Examining the Viability of Patent Pools to the Growing Nanotechnology Patent Thicket

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Abstract

A patent pool is a cooperative arrangement between several patent holders, all of them necessary and fundamental to the creation of a product or process, where all of the patents can be licensed at a single price. They are an attractive option for fragmented patent landscapes, where they are created in hopes of avoiding the high cost associated with acquiring numerous licensing agreements, avoid widespread patent disputes, and help create a standard, amongst other reasons. This issue is especially relevant to the emerging scientific field of nanotechnology, where there is widespread concern about the fragmentation of the intellectual property landscape. This paper aimed to develop a general list of criteria to aid in determining whether patent pools are a viable option for a market by examining relevant literature and conducting interviews; it was then applied to the dendritic nanotechnology's drug delivery and pharmaceutical applications. The completed list had nine criteria and, when applied to the dendritic nanotechnology market, concludes that a patent pool will not be necessary for the continued advancement of this application. The primary reason is that a huge amount of patents are in control of one company alone, Dendritic Nanotechnologies, and seem to be the primary source for the most highly sought after dendritic patents.

I. Introduction

Nanotechnology, the emerging discipline that ultimately aims to manipulate matter on the atomic, molecular, and supramolecular level on a length scale of approximately 1-100 nm range,² is quickly becoming the term of choice among scientific communities around the world. By having control of how matter is arranged, scientists and engineers hope to one day create new materials that "often have properties (such as strength, electrical resistivity, electrical conductivity, and optical absorption) that are significantly different from the properties of the same matter at either the single-molecule scale or the bulk scale".³ Some possibilities include stronger yet lighter materials for usage in buildings and vehicles; more effective means of drug delivery within the body; and environmental remediation through breakdown of toxic substances found in the soil and water into its benign subcomponents.

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² What is Nanotechnology? National Nanotechnology Initiative. Viewed on July 6, 2005. Available Online: <<u>http://www.nano.gov/html/facts/whatIsNano.html</u>>

³ Small Wonders. Endless Fronteirs: A Review of the National Nanotechnology Initiative. National Research Council/National Academy of Science. 2002.

Commercial uses of nanotechnology do not have to be free standing as nanotechnological discoveries can be incorporated into existing products; thereby changing characteristics, enhancing properties, or giving new abilities. Examples of existing nanotechnology infusion include scratch-resistant coatings for windows, and pants that have a nano-coating which makes them stain and wrinkle resistant.⁴

Such potential is understandably exciting the business world. The National Science Foundation estimated that the "global impact of nanotechnology enabled products and services" will reach upwards of \$1 trillion by 2015, while Lux Research, a leading nanotechnology analyst group, estimates a market value of \$2.6 billion in the same timeframe.⁵ Considering that Lux Research found that \$13 billion worth of products worldwide incorporated nanotechnology in October 2004 alone, the potential for growth is astounding.⁶ Nearly all of the Fortune 500 companies invest in nanotech R&D.⁷ Expectations are so positive towards this is discipline that Sean Murdock, executive director of the NanoBusiness Alliance, believes "[n]anotechnology is likely to be the engine of innovation for the next fifty years".⁸ The Woodrow Wilson Center for International Scholars has descriptions of over 200 nanotechnology-based consumer products online for browsing.

Yet for all the economic possibilities forecasted for nanotechnology, such enthusiasm has been tapered by fears of a patent landscape filled with overlapping IP and claims that are exceedingly broad in scope. Apprehension is rising that nanotechnology's constantly growing patent landscape, instead of fostering innovation, may actually retard its rate of development due to uncertainty over who is infringing on whose patent; and, while the landscape is at peace now, may one day explode into a veritable war over intellectual property that could threaten the future existence of this field even before anything substantial comes to fruition.⁹

Furthermore, in order to tap into this potential new source of opportunity, companies interested in producing goods and services may need to acquire numerous licenses for patents essential to its creation. Such endeavors, however, can be very costly in terms of time, money, and personnel. Others in the patent field have voiced concerns that some companies would rather use their patent exclusively than license them out; or, allow for licensing but at an unreasonably high cost.

One possible solution to the above problems is using patent pools as a means of creating "harmony" within the increasingly dense nanotechnology patent landscape. This thesis examined the viability of this alternative in dealing with the growing nanotech patent thicket by applying a list of nine criteria created exactly for this purpose – focusing

⁴ U.S. House of Representatives Committee on Science Subcommittee on Research ("Congressional Subcommittee on Research"). Hearing Charter: *Nanotechnology: Where does the U.S. Stand?* 29 June, 2005.

⁵ Murdock, Sean Congressional Hearing on: "Nanotechnology: Where Does the U.S. Stand?" 29 June, 2005.

⁶ Lux Research. "Sizing Nanotechnology's Value Chain." October 2004. P. 1

⁷ ETC Group. "Nanotech's 'Second Nature' Patents: Implications for the Global South." June 2005. P. 6 ⁸ Murdock, Sean Congressional Hearing on: "Nanotechnology: Where Does the U.S. Stand?" 29 June,

^{2005.} ⁹ Choi, Charles. "Nano World: Nanotech Patent Wars may Come " ("Patent War"). <u>United Press</u>

International 1 Oct, 2004. Available at <<u>http://washingtontimes.com/upi-breaking/20040930-033823-3588r.htm</u>> P. 3

specifically on submarket of dendritic nanotechnology's drug and pharmaceutical application.

II. The Power of Patents

In the United States, a patent (which is a type of intellectual property (IP)) is a government sanctioned documents granted exclusively by the United States Patent and Trademark Office.¹⁰ Patents are granted to an invention (which may include a product, process, machine, or composition of matter) as long as it is "novel, obvious, and useful".¹¹

The goal of establishing an IP system is to encourage innovation and ingenuity by granting the patent holder monopoly like powers for a period of 17 years from the date of issue.¹² Such powers include "exclud[ing] others from making, using or selling in the United States the invention claimed by the patent".¹³ Also during this time, a patent holder may license their patent in return for royalties, use it exclusively, or sell it outright. The other side of the "patent bargain" is that the inventor discloses information about the invention in the patent so it becomes a public good.

Ideally, the patent system provides an economically attractive alternative to trade secrecy and "encourages the dissemination of scientific and technical information"¹⁴. Without IP protection, would-be imitators could quickly copy someone else's invention and reap the rewards without suffering from the cost associated with developing the artifact and securing the patent. This would reduce the incentive for people to innovate thereby slowing down the rate of technological growth and advancement.¹⁵

A typical trend for an emerging field, like nanotechnology, is that parties interested in the field will try to acquire as many patents as fast as possible in hopes that their portfolio will contain an IP that will be fundamental to one or more profitable products in the future. However, this presents a problem for the USPTO, which is not familiar with the emerging technology.

Patents are issued based on what has been granted before, known as prior art, to determine its validity and proper scope of the applicant. As such, patents that have very broad claims are often granted with a technology that has little to no prior art. Nicholas Godici, Commissioner for Patents in the USPTO, puts it, "First, the breadth of a patent is determined by the available state of the art prior to the date of the invention. In emerging technologies, it is reasonable for pioneering inventions and discoveries to be granted patents of broad scope because, as expected, there is no scientific or technical evidence to restrict the scope".¹⁶ Such enthusiasm for obtaining the broadest patent possible may actually be counter to the original goal of patents by reducing innovation.

¹⁰ United States Patent and Trademark Office. <u>General Information Concerning Patents</u>. Washington. No Year of Print Provided

¹¹ Department of Justice and Federal Trade Commission . Antitrust Guidelines for the Licensing of Intellectual Property ("IP Guidelines"). 6, April 1995. Viewed on July 5, 2005. Available Online: <<u>http://www.usdoj.gov/atr/public/guidelines/ipguide.htm</u>>

¹² Ibid. P. 2 ¹³ Ibid. P. 3

¹⁴ Resnik, David B. "A Biotechnology Patent Pool: An Idea Whose Time has Come?" The Journal of Philosophy, Science, and Law. January 2003. Volume 3. Available Online: <www.psljournal.com/archives/papers/biotechPatent.cfm> P. 1

¹⁵ Department of Justice and Federal Trade Commission. P. 3

¹⁶ Godici, Nicholas P. "No Uncontrolled Patenting of Emerging Technologies." *Wall Street Journal.* 13, July 2004.

One reason for this turn around stems from the cost associated with securing licensing agreements, also known as transaction costs. The cost of hiring patent lawyers that can command a high price for an extend period of time can quickly add up, especially if multiple patent licenses are needed among several different patent holders. The potential transactional costs that a company could face may be more than is they can afford; thus, potentially preventing them form attempting to enter the market and thereby reducing innovation. If a company does decide to proceed with securing licensing agreements, the transactional costs may accumulate to the point where they present a serious financial burden to the present and future prospects of a fledgling company – particularly if they have no products available or revenue source. One strategy for displacing the transactional costs is to increase the price of the good or service they hope to provide.

