintenance and forcibility responsibility will be of SPV

SPV Indicators

Following are minimal indicators intended to provide Simple, transparent and comparable SPV Structures. These indicators can be provided with the initial offer of SPV to the investors. The prime focus of setting these SPV indicators in developing this SPV model, is mainly in identifying and assisting investors in their due diligence but not to substitute that.

The Simple, transparent and comparable Indicators -

A. IP Asset (Patent) Related-

- 1) Nature and value of protected technology
- 2) Dependent product or process (Current or Future)
- 3) Payment status of patent (maintenance fee)
- 4) Patent Assignment status
- 5) Litigation status of patent

B. SPV Structure Related-

- 1) Number of equity holders and their interest
- 2) Working Responsibilities
- 3) Status of Legal independence
- 4) Revenue distribution and related priorities
- 5) Decisive and Enforcement rights

5.6.2 Objectives of New model

The Primary objective of this model is to show IPB-SPV can promote financing to the parent company through IP assets

- 1) IPB-SPV can own the property rights to R&D and IP
- 2) Totally separate legal entity and differs in financial statements from parent company

- 3) Here financing will come from Investors like VCs, Banks, Crowd Funding etc. with the Call and Put Options to minimize risk in transactions.(So Either the parent company can buy the SPV or can remove the patent rights from it)
- 4) Avoid the risk of Bankruptcy- as a primary purpose of IPB-SPV is for attracting finance totally by Equity (and then even debt can be possible in case of Loan). So here Bankruptcy costs can be avoided, because only equity financing is intended to be used.

5.6.3 Concept of Simple, transparent and comparable SPV Structure.

Simplicity in representing, current or future cash flow and possibility of an interruption in the process help investors to understand the feasibility of investment in a particular financial instrument. This factor got more importance after the previous financial crisis and emphasized that complexity in securitization structure itself may become a source of risk in investment. But at the other end, even simple and transparent structures may fail in absence of strong underwriting (in the case of Securitization) and governance so investors need to undergo careful due diligence at each level (64). So it's important to formulate simple and transparent securitization structure of SPVs to facilitate the process of assessment of investment. The indicators showing the Simplicity, Transparency and comparability can help most of the transecting players in their assessment.

Simplicity- Although the nature of securitization based on future revenues (mostly in case of medicinal drugs) is comparatively more complex, it needs to simplify the inflow structure at initial time of SPV offering to investors to get the broad idea about returns on their

investments (9, 64).

Transparency- It's expected that, the relevant display of information may support investors in due diligence and assessment (65, 66). So Information about underlying assets, Structure of SPV, equity holders etc. can be helpful in this context.

Comparability- Patented Technology position and its importance on whole technology landscape and marketability in regard to the specific family members of a patent can give the comparative idea for strategic investment in (a portfolio or) the SPV(66).

The motto of setting these SPV indicators in developing this SPV model is mainly in identifying and assisting investors in their due diligence but not to pass that process.

5.6.4 The features of new proposed model

- 1) This model could be innovation promoting model and expected to encourage firms for R&D as well as internal development.
- 2) IPB-SPV could be like a contract research sponsor and financial intermediary. As it allows the parent company to perform product development or required activities, and generates funds from investors to pay required expenses as well as minimize the risk (in case of litigation financing)
- 3) The purchase option on the new venture shares and related licensing agreements, provide the parent company control over developed technologies and product.

4) Structural Benefits

- a) Avoid Commingling of project and funds- Since the new funds will not comingle with firms other assets of parent's (in case University or Cooperation Programs) existing projects will not be hindered.
 - b) As SLB has been found a valuable and most practiced industry practice in licensing, it facilitates any dependent future transactions.
- 5) The model tries to protect investor's interest by indicating clear initial idea about transparency in technological, structural and legal concerns of investors.