Yet it is understandable that a patent holding party would want the most they can get from a patent, especially if it is critical to the development of highly profitable goods or services. The owner of an "upstream"¹⁷ patent in thus in the position to demand "a percentage of profits from downstream¹⁸ products".¹⁹ If a start-up company manages to develop and market a product but is straddled with multiple royalty agreements of such magnitude, the high fees can endanger their present and long term prospects for surviving. As the *Wall Street Journal* put it, "companies that hold pioneering patents could potentially put up tolls on entire industries".²⁰

Another possible hindrance to advancement comes from the strategy where firms try to suppress competition by "slowly starv[ing] their start-up competitors into extinction by waging a protracted battle on the IP front"²¹ in the hopes of being the only remaining player in the market. Based on a survey of intellectual property lawyers in 2000, the cost of defending a large (more than \$25 million at risk) patent infringement suit range from \$2 million to \$4.5 million. For cases with less than \$1 million at risk, the cost was \$300,000 to \$750,000 or about half the amount in dispute.²² Such large fees are often outside the financial capabilities of smaller companies, which give rise to intimidation tactics. Larger and better funded companies, capitalizing on the financial disparity, will threaten smaller firms with a lengthy patent dispute; so rather than fight and risk losing everything, some firms will concede to the demands of better funded companies.

Patent holders are also able to refuse to license their patent. Unlike some European systems, the United States does not have laws that require licensing. Such a situation is particularly troubling for companies that almost have all the patents they need, only to be denied a licensing agreement for one of their final patents. Or, if another company knows that their patent is one of the last patents needed by a competitor, they

¹⁷ "Upstream" Technology – Technology that

¹⁸ "Downstream" Innovation – An innovation that's existence is derived from other technology.

¹⁹ Resnik. P. 5

²⁰ Regaldo, Antonio. "Nanotechnology Patents Surge as Companies Vie to Stake Claim." Wall Street Journal. 18 June, 2004. P. 2

 ²¹ Miller, John C. et al. <u>The Handbook of Nanotechnology: Business, Policy, and Intellectual Property Law</u>.
P. 65

²² ETC Group. P. 10

are in a strong position to demand a higher than normal royalty.²³ Another troubling situation involves a company refusing to license an "upstream" technology to gain a competitive advantage across the whole market, as this effectively blocks all potential "downstream" inventions.²⁴

An interesting fact to note is that after all the costs from getting and securing a patent, roughly only about two percent of all issued patents end up generating more revenue than the cost of obtaining the patent. Among this small group of "profitable" patents, only some will end up being worth the price of litigation.²⁵ Refer to Appendix I for additional costs associated with securing and maintaining a patent.

²³ Clark, Jeanne, et al. "Patent Pools: A Solution to the Problems of Access in Biotechnology Patents?" United States Patent and Trademark Office. 5 December, 2000. Available Online: http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf. P. 9 ²⁴ Resnik. P. 4

²⁵ ETC Group. P. 10

III. Background on Patent Pools

A. Background

Patent pools are typically created when several patent holders, who recognize that they need each other's patents to develop a product, come together and "pool" their patents so all members of the pool have access to the collective IP. 3rd parties, those that do not contribute to the pool, are able to license the pool itself thereby gaining licensing agreements from one source. Patent pool can be more formally defined as "the aggregation of intellectual property rights which are the subject of cross-licensing, whether they are transferred directly by patentee to licensee or through some medium, such as a joint venture, set up specifically to administer the patent pool".²⁶ They are often viewed as the "simplest solution" to intellectual property rights (IPR) bottlenecks with multiple stakeholders that have overlapping sets of IP (a.k.a patent thickets) or are uncertain if there is possible infringement of patent issues (a.k.a. Patent Hold-Up).²⁷ Their successful implementation, however, is far from simple and this will be explained later.

Patent pooling is sometimes confused with cross licensing, which an agreement between two parties or more parties to open up certain IP to one another with no specific intent on allowing 3rd parties to license said patents. Unlike centralizing patents in a pool, cross licenses leave individual patent holders to create licensing agreements. This may be potentially advantageous if one patent seeker is looking for one or two pieces of IP, but the licensing process can become expensive with each additional patent needed. There may also be a great deal of "inefficiency" if multiple patents holders license out and seek the same patents that other parts want and have. The differences between patent pools and cross licensing can be seen in Figures 1 and 2, respectively.



²⁶ Clark. P. 4

²⁷ Richard Johnson of Arnold & Porter LLP. Phone Interview. January 30th, 2006.

²⁸ Gates, Sean P. "Standards, Patent Pools and Cross-Licensing: The Agency Guidelines." Conference: Law Seminars International – Standards and Patent Pools. 18 October, 2005. Slide 6.



Figure 2: Diagram of Cross-Licensing Agreements²⁹

Patent pools can exist for however long members of the pool decide to stay in the agreement or until the patents themselves expire. Other pools have been broken up by the Department of Justice for violation of antitrust laws under the Sherman Act of 1890.

It should be noted that, in the United States, the government does not play a role in the creation of a patent pool. The only obligation of the Department of Justice, the branch of the federal government which regulates antitrust law, is to ensure that the patent pool does not violate antitrust rules by conducting a review and publishing their findings via business review letters.³⁰ Past patent pools that have been reviewed include the MPEG-2, DVD 3C and DVD 6C pools. These reviews can be found on the Department of Justice's website, within the Antitrust Division at http://www.usdoj.gov/atr/public/busreview/letters.htm.

B. Recent Trends in Patent Pooling

Below is a list of current patent pooling characteristics as of 2000, as identified by the US PTO:³¹

- 1. "All licensors of the patent pool grant non-exclusive licenses to the pool, e.g, the licensors are free to license their patent(s) outside of the patent pool;
- 2. An independent patent expert evaluates which patents are deemed essential in the formation of the patent pool. There is also some mechanism for future review of the current patents in the pool as well as evaluation of any desired additions to the patent pool;"
- 3. "The pool is licensed to any interested party in the technology in a nondiscriminatory manner;"

²⁹ Ibid. Slide 7

³⁰ Merges, R., Institutions for Intellectual Property Transactions: The Case of Patent Pools, 1999, s.18. Available Online: <<u>http://www.law.berkeley.edu/institutes/bclt/pubs/merges/pools.pdf</u>>. P. 28

³¹ Clark. P. 14

- 4. "All royalty rates are reasonable and distributed based on an agreed upon formula; and"
- 5. "All grant back provisions are limited to essential patents and require nonexclusive licenses with fair and reasonable terms. These provisions must be reasonable so as not to discourage further innovation"

In addition to the responsibilities of the independent patent expert(s) detailed in Point 2, the expert may also be charged with dividing the royalties the pool receives based on a pre-agreed upon dividend structure. The expert may additionally be in charge of enforcing the laws and guidelines of the licensing agreements that are in the pooling agreement.³² It should be noted that having an impartial 3rd party is not required for the formation of a patent pool.

B. Benefits of Patent Pooling

Below is a list of the four major benefits of patent pooling as identified by the US PTO's recent analysis of patent pools in 2000.³³

The first benefit is an increased rate of development through the removal of problems that result from "blocking"³⁴ patents and "stacking"³⁵ licenses. Parties that control fundamental patents to a technology may have the power to restrict its development and advancement depending on their intentions. As mentioned earlier, companies in the United States are not required to license their patents, thereby preventing other companies from bringing new commercial products to market. Patent pools eliminate this problem by creating a centralized location for parties to obtain all the essential licenses from a single entity; rather than having to obtain each patent through individual licensing agreements. In a sense, it is like "one-stop shopping." This benefit can potentially save companies looking to license the patents in the pool a great deal of money associated with transaction costs and royalties. Such a benefit, in turn, helps foster a sense of cooperation among pool members since all members and licensees have access to the all the same patents. Faster development is therefore encouraged as well as making the creation of standards amongst pool members and licensees easier. Creating a standard is viewed positively because it helps focus the efforts of companies into one set of requirements, rather than spreading out numerous companies over different formats. For example, the patent pool for the MPEG-2 technology "led to the rapid formation of a standardized protocol to protect copyrighted works on the Internet".³⁶ In order to ensure that the patent pool does not become a patent cartel, the pool should be open to all patent holders with relevant patents, and "should not exclude particular patent holders in order to keep them from competing".³⁷

³⁶ Clark. P. 8

³² Clark. P. 14

³³ Clark. P. 9-12

³⁴ Blocking Patent: Patents that overlap one another such that the "invention claimed in one patent cannot be practiced without infringing the claims of the other patent and vice versa" (Clark, 9). For instance, "an improvement on a patented machine can be blocked by the patent on the machine" (Department of Justice & Federal Trade Commission).

³⁵ Stacking Licenses: Grants owner of a "patent invention used in upstream research rights in subsequent downstream inventions"

³⁷ Resnik. P. 8

The second advantage is that patent pools significantly reduce costs from licensing transaction and litigation.³⁸ As noted earlier, creating licensing agreements takes time, money, and personnel. When necessary patents are scattered amongst multiple parties and companies, it can be very costly to secure all the needed licensing agreements. By collecting a number of necessary patents in one entity, interested parties do not have to expend as much resources achieving a complete set of licensing agreements. Universities may find patent pools particularly attractive as it saves their limited resources from having to work on numerous licensing agreements. Litigation concerns are also dealt with, since members in a pool are not working against each other for market share. The importance of who owns what patent is therefore reduced. Furthermore, members are in a sense working together for the prosperity of every member of the pool. If a dispute does arise, members should ideally be able to resolve the matter out of court. This reduction or elimination of patent litigation will save a great deal of both time and money, as well as remove the uncertainty of "patent rights caused by litigation".³⁹

Distribution of risk is the third benefit of engaging in a patent pool. Developing a new product and procedure, especially with little prior knowledge or market to build on, is often very costly. For small operations, costs can be prohibitive to growth or out of their means entirely. By entering a pool, all members can agree to share in the risk associated with R&D thereby "increase[ing] the likelihood that a company will recover some, if not all, of its costs of research and development".⁴⁰ In return, all members get a share of any success obtained by other members with an agreed upon payment structure. This acts as a kind of guarantee that there their participation in the pool will make a return as long as the pool is licensed. It may therefore be in a company's best interest to enter a pool rather than holding out, thereby earning some return on their patent and recovering the costs associated with securing and maintaining IP [Refer to "Appendix I: Patent Licensing and Maintenance Fees"].

The final advantage of patent pools is the transfer of non-patented information among pool members.⁴¹ Since members often work together through mutual (though not legally binding) agreement, this creates an avenue for "free sharing" of information and findings related to the pool's patents amongst members and licensees. This transparency can reduce the chances of different members working on overlapping areas since it would be an inefficient usage of resources. Such an advantage also lends itself to faster development times.

C. Possible Disadvantages to Patent Pools

The US PTO's recent patent pool analysis also listed three often cited disadvantages to patent pools, but made counter arguments to try and disprove them.⁴²

First, patent pools lead to possible inflation of the costs of goods. The argument is that, if multiple parties that hold legitimate blocking patents for a technology enter a pool together, they can stifle competition and create a relationship akin to an intellectual

³⁸ Clark. P. 9

³⁹ Clark. P. 9

⁴⁰ Clark. P. 9

⁴¹ Clark. P. 12

⁴² Clark. P. 11-12

property cartel. This case comes from the "assumption that while certain patents may be considered to be legally blocking, such patents actually cover competitive alternatives to a certain technology, and that the pooling of these patents will expand monopoly pricing".⁴³ The counter argument is that this concern is unnecessary when carefully examining the patent pool agreements established by the Department of Justice and Federal Trade Commission's *Antitrust Guidelines for the Licensing of Intellectual Property* on what determines whether patents are truly "blocking."

The next objection of patent pools is that they shield invalid patents from being invalidated in court. This argument contends that, in an attempt to protect patents that companies fear will be invalidated by the courts; they enter a patent pool for protection. The public is therefore harmed by having to "pay royalties on technology that would have become part of the public domain if the patents were actually litigated in court",⁴⁴ which ultimately drives up the costs of goods and services. However, this concern is unwarranted because patent pools often avoid such situations by examining and reviewing all candidate patents by an impartial expert to determine its validity. Furthermore, the FTC takes steps towards ensuring that no pool is protecting an invalid patent.⁴⁵

The final argument against patent pools is the potential elimination of competition through collusion and price fixing. Drawing upon the IP cartel idea, companies that are not involved with the pool are at a competitive disadvantage since they will not be able to obtain the needed licenses in order to produce a good. The company will then struggle to survive as they will miss out on a potentially lucrative new market. The counter argument is, again referring to the *Antitrust Guidelines for the Licensing of Intellectual Property*, companies and parties that engage in such behavior may be violating antitrust laws. Should the pool be found guilty of such behavior, the pool will be broken up and fined according to the law.

In the 1960s, the Department of Justice also created a listed of nine patent licensing practices that are per se violations of antitrust laws after careful review of all patent pools. The list can be found in Appendix II: The "Nine No-Nos".

Another concern not mentioned in the USPTO publication deals with including patents that are not "necessary and fundamental," which once again drives up the costs of goods and services on account of the increased royalty burden. The counter to this argument is that it can be very difficult to decide which patents are "necessary and fundamental" as opinions could vary depending which market the pool is being used in. So while one licensee may not use a patent, another party may. It can also be difficult depending on how long the pool has existed – as it is often harder to tell which patents are "fundamental and necessary" in younger pools. Paying for more patents than may be necessary is also a type of insurance against patent litigation in the future. For example, say seven patents out of twenty are frequently used for the first five years of the pool's existence. A new product is developed, which uses three more patents in the pool brining

⁴³ Clark. P. 11

⁴⁴ Clark. P. 11

⁴⁵ The FTC recently charged Summit and VISX with unlawful price fixing involving their engagement in patent pooling even though they could have entered the market independently, in addition to their challenge that they were protecting an invalid patent. See Clark. P. 11.

the total that are frequently used to ten. Therefore, having more patents in a pool can stave off not only litigation but also additional licensing agreements.

D. Case Examples of Patent Pools in American History

Patent pools have been an important tool in the development of goods and services in American history for the past one hundred and fifty years. The Sewing Machine Combination patent pool of 1856 was one of the first patent pools formed.⁴⁶ Before the pool, the manufacturers Grover, Baker, Singer, Wheeler, and Wilson were all accusing the others of patent infringement. They agreed to meet in Albany, New York to pursue their suits. At the meeting, Orlando B. Potter, a lawyer and president of the Grover and Baker Company, proposed that they create a patent pool in lieu of suing each other into destruction.⁴⁷

Some of the most important patent pools of the past only came into existence after government intervention, before which patent holding companies were continually involved in litigation attempting to invalidate each other's patents. Two important examples took place during World War I. When American entered global conflict in 1917, the armed services did not have ready access to airplanes. The Wright Company, who owned a number of key airplane patents, refused to license them out to competitors and resulted in few planes being produced. It was not until the Secretary of the U.S. Navy proposed an avionics patent pool solved the impasse.⁴⁸

The radio industry also benefited from creation of a radio patent pool, which had been stalled for over 10 years prior to government intervention that took place shortly after the United States formally entered World War I. The federal government imposed a temporary suspension of all patent litigation as hostilities between competing radio companies was retarding the progress of this technology, and even blocking development all together. One such example includes the suit over rights to manufacture the audion brought by the Marconi Wireless Telegraph Company of America that was brought against De Forest Radio Telephone and Telegraph Company.⁴⁹

This temporary suspension of all litigation had the unintended affect of essentially creating a "well-stocked pool of radio inventions for the duration of the war" that removed all necessity for companies to fight each other. Through government contracts and the war itself, the industry was unknowingly being driven by a larger and more uniform scale than ever before that led to standardization among different components within a radio. This is in sharp contrast to the state of manufacturing before the war when companies often made components, like radio tubes, that lacked consistent quality due to hundreds of processes that were all time consuming, laborious, and expensive.⁵⁰

In the end, the consequences of government intervention in the radio patent landscape and the eventual creation of an unofficial patent pool ultimately resulted in higher quality products that were more economical and widely available on the market.⁵¹

⁴⁶ Merges. P. 18

⁴⁷ No Author Provided. "Isaac Singer." Wikipedia.com. 27 April, 2006. Available Online: <<u>http://en.wikipedia.org/wiki/Isaac_Singer</u>>

⁴⁸ Resnik. P. 5

⁴⁹ Lewis, Thomas. Empires of the Air: The Men Who Made Radio. Harpercollins. New York. 1991. P. 123

⁵⁰ Ibid. P. 124

⁵¹ Ibid. P. 125

Recent patents pools of the past few decades have been created entirely by the initiative of private companies. A primary reason is for to create a standard, in hopes of focusing an industry's efforts to increase the speed of development and introduction to market. An example is the MPEG-2 pool of 1995, which was created when nine patent holders agreed to pool 27 Essential Patents out of potentially 8,000 patents in order to create this technological standard.⁵² The two patent pools concerning DVD technology were also created by industry initiative in hopes of creating a set standard.

⁵² Merges. P. 30

IV. Development of Nanotechnology's IP Landscape

In order to determine whether or not patent pools are a good option for the various developing markets of nanotechnology it is important to first understand the formation and current state of nanotechnology's patent landscape, and potential dangers that may arise if the situation develops in a highly fragmented and litigious manner.