| Sr.No | Publication Number | Title |
|-------|--------------------|--|
| 1 | US8694419 | Methods and systems for utilizing intellectual property assets and rights |
| 2 | US7216100 | Method for obtaining and allocating investment income based on the capitalization of intellectual property |
| 3 | US20050108118 | System and method for creation of a patent investment entity |
| 4 | US20060064367 | Systems and methods for insuring intellectual property holding companies |
| 5 | US20070226094 | System and method for using intellectual property holding companies to validate the market value of intellectual property and provide investment opportunities |
| 6 | US20080097931 | Computer assisted process for providing liquidity to an enterprise by utilizing intellectual property assets |
| 7 | US20080201209 | Computer assisted process for providing liquidity by sale of intellectual property trust certificates |
| 8 | US20030061133 | Funding an intellectual property licensing program |
| 9 | US20090216589 | System and method for developing technology assets |
| 10 | US20050021434 | System and method for whole company securitization of intangible assets |
| 11 | US20060200399 | Generating royalty revenue using intellectual property |
| 12 | US20090271310 | System and method for creating and managing intellectual property investment trusts |
| 13 | US20080215474 | Systems and methods for management of intangible assets |
| 14 | US20030004843 | Patent portfolio management method |

Table 9- Some of the Interesting patents on IP-based SPVs¹³

¹³ Key word and patent classification based search strategy was applied to search and analyze relevant patents based on IP Financing.

Keywords- (1)Finance-Finance, Fund, Support, Subsidize, back, underwrite, subvent , sponsor, bankroll, stake, capitalize, promote, pay, maintain, endow, assist, bank,

5.6.5 What the Patent suggests.

Some of the specific patents relevant to this study suggests several options to carry out through their claims. First, in licensing contract which will be based on SLB type the parent company can have back license with the obligation to offer royalties or without an obligation to offer royalties, i.e. SPV may offer royalty-free, Non-exclusive rights to parent organization back (US20030004843A1). These agreements can be decided for a particular time period and with renewal options provided to contact (US20050108118). Parents can take help of some software programs which helps in revenue distribution of such intermediaries (US7216100). Further during future development in the related area and IP, the parent can offer such patents to SPV after its registration or proper protection. In the case of Equity arrangement, parent company can initially have 100 % shares in the SPV and further they can sell such shares to investors (US20070226094; US20090271310A1). As parent company can have control over the technology of SPV by Call and Put options, investors can add the clauses for receiving proper reacquisition fee from parent side (US8560419B).

5.6.6 Simple, transparent and comparable indicators in detail

The possible scope of mentioned indicators could be

grubstake, invest, patronize, guarantee, defray, angel, pay, redeem, venture (2) IP- Patent, IP, intellectual property, intangible asset (3) Patent Classification- International patent classification (IPC) and cooperative patent classification (CPC) both i.e. G06Q 40/06
•Investment, e.g. Financial instruments, portfolio management or fund management

A. IP Asset (Patent) Related-

- 1) Nature and value of protected technology-Originator can provide the technology related information its comparative position in the related technology landscape, strategic importance etc. related to SPVs holding patent or portfolio.
- 2) Dependent product or process (Current or Future)- relevant product or process based on the protected technology and related importance of technology in related product
- 3) Status of patent and related payments- status related to pendency or grant, remaining life of patent, payments related to maintenance fees can be indicated in this criteria
- 4) Patent Assignment status- details on assignment history
- 5) Litigation status of patent- Information of Any claims related to ownership, infringement, pre-grant or post-grant oppositions etc. can be showed at this point

B. SPV Structure Related-

- 1) Number of equity holders and their interest- current members of SPV and information related to their relative shares
- 2) Working Responsibilities- Information related to responsibilities related to working and maintenance of SPV can be helpful to know the administrative side of the SPV

- 3) Status of Legal independence- Independence status of SPV from its parent is important characteristic to know from the investor side. As it's expected to treat it individual company rather than dependent one. This factor deserves more impact in case of Spin-off from the institutions.
- 4) Revenue distribution and related priorities- Info related to Flow of revenue and related distribution (tranches in the case of Securitization) or info regarding the name of the system/software's used in a process.
- 5) Decisive and Enforcement rights- the relative decisive powers of SPV and enforcement related decision information.

5.7 Application of IPB-SPV

The proposed model can be used as a facilitating tool effectively, by making it as an industry standard practice. Interestingly it can be used for individual companies and also big research institutions to manage their IP specific programs.