A. Formation and Current Shape of Nanotech's IP Landscape

The nanotechnology patent landscape has developed in an fashion similar to that of biotechnology's - even though there are no real products available on the market that are solely based on nanotechnology, investors and companies are trying to secure as many nanotechnology patents as they can in hopes that their next piece of IP will be a keystone intellectual property.⁵³ In April 2005, Lux claimed to have identified 3,818 nanotech-related patents issued between 1985-March 2005, with an additional 1,777 patent applications pending.⁵⁴ The number of granted nanotech patents has risen by a compound annual growth rate of about 18% – up from 29 in 1985 to 665 in 2004.⁵⁵ Yet this number does not necessary identify all potential nanotech patents as Lux Research used a "fairly strict definition of 'nanotechnology patent" when conducting their search; "the definition required the word stem 'nano' to appear both in the abstract of a patent as well as in at least one claim".⁵⁶

A number of these patents contain claims which some in the industry and academia feel are too broad and may hinder market development. Take Harvard University's Charles Lieber's patent on nano-scale metal oxide nanorods (US patent 5,897,945) for example. His patent didn't claim nanorods composed of a single type of metal; but instead claimed a metal oxide selected from up to 33 chemical elements. In a single patent, Lieber's claims extended to nearly 1/3 of the chemical elements in the Periodic Table.⁵⁷

The nanotech IP field has also seen the advent of multi-industry nanotechnology patents. Due to the interdisciplinary nature of nanotechnology it is important to understand that "nano IP is not simply that the patents span a broad range of fields, but that a single invention can be relevant for widely divergent applications".⁵⁸ Companies, hoping to strengthen their IP portfolio, will try to get a patent that covers as many applications and markets as possible in order to maximize their profit potential. Take the following two examples, found by the ETC Group:

- **Patent ID**: US 5,874,029 University of Kansas: Method for particle micronization and nanoization by recrystallization from organic solutions sprayed into a compressed antisolvent:
 - **Description**: Patent can be used in pharmaceutical, food, chemical, electronics, catalyst, polymer, pesticide, explosives, and coating industries, all of which have a need for small diameter particles

⁵³ Regaldo. P. 2

⁵⁴ Choi, Charles Q. "Nano World: Nano Patents in Conflict". UPI. April 25, 2005. P. 3

⁵⁵ Lux Research. "The Nanotech Intellectual Property Landscape." New York. March 2005. P. 4

⁵⁶ Ibid. P. 4

⁵⁷ ETC Group. P. 11

⁵⁸ ETC Group. P. 12

- Patent ID: US 6,667,099 Creavis Gesellschaft fur Technologie and • Innovation mbH: Meso- and nanoteubes: The invention related to mesotubes and nanotubes (hallow fibers) having an inner diameter of 10 nm- 50 µm and to a method for the production thereof
 - **Description**: Patent can be used in separation technology, catalysis, micro-electronics, medical technology, material technology or in the clothing industry.

B. Possible Dangers from Current Nanotechnology Patent Landscape

With an ever increasingly dense landscape with broad and overlapping claims, nanotechnology could face three potentially serious implications: (1) Decreased rate of innovation, (2) Widespread nanotechnology IP disputes,⁵⁹ and (3) Reduced rate of consumer acceptance.

1) Decreased Rate of Innovation

Patents were originally designed to help spur innovation by granting exclusivity to the creator. However, the potentially large number of poor quality patents may actually slow down this field's pace of advancement.⁶⁰

With so many patents being accepted, those who consider conducting research and hopefully one day patenting their discoveries may hesitate to start for fear that their idea may already be patented. After all the money, time, and energy invested into their work, they may unwelcomingly find a patent that already covers their desired topic. They see no economic reward for their efforts in the end as a result. That apprehension of not gaining anything worthwhile, besides increasing the general body of knowledge, may weigh heavily on researchers' minds and their corporate sponsors sponsor alike. If such feelings become common among the nanotechnology research sector, retardation in the rate of innovation and progress is a possibility.

2) Outbreak of Widespread Nanotechnology IP Disputes

Another potentially negative consequence of having too many overlapping and conflicting nanotechnology patents is an "intellectual property war," as described by Mathew Nordan, the vice president of research for nanotechnology analyst firm Lux Research. He likens the looming situation to an "elephant in the room that everybody knows is there but nobody wants to talk about".⁶¹ Howard Barnet, CEO of Southwest Nanotechnology, believes that such a war is "absolutely, unequivocally" likely.⁶²

Many people predict that the first salvo of law suits on patent infringement will occur after the initial round of successful nanotechnology products has been released because, as Stephen B. Maeibus puts it, "Nobody really litigates until

⁵⁹ Choi. P. 3

⁶⁰ Kirk, Michael. "Patent Quality Improvement: Post-Grant Opposition." <u>American Intellectual Property</u> Law Association. 21, June. 2004. ⁶¹ Choi. P. 1

⁶² Choi. P. 2

there is money to be made".⁶³ Nordan foresees the clashes beginning once a company reaches the "\$3 million or \$4 million sales mark"⁶⁴ Waiting also narrows down which patents to focus on since patent litigation is incredibly expensive. When the gates are open, the "fights are going to be brutal".⁶⁵

In line with the first potential consequence above, the length and cost of litigation will be another reason for the decreased rate of advancement. Investors may be unwilling to invest or keep money in a company that is being charged with infringement for fear that, if they lose a patent dispute, they will not only lose an important market but also will be forced to pay a licensing fee, will be penalized with a patent infringement fine, or will have to buy the patent outright.⁶⁶ Companies may, as a precaution, be forced to keep a sort of security deposit in case of an infringement battle. Mr. Wieland anecdotally jokes that companies should "budget \$3-\$4 million for lawsuits when creating a new product".⁶⁷

The adverse effect of such a measure is the money in the security deposit is essentially frozen, and not being used for such things as research and development (R&D). There is also the chance that no infringement case will be brought up, thereby freezing that money indefinitely.

3) Reduced Rate of Consumer Acceptance

The final societal implication of poor nanotechnology patent quality stems once again from the possibility and handling of patent disputes. Increased costs for legal action could reduce the enthusiasm with which companies market their products for fear that they may, unknowingly and unintentionally, be infringing on other company's patent. Consumers will then be less likely to buy said products because they do not know about it; lack of public consumption will hurt a company's bottom line and see no need to further promote and manufacture said goods. So it is a cycle: lack of company support affects consumer buying patterns which in turn affect company support.

⁶³ Blumenstyk, Goldie. "Big Bucks for Tiny Technology." <u>The Chronicle of Higher Education</u> 2004. P. 1

⁶⁴ Regaldo. P. 3

⁶⁵ ETC Group. P. 10

⁶⁶ Sullivan, Andy. "The Nanotechnology of Stain Resistant Pants." Online Posting, No Date Provided. NZOOM.com. January 31, 2005 <<u>http://technology.nzoom.com/cda/printable/1,1856,208440,00.html</u>> P. 1.

⁶⁷ Weiland, Charles. Phone Interview. January 05, 2005.

V. Criteria for Determining the Viability of Creating a Patent Pool

Below is a list of nine considerations that companies can mull over when examining the viability of applying a patent pool to their particular industry (including nanotechnology). With the exception of the patent pools formed at the behest of the United States government (e.g. radio, airplane, etc), the majority of patent pools that were created by the will of companies share several of the criteria listed below. (**Note**: The criteria are listed in no particular order of importance. If the assignment of weights is desired, they should be done via a case-by-case basis.)

1. Product Development Driven by Standards

Creating an industry standard can be one of the more powerful driving forces towards the creation of a patent pool as it provides a great benefit to manufacturers of technologically intensive products and consumers alike. The biggest benefit is that a standard helps an industry focus its resources on one possible path of product creation and utilization, as opposed to spreading their reserves across severally different formats. This ultimately increases the speed of product research and development and, ideally, results in a faster reduction in cost of production at a better cost to the public. Consumers benefit by knowing that their technological purchase will be supported of the mid-tolong-term future and that their purchase will not be obsolete within a short period of time.

To best explain this benefit, consider the example of Beta Max and VHS format battle in the 1980's. A number of electronics manufactures, not sure which format would be the eventual winner, devoted resources to manufacturing a media player for each format, possibly out of the fear of losing out on a market if they solely backed a losing format. The majority of consumers most likely only chose on media player, not sure of whether or not their format of choice would survive. For those who bought the ill fated Beta Max, they were unfortunate victims as this format met with an early end while the VHS continued to prosper well into the 1990's. Had both producers and consumers known that the VHS format would win then manufacturers would rationally reallocate the funds allotted for Beta Max production to VHS production and/or possibly the next form of media distribution. Consumers, likewise, would rationally invest in the VHS instead of Beta Max and potentially save the money needed for buying a new VHS player and the appropriate video library.

The DVD 3C created by such companies Sony Corporation, Pioneer Corporation, and Philips Electronics could have been a result of the lessons learned from the magnetic tape era – rather than fight for market share make sure that their format is the only one available.

2. Moderate Fragmentation of Patent Landscape

As noted in the "Benefits of Patent Pools Sections," the successful creation of a patent pool should eliminate a great deal of the cost associated with negotiating and maintaining cross-licensing agreements as all the needed licenses can be obtained from in one location. However, the problems also mentioned earlier arise when the patent landscape is highly fragmented amongst a dozen or more parties. The largest issues that

come up are 1) Determining whose patents are "fundamental" to the creation of the pool, and 2) Determining the relative contribution of each patent to decide on what percentage of the licensing royalties each pool member will receive for the patents they put in. With each successive party, the negotiations become more difficult and complex to the point of possibly holding up the successful creation of the pool or even preventing its formation altogether.

The other end of the fragmentation spectrum is when the key and fundamental patents are held by two to three different parties. In this situation, a patent pool is not necessarily needed as each party should be able to reach cross licensing agreements in a reasonable amount of time and effort assuming that all interested parties want to cross license.

Determining a threshold for when to and not to use a patent pool is unrealistic, and should be determined on a case by case basis.

3. At Least Five Members

Taking into direct consideration of Criteria #2, a reasonable minimum number of members for a patent pool would be about five. Any less and cross-licensing agreements should be readily doable assuming all interested parties are willing to negotiate reasonably. There is no hard set upward bound of how many members can be in a successful pool, but the increased complexity of negotiations brought about by each additional member should be kept in mind. If the founders of a potential pool feel like the number of pool candidates is getting too large, they may find it more advantageous to create a corporation that will act as a type of clearing house for a company's intellectual property.⁶⁸

4. Each Member Working on Specific Subcomponent of a Greater Good

A close tangent to the first point, it wouldn't make sense for several companies to come together and form a patent pool if the patents they want to contribute do not need each other for the ultimate creation of a good.

Take for example the hypothetical patent pool for the creation of a DVD player that has five members. Each of the five members holds a patent fundamental to the creation of a DVD player, without one then the player would not function. It would not make sense to include a sixth member whose patent contribution would not aid in the function of a DVD player.

5. Willingness of Patent Holders to Negotiate

A possible measure of "success or failure" of a patent pool could be the completeness the patents within the pool towards the ultimate creation of the product. If the pool contains all of the necessary and fundamental patents needed to create a product or utilize a service, than the pool is largely considered a success. However, if even one of the needed patent holders does not agree to the terms in the patent pool agreement (percentage of royalty received) or is focused on being the sole controller of their intellectual property, this situation will reduce the overall effectiveness of the pool by some degree. This state of affairs of having to get two agreements, one from the pool and

⁶⁸ Kimble, Karen. Phone Interview. 31 March, 2006

one from the hold-out party, is still more agreeable then having to go to each party individually.

6. Commitment to Creation of the Pool

There is no average length of time or amount of money needed for successfully creating a patent pool, as it really depends on how many members are involved in the negotiations and how determined they are to get the share of royalties they feel their contributions are worth. If, for example, all of the potential members of a six party pool feel like their respective contributions warrant 33% of the royalties, it is highly conceivable that negotiations would take longer than if the founders of a pool expect to receive a smaller portion of the royalties and/or are open to negotiations.

There is also the consideration that potential members could scrutinize all of the other potential member's contributions to determine if their IP additions would really add value to the pool itself. Otherwise, these members could be taking royalties that they "do not deserve."

Many early patent pools have failed to be successfully created due to the inability of the founding members to reach an agreement, coupled with the amount of time taken to create the pool. If too much time passes, the parties may feel it would be easier to simply work out cross-licensing agreements. Unless all the members are really certain that the patent pool would provide a more attractive option than doing individual crosslicenses and are willing to invest the time (most likely several years) and resources (money, manpower, etc), they should not consider this option.

7. Later Stage of Product Development

With technologies that have potentially lengthy production cycles, including nanotechnology, companies may be inclined to adopt a "Wait and See" strategy to monitor how the market develops before expending resources to create a patent pool.⁶⁹ The potential novelty and complexity of an emerging technological may make it less clear as to what a given patent covers and how various patents can be used together in order to create various kinds of products that fulfill different applications what kind of product. This kind of situation is relatively new; as opposed to older patent pools like the radio that were created with great understanding early on of how component worked with others.⁷⁰ Companies will thus likely not know which patents will be needed until their research and development is nearing the stage of market testing and entry.

8. Certainty of Patent Ownership

As noted earlier, there is always the chance that a patent used in the development of a successful commercial venture could overlap with another patent, thereby drawing attention and potentially a patent dispute depending on how successful the product is. Therefore there is always a possibility for a patent dispute to arise amongst a member of a pool from an "outsider." This is akin to a patent ambush – where patent holders will wait hold a patent but not develop it. They then wait for someone else to spend the resources in creating and marketing a product. Only if this product is successful will they assert their claim.

⁶⁹ Maebius, Steven. Phone Interview. January 10, 2005

⁷⁰ Maebius

The fear and anxiety arises from the potential of being held "hostage" by an "outsider" should a dispute arise with one of the members. During the time in which the legal dispute is being handled, there is uncertainty as to whether or not the pool could be jeopardized should a ruling against their co-member be given. In the event that the courts rule in favor of the "outsider," the member found guilty of infringement (or perhaps even the entire pool itself) may have to pay lost royalties and damages, possibly even having to give up their position in the pool. There is also the possibility that the outsider may want to join the pool, in which case the remaining members would need to decide amongst themselves whether or not to allow the IP dispute victor to enter the pool. If the product has proven itself to be a commercial success and the outsider wants to play hardball, they are in a position to demand a large percentage of the royalties or the pool members risk the complete halting of manufacture and sale of the product. It is unlikely, however, that the outsider should ask for an unreasonably high percentage of the royalty because if they do, the members may decide to dissolve the pool, thereby halting sales and resulting in the outsider getting nothing after spending so much resources to win the legal fight in the first place.

There is some belief that waiting 4-5 years before releasing a product into market is the best strategy in situations of patent uncertainty, like nanotechnology, in anticipation of a flurry of patent disputes that will ultimately lead to a shake out of companies and eventual consolidation of intellectual property.⁷¹ Yet, this strategy could delay product release indefinitely – imagine if every company waited and no products were released. In such a situation, there would be no patent disputes as there would be no products turning a profit, and thus no patents worth fighting for. So in the end, it could become a giant "staring game" where no one is willing to make the first move. In the end, however, the manufacturer of goods have more to lose than those waiting to "ambush" as manufacturers could lose a potential revenue stream and more money due to R&D.

9. Clear of Potential Anti-Trust Violation with Department of Justice

The final point is rather self evident, but the members of the potential pool should closely examine the formation of their pool to ensure that it has the smallest possible chance of violating antitrust regulations as determined by the Department of Justice.

⁷¹ Weiland , Charles. Phone Interview. January 05, 2005.

VI. Case Study: Dendritic Nanotechnology

What is Dendritic Nanotechnology?

Dendrimers are treelike molecules that have branching tendrils that all stem from a central core. Within those branches is an internal void that can be used to house a variety of products including, but not limited to, medicine, and image-enhancing agents. Dendrimers are highly customizable in that altering their chemical composition of the core and number of layers (also known as generations) can result in precise control of the molecule's size, shape, void space, and reactivity according to the manufacture's desire.⁷² It would be understandable that the configurations for these dendritic structures are practically limited by the imagination of the engineers and scientists.

Trying to categorize all of a polymer's properties is a very difficult proposition, as its characteristics are often also determined by how it is used. Depending on how the components on the polymer are designed, it can do a vast number of different things.⁷³

Take transistors for example – the original inventor may have thought that they would be used only in computers and therefore not have anticipated so many different goods and products being installed with chips. It should be noted that it is extremely unlikely for any one company to essentially maximize all of a molecule's uses if it cover wide ranging applications – the inventor simply may not have enough resources necessary to split their attention, or tangential applications may be in business areas outside of the inventor's focus. The inventor may therefore offer some sort of out licensing program to help get money through royalties.⁷⁴

The concept of dendrimers was first reported by Fritz Vögtle (University of Bonn, Germany) in 1978, where he was able to create a molecule with branch like structures coming out of the core⁷⁵ by employing a divergent iterative methodology using acrylonitrile.⁷⁶ This methodology resulted in low yields, poor purity, and spurification problems. Furthermore, the procedure was not able to produce molecules with enough generations. This is a serious issue because it is only after the molecules have reached at least three or more generations that dendritic polymers begin to display its unique properties; as too few generations often result in molecules that are generally more open, have non-rigid structure, and therefore cannot hold its shape. Hence, the more generations a dendritic polymer is made of, the more robust and less susceptible to deformation is the molecule.⁷⁷ It was not until the Dow Chemical Company laboratories were able to utilize the iterative methodology *with* acrylate monomers that high yields of multi-generation dendritic molecules were producible.⁷⁸ This discovery was considered

⁷² Roth, Kimberlee. "Recent announcements spur growth at Dendritic Nanotechnologies." *Michigan Small Tech.* 28 Nov, 2005. P. 1

⁷³ Phone Interview with Ms. Kimble

⁷⁴ Phone Interview with Ms. Kimble

⁷⁵ Halford, Bethany. "Dendrimers Branch Out." *Chemical and Engineering News*. Vol 83, No. 24. 13 June, 2005.