Auto Validation of SLB effectivity model

Comparative practical study on SLB model with option, option and equity/bond investment, Funding through SPV, Securitization, R&D cooperative model after a case by case practical application and relevant validation has revealed that the SLB model with option and equity/Bond investment could be the best possible model for VC investors in a small companies (36).whereas from IP holding company concerns, stakes in whole company equity shares is major matter of

concern. Here IPB-SPV model mitigates the concerns of both parties in the transaction by providing an option of safe investment and another side also minimizes the risk of IP holder, by allowing equity stakes in SPV but not in the whole company and fulfills investors as well as IP holding companies concerns automatically.

5.7.1 In Biotech company IP monetization program

Licensing-

Case I - If parent company is in manufacturing or research of IP-based product-

SLB contract (with royalty to IPB-SPV) will provide the parent company a lease back license as well as sole ownership of new SPV. Later upon arrival of investor parent company can sell their percent of equity shares to investors in return for funds where investors will benefit by equity ownership in SPV and the profit share accordingly.

Case II- If parent company is not working in IP area-

SLB contract (without royalty to IPB-SPV) will give a sole equity ownership to the parent company. A Latter investor can invest and take equity ownership in SPV. After a successful licensing to the third party from SPV the both shareholders i.e. parent company and the investor can get benefited by a profit share from a money inflow from a new licensing deal.

Case III- If parent company wants to collaborate with other partners (cross-licensing)

As discussed above, parent company can sell equity to other collaborating partners in return of his IP in a venture and depending on

IP; they can also decide a percent share accordingly. After the success in generating a new collaborative technology the venture will have rights on that technology and both partners can get benefit from any related cash flows accordingly.

IP backed lending

The IPB-SPV will facilitate the lending institutions to recognize asset separately and related operations on it. Whereas on other side Parent company don't get affected on other company products or operations in case of default, as it will be only limited up to SPV

IP Securitization

As SPV is an integral part of the securitization process, this process will facilitate the readymade setup for future securitization and further can be modified accordingly with specific securitization related needs.

IP litigation

The most important benefit of IPB-SPV will go with the litigation financing. In this case, Litigation financer can buy the shares of already generated SPV handling the litigating Patent in return of funds (49). But interestingly it's been found that, this financer's are very much concern about the expense of provided funds only for litigation purposes. So by the IPB-SPV structure the financer's can easily track the funds, whereas even to parent company it's easy to handle related matters separately.

5.7.2 Institutional Benefits

Sometimes big research institutions like universities and research cooperative projects (like IMEC) deals with more number of research projects at a same time and they are also with the more number of patents, as well as, portfolios. Many times they have other dependent things with patents and related technology like trade secret, know-how, documentation, prototypes, pre- production units, production samples, tooling, demonstration frameworks etc. (67). In that case these IPB-SPVs can help these institutions to track related information in a single bundle by which they can know various related matters separately with that unit e.g. expenditure.

Technology specific bundling

These institutions can generate IPB-SPV related to a particular technology by handling a relevant technology catalog from the institution. Later such IPB-SPVs can be used for various purposes like cross licensing; project financing etc. Especially they can play a very important role in possible spinoff generation and relevant financing.

Chapter 6. Conclusion and Future Remarks

The Biotechnology industry is attracting increasing amount of financing year by year. These Funding's are not only in promising existing products but also majorly in new developmental and advanced technologies like gene therapy, immune therapy, RNA interference. These new technologies are assumed to have strong future applications in related areas which also denote that, investors are ready to take risky decisions in this area. Most innovative companies are small, pre-revenue companies in need of funding, but backed with IP and Knowhow from these technologies. IP helps investors to separate investment without commingling of other assets of the investee, but risk diversification with ownership and returns are at the center of investment decisions.