⁷⁶ Frechet, Jean M and Tomalia, Donald. <u>Dendrimers and Other Dendritic Polymers</u>. John Wiley & Sons, Ltd. West Sussex, UK. 2001. P. xxviii.

⁷⁷ Frechet. P. 23

⁷⁸ Frechet. P. xxviii

the first true "dendrimer" discovery and during the time period between 1979-1983, Dow was busy filing as many patents as they could dealing with dendrimer "composition of matter," which was later known as Dow Starburst®. It was 1985 that a full paper describing dendrimers was published by then Dow scientist Donald Tomalia and a number of other scientists.⁷⁹

Since that time, the amount of research conducted by both academia and commercial ventures in this field has increased significantly. The number of dendrimer-related papers published each year from the early 1990's to mid 2000's rose from a couple dozen to just under 1,000 in 2004 alone.⁸⁰ Many different types of dendrimers have been created by researchers around the world, including but not limited to:^{81 82}

- Graphite like dendrimers
- Light harvesting dendrimers
- Dendrimers with cross-linked surfaces
- Dendrimers that self-destruct
- Hyper-branched dendrimer polymer for dental adhesives

Dendritic Nanotechnology Patent Landscape

Along with all the research has come a huge rise in the number of patents filed relating to dendritic nanotechnology. Based on patent searches conducted by Lux Research on the make-up on the dendritic nanotech landscape, they have fond that the number of dendrimer patents has seen a dramatic increase after 1996. At the point of the research paper's publication, 229 patents on dendrimers have been granted by the USPTO according to Lux's search criteria.⁸³ Along with the increase in patents has been an increase in the number of claims covered – containing 4,385.⁸⁴

While the large number of patent being granted could be considered a positive sign of application maturation, it also causes concern that the IP landscape could be becoming very crowded.

Lux research broke down the dendritic patents into several categories. Within each category and contained in the same table, they determined a number of statistics; perhaps the most important statistic being the average number of cross-references per patent. This statistic tells the number patents that make similar claims, or depend on other inventions to support their own claims.⁸⁵ This can potentially cause issues of claim ownership to arise and may eventually lead to a legal dispute. Lux determined that the average number of cross-references for dendritic nanotechnology is 3.0, 50% higher than all the other applications they conducted patent searches on.⁸⁶ Such a high statistic has

⁷⁹ Frechet. P. xxx

⁸⁰ Halford. P. 1

⁸¹Halford. P. 1

⁸² Phone Interview with Ms. Kimble

⁸³ Lux Research Search Critiera – The name of the nanomaterial (e.g. "quantum dots"), or a synonym for it (e.g. "semiconductor nanocrystal"), appear in both the abstract and in at least one claim. They then expanded their search to include important researchers and companies as inventors and assignees, respectively. Lux Research. P. 10

⁸⁴ Lux Research. "The Nanotech Intellectual Property Landscape." New York. March 2005. P. 16

⁸⁵ Lux Research. P. 18

⁸⁶ Lux Research. P. 19

led them to the belief that the patent landscape could cause significant legal problems down the road.

It is because of the potentially growth-reducing density of the patent landscape that dendritic nanotechnology was chosen for the case study.

Market Potential

There are a number of factors that are working against the market success of dendritic nanotechnology. First, there are the possible legal disputes that could result from the patent situation detailed directly above. Second, toxicity is a major concern with regards to applications that take place within a living organism, including humans. This is considered to be a significant hurdle to the viability of any dendritic nanotechnology artifacts. Part of this stigma is a by-product of the research conducted on the toxicity studies on carbon nanotubes and buckyballs, where the toxicity levels were too high for human usage. Dendrimers, on the other hand, have been found to be less toxic than the other two alternatives, thus much better suited for usage in living organisms.⁸⁷

In addition, there is only a handful of applications and discoveries that are currently considered commercially viable and worth pursuing due to the very high cost of producing even small quantities of dendritic molecules. The high cost is largely brought about by the complexity of manufacturing these molecules, high cost of equipment, and the fact that not all molecules are usable (due to lack of production purity). For example, producing just 300 milligrams of a 7th generation polyamidoamine, or PAMAM, dendrimer costs approximately \$600.⁸⁸

There are, however, two applications that do show promise and have given hope to the future development and growth of the dendritic molecular market: drug delivery and pharmaceuticals, and diagnostics.⁸⁹ Such hope has led to the projected value of dendritic nanotechnology market to reach upwards of \$20 million by 2008, according to The Freedonia Group's Nanomaterials to 2008 report.⁹⁰ Incidentally, these three applications are the farthest along the road of R&D. Some companies are very close to, or have already entered, various stages of clinical efficacy and toxicity testing and working towards approval by the Food and Drug Administration (FDA). Because dendritic polymers for usage in drug delivery and pharmaceuticals are amongst the applications closest to market release, the remainder of this thesis will focus on the patent landscape for these this application.

IP Landscape of Dendritic Usage in Drug Delivery and Pharmaceuticals

Even though Lux Research identified 80 dendritic patents as dealing with healthcare and cosmetics, it is unlikely that those were all the patents that could be used in drug delivery and pharmaceuticals. As noted earlier, the properties of a dendritic molecule are determined by both its composition, engineering, and for what purpose it is used. This fact essentially reduces the effectiveness of conducting a patent search because the number of patents that do explicitly state drug usage in their descriptions is possible a

⁸⁹ Roth. P. 1

⁸⁷ Halford. P. 18

⁸⁸ Halford. P. 1

⁹⁰ Roth. P. 1

small subset of all the patents that could someday find their way into pharmaceutical applications.

As such, the most efficient method for finding out which companies and parties are in the best patent position was to look into press releases, various journal publications, and conducting interviews. Since this market of dendritic nanotechnology is still developing, it is hard to determine whose patent portfolio could contain the next "big thing." The only reasonable thing to do thing to do in this situation, therefore, is to see which companies has the most patents. In a very general sense, the logic is akin to lottery tickets – the more tickets you have the greater your odds of holding a winning ticket. According to the research, one of the biggest players in the field was Dow Chemical Company – possibly the very first patent holders for anything classified as a dendritic polymer. At one point, Dow held over 200 patents (making up more than 41 patent families) covering dendritic technology and had licensing agreements with many parties interested in conducting commercial research. One such company was Dendritic Nanotechnologies (DNT), who was fast at work trying to speed up research for clinical testing.⁹¹

DNT constantly ran into "speed bumps" however, as they would frequently needed to negotiate specific IPs one by one with Dow. Even though the two companies had worked well together in the past, negotiations still took time and thus inhibited the rate of advancement.⁹²

That changed, however, in 2004 when Dow signed over 196 patents from their dendrimer portfolio to DNT in exchange for a 'significant' equity stake in the company - estimated to be around 31%. Dow still holds some of the dendritic patents, but willingly licenses them to any party interested – including DNT. In essence, DNT has access to all of Dow's dendritic IP.⁹³

Another large IP consolidation deal involves DNT and the Australia based Starpharma, which is another leading company in the field of dendritic nanotechnology. They are especially well known in the fields of pharmaceuticals and drug delivery as they are currently working on a product known as VivaGel that using proprietary dendritic polymers to prevent the spread of HIV and other STDs when applied to the vagina prior to sexual intercourse.⁹⁴ Before the deal in January 2005, Starpharma already held 42% ownership of DNT but gained further equity by granting DNT exclusive rights for certain pharmaceutical applications.⁹⁵

DNT originally held more than 30 patents in this area and already sold and licensed more than 200 variations of dendrimers to pharmaceutical, biotechnology, and diagnostic companies.⁹⁶

As the patent landscape now currently stands, there is a large consensus that believes that there is only one major player in the dendritic nanotechnology market of drug delivery and pharmaceuticals - DNT. So impressive is their IP portfolio that Lux

⁹¹ News Media SAS. "Dow Spins Out Dendrimer Portfolio to Nanotech Firm." In-PharmaTechnologist.com. 26 Jan, 2005. Available Online: <<u>http://in-</u> pharmatechnologist.com/news/printNewsBis.asp?id=57592>

⁹² News Media SAS

⁹³ News Media SAS

⁹⁴ Halford. P. 2

⁹⁵ Lux Research. P. 16

⁹⁶ News Media SAS

Research believes they could become a sort of patent "clearinghouse" where the majority of companies wanting to do research on dendritics would need to go to DNT for licensing agreements, thereby essentially making them a part of possibly every commercially successful discovery.⁹⁷

This does not mean that DNT will become the one-stop-shop patent holder as some predict, as there is still the possibility that there are patent holders out there with IP DNT does not have direct access to and thus necessitating the need for licensing agreements across multiple patent holders.

Down the Pipeline

In addition to potentially holding the largest IP portfolio for dendritic nanotechnology, DNT is poised to further solidify their importance in the drug delivery and pharmaceutical application through their newest up-and-coming offering – Priostar®. Announced in May 2005 and having won the Frost & Sullivan "Technology Innovation of the Year Award," this new family of dendritic molecules could cause another revolution in this field much like Starburst® did 20 years ago. Frost Technical Insights Analyst Sangeetha Prabakar cited the reasoning behind bestowing the award to Priostar is because this new nanostructure "represent[s] a potent delivery platform for a vast array of diagnostics and therapeutics and could be employed to manufacture a variety of biotechnology and pharmaceutical products due to their specific, precise, and predictable architecture".⁹⁸ So precise is the level of control that Dr. Donald Tomalia of DNT says that the new production processes allow for control of design specifications that could result in over 50,000 different combinations of the characteristics listed above.⁹⁹

Priostar's applications would not be limited to drug delivery and pharmaceuticals, however, due large in part to the greater control granted to the engineers over size, composition, surface functionality, and interior space over existing dendritic molecules. This expands the functionality of Priostar to such markets as food and agriculture, energy and electronics, environmental and industrial safety, personal and household, and chemicals and manufacturing. It essentially could become the key platform from which the majority of all dendritic molecules are based on.¹⁰⁰

Yet these advances would mean little if Priostar was not producible in a cost efficient and timely fashion. As mentioned earlier, the cost of making the more commonly used ploy(amidoamine), or PAMAM, dendrimers can several hundreds of dollars per gram while also taking about a month's worth of time. The production time of Priostar, on the other hand, is expected to be three steps over five days for about \$10 a gram.¹⁰¹ This decrease in cost and time are due to the cleaner, faster chemistry, less reagent waste, lower levels of dilution, and expected ease of scalability via a patent

⁹⁷ Lux Research. P. 19

⁹⁸ Roth. P. 2

⁹⁹ Roth. P. 2

¹⁰⁰ Dendritic Nanotechnologies. "Dendritic Nanotechnologies' Priostar Family of Dendrimers Receives 'Technology Innovation of the Year Award." 10 Nov, 2005. Available Online: <<u>http://nanotechwire.com/news.asp?nid=2560</u>>

¹⁰¹ Uldrich, Jack. "Dendritic Nanotechnologies: A Nanotech Rule Breaker." 24 May, 2005. Online Blog. Available Online: <<u>http://nanonovusblog.blogspot.com/2005/05/dendritic-nanotechnologies-nanotech.html</u>>

pending process.¹⁰² At such an inexpensive cost to manufacture, there is widespread speculation that numerous industries will start to seriously consider using dendrimers as their nanotechnology platform.

Dr. Tomalia says that Priostar has received positive feedback from the government and commercial partners that are have been using it over the two years of development. Further testing and characterizing of this family's properties need to be conducted to more fully understand them, as well as completing the patent process and securing business partners before Priostar can find its way to the marketplace. Currently, DNT is looking to establish limited partnerships in hopes of identifying new suitable applications.¹⁰³

Such focus of this thesis has been centered on this one application because it has been receiving the most press during the past year. There are practically no other research ventures in dendritic pharmaceuticals in the press. Hence, if Priostar does become the raging success the press makes it out to be, there may be no other alternative for manufacturers to choose if they so desire.

Applying the Criteria List to Dendritic Nanotechnology

1. Product Development Driven by Standards

This is a difficult criterion to apply to the dendritic nanotechnology market in general, as dendritic molecules are highly customizable. This should, theoretically, make changing the molecules to be compatible with other molecules that engineers want to attach an easier venture. There are also possibly many different ways for dendrimers to be created, each potentially having similar effectiveness and toxicity levels. As such, dendritic nanotechnology may not be driven by standards and hence, a patent pool not needed to address this point.

2. Moderate Fragmentation of Patent Landscape

The patent landscape for the drug delivery and pharmaceutical applications of dendritic nanotechnology is moderately/highly fragmented in that there are a large number of patents dealing with this area. As a huge number of said patents are under the control of DNT however, a patent pool is not necessary to address this point.

3. At Least Five Members

As there are currently no key players in the dendritic nanotechnology market outside of the DNT and Starpharma, a patent pool is not necessary to address this point.

4. Each Member Working on Specific Subcomponent of a Greater Good

As there are currently no key players in the dendritic nanotechnology market outside of the DNT and Starpharma, a patent pool is not necessary to address this point.

5. Willingness of Patent Holders to Negotiate

¹⁰² Roth, Kimberlee (Roth Priostar). "DNT's Priostar May Mean Growth in Dendrimer Applications." Michigan Small Tech. 23 May, 2005.

¹⁰³ Roth Priostar. P. 2

As there are currently no key players in the dendritic nanotechnology market outside of the DNT and Starpharma, a patent pool is not necessary to address this point.

6. Commitment to Creation of the Pool

As there are currently no key players in the dendritic nanotechnology market outside of the DNT and Starpharma, a patent pool is not necessary to address this point.

7. Later Stage of Product Development

The drug delivery and pharmaceutical applications that are receiving the highest amount of press (Vivagel and Priostar) are at various stages of clinical testing, with both expected to hit the market by 2008. So this point would be in favor of creating a patent pool.

8. Certainty of Patent Ownership

As there are currently no key players in the dendritic nanotechnology market outside of the DNT and Starpharma, a patent pool is not necessary to address this point. This point will not become more concrete until more time has passed, however.

9. Clear of Potential Anti-Trust Violation with Department of Justice

As a patent pool has not been created, this point does not have to be taken into consideration. As for whether or not DNT will be examined for possible monopolistic practices by the Department of Justice, that will be addressed after DNT has started to release products onto the market and a clearing understanding of their licensing practices emerges.

VII. Conclusions

This thesis hereby concludes that the usage of a patent pool is not necessary for the drug delivery and pharmaceutical applications of dendritic nanotechnology. The two primary reasons for this are the shape of the developing patent landscape and high potential success of Dendritic Nanotechnology's Priostar® family of dendritic polymers.

First – the layout of the developing patent landscape. As noted above, the dendritic nanotechnology's drug and pharmaceutical applications market has largely been consolidated into DNT. Based on the research and discussions, no other company involved with dendrimers has a patent portfolio as large. With such a powerful IP position and so much continued investment in dendritic research, it would seem unlikely that several or more other research organizations not already associated with DNT could come up with a patent that Dendritic Nanotechnologies would need. Instead, it may be more cost and time efficient for all interested parties to negotiate cross-licensing agreements.

Finally, patent pools will not be necessary if DNT's Priostar becomes the industry standard for a dendritic platform as they control all the key patents to this pending technology. Despite the high praise and comments about this emerging platform, there are a number of reasons why Priostar would not succeed – at least, not for some time. One reason deals with the stage of development various products that use a dendritic platform are in. If the research has progressed to a point where switching platforms, regardless of the benefits DNT's new offering may offer over the currently used platform could offer, is not practical in terms of time and cost then companies will not switch to Priostar. The second possible reason for delayed acceptance is that some companies that want to use a dendritic platform may not want to pay DNT any royalties and thus try to find an analogue for the Starburst platform, which is sufficiently different to not require a licensing agreement.¹⁰⁴

If Priostar is able to meet all the positive criticism and really provide a less toxic, more time and cost efficient platform that can fulfill even a fraction of the possible roles put forth, this product could very well accomplish DNT's goal of "establishing dendrimer technology as the preferred nanotechnology enabling platform".¹⁰⁵

It is difficult to determine whether or not DNT is a monopoly. A simple definition of monopoly is "a market structure in which there is only one seller that has the power to control price and supply." The term monopoly typically has a connotation of anti-trust practices, and thus looked upon negatively. Yet, there is precedence for a company to control a market and essentially have a monopoly through patents as was seen with Bell Systems in the last 19th century. During the time in which Bell Systems had a monopoly, they did not face any anti-trust litigation. This is possibly due to the fact that the Sherman Anti-Trust Act of 1890, which contained powerful anti-trust provisions, was enacted after the landmark Supreme Court case of 1976 where the highest court awarded the basic

¹⁰⁴ Phone Interview with Ms. Kimble

¹⁰⁵ Roth, Kimberlee (Roth Priostar). "DNT's Priostar May Mean Growth in Dendrimer Applications." Michigan Small Tech. 23 May, 2005.

patent right of the telephone to the Bell over Western Union.¹⁰⁶ Hence, Bell could have been protected by the Grandfather Clause.

It should be noted, however, that the growth of the telephone market was quite slow during the era of the Bell patent monopoly. According to Adam D. Thierer:¹⁰⁷

From 1880 to 1895, average daily calls per 1,000 of population rose from only 4.8 to 37. Contrasting this 15-year patent monopoly period with the competitive period that followed the expiration of the Bell patents in 1894, average daily calls per 1,000 people jumped from 37 in 1895 to 391.4 in 1910. The number of telephones per 1,000 people also showed much more dramatic expansion during the competitive period after patent expiration than before. Telephones per 1,000 people rose from only 1.1 in 1880 to 4.8 in 1895, but skyrocketed to 82 by 1910.