Earlier SPVs have played important role in development of Biotech industry. SPV based models like SWORD were used by big biotechnology companies to raise money through IPO. These SPVs had facilitated investments from outside investors for new projects and also provided some of the billion dollar drug entities to the industry. These Biotech SPVs were better options than corporate alliance and VC financing. Although these SPVs were strictly following financial and accounting standards, their use got stopped after 1998 without a presence of an alternative model. Recently it's been again observed that investors started experimenting with SPVs by financing some of the clinical stage products successfully in pursuit to become less dependent on traditional exit strategies. So earlier proved effectiveness of SPVs in bio industry and recent experiments with use, increased operating

and developmental cost with changed IP-based market conditions, paved the way for the restructuring of SPVs with current industry conditions for similar benefits.

Based on studied risk-related factors and value of patents in biotech industry thesis proposes the use of SPV's collateralizing patents owned by small biotech companies (not primarily by big biotech companies and Investment institutions), mainly in their commercialization efforts with the series of contracts comprising IP transfer and SLB, Service and Equity with future control secured by call and put options. Where model also proposes the use of IP asset and SPV structure related Indicators to assure transparency in such transactions; assisting investors in their due diligence but not substituting it. Practice of using proposed IP-based SPV model is supposed to minimize prosecution cost over patents especially in case of technology transfer from parent company, provides a readymade infrastructure of intermediary in transactions like sale and lease back licensing and securitization, minimize parent companies risk in defaults of patent loans, with effective benefits in cross-licensing projects and Litigation financing programs. Here these SPVs are assumed to effectively separates IP from firms other assets and avoid commingling of investors' funds with parallel projects and also facilitate the easy-simple tracking of funds and their returns through SPV. The proposed IP-based SPV model could also become helpful in technology bundling of bigger research-based institutions in the relevant projects and spinoff management. It can provide minimal infrastructure to the small biotech company to manage their IP effectively and then its offer to new investors in a simple, transparent

way. As the current market environment is primly based on firms IP assets, these restructured biotech SPVs can facilitate the needs of investors and IP owners effectively. Contracts not only allow the parent company to use IP, but also provide the future control over technology with “Call” option which automatically removes the cons of traditional dependent IP commercialization models.

Further, modified forms of IP-based SPVs can open the doors of new age financing, like crowd funding and IP trading platforms. But enablement of such models in Securitization requires amendments in concern statutory laws especially with traditional accounting principles for asset definition. Further country wise clarity on development and enactment of dependent or independent legislation is primly required to develop future IP-based commercial markets globally.

Thank You.

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국문 초록

생명공학기술 분야는 매년 투자 규모가 성장하고 있는 분야이다. 이러한 투자는 현존하는 제품에 국한되지 않고 유전자 치료, 면역 치료, RNA 간섭 등과 같은 새로운 기술에 대해서도 이루어지고 있다. 혁신적인 기업은 소규모이고 자금조달이 필요한 매출 발생 이전의 기업인 경우가 많으며, 이들 중 대부분은 생명공학기술에 관한 지식재산권과 노하우로 뒷받침되고 있다. 지식재산권은 투자대상이 가진 다른 자산과 혼합되지 않고 투자자들이 투자를 분리시키도록 도와주지만, 소유와 수익에 관한 리스크 분산이 투자 결정의 핵심이다. 실증 자료는 특수목적회사가 대규모 생명공학기술 회사를 위한 자금조달에 효과적이라는 점을 증명해왔다. 따라서 본 연구는 IP 기반의 소규모 특수목적회사라는 자금조달 수단의 효과적인 이용에 관하여 초점을 맞추도록 한다.

본 연구의 주된 목적은 대부분의 IP자금조달 거래에 관한 최소한의 필요를 충족시키고 소규모 생명공학기업에서의 효율적인 지식재산권 활용을 용이하게 하는 특수목적회사 구조를 만들어 내는 것이다. 본 연구는 1) 생명공학산업의 분야별 필요 사항들은

무엇이고, 2) 공통적인 IP 현금화 수단과 한계점이 무엇이며, 3) 특수목적회사가 투자자와 IP기반 소규모 생명공학기업에 모두 이익이 되도록 어떠한 방식으로 수정될 수 있는지에 관한 질문들을 이해하고 해답을 제시하고 하였다. 결론으로 제안된 특수목적회사 모델은 소규모 생명공학기업 뿐만 아니라 다른 기술분야의 IP기반 회사에도 도움이 된다는 점을 확인하였다.