Given DNT's willingness to license their patents sometime in the future, the slow rate of growth experienced by such situations, like radios, will most likely not come to pass with dendritic nanotechnology.

Another important point to keep in mind is that even though patent pools are not a viable option at this time, it does not mean that they will not play an important role in the nanotechnology market down the road. As noted earlier, dendritic nanotechnology (and nanotechnology as a whole) is still in a very nascent stage of development that focuses on the individual molecule – eg. Passive nanostructures (coatings, polymers, ceramics), active nanostructures (transistors, targeted drug delivery structures). It therefore unlikely that patent pools will become a viable option until roughly two or three decades down the road when more complex nanosystems are under development, as suggested by the timeline created by MC Roco (Refer to Figure 9):



Figure 9: Proposed Timeline for Nanotechnology Development¹⁰⁸

¹⁰⁶ Carlton, Dennis W. and Perloff, Jeffery M. "A Bell Patent Monopoly." 2000. Viewed on May 5, 2006. Available Online: <<u>http://wps.aw.com/aw_carltonper_modernio_4/0,9313,1425024-content,00.html</u>>

¹⁰⁷ Thierer, Adam D. "Unnatural Monopoly: Critical Moments in the Development of the Bell System Monopoly." The Cato Journal. Volume 14, No 2. Fall 1994. Available Online: http://www.cato.org/pubs/journal/cjy14n2-6.html>

¹⁰⁸ Rejeski, David ("Roco"). Congressional Hearing on: "Environmental and Safety Impacts of Nanotechnology: What Research is Needed?" 17 Nov. 2005.

IX. Alternatives to Patent Pools

One of the key criteria for the consideration of whether or not to create a patent pool dealt with the possible number of members involved with the initial creation. As noted, creating a pool is no longer a practical option if there are numerous potential members on account of the difficulty, time, and cost associated with determining (among other things) the relative worth of each pool members' patent offering(s).

Should the number be too large, the best alternative is the creation of a corporation to act as a type of clearing house for the patents (Kimble). There are a number of different variations to this idea but the general concept is that each pool member permanently gives up control of their patent in exchange for an agreed-upon stake in the corporation (e.g. stocks, position on the Board, etc.).

There are a number of benefits to the creation of a corporation. First, the licensing agreements are handled by the corporation thus freeing up the resources of the patent contributors. When outsides companies want to enter the pool, those in charge of overseeing the corporation are typically in charge of determining whether or not the potential new member's contribution warrants their entrance, again freeing up the resources of all pool members. Pool members also enjoy a reduced cost of licensing other pool members' patents – sometime even with no cost depending upon the agreed upon fee structure.

There are several downsides as well. First and foremost is that contributing members no longer have any control of their patents – even in terms of usage or licensing. A contributing member cannot therefore enter the pool and then leave the next week; they lose control indefinitely regardless of how much time has passed. Usually, the only situation where companies regain control of their patent is when the corporation is dissolved. If a member does not wish to remain within the corporation, they are usually only able to cash in their shares or get some prior agreed upon compensation. They will also most likely have to give up any positions they held within the corporation. Parties are also sometimes barred from charging variable licensing costs to outside members as it is usually up those in charge of the corporation to decide a set fee structure for all patents under its control. There is also an up-front cost that all members must pay for the start up and maintenance of the corporation, which can be a substantial sum and thus not overlooked when doing a cursory examination of the viability of this option.

The timing of when these corporations are created is usually after the technology has been established and stably making money. It would make no sense to invest the time and money in a venture that is not a steady money maker, or has a high chance of market success. Speaking of time, the period it takes a corporation can be pretty large depending on how many members as negotiating initial agreements could be very complicated.

When asked about any such corporations that exist in any market, none were found through the review of literature. Also, when asked about the names of a corporation to Ms. Kimble, she responded that she was not at liberty to give any further information about both companies in existence and in development (Kimble).

X. Recommendations and Future Improvements

Ms. Karen Kimble has been a primary source of knowledge and guidance throughout all stages of this thesis. She has been invaluable during the creation of the criteria list of considerations when possibly examining the viability of creating a patent pool as well as during the case study on dendritic nanotechnology. Without her help, I am sure that this thesis would not have as much substance as it now contains.

As with all research projects that are heavily dependent on interviews, successfully contacting an individual and then subsequently getting some of their time for questioning is fundamental to a successful project. Yet not all successful interviews will lead to worthwhile information. As mentioned in the "Special Thanks" section, Ms. Karen Kimble has been so instrumental because of her extensive knowledge, background, and experience in the field of patent pools and dendritic nanotechnology due to her past experience and position held with DNT. Yet it is possible that, because of her position with DNT, a conflict of interest may exist. There was therefore the possibility her opinions may be biased towards the success of DNT as opposed to an objective assessment.

There are, however, two reasons why I believe that her opinions were a honest evaluations. First, when asked about the position of other potential players in the dendritic field, she was most forthcoming with other companies who might be worth talking to and sharing whatever information she had and was at liberty to give. Second, her assessments of the situation are in line with a number of news articles and journals that I have found during my literature review. Had her opinions been far out of line with what my other research was showing, then there would have been cause for concern. It is therefore my personal opinion that she gave me her insights based on an objective stance rather than a potential company line.

Should this thesis be continued, possible other areas of interest include examining other emerging areas of nanotechnology whose patent landscape is fragmented across several parties while also showing commercial promise. There should be caution as many of the emerging markets within nanotechnology are still well within the R&D stages with no clear projection as to when products will become available on the market. Until these areas reach such a stage, it may be premature to begin considering whether or not applying patent pools would be a good option.

Another area that could be taken into consideration is how the patent landscapes for various markets of nanotechnology are developing internationally. Along these lines, examining if there are any foreign companies that could hold key nanotechnology patents would provide insight about the potential prowess of international parties in comparison to their counterparts in the United States. This could be particularly interesting to examine, as many nations around the world are trying to become the forerunner for nanotechnology products, goods, and services both academically and commercially.

VII. Appendices

Appendix I:

Patent Licensing and Maintenance Fees

- 1. Filing Fees: In the US, depending on the complexity, claims, and length of the application, filing fees can go as high as \$1,000.
- 2. <u>High Up-Keep Costs</u>: For nanotech start-up companies, patent fees are often a major cost of doing business – sometimes second only to payroll.¹⁰⁹ All patent holders, regardless of whether or not they have succeeded in commercializing their good or service in the marketplace, have to pay a maintenance fee every 3 1/2, 7 1/2 and 11 1/2 years from the date the patent is granted to "maintain the patent in force." Otherwise, the patent will expire and enter the public domain.¹¹⁰

Patent Maintenance Fees		
Fee	Small Entity Fee ¹¹¹	
	(if applicable)	
\$900.00	\$450.00	
\$2,300.00	\$1,150.00	
\$3,800.00	\$1,900.00	
	E Maintenance Fee \$900.00 \$2,300.00 \$3,800.00	

Below are the maintenance fees for Fiscal Year 2005:

Table 2: Patent Maintenance Fees for Fiscal Year 2005¹¹²

3. International Fees: Outside the US, countries charge around \$5,000 per year on each pending patent. The translation fees alone to win a patent in Japan are between \$12,000 and \$20,000.¹¹³

¹⁰⁹ Regaldo. P. 1

¹¹⁰ Fees – FY 2005 Fee Schedule ("Maintenance Fees Table"). United States Patent and Trademark Office. Viewed on 5 July, 2005. Available Online:

<<u>http://www.uspto.gov/web/offices/ac/qs/ope/fee2005jul01.htm#patapp</u>> ¹¹¹ Small Entities – For "an independent inventor, a small business concern, or a nonprofit organization eligible for reduced patent fees." Refer to http://www.uspto.gov/main/glossary/index.html#smallentity for more information.¹¹² Maintenance Fees Table

¹¹³ Harris, D. et al. "Strategies for Resolving Patent Disputes over Nanoparticle Drug Delivery System." Nanotechnology Law & Business Journal. Vol. 1, April 2004. P. 7

Appendix II:

The Nine "No-Nos"¹¹⁴

(1) tying the purchase of unpatented materials as a condition of the license,

(2) requiring the licensee to assign back subsequent patents,

(3) restricting the right of the purchaser of the product in the resale of the product,

(4) restricting the licensee's ability to deal in products outside the scope of the patent,

(5) a licensor's agreement not to grant further licenses,

(6) mandatory package licenses,

(7) royalty provisions not reasonably related to the licensee's sales,

(8) restrictions on a licensee's use of a product made by a patented process, and

(9) minimum resale price provisions for the licensed products.

¹¹⁴ Wilson, Bruce B, Deputy Assistant Attorney Gen., Remarks before the Fourth New England Antitrust Conference, Patent and Know-How License Agreements: Field of Use, Territorial, Price and Quantity Restrictions (Nov. 6, 1970).